DOPORUČENÍ

DOPORUČENÍ RADY (EU) 2020/1475

ze dne 13. října 2020

o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19

(Text s významem pro EHP)

RADA EVROPSKÉ UNIE,

s ohledem na Smlouvu o fungování Evropské unie, a zejména na čl. 21 odst. 2, čl. 168 odst. 6 a čl. 292 první a druhou větu této smlouvy,

s ohledem na návrh Evropské komise,

vzhledem k těmto důvodům:

- (1) Občanství Unie přiznává každému občanu Unie právo volného pohybu.
- (2) Podle čl. 21 odst. 1 Smlouvy o fungování Evropské unie (dále jen "Smlouva o fungování EU") má každý občan Unie právo svobodně se pohybovat a pobývat na území členských států s výhradou omezení a podmínek stanovených ve Smlouvách a v opatřeních přijatých k jejich provedení. Směrnicí Evropského parlamentu a Rady 2004/38/ES se toto právo provádí (¹). Článek 45 Listiny základních práv Evropské unie (dále jen "Listina") rovněž stanoví volný pohyb a pobyt. Vzhledem k tomu, že se ukazuje, že k dosažení cíle stanoveného v článku 21 Smlouvy o fungování EU je nezbytná činnost Unie, a Smlouvy jinak pro takovou činnost nestanoví nezbytné pravomoci, může Rada přijmout ustanovení s cílem usnadnit výkon práva volného pohybu a pobytu.
- (3) Podle čl. 168 odst. 1 Smlouvy o fungování EU má být při vymezení a provádění všech politik a činností Unie zajištěn vysoký stupeň ochrany lidského zdraví.
- (4) Dne 30. ledna 2020 vyhlásil generální ředitel Světové zdravotnické organizace (WHO) ohrožení veřejného zdraví mezinárodního významu z důvodu globální nákazy novým koronavirem, který způsobuje onemocnění koronavirem 2019 (COVID-19). Dne 11. března 2020 dospěla WHO k závěru, že COVID-19 lze označit za pandemii.
- (5) S cílem omezit šíření viru přijaly členské státy různá opatření, z nichž některá měla dopad na právo občanů Unie svobodně se pohybovat a pobývat na území členských států, například omezení vstupu nebo požadavky na to, aby přeshraniční cestující podstoupili karanténu.
- (6) Dne 13. února 2020 přijala Rada závěry o nákaze COVID-19 (²), ve kterých naléhavě žádá členské státy, aby společně a ve spolupráci s Komisí přiměřeným a vhodným způsobem rozvinuly úzkou a intenzivní koordinaci mezi členskými státy s cílem zajistit účinnost všech opatření, případně včetně opatření týkajících se cestování, při zachování volného pohybu uvnitř EU a zajistit optimální ochranu veřejného zdraví.

^{(&}lt;sup>1</sup>) Směrnice Evropského parlamentu a Rady 2004/38/ES ze dne 29. dubna 2004 o právu občanů Unie a jejich rodinných příslušníků svobodně se pohybovat a pobývat na území členských států, o změně nařízení (EHS) č. 1612/68 a o zrušení směrnic 64/221/EHS, 68/360/EHS, 72/194/EHS, 73/148/EHS, 75/34/EHS, 75/35/EHS, 90/364/EHS, 90/365/EHS a 93/96/EHS (Úř. věst. L 158, 30.4.2004, s. 77).

^{(&}lt;sup>2</sup>) Úř. věst. C 57, 20.2.2020, s. 4.

CS

- (7) Dne 10. března 2020 hlavy států nebo předsedové vlád Evropské unie zdůraznili potřebu společného evropského přístupu k onemocnění COVID-19.
- (8) Od března 2020 přijala Komise řadu pokynů a sdělení s cílem podpořit koordinační úsilí členských států a zachovat volný pohyb uvnitř Unie během pandemie COVID-19 (³).
- (9) Jelikož pandemie COVID-19 vyvolala bezprecedentní zdravotní krizi, stala se ochrana veřejného zdraví pro Unii i členské státy nejvyšší prioritou. Členské státy mohou z důvodu ochrany veřejného zdraví přijmout opatření, která omezují volný pohyb osob v Unii. Podle čl. 168 odst. 7 Smlouvy o fungování EU odpovídají za stanovení vnitrostátních zdravotních politik, včetně organizace zdravotnictví a poskytování zdravotní péče, členské státy, a proto se tyto politiky mohou v jednotlivých členských státech lišit. Třebaže členské státy mají pravomoc rozhodovat o nejvhodnějších opatřeních na ochranu veřejného zdraví, mimo jiné například o požadavcích na karanténu nebo testování, měla by být zajištěna koordinace těchto opatření, a to s cílem zachovat možnost výkonu práva volného pohybu a bojovat proti takto vážné přeshraniční zdravotní hrozbě, jako je COVID-19.
- (10) Při přijímání a uplatňování omezení volného pohybu by členské státy měly dodržovat zásady práva EU, zejména zásadu proporcionality a zákazu diskriminace. Cílem tohoto doporučení je usnadnit uplatňování těchto zásad na výjimečnou situaci způsobenou pandemií COVID-19 koordinovaným způsobem. Mechanismy zavedené tímto doporučením by tudíž měly být přísně omezeny co do rozsahu a času na omezení přijatá v reakci na tuto pandemii.
- (11) Jednostranná opatření v této oblasti mohou způsobit značná narušení, neboť podniky a občané se musí vyrovnat s celou řadou rozdílných a rychle se měnících opatření. To je zvláště škodlivé v situaci, kdy již bylo evropské hospodářství virem výrazně postiženo.
- (12) Cílem tohoto doporučení je zajistit větší koordinaci mezi členskými státy zvažujícími přijetí opatření omezujících volný pohyb z důvodu veřejného zdraví. Aby omezení nepřekračovala rámec toho, co je nezbytně nutné, měly by členské státy nediskriminačním způsobem a v maximální možné míře uplatňovat tato omezení spíš na osoby přijíždějící z konkrétních oblastí nebo regionů, které jsou zvlášť postiženy, než na celé území členského státu.
- (13) Koordinovaný přístup členských států vyžaduje společné úsilí v oblasti těchto klíčových bodů: uplatňování společných kritérií a prahových hodnot při rozhodování o tom, zda omezení volného pohybu zavést, mapování rizika přenosu onemocnění COVID-19 na základě dohodnutého barevného kódu a koordinovaný přístup, pokud jde o (případná) opatření, která se mohou odpovídajícím způsobem uplatnit na osoby pohybující se mezi oblastmi, v závislosti na úrovni rizika přenosu v uvedených oblastech.
- (14) Kritéria a prahové hodnoty nastíněné v tomto doporučení se zakládají na údajích poskytnutých členskými státy. Komplexní soubor údajů a mapy uvádějící status společných kritérií pro regiony EU by měly být Evropským střediskem pro prevenci a kontrolu nemocí zveřejněny a každý týden aktualizovány za použití údajů poskytovaných členskými státy.

^{(&}lt;sup>3</sup>) Pokyny Komise týkající se opatření správy hranic v zájmu ochrany zdraví a zajištění dostupnosti zboží a základních služeb (Úř. věst. C 86I, 16.3.2020, s. 1), pokyny Komise k výkonu volného pohybu pracovníků během šíření onemocnění COVID-19 (Úř. věst. C 102I, 30.3.2020, s. 12), "společný evropský plán rušení opatření proti šíření COVID-19" předsedkyně Evropské komise a předsedy Evropské rady, pokyny Komise pro volný pohyb zdravotnických pracovníků a minimální harmonizaci odborné přípravy v souvislosti s mimořádnými opatřeními v důsledku COVID-19 (Úř. věst. C 156, 8.5.2020, s. 1), sdělení Komise "Směrem k rozfázovanému a koordinovanému přístupu pro obnovu volného pohybu a zrušení kontrol na vnitřních hranicích" (Úř. věst. C 169, 15.5.2020, s. 30), sdělení Komise o třetím posouzení uplatňování dočasného omezení cest do EU, jež nejsou nezbytně nutné (COM(2020) 299 final), pokyny Komise týkající se sezónních pracovníků v EU v souvislosti s šířením onemocnění COVID-19 (Úř. věst. C 235I, 17.7.2020, s. 1), sdělení Komise o zavádění zelených pruhů podle Pokynů týkajících se opatření správy hranic v zájmu ochrany zdraví a zajištění dostupnosti zboží a základních služeb (Úř. věst. C 96I, 24.3.2020, s. 1), pokyny Komise: Usnadnění leteckého nákladního provozu během výskytu onemocnění COVID-19 (Úř. věst. C 100I, 27.3.2020, s. 1) a pokyny Komise pro ochranu zdraví, repatriaci a cestování pro námořníky, cestující a jiné osoby na palubách lodí (Úř. věst. C 119, 14.4.2020, s. 1).

- (15) S ohledem na vyvíjející se epidemiologickou situaci by Komise za podpory Evropského střediska pro prevenci a kontrolu nemocí měla pravidelně posuzovat kritéria, potřeby v oblasti údajů a prahové hodnoty nastíněné v tomto doporučení, včetně toho, zda by se měla zvážit další kritéria nebo zda by se měly upravit prahové hodnoty, a svá zjištění by Komise měla případně spolu s návrhem na změnu doporučení předávat Radě ke zvážení.
- (16) Toto doporučení by nemělo být chápáno tak, že usnadňuje nebo podporuje přijímání omezení volného pohybu zavedených v reakci na pandemii, ale jeho cílem je spíše zajistit koordinovaný přístup v případě, že by se členský stát rozhodl taková omezení zavést. Za rozhodnutí, zda omezení volného pohybu zavést, jsou i nadále odpovědné členské státy, které musí dodržovat požadavky práva Unie. Stejně tak si členské státy ponechávají flexibilitu omezení nezavádět, ani když jsou kritéria a prahové hodnoty uvedené v tomto doporučení splněny.
- (17) O omezeních volného pohybu by se mělo uvažovat pouze tehdy, když mají členské státy dostatečné důkazy k odůvodnění těchto omezení z hlediska jejich přínosu pro veřejné zdraví a mají opodstatněné důvody se domnívat, že by daná omezení byla účinná.
- (18) Aby se omezilo narušení vnitřního trhu a rodinného života během pandemie, nemělo by se podstoupení karantény vyžadovat v případě cestujících s nezbytnou funkcí či potřebou, jako jsou pracovníci nebo osoby samostatně výdělečně činné vykonávající kritická povolání, příhraniční pracovníci, pracovníci v dopravě nebo poskytovatelé dopravních služeb, námořníci a osoby cestující z naléhavého obchodního nebo rodinného důvodu, včetně členů přeshraničních rodin cestujících pravidelně.
- (19) Jasné, včasné a komplexní informování ostatních členských států a široké veřejnosti má zásadní význam pro snížení dopadů veškerých zavedených omezení volného pohybu a zajišťuje předvídatelnost, právní jistotu a dodržování ze strany občanů,

PŘIJALA TOTO DOPORUČENÍ:

Obecné zásady

Při přijímání a uplatňování opatření na ochranu veřejného zdraví v reakci na pandemii COVID-19 by členské státy měly své činnosti v rámci možností koordinovat na základě těchto zásad:

- Veškerá omezení volného pohybu osob v Unii zaváděná za účelem omezení šíření onemocnění COVID-19 by měla být založena na specifických a omezených důvodech veřejného zájmu, konkrétně na ochraně veřejného zdraví. Je nezbytné, aby taková omezení byla uplatňována v souladu s obecnými zásadami práva Unie, zejména se zásadou proporcionality a zákazu diskriminace. Jakákoli přijatá opatření by tudíž neměla překračovat rámec toho, co je nezbytně nutné k ochraně veřejného zdraví.
- 2. Veškerá taková omezení by měla být zrušena, jakmile to epidemiologická situace dovolí.
- Nesmí docházet k diskriminaci mezi členskými státy, například uplatňováním velkorysejších pravidel na cestování do a ze sousedního členského státu ve srovnání s cestováním do a z jiných členských států ve stejné epidemiologické situaci.
- 4. Omezení se nemohou zakládat na státní příslušnosti dotčené osoby, měla by se však zakládat na místě (místech), kde se dotčená osoba nacházela během čtrnácti dnů před příjezdem.
- 5. Členské státy by měly vždy povolovat vstup svým vlastním státním příslušníkům a občanům Unie a jejich rodinným příslušníkům, kteří jsou rezidenty na jejich území, a měly by usnadňovat rychlý průjezd přes svá území.
- 6. Členské státy by měly věnovat zvláštní pozornost specifikům přeshraničních regionů, nejvzdálenějších regionů, enkláv a zeměpisně izolovaných oblastí, jakož i potřebě spolupráce na místní a regionální úrovni.

CS

7. Členské státy by si měly pravidelně vyměňovat informace o všech záležitostech, na něž se vztahuje oblast působnosti tohoto doporučení.

Společná kritéria

- 8. Zvažují-li členské státy v reakci na pandemii COVID-19 omezení volného pohybu, měly by zohlednit tato klíčová kritéria:
 - a) "čtrnáctidenní kumulativní míru hlášení případů COVID-19", tj. celkový počet nově hlášených případů COVID-19 na 100 000 obyvatel za posledních 14 dnů na regionální úrovni;
 - b) "míru pozitivity testů", tj. procentní podíl pozitivních testů ze všech testů na infekci COVID-19 provedených během posledního týdne;
 - c) "míru testování", tj. počet testů na infekci COVID-19 na 100 000 obyvatel provedených během posledního týdne.

Údaje o společných kritériích

9. Aby se zajistilo, že budou k dispozici komplexní a srovnatelné údaje, měly by členské státy každý týden poskytovat Evropskému středisku pro prevenci a kontrolu nemocí dostupné údaje o kritériích uvedených v bodě 8.

Členské státy by rovněž měly poskytovat tyto údaje na regionální úrovni, aby se zajistilo, že případná opatření bude možné zaměřit na ty regiony, kde jsou nezbytně nutná.

Členské státy by si měly vyměňovat informace o veškerých strategiích testování, které uplatňují.

Mapování rizikových oblastí

- 10. Na podporu rozhodování členských států by Evropské středisko pro prevenci a kontrolu nemocí mělo na základě údajů poskytovaných členskými státy zveřejňovat mapu zemí členských států EU rozdělenou podle regionů. Tato mapa by měla rovněž zahrnovat údaje z Islandu, Lichtenštejnska, Norska a, jakmile to situace umožní (⁴), i ze Švýcarské konfederace. Na této mapě by měla být oblast označena touto barvou:
 - a) zeleně, pokud je čtrnáctidenní kumulativní míra hlášení případů COVID-19 nižší než 25 a míra pozitivity testů na infekci COVID-19 je nižší než 4 %;
 - b) oranžově, pokud je čtrnáctidenní kumulativní míra hlášení případů COVID-19 nižší než 50, ale míra pozitivity testů na infekci COVID-19 činí 4 % nebo více, nebo pokud se čtrnáctidenní kumulativní míra hlášení případů COVID-19 pohybuje v rozmezí od 25 do 150, ale míra pozitivity testů na infekci COVID-19 je nižší než 4 %;
 - c) červeně, pokud čtrnáctidenní kumulativní míra hlášení případů COVID-19 činí 50 nebo více a míra pozitivity testů na infekci COVID-19 činí 4 % nebo více, nebo pokud je čtrnáctidenní kumulativní míra hlášení případů COVID-19 vyšší než 150 na 100 000 obyvatel;
 - d) šedě, pokud není k dispozici dostatek informací k posouzení kritérií v písmenech a) až c), nebo pokud míra testování činí 300 nebo méně testů na infekci COVID-19 na 100 000 obyvatel.

Evropské středisko pro prevenci a kontrolu nemocí by mělo rovněž zveřejňovat samostatné mapy pro jednotlivé klíčové ukazatele, které jsou zohledňovány v souhrnné mapě, tj. čtrnáctidenní míru hlášení u jednotlivých regionů, jakož i míru testování a míru pozitivity testů na celostátní úrovni během posledního týdne. Jakmile budou k dispozici údaje na regionální úrovni, všechny mapy by měly vycházet z těchto údajů.

⁽⁴⁾ V závislosti na uzavření dohody mezi EU a Švýcarskou konfederací o spolupráci v oblasti veřejného zdraví, mimo jiné o účasti Švýcarské konfederace na Evropském středisku pro prevenci a kontrolu nemocí v souladu s nařízením Evropského parlamentu a Rady (ES) č. 851/2004 ze dne 21. dubna 2004 o zřízení Evropského střediska pro prevenci a kontrolu nemocí (Úř. věst. L 142, 30.4.2004, s. 1).

11. Evropské středisko pro prevenci a kontrolu nemocí by mělo každý týden zveřejňovat aktualizované verze map a podkladové údaje.

Společné prahové hodnoty při zvažování omezení volného pohybu z důvodu veřejného zdraví

- 12. Členské státy by neměly omezovat volný pohyb osob cestujících do nebo z oblastí jiného členského státu klasifikovaných jako "zelené" podle bodu 10.
- 13. Při zvažování, zda uplatnit omezení na jiné než "zelené" oblasti podle bodu 10,
 - a) by členské státy měly zohlednit rozdíly v epidemiologické situaci mezi oranžovými a červenými oblastmi a jednat přiměřeně;
 - b) by členské státy mohly vzít v úvahu další kritéria a trendy. Evropské středisko pro prevenci a kontrolu nemocí bude za tímto účelem každý týden poskytovat údaje o počtu obyvatel, míře hospitalizace, míře obsazenosti jednotek intenzivní péče a míře úmrtnosti, budou-li tyto údaje k dispozici;
 - c) by členské státy měly rovněž zohlednit epidemiologickou situaci na svém vlastním území, včetně politik testování, počtu provedených testů a míry pozitivity testů, a další epidemiologické ukazatele;
 - d) by členské státy měly zohledňovat strategie testování a věnovat zvláštní pozornost situaci v oblastech s vysokou mírou testování.

Koordinace mezi členskými státy

14. Členské státy, které na základě svých vlastních rozhodovacích procesů hodlají uplatnit omezení na osoby cestující do nebo z oblasti klasifikované jinak než jako "zelená" podle bodu 10, by měly ještě před vstupem takového opatření v platnost nejprve informovat postižený členský stát. Zvláštní pozornost by měla být věnována přeshraniční spolupráci, nejvzdálenějším regionům, enklávám a zeměpisně izolovaným oblastem. Před vstupem tohoto opatření v platnost by o svém úmyslu měly informovat rovněž ostatní členské státy a Komisi. Informace by měly členské státy poskytnout pokud možno 48 hodin předem.

K informování ostatních členských států a Komise by členské státy měly využívat zavedené komunikační sítě, mimo jiné síť integrované politické reakce na krize (IPCR). Kontaktní místa IPCR by měla zajistit, aby byly informace neprodleně předány jejich příslušným orgánům.

15. Členské státy by měly neprodleně informovat ostatní členské státy a Komisi o zrušení či zmírnění jakýchkoli dříve zavedených omezujících opatření, jež by mělo vstoupit v platnost co nejdříve.

Omezení volného pohybu by měla být zrušena tehdy, když je oblast znovu klasifikována jako "zelená" podle bodu 10, pokud od jejich zavedení uplynulo alespoň 14 dní.

16. Nejpozději sedm dní po přijetí tohoto doporučení by členské státy měly postupně zrušit omezení uplatňovaná před přijetím tohoto doporučení na oblasti klasifikované jako "zelené" podle bodu 10.

Společný rámec ohledně možných opatření pro cestující přijíždějící z oblastí s vyšším rizikem

17. Členské státy by v zásadě neměly odpírat vstup osobám cestujícím z jiných členských států.

Členské státy, které považují za nutné zavést omezení volného pohybu na základě svých vlastních rozhodovacích procesů, by mohly vyžadovat, aby osoby cestující z oblasti klasifikované jinak než jako "zelená" podle bodu 10

- a) podstoupily karanténu / domácí izolaci; a/nebo
- b) po příjezdu podstoupily test na infekci COVID-19.

CS

Členské státy mohou dát cestujícím možnost nahradit test uvedený v písmenu b) testem na infekci COVID-19 provedeným před příjezdem.

Členské státy by měly zvýšit úsilí o koordinaci ohledně délky karantény / domácí izolace a náhradních možností. Kdykoli je to možné a v souladu se strategiemi, o nichž rozhodují členské státy, měl by být podporován vývoj testování.

- 18. Členské státy by měly vzájemně uznávat výsledky testů na infekci COVID-19 provedených v jiných členských státech autorizovanými zdravotnickými orgány. Členské státy by měly posílit spolupráci v různých aspektech souvisejících s testováním, včetně ověřování certifikátů testů, s přihlédnutím k výzkumu a poradenství epidemiologických odborníků, jakož i k osvědčeným postupům.
- Podstoupení karantény by se nemělo vyžadovat v případě cestujících s nezbytnou funkcí či potřebou, pokud cestují v souvislosti s výkonem této nezbytné funkce, zejména v případě:
 - a) pracovníků nebo osob samostatně výdělečně činných vykonávajících kritická povolání včetně zdravotnických pracovníků, příhraničních a vyslaných pracovníků, jakož i sezónních pracovníků podle pokynů k výkonu volného pohybu pracovníků během šíření onemocnění COVID-19 (³);
 - b) pracovníků v dopravě nebo poskytovatelů dopravních služeb, včetně řidičů nákladních vozidel přepravujících zboží pro použití na daném území, jakož i těch, která pouze projíždějí;
 - c) pacientů cestujících z naléhavých zdravotních důvodů;
 - d) žáků, studentů a stážistů, kteří do zahraničí cestují denně;
 - e) osob cestujících z naléhavých rodinných nebo obchodních důvodů;
 - f) diplomatů, zaměstnanců mezinárodních organizací a osob pozvaných mezinárodními organizacemi, jejichž fyzická přítomnost je vyžadována pro řádné fungování těchto organizací, příslušníků ozbrojených sil a policie, pracovníků poskytujících humanitární pomoc a pracovníků civilní ochrany při výkonu jejich funkcí;
 - g) tranzitních cestujících;
 - h) námořníků;
 - i) novinářů při výkonu jejich povinností.
- 20. Členské státy by mohly vyžadovat, aby osoby vstupující na jejich území předložily formuláře pro vyhledávání cestujících v souladu s požadavky na ochranu údajů. Měl by být vytvořen společný evropský formulář pro vyhledávání cestujících, který by členské státy mohly používat. Kdykoli je to možné, měla by být pro informace k vyhledávání cestujících použita digitální možnost, aby se zjednodušilo zpracování, a to při současném zajištění rovného přístupu pro všechny občany.
- 21. Případná opatření vztahující se na osoby přijíždějící z oblasti klasifikované jako "červená", "oranžová" nebo "šedá" podle bodu 10 nesmí být diskriminační, tj. měla by se vztahovat stejně tak na vracející se státní příslušníky dotčeného členského státu.
- 22. Členské státy by měly zajistit, aby veškeré formální požadavky uložené občanům a podnikům představovaly konkrétní přínos pro úsilí v oblasti veřejného zdraví za účelem boje proti pandemii a nevytvářely nepřiměřenou a zbytečnou administrativní zátěž.
- 23. Pokud se u osoby po příjezdu do místa určení objeví příznaky, mělo by se v souladu s místní praxí uskutečnit testování, diagnostika, izolace a vysledování kontaktů a neměl by být odepřen vstup. Informace o případech zjištěných při příjezdu by měly být prostřednictvím systému včasného varování a reakce neprodleně sdíleny s orgány veřejného zdraví zemí, v nichž dotčená osoby během předchozích 14 dnů pobývala, pro účely vysledování kontaktů.
- 24. Omezení by neměla mít podobu zákazů provozování některých dopravních služeb.

^{(&}lt;sup>5</sup>) Úř. věst. C 102I, 30.3.2020, s. 12.

Komunikace a informování veřejnosti

25. Členské státy by měly příslušným zúčastněným stranám a široké veřejnosti co nejdříve před vstupem nových opatření v platnost poskytovat jasné, komplexní a včasné informace o veškerých omezeních volného pohybu, případných doprovodných požadavcích (například negativní testy na infekci COVID-19 nebo formuláře pro vyhledávání cestujících), jakož i o opatřeních, která se vztahují na osoby cestující z rizikových oblastí. Obecně by tyto informace měly být zveřejněny 24 hodin před tím, než začnou být daná opatření uplatňována, přičemž je třeba přihlédnout k tomu, že v případě mimořádných událostí epidemiologické povahy je zapotřebí určité míry flexibility.

Tyto informace by měly být rovněž zpřístupněny na internetové platformě "Re-open EU", která by měla obsahovat křížový odkaz na mapu pravidelně zveřejňovanou Evropským střediskem pro prevenci a kontrolu nemocí podle bodů 10 a 11.

Je třeba jasně popsat podstatu opatření, jejich zeměpisnou působnost a kategorie osob, na něž se vztahují.

Přezkum

26. Komise by měla provádět pravidelný přezkum tohoto doporučení za podpory Evropského střediska pro prevenci a kontrolu nemocí. O tomto přezkumu by Komise měla pravidelně podávat zprávy Radě.

V Lucemburku dne 13. října 2020.

Za Radu předseda M. ROTH



V Bruselu dne 17.3.2021 COM(2021) 129 final

SDĚLENÍ KOMISE EVROPSKÉMU PARLAMENTU, EVROPSKÉ RADĚ A RADĚ

Společná cesta k bezpečnému a trvalému opětovnému otevření

1 **ÚVOD**

Příštích několik měsíců pandemie COVID-19 bude vyžadovat pečlivě vyvážený přístup. Virus zůstává nadále významnou celosvětovou hrozbou. Občané EU a systémy zdravotní péče jsou i nadále pod tlakem, jelikož se objevují varianty viru, které vedou k novému nárůstu případů. Zároveň máme důvod očekávat podstatné zamezení šíření viru, přičemž existují vyhlídky na zrušení omezení, která postihují jak občany, tak hospodářství. Toto sdělení nastiňuje další cestu k vyvážené politice a společnému přístupu EU a uvádí, co musíme udělat, abychom co nejdříve mohli obnovit náš evropský způsob života, avšak bezpečným a udržitelným způsobem, kdy budeme mít virus pod kontrolou.

Boj proti pandemii COVID-19 si vyžádal nebývale rozsáhlá omezení. S těmito omezeními jsou i nadále spojeny vysoké a stále rostoucí náklady pro jednotlivce, rodiny, společenství a podniky. Vzhledem k riziku vzniku nových variant některé členské státy omezení rozšířily nebo zavedly nová, a tato omezení měla negativní dopad na občany i dodavatelské řetězce. Na celém jednotném trhu musí být vytvořeny podmínky, které umožní bezpečné a koordinované opětovné otevření, aby občané mohli plně požívat svých práv a aby se mohli obnovit hospodářské a společenské aktivity. To nám poskytne základ v podobě pevného veřejného zdraví, díky němuž můžeme zahájit obnovu, kterou občané a podniky velmi naléhavě potřebují.

Občané EU mají dobrý důvod očekávat zlepšení situace, a to především díky očkování. Očkování je naším hlavním prostředkem v boji proti viru a již existují jasné důkazy o tom, že skupiny obyvatelstva, které byly naočkovány, mají před touto nákazou značnou úroveň ochrany. Investice EU a členských států do vývoje a výroby očkovacích látek v roce 2020 a probíhající kroky na podporu výroby očkovacích látek a jejich dodávek do EU se vyplácejí: ve všech členských státech se nyní zvýší nabídka očkovacích látek, přičemž ve druhém čtvrtletí roku 2021 se očekává 300 milionů dávek očkovacích látek, které jsou v současné době schváleny. Rychlá a účinná distribuce těchto očkovacích látek členskými státy bude klíčovou hnací silou při snižování počtu nových případů nákazy, a tedy při určování toho, kdy a jak lze omezení zrušit. Dokud nebude dosaženo vysoké úrovně proočkovanosti, zůstanou zásadními opatřeními pro kontrolu viru hygienické podmínky a omezení fyzického kontaktu.

Při odstraňování omezení si musíme vzít ponaučení z roku 2020 a vyvarovat se dodatečných nákladů spojených s neustálým uvolňováním a opětovným zaváděním opatření. Všechny kroky k opětovnému otevření musí být udržitelné, musí vzbuzovat důvěru občanů a poskytnout pevný základ pro obnovu. Jedním z klíčových kroků je Inkubátor HERA, který se konkrétně zaměřuje na riziko, že varianty povedou k opětovnému šíření viru a omezení dopadu očkovacích látek¹.

Toto sdělení vyzývá členské státy, aby přijaly koordinovaný přístup k bezpečnému opětovnému otevření, a stanoví kroky a nástroje, které je třeba přijmout k dosažení tohoto společného cíle. Každý krok směrem k opětovnému otevření bude účinnější a přesvědčivější, pokud bude přijat v rámci celoevropského přístupu k bezpečnému a udržitelnému opětovnému otevření. Cílem je zrušit omezení pomocí společného souboru opatření a jasně porozumět tomu, jak zajistit a udržet účinné potlačení viru. Pokud členské státy nebudou spolupracovat, bude opětovné otevření trvat

¹ "Inkubátor HERA: Společně proti hrozbě, kterou představují budoucí varianty COVID-19", COM(2021) 78, 17. února 2021.

déle, bude nákladnější a méně udržitelné. Koordinované opětovné otevření navíc zajišťuje kontinuitu vnitřního trhu, který je neoddělitelně spjat s hospodářským a společenským životem Evropanů, jakož i se vztahy v oblasti obchodu, hospodářství a mobility s našimi partnery. Naše vzájemná závislost znamená, že dokud budou některé členské státy uplatňovat omezení, bude úspěšné opětovné otevření v jiných členských státech omezeno.

Naše práce v rámci EU nesmí ztratit ze zřetele, co se děje ve světě NEBO musí postupovat v souladu se zbytkem světa. Závazek EU k otevřenosti bude hnací silou postupného obnovení otevřených společností a ekonomik. Řešení této globální výzvy může přinést pouze globální přístup a nejlepším způsobem, jak zajistit udržitelné oživení, jsou společná globální řešení.

2 SPOLEČNĚ K OPĚTOVNÉMU OTEVŘENÍ

Epidemiologická situace se v EU a v jednotlivých členských státech liší, stejně jako opatření přijatá k omezení šíření viru. Jedním z dosavadních ponaučení však je, že naše vzájemná závislost má za následek, že uložení omezení v jedné části EU má důsledky pro všechny. Můžeme očekávat, že totéž platí v případě uvolňování těchto omezení. To si vyžaduje, aby v celé EU byl při přijímání opatření uplatňován společný přístup.

Různá omezení uplatňovaná vládami v členských státech na pohyb a cestování, setkávání s přáteli a rodinou, na školy a univerzity, obchody, kulturní akce, restaurace a bary hrála zásadní úlohu při potlačování viru. Rozhodnutí týkající se načasování a kombinace těchto omezení reagovala na rozšíření viru a měla na ně dopad. Zkušenosti z minulého roku ukázaly, že je výhodnější proaktivně řídit situaci, než reagovat na situaci, která se vymyká kontrole. Totéž bude platit, když budeme postupně posuzovat dopad očkování na přerušení řetězců přenosu a omezování počtu nakažených. Proto bude pro otevření ve správný okamžik klíčové rozhodování založené na důkazech, které vychází ze spolehlivých epidemiologických ukazatelů, přičemž virus bude muset být pod kontrolou, aby se umožnilo uvolnění a zabránilo tomu, že omezení budou trvat déle, než je nezbytné.

Evropské středisko pro prevenci a kontrolu nemocí (ECDC) dnes stanoví rámec, který má členským státům pomoci při přijímání takových rozhodnutí. Tento přístup by definoval úrovně, které by odrážely epidemiologickou situaci v každém členském státě. Umožnily by se tím simulace, které ilustrují, do jaké míry má každý členský stát volnost zmírnit opatření v oblasti reakce, aniž by hrozilo, že dojde k opětovnému šíření viru. Jasné orientační epidemiologické prahové hodnoty pomohou koordinaci, předvídatelnosti a transparentnosti. Jasnější vědecký základ² pomůže pochopit a řešit souvislost mezi zrušením opatření a dopadem na výskyt onemocnění COVID-19 a úmrtnost na něj při zrychlujícím se postupu očkování. V dubnu bude členským státům k dispozici interaktivní digitální nástroj vyvinutý Evropským střediskem pro prevenci a kontrolu nemocí³. Jednotlivé členské státy budou i nadále přijímat různá rozhodnutí,

² Soubor nástrojů Společného výzkumného střediska Komise pro analýzu scénářů COVID-19 již poskytuje interaktivní nástroje pro simulaci účinků očkovacích strategií v kombinaci s různými opatřeními na vnitrostátní a regionální úrovni.

³ Byl by navržen tak, aby subjekty s rozhodovací pravomocí a odborníci v oblasti veřejného zdraví v členských státech mohli podle vlastního uvážení použít své vlastní odhady pro efektivní reprodukční číslo a míru proočkovanosti nebo využít odhady Evropského střediska pro prevenci a kontrolu nemocí.

pokud jde o to, která omezení budou nadále uplatňována a která budou zrušena: tento rámec pomůže členským státům stanovit při těchto rozhodování priority na základě společného porozumění pravděpodobného dopadu.

Společný základ dohodnutého rámce rovněž napomůže dosáhnout pokroku v tomto procesu na základě vzájemné důvěry mezi členskými státy. V opačném případě bude obezřetnost členských států ohledně možného dopadu situace v jiných členských státech působit jako brzda opětovného otevření. Komise vyzývá členské státy, aby tento přístup schválily a urychleně přijaly návazná opatření.

Společný rámec může rovněž zvýšit důvěru občanů v přijatá rozhodnutí, což má zásadní význam, neboť dodržování opatření je oslabeno únavou z pandemie nebo ztrátou ostražitosti v důsledku zavádění očkování. Zásadní význam má rovněž spolupráce při poskytování objektivních informací a v boji proti záplavám dezinformací, které brzdí účinné očkovací kampaně.

3 BEZPEČNÉ OPĚTOVNÉ OTEVŘENÍ

Bezpečný návrat k volnému pohybu

Pro občany EU bude důležitou součástí zrušení omezení obnovení neomezeného volného pohybu a dalších základních práv v celé EU. Jakmile se epidemiologická situace dostatečně zlepší, koordinovaný přístup k volnému pohybu poskytne jistotu, že opětovným otevřením neztratíme kontrolu nad virem. Občané musí mít rovněž možnost uplatňovat svá práva bez jakékoli diskriminace.

Komise přijímá legislativní návrh, kterým se zavádí společný rámec pro *digitální zelený certifikát* o očkování, testování a uzdravení se. Tím bude na úrovni EU zaveden přístup k vydávání, ověřování a přijímání těchto certifikátů s cílem pomoci držitelům uplatňovat jejich právo na volný pohyb v rámci EU a usnadnit ukončení omezení z důvodu pandemie COVID-19 v souladu s právem EU. Umožní všem občanům EU a jejich rodinným příslušníkům získat bezpečný a interoperabilní certifikát. Všechny členské státy by v relevantních případech akceptovaly certifikát jako dostatečný důkaz k tomu, aby upustily od omezení volného pohybu – jako jsou požadavky na karanténu nebo testování – zavedené s cílem omezit šíření onemocnění COVID-19. Je důležité zdůraznit, že osobám bez takového certifikátu musí být nadále umožněno cestovat a že držení certifikátu, není předpokladem uplatňování práva na volný pohyb nebo jiných základních práv. Aby s certifikáty byly akceptovány, je důležité, aby s nimi byla spojena důvěra. Certifikáty by se mohl používat k ověření toho, zda lidé mohou či nemohou cestovat, aniž by podléhali dočasným omezením, která by mohla být zavedena s cílem omezit šíření viru, jako je testování při příjezdu a karanténa. Tento balíček se bude rovněž vztahovat na občany třetích zemí, kteří legálně pobývají v EU nebo zde mají bydliště.

Návrh, který byl dnes předložen, je flexibilním a jednoduchým nástrojem, který má být k dispozici jak v digitální, tak papírové podobě. Umožní orgánům v jednom členském státě provést v případě potřeby rychlou, bezpečnou a jednoduchou kontrolu certifikátu vydaného v jiném členském státě. Použilo by se pouze minimální množství nezbytných údajů (např. datum očkování a použitá očkovací látka nebo datum provedení testu na COVID-19). Abychom byli

připraveni na nárůst míry cestování v letních měsících, je třeba, aby byl návrh urychleně projednán a schválen Evropským parlamentem a Radou. V nejbližší budoucnosti Komise rovněž zváží, zda by měla navrhnout změny doporučení o koordinovaném přístupu k omezením volného pohybu⁴. V každém případě by se nadále měly uplatňovat veškeré výjimky pro nezbytně nutné cesty, jako jsou např. výjimky doporučené pro sezónní pracovníky, pracovníky v dopravě a příhraniční pracovníky. Rovněž v případě, že budou dočasně znovu zavedeny kontroly na vnitřních hranicích jakožto krajní opatření, musí být za všech okolností nadále v plném rozsahu uplatňovány zásady "zelených pruhů" pro nákladní dopravu.

Provádění právních předpisů o digitálním zeleném certifikátu rovněž vyžaduje kompatibilní *technický rámec*, který musí být stanoven na úrovni EU a zaveden členskými státy. Tím by se měla zajistit interoperabilita a plné dodržování pravidel ochrany osobních údajů. Cílem by mělo být dokončení příprav a zavedení systému do poloviny června. Technický rámec bude zohledňovat celosvětové úsilí o zmírnění cestovních omezení: již od samého počátku by měla být zohledněna interoperabilita se systémy vyvíjenými Světovou zdravotnickou organizací (WHO). Rámec bude rovněž možné rozšít na kompatibilní certifikáty vydávané ve třetích zemích. Návrh digitálního zeleného certifikátu je dostatečně pružný, aby mohl zohlednit nové vědecké poznatky a pokyny, jak se budeme postupně dozvídat více o účinku očkování, důsledcích nových variant a o tom, do jaké míry jsou chráněny osoby, které se z infekce zotavili.

Komise rovněž přijímá doplňující návrh, který se zabývá vydáváním digitálního zeleného certifikátu státním příslušníkům třetích zemí, kteří legálně pobývají v členském státě nebo v něm mají bydliště a kteří jsou oprávněni cestovat v rámci EU⁵. Cestování v rámci EU by usnadnilo, pokud by takový státní příslušník třetí země byl držitelem certifikátu, který je dostatečně spolehlivým dokladem o očkování nebo byl vydán v rámci systému, který je interoperabilní s rámcem důvěry digitálního zeleného certifikátu.

Důležitou součástí opětovného otevření bude umožnění bezpečného cestování státních příslušníků třetích zemí do EU. *Cestovní ruch a jiné cesty ze zemí mimo EU* jsou důležitým prvkem otevřenosti EU a měly by se stejně jako jiné činnosti zaměřit na bezpečné otevření. Doporučením byl již zaveden rámec, v němž jsou určeny země, jejichž epidemiologická situace umožňuje i cesty do EU, jež nejsou nezbytně nutné⁶. Rada by měla i nadále věnovat pozornost vývoji situace v zemích mimo EU, a zejména tam, kde lze mít za to, že výskyt onemocnění COVID-19 se snižuje udržitelným způsobem, například díky plošnému očkování vakcínami s prokázanou účinností. Dalším důležitým faktorem by byla nízká úroveň variant vzbuzujících obavy ve třetí zemi.

V bezprostřední budoucnosti bude Komise provádění doporučení pozorně sledovat a navrhne změny v souladu s vývojem v této oblasti. Takovou změnou by mohlo být sladění doporučení s digitálním zeleným certifikátem a globálními iniciativami organizace WHO nebo Mezinárodní organizace pro civilní letectví. Tím by v budoucnu mohla být snadněji přizpůsobována omezení

⁴ Doporučení Rady (EU) 2020/1475 ze dne 13. října 2020 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19.

⁵ Na základě článku 77 SFEU (schengenský právní základ).

⁶ Doporučení Rady (EU) 2020/912 ze dne 30. června 2020 o dočasném omezení cest do EU, jež nejsou nezbytně nutné, a o možném zrušení tohoto omezení.

v případech, kdy cestující ze třetích zemí jsou schopni předložit certifikáty potvrzující příslušný status onemocnění COVID-19 vydaný v rámci systému, jenž je považován za dostatečně spolehlivý nebo interoperabilní s digitálním zeleným certifikátem, jakmile budou v členských státech EU k dispozici. Souběžně Komise úzce spolupracuje s mezinárodními organizacemi, včetně Organizace pro hospodářskou spolupráci a rozvoj⁷, Světovou organizací cestovního ruchu OSN⁸ a pracovní skupinou G20 pro cestovní ruch na opětovném zahájení a obnově světového cestovního ruchu udržitelným způsobem.

Používání digitálního zeleného certifikátu by mělo být doprovázeno jasnou a transparentní komunikací s občany, v jejímž rámci by měl být vysvětlen jeho rozsah působnosti, používání, objasněny záruky ochrany osobních údajů a občané by měli být ujištěni, že se jedná o nástroj, který jim pomůže plně využívat práva na volný pohyb.

Pokyny týkající se testování a karantény uplatňované na cestující⁹ budou aktualizovány, aby ve vztahu k opatřením na hranicích byl zaveden harmonizovanější a předvídatelnější přístup, který bude pro cestující a poskytovatele dopravních služeb srozumitelnější.

Testování a trasování kontaktů jakožto nástroje pomáhající otevírání

K vymýcení viru nebude stačit jen úspěšné očkování. Bude třeba nadále sledovat epidemiologickou situaci a reagovat na ni, takže testování a trasování kontaktů zůstanou nadále nepostradatelnými nástroji. To bude obzvláště důležité ve fázi opětovného otevření, za účelem ujištění, že jakékoli opětovné rozšíření bude rychle odhaleno.

EU zveřejnila pokyny na podporu rozvoje a provádění testovacích strategií v celé EU a doporučení na podporu společného přístupu k používání, validaci a vzájemnému uznávání různých testů.¹⁰ Členské státy v rámci Výboru pro zdravotní bezpečnost pravidelně jednají o testovacích strategiích a nových testech vstupujících na trh. Výbor pro zdravotní bezpečnost se rovněž dohodl na společném seznamu rychlých antigenních testů k diagnostice onemocnění COVID-19 a na výběru rychlých antigenních testů, jejichž výsledky členské státy vzájemně uznávají¹¹. Kromě toho Komise nyní dává členským státům k dispozici 20 milionů rychlých antigenních testů¹². Přesnost a dostupnost rychlých antigenních testů se nadále zlepšuje, jsou stále častěji využívány a jsou užitečné v souvislosti s usnadňováním služeb a bezpečným cestováním.

Na trh nyní začínají vstupovat *samotesty* na COVID-19 (samostěrné sady a samotestovací sady). Komise a Evropské středisko pro prevenci a kontrolu nemocí je přezkoumávají. Evropské

⁷ http://www.oecd.org/coronavirus/policy-responses/covid-19-international-mobility-and-trade-in-services-theroad-to-recovery-ec716823/

⁸ https://www.unwto.org/unwto-convenes-global-tourism-crisis-committee

⁹ https://www.ecdc.europa.eu/en/publications-data/guidelines-covid-19-testing-and-quarantine-air-travellers

 ¹⁰ Doporučení Komise (EU) 2020/1595 ze dne 28. října 2020 o strategiích testování na COVID-19, včetně použití rychlých testů na antigen (C/2020/7502)

¹¹ https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

¹² Dne 18. prosince 2020 Komise podepsala rámcovou smlouvu se společnostmi Abbot a Roche, na jejímž základě bude možné nakoupit více než 20 milionů rychlých antigenních testů až do 100 milionů EUR z nástroje pro mimořádnou podporu.

středisko pro prevenci a kontrolu nemocí dnes zveřejní technické pokyny k samotestovacím sadám na COVID-19, včetně podrobností týkajících se například jejich dostupnosti a možných dopadů na provádění preventivních a kontrolních opatření, jejich klinické výkonnosti ve srovnání se zlatým standardem testů RT-PCR, jejich důsledků pro podávání zpráv a epidemiologický dozor a předpokladů jejich vhodného použití. Prostřednictvím Výboru pro zdravotní bezpečnost Komise sleduje, zda a jak země rychlé antigenní samotesty používají nebo jejich používání zvažují.

Důležitým způsobem využívání testování je sledování viru a jeho variant v odpadních vodách. Tak můžeme získat rychlé a nenákladné informace o přítomnosti viru, a tedy i o jeho případném novém šíření: monitorováním pouze 6 000 sběrných míst můžeme sledovat odpadní vody 70 % populace EU. Dohled nad odpadními vodami lze využít pro účely prevence nebo včasného varování, neboť detekce viru v odpadních vodách je známkou případného nového výskytu viru. Podobně nepřítomnost viru v odpadních vodách by mohla naznačovat, že danou populační zónu lze považovat za méně ohroženou a že opatření zavedená za účelem omezení přenosu viru zafungovala. Je proto velmi důležité, aby členské státy zavedly účinné systémy dohledu nad odpadními vodami, které zajistí, že příslušné údaje budou neprodleně poskytnuty příslušným zdravotnickým orgánům.

Komise dnes přijímá doporučení na podporu konzistentního přístupu k využívání *monitorování odpadních vod* za účelem sledování viru COVID-19 a jeho variant¹³. Doporučení vychází ze znalostí a zkušeností členských států a obsahuje konkrétní pokyny týkající se koncepce a řízení sítě pro dohled nad odpadními vodami pro rychlý přenos údajů zdravotnickým orgánům. Bude prosazovat používání společných metod pro odběr vzorků, testování a analýzu údajů za podpory evropské platformy pro výměnu údajů. Na podporu zavádění soudržných strategií a činností v oblasti monitorování a dohledu nad odpadními vodami v celé EU a na dlouhodobé posílení kapacit členských států a partnerských zemí bude poskytnuta finanční podpora.

Pouhým testováním nezískáme kontrolu nad infekčními onemocněními. Testování musí být účinně využíváno a musí být doprovázeno následnými opatřeními. Jakmile se celková situace bude zlepšovat, bude mít pro bezpečné otevření zásadní význam trasování, a to zvláště s ohledem na účinné omezení šíření izolovanějších ohnisek. Doplnění tradičního manuálního trasování kontaktů *mobilními aplikacemi pro trasování kontaktů* může pomoci přerušit přenosové řetězce a zachraňovat životy. S ohledem na zvýšenou nakažlivostí nových variant je důležité, aby parametry používané v aplikacích byly přezkoumány a v případě potřeby upraveny ve spolupráci s Evropským střediskem pro prevenci a kontrolu nemocí a vnitrostátními orgány. Komise bude podporovat členské státy v tom, aby zvážily další funkce, které by posílily aplikace pro trasování kontaktů a podpořily by jejich rozšiřování a využívání. Tyto další funkce by mohly zahrnovat například přehled uvádějící nejnovější informace o situaci v oblasti veřejného zdraví a o zahájení očkovacích kampaní nebo informování uživatelů o tom, že byli přítomni na akci nebo na místě, kde byly zjištěny potvrzené případy onemocnění COVID-19.

Členské státy rovněž shromažďují údaje od přeshraničních cestujících vstupujících na jejich území prostřednictvím vnitrostátních *formulářů pro trasování cestujících* ("PLF"). Výměna

¹³ C(2021) 1925

údajů mezi orgány členských států pro trasování kontaktů může být obzvláště důležitá, když cestující překračují hranice v těsné vzájemné blízkosti, například v letadlech nebo vlacích. Komise vyvinula platformu, která umožňuje výměnu údajů mezi systémy PLF členských států.

Aby si členské státy mohly vyměňovat příslušné údaje o cestujících prostřednictvím platformy pro výměnu údajů, Komise zveřejní návrhy opatření, která mají zajistit, aby do letní cestovní sezóny bylo zákonné zpracování osobních údajů založeno na právním základě EU¹⁴. Tím se stanoví omezené a přesně vymezené soubory údajů, které mají být vyměňovány, a úlohy a povinnosti jednotlivých uživatelů.

Pro členské státy, v nichž nebyl digitální systém PLF zaveden, byla v rámci společné akce EU Healthy Gateways vyvinuta platforma pro unijní digitální PLF jako jednotné kontaktní místo a služby pro cloud-hosting umožňující ukládání shromážděných formulářů PLF. Obě platformy – platforma pro výměnu PLF a platforma pro unijní digitální PLF – jsou vzájemně se doplňujícími a vzájemně propojenými projekty. Tyto nástroje umožní rychlejší a účinnější trasování kontaktů přeshraničních cestujících.

Další postup při boji s virem: léčba a zdravotnické vybavení

Rozvoj *terapeutické léčby* pomohl zachraňovat životy, zrychlit dobu zotavení a zkrátit dobu hospitalizace, a to jak ku prospěchu pacientů, tak i systémů zdravotní péče, které jsou pod silným tlakem. Komise využívá řadu nástrojů, včetně společného zadávání veřejných zakázek, k zajištění přístupu členských států k omezenému počtu léčebných postupů, které se v současné době používají k léčbě případů onemocnění COVID-19, jakož i k výzkumným programům. Potřebujeme další a rychlejší opatření. *Společná strategie EU v oblasti léčby* je plánovaná na polovinu dubna. Podobně jako přístup úspěšně používaný u očkovacích látek, se strategie zaměřuje na urychlení výzkumu a výroby, aby členské státy měly přístup k cenným léčebným postupům v požadovaném rozsahu a rychlosti. Budou zavedena pružnější regulační opatření pro léčebné postupy, jako např. usnadnění označování, aby během pandemie bylo možné realizovat rychlé rozsáhlé dodávky.

Technologie lze využívat i jinými způsoby. *Roboti dezinfikující ultrafialovým zářením* mohou dezinfikovat pokoj pro pacienty o standardní velikosti do 10 minut pomocí ultrafialového světla a dezinfikovat více než 18 pokojů najednou. Mohou pomoci zajistit sterilní prostředí v nemocnicích, aniž by zaměstnanci byli vystaveni zbytečnému riziku. V současné době probíhá program v hodnotě 12 milionů EUR, v jehož rámci je realizován nákup nejméně 200 robotů, které jsou zaváděny v členských státech, přičemž ke skutečnému dodání robotů dojde v průběhu roku 2021.

Pomoc nejvíce zasaženým odvětvím při přípravě na bezpečné znovuotevření

Některá z nejdynamičtějších odvětví Evropy – cestovní ruch, kultura a doprava – patří k nejvíce zasaženým pandemií. Čím více učiníme pro to, aby se tato odvětvím mohla znovu bezpečně otevřít pro pracovníky¹⁵ a pro veřejnost, a to způsobem vytvářejícím důvěru, tím rychleji se tato

¹⁴ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives?frontEndStage=ISC_WORKFLOW

¹⁵ https://oshwiki.eu/wiki/COVID-19:_Back_to_the_workplace_-_Adapting_workplaces_and_protecting_workers

odvětví, v nichž mnoho podniků je ohroženo a na nichž závisí řada pracovních míst, začnou oživovat.

Evropský ekosystém *cestovního ruchu* byl silně narušen. Ve 12 členských státech tvoří cestovní ruch 25 % až 10 % národního HDP, zatímco čtyři členské státy EU se v roce 2019 zařadily mezi deset hlavních světových turistických destinací, pokud jde o příjezdy zahraničních turistů a příjmy. S poklesem příjmů o 70 % v roce 2020 a až 11 milionů ohrožených pracovních míst¹⁶ se služby cestovního ruchu nacházejí na spodní příčce podnikatelského indikátoru důvěry. Počet přenocování v EU klesl v roce 2020¹⁷ o 52 % a mezinárodní cestovní ruch se v roce 2020 snížil o 68 %. Hospodářství některých členských států jsou rovněž silně závislá na mezinárodním cestovním ruchu a nejsou schopna kompenzovat ztrátu zahraničních turistů domácím cestovním ruchem. Bezpečné opětovné otevření cestování a cestovního ruchu vrátí milionům Evropanů jejich pracovní místa a v mnoha regionech EU může urychlit obnovu¹⁸.

Obnovení cestování bezpečným a předvídatelným způsobem vyžaduje obnovení důvěry spotřebitelů v ochranu jejich zdraví a práv. Aplikace *Re-open EU*, kterou je možné si stáhnout, bude občanům nadále poskytovat spolehlivé informace o epidemiologické situaci a o pravidlech zavedených v EU (včetně digitálních zelených certifikátů) a obsahuje vylepšené nové, uživatelsky vstřícné funkce "cestovní trasy¹⁹. Jasný, celoevropský systém, který poskytne lidem plnou důvěru v normy v oblasti veřejného zdraví, může být skutečným krokem vpřed, pokud jde o zajištění jasnosti pro cestující a zároveň rozptýlení zbývajících obav a otevření dveří pro nadcházející letní sezónu. V roce 2020 Komise vydala cenné pokyny pro odvětví dopravy²⁰ a pohostinství s cílem pomoci jim minimalizovat rizika²¹. Komise rovněž vyzvala Evropský výbor pro normalizaci, aby připravil normalizační dokument jako základ pro zdravotní a bezpečnostní protokoly pro odvětví pohostinství, který bude k dispozici do léta. Tento dobrovolný nástroj pomůže lépe informovat podniky působící v oblasti cestovního ruchu a připravit je na to, aby přivítaly turisty při zachování plné bezpečnosti. Komise bude spolupracovat s členskými státy a tímto odvětvím s cílem zajistit úspěšné zavedení této "zdravotní pečeti EU v oblasti cestovního ruchu".

Komise, členské státy a odvětví cestovního ruchu by měly dále spolupracovat na komunikačních kampaních, které jsou zaměřeny na obnovení důvěry Evropanů, ale také cestujících ze třetích zemí v bezpečné cestování v Evropě.

Třetím krokem, který má pomoci turistickému odvětví připravit se na bezpečné otevření, je pokračující praktická podpora podniků, zejména malých a středních podniků a mikropodniků, udržovat služby bezpečné, pokud jde o onemocnění COVID, a přizpůsobit cestovní ruch nové realitě. Členské státy mohou mobilizovat podporu a investice pro nejvíce zasažená odvětví a

¹⁹ https://reopen.europa.eu/cs

¹⁶ Zejména v případě mladých lidí (13 % zaměstnanců mladších 24 let) a žen (59 % zaměstnanců).

¹⁷ Zdroj: Eurostat

¹⁸ Dne 13. května 2020 přijala Komise soubor pokynů a doporučení v rámci prvního balíčku opatření v oblasti cestovního ruchu a dopravy: https://ec.europa.eu/commission/presscorner/detail/cs/QANDA_20_870

²⁰ C(2020) 169/02

²¹ Pokyny EU k postupnému obnovování služeb cestovního ruchu a ke zdravotním protokolům v ubytovacích a stravovacích zařízeních C(2020)3251.

regiony v rámci investiční iniciativy pro reakci na koronavirus²² a iniciativy REACT EU, zatímco Nástroj pro oživení a odolnost a fondy politiky soudržnosti přispějí k udržitelné obnově nejvíce zasažených odvětví. Evropský fond pro regionální rozvoj na období 2021–2027 zahrnuje specifický cíl zaměřený na podporu ekonomického vývoje a sociálního začlenění v kultuře a cestovním ruchu. Komise zpřístupní Průvodce financováním z EU s cílem pomoci zúčastněným stranám v oblasti cestovního ruchu určit nejrelevantnější zdroje financování EU pro jejich projekty a investice.

Jedním z nejviditelnějších znaků opětovného otevření bude, že budou opět možné společné zážitky, jako jsou návštěvy kulturních zařízení a akcí, míst kulturního dědictví, jakož i kulturní cestovní ruch. To bude mít zásadní význam i pro přežití *kulturního a kreativního odvětví*, které bylo omezeními uvalenými na kontrolu pandemie obzvláště postiženo. Toto odvětví ztratilo v roce 2020 přibližně 31 % svých příjmů, přičemž nejvíce postiženo bylo scénické umění (pokles o 90 %) a hudba (pokles o 76 %)²³. Společný přístup a společné ukazatele pomohou při rozhodování o zrušení omezení tím, že se posílí důvěra diváků a návštěvníků, že otevírání probíhá odpovědně. Komise využije stávajících struktur spolupráce a sítí²⁴ k výměně informací o bezpečném opětovném otevření kulturního odvětví. Za účelem lepší koordinace opatření členských států na bezpečné obnovení činností v kulturním a tvůrčím odvětví Komise vypracuje pokyny pro odvětví v oblasti hudby (festivaly, místa konání), audiovizuální odvětví (filmové festivaly a trhy, kina, produkce), scénické umění (festivaly, místa konání), výstavní prostory jako např. muzea nebo galerie, knihovny a lokality kulturního dědictví.

Kulturní cestovní ruch podporuje růst a vytváří pracovní místa, přičemž čtyři z deseti turistů si vybírají svoji destinaci na základě kulturní nabídky. Komise zahájí speciální kampaň EU v sociálních médiích o udržitelném kulturním cestovním ruchu, jejímž cílem je propagace lokalit kulturního dědictví a kulturních tras EU, jakož i kulturních akcí a festivalů. Jakmile to podmínky dovolí, budou prostřednictvím programu Erasmus+ a jeho opatřením DiscoverEU podpořeny nové iniciativy na propagaci objevování kulturního dědictví Evropy mladými lidmi po železnici během Evropského roku železnic a i později.

Budování celosvětové odolnosti vůči onemocnění COVID-19

Udržitelná cesta z pandemie COVID-19 v rámci EU závisí na pokroku na celosvětové úrovni. Žádná země či region na světě nebudou před onemocněním COVID-19 v bezpečí, dokud nebude zabráněno šíření onemocnění na celosvětové úrovni, přičemž řešení globální krize může přinést jen celosvětový přístup. Pokud se virus šíří, budou ztráty na životech pokračovat: pandemie si na celém světě již vybrala svoji daň; celosvětově bylo potvrzeno již téměř 120 milionů případů a více než 2,6 milionů úmrtí. Pokračující šíření rovněž znamená trvalé riziko opětovného výskytu a nových variant, které by mohly narušit ochranu vytvořenou očkovacími látkami. EU má jak odpovědnost, tak i zájem na tom, aby dostála svému závazku bojovat proti šíření onemocnění COVID-19 na celém světě.

²² https://cohesiondata.ec.europa.eu/stories/s/4e2z-pw8r

²³ https://www.rebuilding-europe.eu/

²⁴ Například Creatives Unite, platforma pro kulturní a kreativní odvětví, https://creativesunite.eu/

EU stojí v čele mezinárodní reakce. Poskytla konkrétní finanční, naléhavou a věcnou podporu mezinárodním partnerům a zemím po celém světě. Tento přístup týmu Evropa²⁵ dosud přispěl na mezinárodní podporu v boji proti onemocnění COVID-19 částkou přes 40 miliard EUR.

Stejně jako v EU je základem udržitelného přístupu očkování. Proto EU důrazně podporuje práci v rámci nástroje COVAX při zavádění očkovacích látek po celém světě: s financováním ve výši více než 2,2 miliardy EUR patří EU a členské státy jako tým Evropa mezi hlavní podporovatele nástroje COVAX, globální inciativy k zajištění spravedlivého přístupu k vakcínám, a naléhavě vyzvaly všechny partnery, aby se k této práci připojili. V rámci *nástroje COVAX* bylo zahájeno zavádění dávek vakcín a cílem je sdílet vakcíny se všemi zeměmi s nízkými a středními příjmy v první polovině roku 2021. To by mělo být dostatečné k tomu, aby byli naočkováni všichni jejich pracovníci ve zdravotnictví a alespoň 3 % jejich populace, aby se proočkovanost do konce roku zvýšila alespoň na 20 %. Humanitární rezerva ve výši 100 milionů dávek s transparentním mechanismem přidělování pomůže zajistit inkluzivní přístup zranitelných skupin obyvatelstva k vakcínám.

EU a její členské státy zavádějí koordinovaný evropský přístup ke sdílení vakcín vytvořením *mechanismu EU pro sdílení očkovacích látek*, který je založen na zásadách spravedlnosti, postupného budování, nulovém odpadu a přístupu týmu Evropa. Cílem je dále podporovat stávající bilaterální iniciativy členských států a jít nad jejich rámec a vytvořit a rozšířit zásoby EU, které jsou naplňovány udržitelným způsobem sdílením dávek členských států. Mechanismus bude zahájen a bude budován postupně, když se zlepší dostupnost vakcín a stanoví se kvantitativní cíle. Vakcíny budou přednostně poskytovány prostřednictvím nástroje COVAX a mohou být rovněž nadále sdíleny přímo s danými zeměmi, se zvláštním důrazem na země západního Balkánu, zeměmi sousedství a Afrikou. EU bude rovněž pokračovat v usnadňování koordinace a logistiky a spolufinancování přepravy očkovacích látek prostřednictvím Mechanismus civilní ochrany Unie (UCPM).

Souběžně EU a její členské státy budou jako tým Evropa dále podporovat připravenost na strategie očkování na úrovni zemí a regionů a jejich zavádění, přičemž zabezpečí kolektivní opatření v partnerství s regionálními a globálními aktéry, včetně humanitárních aktérů. V dlouhodobém horizontu bude mít zásadní význam spolupráce s partnerskými zeměmi, zejména v Africe, za účelem posílení systémů zdravotní péče a výroby, včetně kapacity očkovacích látek, diagnostiky a léčebných postupů.

Zvýšení výroby vakcín na celosvětové úrovni a jejich dodávání do zemí v nouzi vyžaduje zvýšenou celosvětovou spolupráci mezi veřejnými orgány, společnostmi vyvíjejícími a vyrábějícími vakcíny za účelem zajištění dobrovolného udělování licencí pro nezbytný přenos technologického know-how. EU toto úsilí podporuje, a to i v rámci Světové obchodní organizace. Bude spolupracovat s ostatními zeměmi, které vyrábějí očkovací látky s cílem zabránit narušení úzce integrovaných dodavatelských řetězců. EU rovněž zajistí, že její režim

²⁵ Přístup týmu Evropa je přístup EU, který využívá příspěvky všech institucí EU a kombinuje zdroje mobilizované státy EU a finančními institucemi a současně respektuje pravomoci EU a rozhodovací postupy, včetně pravidel hlasování, stanovených ve Smlouvách EU.

transparentnosti a povolování pro vývoz vakcín proti COVID-19, který poskytuje řadu výjimek²⁶, je uplatňován spravedlivým a rovným způsobem.

Připravenost reagovat na opětovné rozšíření onemocnění COVID-19

Klíčová opatření v oblasti zdraví, která probíhají, tj. očkování, testování a trasování, připravenost na varianty viru, poskytují značné ujištění, že zvrácení pokroku zaznamenaného v minulém roce je méně pravděpodobné. Avšak zkušenosti s uvolněním omezení, po němž následovalo opětovné šíření viru, ukazují, že důležitou součástí budování důvěry je vědomí, že pokud by došlo k opětovnému šíření viru prostřednictvím jeho nové varianty, EU a členské státy by rychle zareagovaly. Rámec Evropského střediska pro prevenci a kontrolu nemocí popsaný výše bude obzvláště významný při rychlejší identifikaci rizika opětovného šíření viru a při zdůraznění nejvhodnějších omezení, která se mají uplatňovat.

Pokud jde o reakci v oblasti zdraví, Komise nadále podporuje členské státy prostřednictvím *mechanismu civilní ochrany Unie*. Jeho *Středisko pro koordinaci odezvy na mimořádné události s nepřetržitým provozem* může do několika hodin usnadnit a financovat nasazení zdravotnických záchranných týmů (jako v nedávném případě nasazení rumunských, dánských a belgických lékařů a zdravotních sester na Slovensku), nezbytného zdravotnického vybavení, vakcín (Francie nedávno poskytla dávky vakcín Slovensku a Česku) a osobní ochranné prostředky (včetně ze zásob systému rescEU). Nástroj pro mimořádnou podporu umožňuje rychlý přeshraniční přesun pacientů s cílem zmírnit tlak na zdravotnická zařízení.

Z dlouhodobého hlediska musí EU rovněž zavést silnější rámec pro odolnost a připravenost v případě budoucích pandemií. To je již cílem návrhů *evropské zdravotní unie*, jakož i probíhající práce na zřízení Úřadu pro připravenost a reakci na mimořádné situace v oblasti zdraví. Tuto práci podpoří i probíhající revize mechanismu civilní ochrany Unie. Návrhy týkající se evropské zdravotní unie na posílení rámce EU pro zdravotní bezpečnost by měly být přijaty co nejdříve. Komise předloží vizi ve *sdělení o získaných zkušenostech*, které požadují členové Evropské rady.

EU by měla rovněž zvážit, zda by úspěch dalších mimořádných kroků přijatých v minulém roce, jako např. systém "zelených pruhů", měl být konsolidován v rámci, který lze aktivovat v reakci na jakoukoli novou krizi. Nadcházející *schengenská strategie* nabídne rovněž příležitost k zavedení spolehlivých mechanismů plánování pro případ nepředvídatelných událostí a koordinaci opatření ve vztahu k vnitřním a vnějším hranicím, přičemž se posoudí dosavadní zkušenosti s krizí a potřeba v co největší míře omezit možné narušení volného pohybu a fungování jednotného trhu.

4 DALŠÍ POSTUP

Příštích několik měsíců pandemie COVID-19 bude vyžadovat rozhodná opatření s cílem zajistit udržitelné a bezpečné opětovné otevření našich společností a ekonomik. Koordinovaná opatření jsou potřebná na všech úrovních a musí zajistit, aby přijímaná opatření byla při snižování

²⁶ Výjimky zahrnují zejména dodávky zemím s nízkými a středními příjmy uvedenými na seznamu závazků COVAX a vývozy vakcín nakoupených a/nebo dodávaných prostřednictvím COVAX.

výskytu viru, podporování občanů a společností co nejúčinnější a umožnila našim společnostem návrat k normálu. Komise vyzývá všechny orgány EU a členské státy, aby pokračovaly ve společném úsilí, přičemž je mimořádně důležité zintenzivnit komunikační úsilí.

Evropská rada

- vyzvat k dohodnutému přístupu k bezpečnému opětovnému otevření na základě spolehlivého vědeckého rámce;
- podporovat další koordinaci úsilí o zastavení pandemie na celosvětové úrovni na základě přístupu týmu Evropa.

Evropský parlament a Rada

- urychlit diskuze a dosáhnout dohody ohledně návrhů digitálních zelených certifikátů;
- urychlit diskuze a před koncem roku dosáhnout dohody ohledně legislativních návrhů zdravotní unie.

Evropská komise

- nadále podporovat zvýšení výroby vakcín a včasného plnění smluvních závazků;
- dále rozvíjet technická řešení na evropské úrovni za účelem zvýšení interoperability vnitrostátních systémů s cílem usnadnit cestování, výměnu informací a trasování kontaktů;
- předložit evropskou strategii pro terapeutické přípravky.

Členské státy

- zajistit urychlení očkovacích programů v souladu se zvýšenou nabídkou;
- zajistit, aby dočasná omezení v boji proti onemocnění COVID-19 byla přiměřená a nediskriminační;
- urychlit činnosti spojené s technickým provedením digitálního zeleného certifikátu v zájmu urychleného přijetí návrhu;
- urychleně provést veškerá doporučení a vytvořit potřebnou infrastrukturu za účelem použití dostupných nástrojů v boji proti pandemii.



A coordinated approach to COVID-19 free movement restrictions

Commission Proposal for a Council Recommendation

IPCR Working-level Roundtable, 7 September 2020

Overview

- Background and key considerations
- Details of the proposal
 - Legal bases and general principles
 - Common criteria
 - Data
 - Common thresholds
 - Mapping of risk areas

- Coordination among Member States
 and common timeline
- Common framework as regards
 possible measures for travellers
- Communication and information to the public



Background

- The right of EU citizens to move freely within the EU key European achievement and important driver of our internal market and economies
- Some measures adopted by MS to limit the spread of COVID-19 impact free movement (e.g. entry bans, mandatory quarantine)
- Unilateral measures have led to significant disruptions businesses and citizens face diverging measures, adopted at short notice, based on very different criteria, or not sufficiently coordinated.
- Result: high level of uncertainty, harmful in a situation where our economies have already been significantly affected



Joint efforts to address restrictions so far

- Regular MS/COM exchanges in the COVID-19 Information Group Home Affairs, IPCR and other fora
- March: Guidelines for border management measures and Guidelines on on the free movement of workers
- May: Communication towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls
- August: French non-paper, Presidency non-paper, letter from COM to MS on principles for free movement restrictions, COM services technical paper, and related discussions



Key considerations

- A well-coordinated, predictable and transparent approach to free movement restrictions on grounds of public health is needed
- Necessary to reduce the impact of restrictions on EU citizens and the economy while ensuring a high level of human health protection
- COM is not proposing the introduction of new restrictions only a coordinated framework in case a MS considers restrictions necessary
- MS not obliged to introduce restrictions



Key dimensions to address

- Building on our discussions and the non-papers, the proposal sets out four key dimensions to address:
 - Common criteria and thresholds for MS when deciding on measures affecting free movement rights, and the need to have the necessary data available
 - Mapping of risk using an agreed colour code
 - A common framework for measures applied to travellers
 - Clear and timely information to other MS and the public



Legal bases and general principles

- Restrictions on entry/exit and other measures such as mandatory quarantine upon entry limit **EU citizens' free movement rights**.
- Free movement restrictions must **based on specific public interest grounds** (e.g. protection of public health) and must comply with general EU law principles, in particular proportionality and non-discrimination.
- Proposal intends to **facilitate the application of these EU law principles**, in a coordinated manner, to the exceptional situation caused by COVID-19
- Legal bases of the proposal are therefore Art. 21 (free mov. of persons), Art. 46 (free mov. of workers), Art. 52 (freedom of establishment and services), Art. 168 (public health) and Art. 292 (Council Recommendations)



General principles (cont.)

- Based on general EU law principles proportionality and non-discrimination:
 - measures taken should not extend beyond what is strictly necessary
 - restrictions should be lifted as soon as the epidemiological situation allows it
 - no discrimination between Member States
 - restrictions cannot be based on nationality but only on the location(s) prior to arrival
 - MS should always admit own nationals and resident EU citizens and facilitate transit
- Regular exchange of information among MS
- Particular attention to cross-border regions



Common criteria

14-day cumulative COVID-19 case notification rate

(newly notified cases per 100 000 in a given area in the last 14 days)

• test positivity rate

(percentage of positive tests among all tests in a given area during the last week)

testing rate

(Number of tests per 100 000 in a given area during the last week)

• Why?

- Already in use by certain MS
- Relatively easy to use compared to other possible parameters
- Data already available (albeit patchy/delayed notification to ECDC)
- Captures current situation, unlike other possible parameters (death rates, ICU occupancy, etc.)



Data on common criteria

- To share a common analysis of the epidemiological risk at EU level, MS should provide **ECDC** with data on the common criteria on a **weekly basis**
- MS should also provide data at **regional level** to ensure that measures can be targeted to what is strictly necessary

Crucial to ensure that comprehensive, reliable and timely data is available to ECDC



Common thresholds

- No restrictions on movement to/from MS if
 - a) notification rate less than 50 or
 - b) test positivity rate less than 3%
- provided a testing rate more than 250 in the MS concerned
- Where notification rate is more than 150 per, letter (b) should not apply

- Regional approach wherever possible
- For this purpose, thresholds should be applied to the regional level rather than MS level, not limiting free movement to/from other regions



Mapping of risk areas

 Based on MS data provided, ECDC should publish map to support MS' own decision-making



- Testing rate ≤250 per 100 000 population
- No data available on number of tests performed

- **Green**, if notification rate <25 **AND** the test positivity rate <3%
- Orange, if notification rate <50 BUT the test positivity rate ≥3%, OR notification rate is 25-150 BUT the test positivity rate <3%
- Red, if notification rate ≥50 AND the test positivity rate ≥3%, OR if notification rate >150
- Grey, if insufficient information available
 OR testing rate ≤250



Mapping of risk areas (cont.)

Why the combination of notification rate/testing rate, and why the thresholds?

- Criteria used should not discourage testing
- Criteria should be fair, manageable and transparent, as requested by MS
- MS currently use different thresholds (typically notification rate)
- Suggested COM threshold based on MS practices and suggestions
- No specific thresholds suggested by ECDC, as it considers that available evidence does not support travel restrictions



MS coordination and common timeline

- **Thursday**: MS intending to apply restrictions on travel to/from 'red' or 'grey' area, based on own decision-making process, should inform other MS/COM
- **Monday**: Restrictions communicated by MS should enter into force, save for exceptional circumstances
- Restrictions should be lifted when area moves from 'red'/ 'grey' to 'green'/'orange' provided 14 days have elapsed since introduction (to avoid weekly changes). Information to other MS/COM
- MS should take into account own epidemiological situation and measures applied to 'red' and 'grey' areas in own territory
- Phase out of current restrictions on 'green'/'orange' areas



Common framework for possible measures

- No entry bans on travel within the EU
- MS introducing restrictions could require persons travelling from 'red'/'grey' area to undergo **quarantine** or **test after arrival** (preferred option, option for traveller to substitute with test done prior to departure)
- Mutual recognition of tests carried out in other MS
- MS could require passenger locator form for persons from 'red', 'orange' or 'grey' areas (data protection/GDPR compliant, digital option to simplify processing)
- MS could recommend test for person from 'orange' area
- Non-discrimination: measures also for returning nationals



Common framework for possible measures (cont.)

- No quarantine for travellers with essential function/need:
 - Critical workers/self-employed, transport workers, students travelling abroad daily, imperative family/business reasons, diplomats, passengers in transit, seafarers, journalists when performing duties
- Any measures should provide concrete public health benefit and not create undue administrative burden
- If a person **develops symptoms** upon arrival: testing, diagnosis, isolation and contact tracing according to local practice, no entry ban.
- Restrictions should not take the form of prohibitions on the operation of transport services


Communication and information to the public

• Clear, comprehensive and timely information about restrictions, additional requirements (negative tests, passenger locator forms) and measures applied

 In particular, information as quickly as possible on any newly introduced or lifted measures

 Information to be published on 'Re-open EU' website, including the map prepared by ECDC



Thank you

Contacts:

Ms Marie-Hélène Boulanger, Head of Unit, DG JUST.D3 Ms Monika Moßhammer, Deputy Head of Unit, DG JUST.D3 Mr Jan Stadler, Desk Officer, DG JUST.D3

© European Union 2020



Unless otherwise noted the reuse of this presentation is authorised under the <u>CC BY 4.0</u> license. For any use or reproduction of elements that are not owned by the EU, permission may need to be sought directly from the respective right holders.





EVROPSKÁ UNIE

RADA

Brusel 9. června 2021 (OR. en)

2021/0071 (COD)

PE-CONS 26/21

COVID-19 167	TRANS 238
JAI 440	COCON 27
POLGEN 54	COMIX 230
FRONT 158	SCHENGEN 33
FREMP 105	AVIATION 98
IPCR 46	PHARM 66
VISA 81	RELEX 358
MI 283	TOUR 26
SAN 241	CODEC 583

PRÁVNÍ PŘEDPISY A JINÉ AKTY

Předmět: NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19 (digitální certifikát EU COVID) ve vztahu ke státním příslušníkům třetích zemí s oprávněným pobytem nebo bydlištěm na území členských států během pandemie COVID-19

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY (EU) 2021/...

ze dne ...

o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19 (digitální certifikát EU COVID) ve vztahu ke státním příslušníkům třetích zemí s oprávněným pobytem nebo bydlištěm na území členských států během pandemie COVID-19

(Text s významem pro EHP)

EVROPSKÝ PARLAMENT A RADA EVROPSKÉ UNIE,

s ohledem na Smlouvu o fungování Evropské unie, a zejména na čl. 77 odst. 2 písm. c) této smlouvy,

s ohledem na návrh Evropské komise,

po postoupení návrhu legislativního aktu vnitrostátním parlamentům,

v souladu s řádným legislativním postupem¹,

Postoj Evropského parlamentu ze dne 9. června 2021 (dosud nezveřejněný v Úředním věstníku) a rozhodnutí Rady ze dne

vzhledem k těmto důvodům:

- Podle schengenského *acquis* se státní příslušníci třetích zemí s oprávněným pobytem nebo bydlištěm na území členských států mohou po dobu 90 dnů během jakéhokoliv období 180 dnů volně pohybovat na území všech ostatních členských států.
- (2) Dne 30. ledna 2020 vyhlásil generální ředitel Světové zdravotnické organizace (WHO) ohrožení veřejného zdraví mezinárodního významu z důvodu globální nákazy koronavirem 2 způsobujícím těžký akutní respirační syndrom (SARS-CoV-2), který vyvolává onemocnění koronavirem 2019 (COVID-19). Dne 11. března 2020 provedla WHO posouzení, na jehož základě označila COVID-19 za pandemii.
- (3) S cílem omezit šíření SARS-CoV-2 přijaly členské státy některá opatření, která měla dopad na cestování do těchto členských států i na jejich na území, například omezení vstupu nebo požadavky, aby přeshraniční cestující podstoupili karanténu či domácí izolaci nebo test na infekci SARS-CoV-2. Tato omezení mají škodlivé účinky na osoby a podniky, zejména na osoby, které žijí v příhraničních regionech a denně nebo často cestují přes hranice za účelem práce, podnikání, vzdělávání, za rodinou, zdravotní péčí nebo za účelem poskytování péče.

- (4) Dne 13. října 2020 přijala Rada doporučení (EU) 2020/1475¹, které zavedlo koordinovaný přístup k omezení volného pohybu v reakci na pandemii COVID-19.
- (5) Dne 30. října 2020 přijala Rada doporučení (EU) 2020/1632², v němž doporučila členským státům, které jsou schengenským *acquis* vázány, aby uplatňovaly obecné zásady, společná kritéria, společné prahové hodnoty a společný rámec opatření, včetně doporučení týkající se koordinace a komunikace, stanovené v doporučení (EU) 2020/1475.
- (6) Mnoho členských států již zahájilo nebo plánuje zahájit iniciativy na vydávání certifikátů o očkování proti onemocnění COVID-19. Aby tyto certifikáty o očkování však mohly být účinně využity při přeshraničním cestování v rámci Unie, musí být plně interoperabilní, kompatibilní, zabezpečené a ověřitelné. Je nezbytné, aby se členské státy zaujaly společný přístup k obsahu, formátu, technickým normám a úrovni zabezpečení těchto certifikátů o očkování a zásadách jejich používání.

Doporučení Rady (EU) 2020/1475 ze dne 13. října 2020 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19 (Úř. věst. L 337, 14.10.2020, s. 3).

² Doporučení Rady (EU) 2020/1632 ze dne 30. října 2020 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19 v schengenském prostoru (Úř. věst. L 366, 4.11.2020, s. 25).

(7) Přede dnem použitelnosti tohoto nařízení některé členské státy již osvobodily očkované osoby od určitých cestovních omezení. Pokud členské státy uznají potvrzení o očkování, aby mohly upustit od cestovních omezení zavedených v souladu s právem Unie s cílem omezit šíření SARS-CoV-2, například od požadavku podstoupit karanténu či domácí izolaci nebo test na infekci SARS-CoV-2, měly by být povinny uznat za týchž podmínek platné certifikáty o očkování vydané jinými členskými státy v souladu s nařízením Evropského parlamentu a Rady (EU) 2021/...¹⁺. Toto uznání by mělo probíhat za týchž podmínek, což například znamená, že pokud členský stát považuje za dostačující jednu podanou dávku očkovací látky, měl by ji považovat za dostačující i v případě držitelů certifikátu o očkování, v němž je zaznamenána jedna dávka téže očkovací látky.

¹ Nařízení Evropského parlamentu a Rady (EU) 2021/... ze dne ... o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19 (digitální certifikát EU COVID) za účelem usnadnění volného pohybu osob během pandemie COVID-19 (Úř. věst. L ..., ..., s. ...).

Úř. věst.: vložte prosím do textu číslo nařízení uvedené v dokumentu PE-CONS 25/2021 (2021/0068(COD)) a do poznámky pod čarou číslo, datum, název a odkaz na vyhlášení uvedeného nařízení v Úředním věstníku.

Harmonizované postupy podle nařízení Evropského parlamentu a Rady (ES) č. 726/2004¹ (8) by neměly členským státům bránit uznávat certifikáty o očkování vydané pro jiné očkovací látky proti onemocnění COVID-19 než ty, kterým příslušný orgán členského státu udělil registraci podle směrnice Evropského parlamentu a Rady 2001/83/ES², pro očkovací látky, jejichž distribuce byla dočasně povolena podle čl. 5 odst. 2 uvedené směrnice, a pro očkovací látky, u nichž byl dokončen postup zařazení na seznam WHO k nouzovému použití. V případě, kdy je určité očkovací látce proti onemocnění COVID-19 následně udělena registrace podle nařízení (ES) č. 726/2004, povinnost uznat certifikáty o očkování vydané za týchž podmínek se rovněž vztahuje na certifikáty o očkování vydané členským státem pro tuto očkovací látku proti onemocnění COVID-19, a to bez ohledu na to, zda byl certifikát o očkování vydán před nebo po registraci prostřednictvím centralizovaného postupu. Nařízení (EU) 2021/...⁺ stanoví rámec pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19 (dále jen "digitální certifikát EU COVID") za účelem usnadnění volného pohybu během pandemie COVID-19. Vztahuje se na občany Unie a státní příslušníky třetích zemí, kteří jsou rodinnými příslušníky občanů Unie.

¹ Nařízení Evropského parlamentu a Rady (ES) č. 726/2004 ze dne 31. března 2004, kterým se stanoví postupy Unie pro registraci humánních a veterinárních léčivých přípravků a dozor nad nimi a kterým se zřizuje Evropská agentura pro léčivé přípravky (Úř. věst. L 136, 30.4.2004, s. 1).

² Směrnice Evropského parlamentu a Rady 2001/83/ES ze dne 6. listopadu 2001 o kodexu Společenství týkajícím se humánních léčivých přípravků (Úř. věst. L 311, 28.11.2001, s. 67).

⁺ Úř. věst.: vložte prosím do textu číslo nařízení uvedené v dokumentu PE-CONS 25/2021 (2021/0068(COD)).

- (9) V souladu s články 19, 20 a 21 Úmluvy k provedení Schengenské dohody ze dne 14. června 1985 mezi vládami států Hospodářské unie Beneluxu, Spolkové republiky Německo a Francouzské republiky o postupném odstraňování kontrol na společných hranicích¹ mohou státní příslušníci třetích zemí, na něž se vztahují tato ustanovení, volně pohybovat na území členských států.
- (10) Aniž jsou dotčena společná pravidla týkající se překračování vnitřních hranic osobami, stanovená v nařízení Evropského parlamentu a Rady (EU) 2016/399²⁺, a za účelem usnadnění cestování státních příslušníků třetích zemí, kteří mohou cestovat na území členských států, by se měl rámec pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19 zavedený nařízením (EU) 2021/...⁺ vztahovat rovněž na státní příslušníky třetích zemí, na něž se uvedené nařízení dosud nevztahuje, a to za předpokladu, že mají na území některého z členských států oprávněný pobyt nebo bydliště a mohou v souladu s právem Unie cestovat do jiných členských států.

¹ Úř. věst. L 239, 22.9.2000, s. 19.

² Nařízení Evropského parlamentu a Rady (EU) 2016/399 ze dne 9. března 2016, kterým se stanoví kodex Unie o pravidlech upravujících přeshraniční pohyb osob (Schengenský hraniční kodex) (Úř. věst. L 77, 23.3.2016, s. 1).

⁺ Úř. věst.: vložte prosím do textu číslo nařízení uvedené v dokumentu PE-CONS 25/2021 (2021/0068(COD)).

- (11) Záměrem tohoto nařízení je usnadnit uplatňování zásad proporcionality a zákazu diskriminace, pokud jde o omezení cestování během pandemie COVID-19, a zároveň usilovat o vysokou úroveň ochrany veřejného zdraví. Nemělo by být chápáno tak, že usnadňuje nebo podporuje přijímání omezení volného pohybu nebo omezení jiných základních práv, která byla zavedena v reakci na pandemii COVID-19. Jakýkoli požadavek na ověření certifikátů zavedených nařízením (EU) 2021/...⁺ navíc nemůže sám o sobě odůvodnit dočasné znovuzavedení ochrany vnitřní hranic. Kontroly na vnitřních hranicích by měly zůstat krajním opatřením, jež podléhá zvláštním pravidlům stanoveným v nařízení (EU) 2016/399.
- (12) Vzhledem k tomu, že se toto nařízení vztahuje na státní příslušníky třetích zemí, kteří již mají na území členských států oprávněný pobyt nebo bydliště, nemělo by být vykládáno tak, že státním příslušníkům třetích zemí, kteří si přejí cestovat do některého z členských států, přiznává právo obdržet od tohoto členského státu digitální certifikát EU COVID, před příjezdem na jeho území. Členské státy nemají povinnost vydávat certifikáty o očkování na konzulárních úřadech.
- (13) Dne 30. června 2020 přijala Rada doporučení (EU) 2020/912¹ o dočasném omezení cest do Unie, jež nejsou nezbytně nutné, a o možném zrušení tohoto omezení. Toto nařízení se nevztahuje na dočasné omezení cest do Unie, jež nejsou nezbytně nutné.

⁺ Úř. věst.: vložte prosím do textu číslo nařízení uvedené v dokumentu PE-CONS 25/2021 (2021/0068(COD)).

Doporučení Rady (2020/912) ze dne 30. června 2020 o dočasném omezení cest do EU, jež nejsou nezbytně nutné, a o možném zrušení tohoto omezení (Úř. věst. L 208 I, 1.7.2020, s. 1).

- (14) V souladu s články 1 a 2 Protokolu č. 22 o postavení Dánska, připojeného ke Smlouvě o Evropské unii (dále jen "Smlouva o EU") a ke Smlouvě o fungování Evropské unie, se Dánsko neúčastní přijímání tohoto nařízení a toto nařízení pro ně není závazné ani použitelné. Vzhledem k tomu, že toto nařízení navazuje na schengenské *acquis*, rozhodne se Dánsko v souladu s článkem 4 uvedeného protokolu do šesti měsíců ode dne přijetí tohoto nařízení Radou, zda je provede ve svém vnitrostátním právu.
- (15) Toto nařízení rozvíjí ta ustanovení schengenského acquis, kterých se neúčastní Irsko v souladu s rozhodnutím Rady 2000/192/ES¹; Irsko se tedy nepodílí na jeho přijímání a toto nařízení pro ně není závazné ani použitelné. S cílem umožnit členským státům uznávat za podmínek stanovených nařízením (EU) 2021/...⁺ certifikáty týkající se onemocnění COVID-19 vydávané Irskem státním příslušníkům třetích zemí, kteří mají na jeho území oprávněný pobyt či bydliště, za účelem usnadnění cestování na území členských států, by Irsko mělo těmto státním příslušníkům třetích zemí vydávat certifikáty týkající se onemocnění COVID-19, které splňují požadavky rámce pro důvěryhodnost digitálního certifikátu EU COVID. Irsko a ostatní členské státy by měly uznávat certifikáty vydávané státním příslušníkům třetích zemí, na něž se vztahuje toto nařízení, na recipročním základě.

¹ Rozhodnutí Rady 2002/192/ES ze dne 28. února 2002 o žádosti Irska, aby se na ně vztahovala některá ustanovení schengenského *acquis* (Úř. věst. L 64, 7.3.2002, s. 20).

⁺ Úř. věst.: vložte prosím do textu číslo nařízení uvedené v dokumentu PE-CONS 25/2021 (2021/0068(COD)).

- (16) Toto nařízení představuje akt navazující na schengenské *acquis* nebo s ním jinak související ve smyslu čl. 3 odst. 1 aktu o přistoupení z roku 2003, čl. 4 odst. 1 aktu o přistoupení z roku 2005 a čl. 4 odst. 1 aktu o přistoupení z roku 2011.
- (17) Pokud jde o Island a Norsko, rozvíjí toto nařízení ta ustanovení schengenského *acquis* ve smyslu Dohody uzavřené mezi Radou Evropské unie a Islandskou republikou a Norským královstvím o přidružení těchto dvou států k provádění, uplatňování a rozvoji schengenského *acquis*¹, která spadají do oblasti uvedené v čl. 1 bodě C rozhodnutí Rady 1999/437/ES².
- (18) Pokud jde o Švýcarsko, rozvíjí toto nařízení ta ustanovení schengenského *acquis* ve smyslu Dohody mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji schengenského *acquis*³, která spadají do oblasti uvedené v čl. 1 bodě C rozhodnutí Rady 1999/437/ES ve spojení s článkem 3 rozhodnutí Rady 2008/146/ES⁴.

¹ Úř. věst. L 176, 10.7.1999, s. 36.

² Rozhodnutí Rady 1999/437/ES ze dne 17. května 1999 o některých opatřeních pro uplatňování dohody uzavřené mezi Radou Evropské unie a Islandskou republikou a Norským královstvím o přidružení těchto dvou států k provádění, uplatňování a rozvoji schengenského *acquis* (Úř. věst. L 176, 10.7.1999, s. 31).

³ Úř. věst. L 53, 27.2.2008, s. 52.

⁴ Rozhodnutí Rady 2008/146/ES ze dne 28. ledna 2008 o uzavření dohody mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji schengenského *acquis* jménem Evropského společenství (Úř. věst. L 53, 27.2.2008, s. 1).

(19) Pokud jde o Lichtenštejnsko, rozvíjí toto nařízení ta ustanovení schengenského *acquis* ve smyslu Protokolu mezi Evropskou unií, Evropským společenstvím, Švýcarskou konfederací a Lichtenštejnským knížectvím o přistoupení Lichtenštejnského knížectví k Dohodě mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji schengenského *acquis*¹, která spadají do oblasti uvedené v čl. 1 bodě C rozhodnutí 1999/437/ES ve spojení s článkem 3 rozhodnutí Rady 2011/350/EU².

¹ Úř. věst. L 160, 18.6.2011, s. 21.

² Rozhodnutí Rady 2011/350/EU ze dne 7. března 2011 o uzavření Protokolu mezi Evropskou unií, Evropským společenstvím, Švýcarskou konfederací a Lichtenštejnským knížectvím o přistoupení Lichtenštejnského knížectví k dohodě mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji schengenského *acquis* jménem Evropské unie, pokud jde o zrušení kontrol na vnitřních hranicích a pohyb osob (Úř. věst. L 160, 18.6.2011, s. 19).

- (20) Jelikož cíle tohoto nařízení, totiž usnadnit cestování státních příslušníků třetích zemí, kteří během pandemie COVID-19 mají oprávněný pobyt nebo bydliště na území členských států, zavedením rámce pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19, nemůže být uspokojivě dosaženo členskými státy, ale spíše jej, z důvodu rozsahu a účinků dané činnosti, může být lépe dosaženo na úrovni Unie, může Unie přijmout opatření v souladu se zásadou subsidiarity stanovenou v článku 5 Smlouvy o EU. V souladu se zásadou proporcionality stanovenou v uvedeném článku nepřekračuje toto nařízení rámec toho, co je nezbytné k dosažení tohoto cíle.
- (21) Vzhledem k naléhavosti situace v souvislosti s pandemií COVID-19 by toto nařízení mělo vstoupit v platnost dnem vyhlášení v *Úředním věstníku Evropské unie*.
- (22) Evropský inspektor ochrany údajů a Evropský sbor pro ochranu osobních údajů byli konzultování v souladu s článkem 42 nařízení Evropského parlamentu a Rady (EU) 2018/1725¹ a dne 31. března 2021 vydali společné stanovisko²,

PŘIJALY TOTO NAŘÍZENÍ:

¹ Nařízení Evropského parlamentu a Rady (EU) 2018/1725 ze dne 23. října 2018 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů orgány, institucemi a jinými subjekty Unie a o volném pohybu těchto údajů a o zrušení nařízení (ES) č. 45/2001 a rozhodnutí č. 1247/2002/ES (Úř. věst. L 295, 21.11.2018, s. 39).

² Úř. věst. C

Článek 1

Členské státy použijí pravidla stanovená v nařízení (EU) 2021/ ...+ na státní příslušníky třetích zemí, kteří nespadají do působnosti uvedeného nařízení, ale kteří mají na jejich území oprávněný pobyt nebo bydliště a kteří mohou v souladu s právem Unie cestovat do jiných členských států.

Článek 2

Za předpokladu, že Irsko oznámí Radě a Komisi, že uznává certifikáty uvedené v čl. 3 odst. 1 nařízení (EU) 2021/...⁺ vydávané členskými státy osobám, na něž se vztahuje toto nařízení, uznají členské státy za podmínek uvedených v nařízení (EU) 2021/...⁺ certifikáty týkající se onemocnění COVID-19 vydávané Irskem státním příslušníkům třetích zemí, kteří mohou volně cestovat na území členských států, a jež jsou ve formátu slučitelném s požadavky rámce pro důvěryhodnost digitálního certifikátu EU COVID podle nařízení (EU) 2021/...⁺.

Úř. věst.: vložte prosím do textu číslo nařízení uvedené v dokumentu PE-CONS 25/2021 (2021/0068(COD)).

Článek 3

Toto nařízení vstupuje v platnost dnem vyhlášení v Úředním věstníku Evropské unie.

Použije se od 1. července 2021 do 30. června 2022.

Toto nařízení je závazné v celém rozsahu a přímo použitelné v členských státech v souladu se Smlouvami.

V Bruselu dne

Za Evropský parlament předseda Za Radu předseda nebo předsedkyně



Brusel 18. března 2021 (OR. en)

7128/21

Interinstitucionální spis: 2021/0068(COD)

COVID-19 90 JAI 285 AG 19 FRONT 97 FREMP 54 IPCR 30 VISA 50 MI 179 SAN 153 TRANS 153 COCON 13 COMIX 151 CODEC 407

NÁVRH

Martine DEPREZOVÁ, ředitelka, za generální tajemnici Evropské komise
18. března 2021
Jeppe TRANHOLM-MIKKELSEN, generální tajemník Rady Evropské unie
COM(2021) 130 final
Návrh NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení za účelem usnadnění volného pohybu během pandemie COVID-19 (digitální zelený certifikát)

Delegace naleznou v příloze dokument COM(2021) 130 final.

Příloha: COM(2021) 130 final



V Bruselu dne 17.3.2021 COM(2021) 130 final

2021/0068 (COD)

Návrh

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY

o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení za účelem usnadnění volného pohybu během pandemie COVID-19 (digitální zelený certifikát)

(Text s významem pro EHP)

1. SOUVISLOSTI NÁVRHU

Odůvodnění a cíle návrhu

Právo občanů EU svobodně se pohybovat a pobývat v Evropské unii je jedním z nejcennějších výdobytků EU a důležitým motorem jejího hospodářství.

Podle článku 21 Smlouvy o fungování Evropské unie (dále jen "Smlouva o fungování EU") má každý občan EU právo svobodně se pohybovat a pobývat na území členských států s výhradou omezení a podmínek stanovených ve Smlouvách a v opatřeních přijatých k jejich provedení. Některá z omezení přijatých členskými státy za účelem omezení šíření koronaviru 2 způsobujícího těžký akutní respirační syndrom (dále jen "SARS-CoV-2"), který způsobuje onemocnění koronavirem 2019 (dále jen "COVID-19"), však měla dopad na právo občanů Unie na volný pohyb. Tato opatření často spočívala v omezeních vstupu nebo jiných specifických požadavcích na přeshraniční cestující, jako je podstoupení karantény či domácí izolace nebo podstoupení testu na infekci SARS-CoV-2 před příjezdem a/nebo po příjezdu. Měla dopad zvláště na osoby, které žijí v příhraničních regionech a překračují hranice v každodenním životě, ať už z důvodu výkonu zaměstnání, vzdělávání, zdravotní péče, rodiny či z jiných důvodů.

Aby byl zajištěn dobře koordinovaný, předvídatelný a transparentní přístup k přijímání omezení svobody pohybu, přijala Rada dne 13. října 2020 doporučení Rady (EU) 2020/1475 o koordinovaném přístupu k omezování volného pohybu v reakci na pandemii COVID-19¹. Toto doporučení stanovilo koordinovaný přístup, který se skládá z těchto klíčových bodů: uplatňování společných kritérií a prahových hodnot při rozhodování o tom, zda omezení volného pohybu zavést, vytváření map rizika přenosu onemocnění COVID-19 na základě dohodnutého barevného kódu, jež zveřejňuje Evropské středisko pro prevenci a kontrolu nemocí (ECDC)², a koordinovaný přístup, pokud jde o případná opatření, která se mohou odpovídajícím způsobem uplatnit na osoby pohybující se mezi oblastmi, v závislosti na úrovni rizika přenosu v uvedených oblastech.

Cílem doporučení Rady (EU) 2020/1475 je zajistit větší koordinaci mezi členskými státy zvažujícími v souvislosti s pandemií přijetí opatření omezujících volný pohyb z důvodů veřejného zdraví. Při přijímání a uplatňování omezení volného pohybu by členské státy měly dodržovat právo EU, zejména zásadu proporcionality a zákazu diskriminace. Doporučení Rady (EU) 2020/1475 bylo později pozměněno s ohledem na velmi vysokou míru komunitního přenosu v celé EU, která může být spojena se zvýšenou nakažlivostí nových variant SARS-CoV-2 vzbuzujících obavy³.

Podle bodu 17 doporučení Rady (EU) 2020/1475 by členské státy mohly vyžadovat, aby osoby cestující z rizikových oblastí podstoupily karanténu / domácí izolaci a/nebo podstoupily test na infekci SARS-CoV-2 před příjezdem a/nebo po příjezdu. Na osoby cestující z oblastí označených jako "tmavě červené" by se podle bodu 17 doporučení Rady mohla vztahovat posílená opatření v oblasti veřejného zdraví.

¹ Úř. věst. L 337, 14.10.2020, s. 3.

² <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

³ Doporučení Rady (EU) 2021/119 ze dne 1. února 2021, kterým se mění doporučení (EU) 2020/1475 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19 (Úř. věst. L 36I, 2.2.2021, s. 1).

Na důkaz splnění příslušných požadavků měly cestující osoby předložit různé druhy písemných dokumentů, jako jsou lékařská osvědčení, výsledky testů nebo prohlášení. Kvůli neexistenci standardizovaných a zabezpečených formátů vznikly jejich držitelům problémy s přijímáním těchto dokumentů v jiných členských státech a objevily se i zprávy o předkládání padělaných nebo pozměněných dokumentů⁴.

Tyto problémy, které mohou způsobit zbytečné prodlevy a překážky, se budou pravděpodobně zvětšovat s tím, jak se stále více Evropanů nechává testovat na COVID-19 a očkovat proti tomuto viru a dostává o tom potvrzení. Evropská rada je tím čím dál více znepokojena, a její členové proto ve svém prohlášení přijatém v návaznosti na neformální videokonference konané ve dnech 25. a 26. února 2021⁵ vyzvali k pokračování práce na společném přístupu k certifikátům o očkování.

Členské státy se shodují na nutnosti používat tyto certifikáty pro lékařské účely, například z důvodu zajištění řádných návazných kroků mezi první a druhou dávkou, jakož i případných nezbytných přeočkování. Členské státy pracují na vytvoření certifikátů o očkování, často s využitím informací dostupných v imunizačních registrech.

Komise spolupracuje s členskými státy v rámci sítě pro elektronické zdravotnictví – dobrovolné sítě spojující vnitrostátní orgány odpovědné za elektronické zdravotnictví – na přípravě interoperability certifikátů o očkování. Dne 27. ledna 2021 přijala tato síť pokyny k prokazování očkování pro lékařské účely a následně je dne 12. března 2021 aktualizovala⁶. Tyto pokyny definují ústřední prvky interoperability, zejména minimální soubor údajů pro certifikáty o očkování a jedinečný identifikátor. Síť pro elektronické zdravotnictví a Výbor pro zdravotní bezpečnost zřízený článkem 17 rozhodnutí Evropského parlamentu a Rady č. 1082/2013/EU⁷ rovněž pracují na společném standardizovaném souboru údajů pro certifikáty o výsledcích testů na COVID-19⁸, pokynech pro certifikáty o uzdravení a souvisejících datových souborech, jakož i na nástinu interoperability zdravotních certifikátů⁹.

Na základě dosud vykonané technické práce navrhuje Komise zřídit celounijní rámec pro vydávání, ověřování a uznávání certifikátů o očkování v rámci EU jako součásti "digitálního zeleného certifikátu". Tento rámec by měl zároveň zahrnovat i další certifikáty vydané během pandemie COVID-19, konkrétně potvrzení o negativním výsledku testu na infekci SARS-CoV-2, jakož i potvrzení, že se držitel z infekce virem SARS-CoV-2 uzdravil. Tohoto interoperabilního rámce tak budou moci využít i osoby, které nejsou očkovány nebo dosud neměly možnost se naočkovat, čímž se usnadní jejich volný pohyb. Například děti v současné době nemohou být proti onemocnění COVID-19 očkovány, ale měly by mít možnost získat certifikát o testu nebo o uzdravení (které by jejich jménem mohli obdržet jejich rodiče).

Dále by se mělo vyjasnit, že účelem certifikátů zahrnutých v "digitálním zeleném certifikátu" je usnadnit výkon práv na volný pohyb. Držení "digitálního zeleného certifikátu", zejména certifikátu o očkování, by však nemělo být podmínkou výkonu práv na volný pohyb. Osoby,

⁴ <u>https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates</u>

⁵ SN 2/21.

⁶ <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

 ⁷ Rozhodnutí Evropského parlamentu a Rady č. 1082/2013/EU ze dne 22. října 2013 o vážných přeshraničních zdravotních hrozbách a o zrušení rozhodnutí č. 2119/98/ES (Úř. věst. L 293, 5.11.2013, s. 1).

⁸ K dispozici na adrese <u>https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19 rat_common-list_en.pdf</u>

⁹ K dispozici na adrese <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

které nejsou očkovány – například z lékařských důvodů, protože nejsou součástí cílové skupiny, které se očkovací látka v současné době doporučuje (například děti), nebo protože ještě neměly příležitost se očkovat nebo se rozhodly, že se očkovat nenechají –, musí mít možnost nadále uplatňovat své základní právo na volný pohyb, v případě potřeby s výhradou omezení, jako je povinné testování a karanténa / domácí izolace. Toto nařízení zejména nelze vykládat tak, že zakládá povinnost nechat se očkovat nebo právo na očkování.

K zajištění interoperability mezi různými technickými řešeními, která vyvíjejí členské státy, z nichž některé již začaly přijímat potvrzení o očkování s cílem osvobodit cestující od určitých omezení, jsou zapotřebí jednotné podmínky pro vydávání, ověřování a uznávání certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19.

Rámec "digitálního zeleného certifikátu", který má být vytvořen, by měl stanovit formát a obsah certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19. Komise rovněž navrhuje, že by rámec "digitálního zeleného certifikátu" měl zajistit vydávání těchto certifikátů v interoperabilním formátu a jejich spolehlivé ověřování při předložení držitelem v jiných členských státech, čímž by se usnadnil volný pohyb v EU.

Tyto certifikáty by měly obsahovat pouze nezbytné osobní údaje. Vzhledem k tomu, že uváděné osobní údaje zahrnují citlivé lékařské údaje, měla by se zajistit vysoká úroveň ochrany údajů a dodržování zásad minimalizace údajů. Rámec "digitálního zeleného certifikátu" by především neměl vyžadovat, aby byla zřízena a udržována databáze na úrovni EU, nýbrž by měl umožnit decentralizované ověřování digitálně podepsaných interoperabilních certifikátů.

• Soulad s platnými předpisy v této oblasti politiky

Návrh doplňuje další politické iniciativy přijaté v oblasti volného pohybu během pandemie COVID-19, jako jsou doporučení Rady 2020/1475 a 2021/119, a navazuje na ně. Doporučení Rady 2020/1475 popisuje zejména obecné zásady, na jejichž základě by členské státy měly koordinovat své kroky při přijímání a uplatňování opatření v oblasti volného pohybu v zájmu ochrany veřejného zdraví v reakci na pandemii COVID-19.

Směrnice Evropského parlamentu a Rady 2004/38/ES¹⁰ stanoví podmínky pro výkon práva na volný pohyb a pobyt (přechodný i trvalý) v EU pro občany EU a jejich rodinné příslušníky. Podle uvedené směrnice smějí členské státy omezit svobodu pohybu a pobytu občanů EU a jejich rodinných příslušníků bez ohledu na státní příslušnost z důvodů veřejného pořádku, veřejné bezpečnosti nebo veřejného zdraví.

Stávající právní předpisy EU neobsahují ustanovení o vydávání, ověřování a uznávání certifikátů potvrzujících zdravotní stav držitele, a to ani v případě, že předložení těchto certifikátů může být nezbytné ke zrušení určitých omezení práva na volný pohyb zavedených během pandemie. Je proto nezbytné vypracovat ustanovení, jejichž cílem je zajistit interoperabilitu a bezpečnost těchto certifikátů.

• Soulad s ostatními politikami Unie

Tento návrh je součástí balíčku opatření EU v reakci na pandemii COVID-19. Vychází zejména z předchozí technické práce Výboru pro zdravotní bezpečnost a sítě pro elektronické zdravotnictví.

¹⁰ Směrnice Evropského parlamentu a Rady 2004/38/ES ze dne 29. dubna 2004 o právu občanů Unie a jejich rodinných příslušníků se volně pohybovat a pobývat na území členských států, o změně nařízení (EHS) č. 1612/68 a o zrušení směrnic 64/221/EHS, 68/360/EHS, 72/194/EHS, 73/148/EHS, 75/34/EHS, 75/35/EHS, 90/364/EHS, 90/365/EHS a 93/96/EHS (Úř. věst. L 158, 30.4.2004, s. 77).

Tento návrh je doplněn návrhem COM(2021) xxx, jehož cílem je zajistit, aby se pravidla v něm stanovená vztahovala na státní příslušníky třetích zemí, na něž se nevztahuje tento návrh a kteří oprávněně pobývají nebo mají bydliště na území státu, na nějž se uvedené navrhované nařízení vztahuje, a kteří jsou oprávněni cestovat do jiných států v souladu s právem Unie.

Tímto návrhem nejsou dotčena schengenská pravidla, pokud jde o podmínky vstupu státních příslušníků třetích zemí. Navrhované nařízení by nemělo být chápáno tak, že podporuje nebo usnadňuje znovuzavedení hraničních kontrol, které zůstává krajním opatřením, jež podléhá podmínkám Schengenského hraničního kodexu.

Tento návrh zohledňuje probíhající úsilí na mezinárodní úrovni (například pod záštitou specializovaných agentur Organizace spojených národů včetně Světové zdravotnické organizace (WHO)) o stanovení specifikací a pokynů pro používání digitálních technologií pro dokumentování stavu očkování. Třetí země by měly být vybízeny k tomu, aby "digitální zelený certifikát" uznávaly při rušení omezení cest, které nejsou nezbytně nutné.

Tento návrh rovněž plně respektuje pravomoci členských států při vymezování jejich zdravotní politiky (článek 168 Smlouvy o fungování EU).

2. PRÁVNÍ ZÁKLAD, SUBSIDIARITA A PROPORCIONALITA

Právní základ

Podle čl. 21 odst. 1 Smlouvy o fungování EU má každý občan EU právo svobodně se pohybovat a pobývat na území členských států. V čl. 21 odst. 2 je stanovena možnost EU jednat a přijímat předpisy s cílem usnadnit právo svobodně se pohybovat a pobývat na území členských států, pokud je činnost EU k usnadnění výkonu tohoto práva k dosažení tohoto cíle nezbytná. Použije se řádný legislativní postup,

Cílem návrhu je usnadnit výkon práva na volný pohyb v EU během pandemie COVID-19 zavedením společného rámce pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19. Tento rámec by měl občanům EU a jejich rodinným příslušníkům, kteří využívají svého práva na volný pohyb, umožnit, aby prokázali, že splňují požadavky v oblasti veřejného zdraví uložené členským státem určení v souladu s právem EU. Cílem návrhu je rovněž zajistit, aby omezení volného pohybu, která jsou v současné době zavedena s cílem omezit šíření COVID-19, mohla být koordinovaně zrušena, jakmile bude k dispozici více vědeckých důkazů.

• Subsidiarita

Cílů tohoto nařízení, totiž usnadnění volného pohybu v EU během pandemie COVID-19 zřízením zabezpečených a interoperabilních certifikátů o stavu očkování, testování a uzdravení držitele, nemohou uspokojivě dosáhnout členské státy samostatně, nýbrž spíše jich lze z důvodu rozsahu a účinků navrhované činnosti lépe dosáhnout na úrovni EU. Je proto zapotřebí opatření na úrovni EU.

Absence opatření na úrovni EU by pravděpodobně vedla k tomu, že by členské státy zavedly různé systémy, v důsledku čehož by občané měli při výkonu svých práv na volný pohyb problémy s uznáváním svých dokumentů v jiných členských státech. Zejména je nezbytné se dohodnout na technických normách, které se použijí k zajištění interoperability, zabezpečení a ověřitelnosti vydávaných certifikátů.

Proporcionalita

Opatření na úrovni EU může přinést při řešení výše uvedených výzev značnou přidanou hodnotu a je jediným způsobem, jak lze vytvořit a udržovat jednotný, efektivní a uznávaný rámec.

Přijímání jednostranných nebo nekoordinovaných opatření v oblasti certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19 by pravděpodobně vedlo k nejednotným a roztříštěným omezením volného pohybu, čímž by vznikla pro občany EU nejistota při výkonu jejich práv EU.

Návrh omezuje zpracování osobních údajů na nezbytné minimum tím, že zahrnuje do certifikátů, které se mají vydávat, pouze omezený soubor osobních údajů. Stanoví totiž, že údaje získané při ověřování certifikátů by neměly být uchovávány, a zřizuje rámec, který nevyžaduje vytvoření a vedení ústřední databáze.

Po překonání pandemie COVID-19 by měla být pozastavena ustanovení navrhovaného nařízení týkající se vydávání certifikátů o očkování, testu nebo uzdravení, jakož i rámce pro důvěryhodnost, neboť od tohoto okamžiku nebude opodstatněné požadovat, aby občané při výkonu svého práva na volný pohyb předkládali zdravotní dokumenty. Zároveň však platí, že by jejich používání mělo být obnoveno, pokud WHO vyhlásí další pandemii způsobenou propuknutím nákazy virem SARS-CoV2, jeho variantou nebo podobnými infekčními nemocemi s epidemickým potenciálem.

• Volba nástroje

Nařízení je jediným právním nástrojem, který zajišťuje přímé, okamžité a společné provádění práva EU ve všech členských státech.

3. VÝSLEDKY HODNOCENÍ *EX POST*, KONZULTACÍ SE ZÚČASTNĚNÝMI STRANAMI A POSOUZENÍ DOPADŮ

Konzultace se zúčastněnými stranami

Návrh zohledňuje pravidelná jednání s členskými státy na různých fórech.

Sběr a využití výsledků odborných konzultací

Návrh vychází z odborných diskusí ve Výboru pro zdravotní bezpečnost a sítě pro elektronické zdravotnictví, z informací o epidemiologické situaci v souvislosti s pandemií COVID-19 zveřejněných ECDC a z dostupných relevantních vědeckých důkazů.

Posouzení dopadů

Vzhledem k naléhavosti situace Komise neprovedla posouzení dopadů.

• Základní práva

Tento návrh pozitivně ovlivňuje základní právo na volný pohyb a pobyt podle článku 45 Listiny základních práv Evropské unie (dále jen "Listina"), jelikož občanům poskytuje interoperabilní a vzájemně uznávané certifikáty o očkování, testování a uzdravení v kontextu onemocnění COVID-19, které mohou použít při cestování. V případech, kdy členské státy zruší určitá omezení volného pohybu pro osoby, které jsou držiteli potvrzení o očkování, testu nebo uzdravení, certifikáty zřízené tímto návrhem umožní občanům těchto výjimek využívat. Interoperabilní rámec zdravotních certifikátů by měl členským státům umožnit, aby omezení koordinovaně rušily s tím, jak bude přibývat vědeckých údajů (zejména o účincích očkování proti nákaze virem SARS-CoV-2). Toto nařízení by nemělo být chápáno tak, že usnadňuje nebo podporuje přijímání omezení volného pohybu během pandemie. Jeho cílem je spíše poskytnout harmonizovaný rámec pro uznávání zdravotních certifikátů v souvislosti s COVID-19 v případě, že členský stát taková omezení uplatňuje. Jakákoli omezení volného pohybu v EU z důvodů veřejného pořádku, veřejné bezpečnosti nebo veřejného zdraví musí být nezbytná a přiměřená a musí být založena na objektivních a nediskriminačních kritériích. Za rozhodnutí, zda omezení volného pohybu zavést, jsou i nadále odpovědné členské státy, které musí jednat v souladu s právem EU. Stejně tak si členské státy ponechávají možnost omezení volného pohybu nezavádět.

Tento návrh počítá se zpracováním osobních údajů, včetně údajů o zdravotním stavu. Potenciálně může mít dopady na základní práva jednotlivců, zejména podle článku 7 (respektování soukromého života) a článku 8 (právo na ochranu osobních údajů) Listiny. Zpracování osobních údajů jednotlivců, včetně shromažďování a používání osobních údajů a přístupu k nim, ovlivňuje právo na soukromí a právo na ochranu osobních údajů podle Listiny. Zásah do těchto základních práv musí být odůvodněn.

Pokud jde o právo na ochranu osobních údajů včetně zabezpečení údajů, použije se nařízení Evropského parlamentu a Rady (EU) 2016/679¹¹. Není stanovena žádná výjimka z režimu EU pro ochranu údajů a členské státy musí zavést jasná pravidla, podmínky a spolehlivé záruky v souladu s pravidly EU pro ochranu údajů. Navrhované nařízení nezřizuje evropskou databázi týkající se očkování, testování a uzdravení v kontextu onemocnění COVID-19. Pro účely navrhovaného nařízení musí být osobní údaje zahrnuty pouze do vydaného certifikátu, který by měl být chráněn proti padělání nebo manipulaci.

4. ROZPOČTOVÉ DŮSLEDKY

Při počáteční podpoře nejnaléhavějších opatření této iniciativy použije Komise finanční prostředky z nástroje pro mimořádnou podporu, a jakmile vstoupí v platnost právní základ programu Digitální Evropa, prověří, jakým způsobem by některé výdaje mohly být vynaloženy v rámci tohoto programu. Iniciativa by mohla vyžadovat použití jednoho nebo několika zvláštních nástrojů, jak jsou definovány v nařízení Rady (EU, Euratom) 2020/2093¹². Spolu s tímto návrhem se předkládá legislativní finanční výkaz.

Vzhledem k mimořádné zdravotní situaci se většina přípravných výdajů vynaloží v rámci nástroje pro mimořádnou podporu před vstupem navrhovaného nařízení v platnost. Jakýkoli systém podpory na úrovni EU bude aktivován až po vstupu navrhovaného nařízení v platnost.

5. OSTATNÍ PRVKY

• Plány provádění a způsob monitorování, hodnocení a podávání zpráv

Jeden rok poté, co WHO prohlásí, že pandemie COVID-19 skončila, Komise vypracuje zprávu o uplatňování tohoto nařízení.

Podrobné vysvětlení konkrétních ustanovení návrhu

<u>Články 1 a 2</u> návrhu popisují předmět navrhovaného nařízení a stanoví řadu definic. Navrhovaným nařízením se stanoví digitální zelený certifikát – rámec pro vydávání,

¹¹ Nařízení Evropského parlamentu a Rady (EU) 2016/679 ze dne 27. dubna 2016 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů a o volném pohybu těchto údajů a o zrušení směrnice 95/46/ES (obecné nařízení o ochraně osobních údajů) (Úř. věst. L 119, 4.5.2016, s. 1).

¹² Nařízení Rady (EU, Euratom) 2020/2093 ze dne 17. prosince 2020, kterým se stanoví víceletý finanční rámec na období 2021–2027 (Úř. věst. L 433I, 22.12.2020, s. 11).

ověřování a uznávání interoperabilních zdravotních certifikátů s cílem usnadnit volný pohyb během pandemie COVID-19.

<u>Článek 3</u> uvádí podrobnosti o všech třech typech certifikátů spadajících do rámce digitálního zeleného certifikátu, tj. certifikátu o očkování, certifikátu o testu a certifikátu o uzdravení. Stanoví rovněž obecné požadavky, které musí tyto certifikáty splňovat, jako je zahrnutí interoperabilního čárového kódu, jakož i zřízení nezbytné technické infrastruktury. Uznávány by měly být prostřednictvím začlenění tohoto nástroje do rámce EHP rovněž certifikáty vydané v souladu s tímto nařízením státy EHP Islandem, Lichtenštejnskem a Norskem. Certifikáty vydané na základě tohoto nařízení Švýcarskem osobám požívajícím práv na volný pohyb by měly být uznávány poté, co Komise vydá příslušné prováděcí rozhodnutí na základě zjištění, že uznávání probíhá na recipročním základě.

<u>Článek 4</u> zřizuje rámec pro důvěryhodnost digitálního zeleného certifikátu, který by měl tam, kde je to možné, zajistit interoperabilitu s technologickými systémy zřízenými na mezinárodní úrovni. Stanoví rovněž, že na základě prováděcího rozhodnutí Komise budou uznávány bezpečné a ověřitelné certifikáty, jež obsahují nezbytné osobní údaje, vydané třetími zeměmi občanům EU a jejich rodinným příslušníkům v souladu s mezinárodní normou, která je interoperabilní s rámcem pro důvěryhodnost zavedeným tímto nařízením.

<u>Články 5 až 7</u> stanoví další podrobnosti o vydávání, obsahu a uznávání certifikátu o očkování, certifikátu o testu a certifikátu o uzdravení.

<u>Článek 8</u> zmocňuje Komisi k přijetí nezbytných technických specifikací rámce pro důvěryhodnost, v případě potřeby prostřednictvím zrychleného postupu.

Článek 9 obsahuje pravidla ochrany osobních údajů.

<u>Článek 10</u> stanoví oznamovací postup, jehož cílem je zajistit, aby ostatní členské státy a Komise byly informovány o omezeních práva na volný pohyb, která jsou v důsledku pandemie nezbytná.

<u>Články 11 a 12</u> obsahují pravidla pro výkon přenesené pravomoci ze strany Komise, v případě potřeby prostřednictvím postupu pro naléhavé případy.

<u>Článek 13</u> stanoví pravidla týkající se výboru, který je pověřen, aby Komisi pomáhal při provádění nařízení.

<u>Článek 14</u> stanoví, že by Komise měla jeden rok poté, co WHO prohlásí, že pandemie SARS-CoV-2 skončila, předložit zprávu o uplatňování nařízení, v níž nastíní zejména jeho dopad na volný pohyb a ochranu osobních údajů.

<u>Článek 15</u> stanoví urychlený vstup nařízení v platnost. Stanoví dále, že pokud WHO prohlásí, že pandemie COVID-19 skončila, uplatňování článků 3, 4, 5, 6, 7 a 10 by mělo být prostřednictvím aktu v přenesené pravomoci pozastaveno. Zároveň však by jejich uplatňování mělo být aktem v přenesené pravomoci obnoveno, pokud WHO vyhlásí další pandemii způsobenou propuknutím nákazy virem SARS-CoV-2, jeho variantou nebo podobnými infekčními nemocemi s epidemickým potenciálem.

V <u>příloze</u> jsou uvedeny osobní údaje, které mají být obsaženy v certifikátech, na něž se toto nařízení vztahuje.

2021/0068 (COD)

Návrh

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY

o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení za účelem usnadnění volného pohybu během pandemie COVID-19 (digitální zelený certifikát)

(Text s významem pro EHP)

EVROPSKÝ PARLAMENT A RADA EVROPSKÉ UNIE,

s ohledem na Smlouvu o fungování Evropské unie, a zejména na čl. 21 odst. 2 této smlouvy,

s ohledem na návrh Evropské komise,

po postoupení návrhu legislativního aktu vnitrostátním parlamentům,

v souladu s řádným legislativním postupem,

vzhledem k těmto důvodům:

- (1) Každý občan Unie má právo svobodně se pohybovat a pobývat na území členských států s výhradou omezení a podmínek stanovených ve Smlouvách a v opatřeních přijatých k jejich provedení. Podrobná pravidla pro výkon tohoto práva jsou stanovena směrnicí Evropského parlamentu a Rady 2004/38/ES¹.
- (2) Dne 30. ledna 2020 vyhlásil generální ředitel Světové zdravotnické organizace (WHO) ohrožení veřejného zdraví mezinárodního významu z důvodu globální nákazy koronavirem 2 způsobujícím těžký akutní respirační syndrom (SARS-CoV-2), který způsobuje onemocnění koronavirem 2019 (COVID-19). Dne 11. března 2020 dospěla WHO k závěru, že COVID-19 lze označit za pandemii.
- (3) S cílem omezit šíření viru přijaly členské státy různá opatření, z nichž některá měla dopad na právo občanů Unie svobodně se pohybovat a pobývat na území členských států, například omezení vstupu nebo požadavky, aby přeshraniční cestující podstoupili karanténu, domácí izolaci nebo test na infekci SARS-CoV-2.
- (4) Dne 13. října 2020 přijala Rada doporučení (EU) 2020/1475 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19². V uvedeném doporučení stanoví koordinovaný přístup, který se skládá z těchto klíčových bodů: uplatňování společných kritérií a prahových hodnot při rozhodování o tom, zda omezení volného pohybu zavést, mapování rizika přenosu onemocnění COVID-19 na základě dohodnutého barevného kódu a koordinovaný přístup, pokud jde o (případná) opatření, která se mohou odpovídajícím způsobem uplatnit na osoby pohybující se mezi oblastmi, v závislosti na úrovni rizika přenosu v uvedených oblastech. V

Směrnice Evropského parlamentu a Rady 2004/38/ES ze dne 29. dubna 2004 o právu občanů Unie a jejich rodinných příslušníků svobodně se pohybovat a pobývat na území členských států, o změně nařízení (EHS) č. 1612/68 a o zrušení směrnic 64/221/EHS, 68/360/EHS, 72/194/EHS, 73/148/EHS, 75/34/EHS, 75/35/EHS, 90/364/EHS, 90/365/EHS a 93/96/EHS (Úř. věst. L 158, 30.4.2004, s. 77).
Úř. věst. L 337, 14.10.2020, s. 3.

doporučení se rovněž zdůrazňuje, že na osoby podnikající nezbytně nutnou cestu, jak jsou vymezeny v jeho bodě 19, a přeshraniční cestující, jejichž život je těmito omezeními obzvláště dotčen, zejména ty, kteří vykonávají kritické funkce nebo jsou zásadně důležití pro kritickou infrastrukturu, by se cestovní omezení související s onemocněním COVID-19 v zásadě vztahovat neměla.

- (5) S využitím kritérií a prahových hodnot stanovených v doporučení (EU) 2020/1475 zveřejňuje Evropské středisko pro prevenci a kontrolu nemocí (ECDC) na podporu rozhodování členských států jednou týdně mapu členských států rozdělenou podle regionů³.
- (6) Jak je zdůrazněno v doporučení (EU) 2020/1475, veškerá omezení volného pohybu osob v Unii zaváděná za účelem omezení šíření onemocnění COVID-19 by měla být založena na specifických a omezených důvodech veřejného zájmu, konkrétně na ochraně veřejného zdraví. Tato omezení musí být uplatňována v souladu s obecnými zásadami práva Unie, zejména se zásadou proporcionality a zákazu diskriminace. Jakákoli přijatá opatření by tudíž neměla překračovat rámec toho, co je nezbytně nutné k ochraně veřejného zdraví. Dále by měla být v souladu s opatřeními, která Unie přijala k zajištění plynulého volného pohybu zboží a základních služeb na celém jednotném trhu, včetně zdravotnického vybavení a personálu, prostřednictvím tzv. zelených pruhů uvedených ve sdělení Komise o zavedení zelených pruhů podle Pokynů týkajících se opatření správy hranic v zájmu ochrany zdraví a zajištění dostupnosti zboží a základních služeb⁴.
- (7) Volný pohyb osob, které nepředstavují riziko pro veřejné zdraví, například proto, že jsou vůči viru SARS-CoV-2 imunní a nemohou jej přenášet, by neměl být omezován, neboť tato omezení by nebyla nezbytná pro dosažení sledovaného cíle.
- (8) Mnoho členských států již zahájilo nebo plánuje zahájit iniciativy na vydávání certifikátů o očkování. Aby je však občané mohli v přeshraničním kontextu při výkonu svých práv na volný pohyb účinně využívat, musí být tyto certifikáty plně interoperabilní, zabezpečené a ověřitelné. Je nezbytné, aby se členské státy společně dohodly na obsahu, formátu a technických normách těchto certifikátů a zásadách jejich používání.
- (9) Jednostranná opatření v této oblasti mohou značně narušit výkon práva na volný pohyb, neboť vnitrostátní orgány a služby přepravy cestujících, jako je letecká, vlaková, autokarová či trajektová doprava, jsou konfrontovány s nejrůznějšími formáty dokumentů, které se týkají nejen stavu očkování dané osoby, ale i testů a případného uzdravení z onemocnění COVID-19.
- (10) Aby se usnadnil výkon práva svobodně se pohybovat a pobývat na území členských států, měl by být vytvořen společný rámec pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19, takzvaný "digitální zelený certifikát".
- (11) Toto nařízení by nemělo být chápáno tak, že usnadňuje nebo podporuje přijímání omezení volného pohybu nebo jiných základních práv, která byla zavedena v reakci na pandemii. Zejména by měly nadále platit výjimky z omezení volného pohybu zavedených v reakci na pandemii COVID-19, uvedené v doporučení (EU) 2020/1475.

³ K dispozici na této adrese: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

⁴ Úř. věst. C 96I, 24.3.2020, s. 1.

Rámec "digitálního zeleného certifikátu" zároveň zajistí, aby interoperabilní certifikáty mohly získat i osoby podnikající nezbytně nutnou cestu.

- (12) Základem společného přístupu k vydávání, ověřování a uznávání těchto interoperabilních certifikátů o očkování je důvěra. Falešné certifikáty týkající se onemocnění COVID-19 mohou představovat významné riziko pro veřejné zdraví. Příslušné orgány v jednom členském státě potřebují jistotu, že informace obsažené v certifikátu vydaném v jiném členském státě jsou důvěryhodné, nebyly padělány, týkají se osoby, která je předložila, a že kdokoli, kdo tyto informace ověřuje, má přístup pouze k minimálnímu objemu nezbytných informací.
- (13) Riziko, které falešné certifikáty týkající se onemocnění COVID-19 představují, je reálné. Europol vydal dne 1. února 2021 včasnou výstrahu o nezákonném prodeji zfalšovaných certifikátů o negativním testu na COVID-19⁵. Vzhledem k dostupným a snadno přístupným technologickým prostředkům, jako jsou tiskárny s vysokým rozlišením či různé grafické editory, dokážou podvodníci vyrobit vysoce kvalitní padělané či zfalšované certifikátů. Byly hlášeny případy nezákonného prodeje podvodných certifikátů o testu, do nichž se zapojilo vícero organizovaných padělatelských skupin nebo jednotliví zištní podvodníci, kteří prodávali falešné certifikáty fyzicky i po internetu.
- (14) Aby byla zajištěna interoperabilita a rovný přístup, měly by členské státy vydávat certifikáty tvořící digitální zelený certifikát v digitálním nebo tištěném formátu nebo v obou těchto formátech. Potenciální držitel by si tak mohl vyžádat a obdržet certifikát v tištěné podobě nebo jej uložit a zobrazit na mobilním zařízení. Certifikáty by měly obsahovat interoperabilní, digitálně čitelný čárový kód s příslušnými údaji o certifikátu. Členské státy by měly zaručit pravost, platnost a integritu certifikátů elektronickou pečetí nebo obdobným prostředkem. Informace na certifikátu by měly být rovněž uvedeny ve formátu čitelném pro člověka, buď vytištěné, nebo zobrazené jako prostý text. Rozvržení certifikátů by mělo být snadno srozumitelné, jednoduché a uživatelsky přívětivé. Aby nevznikaly překážky volného pohybu, měly by týt certifikáty vydávat certifikáty tvořící digitální zelený certifikát automaticky nebo na požádání, přičemž by měly zajistit jejich snadné získání a v případě potřeby poskytnout nezbytnou podporu, která všem občanům umožní rovný přístup.
- (15) Bezpečnost, pravost, integrita a platnost certifikátů tvořících digitální zelený certifikát a jejich soulad s právními předpisy Unie o ochraně údajů jsou klíčové pro jejich uznávání ve všech členských státech. Je proto nezbytné vytvořit rámec pro důvěryhodnost, který stanoví pravidla a infrastrukturu pro spolehlivé a zabezpečené vydávání a ověřování certifikátů. Základem rámce pro důvěryhodnost by měl být nástin interoperability zdravotních certifikátů⁶, který dne 12. března 2021 přijala síť pro elektronické zdravotnictví zřízená článkem 14 směrnice 2011/24/EU⁷.
- (16) Podle tohoto nařízení by certifikáty tvořící digitální zelený certifikát měly být vydávány oprávněným osobám uvedeným v článku 3 směrnice 2004/38/ES, tj. občanům Unie a jejich rodinným příslušníkům bez ohledu na jejich státní příslušnost,

⁵ <u>https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates</u>

⁶ K dispozici na této adrese: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

⁷ Směrnice Evropského parlamentu a Rady 2011/24/EU ze dne 9. března 2011 o uplatňování práv pacientů v přeshraniční zdravotní péči (Úř. věst. L 88, 4.4.2011, s. 45).

a to tím členským státem, jenž očkování nebo test provedl nebo kde se uzdravená osoba nachází. Je-li to důležité nebo vhodné, měly by být certifikáty vydávány za očkované, testované nebo uzdravené osoby, například za nesvéprávné osoby nebo rodičům za jejich děti. Certifikáty by neměly vyžadovat legalizaci nebo jiné podobné formality.

- (17) Certifikáty tvořící digitální zelený certifikát by rovněž mohly být vydávány státním příslušníkům nebo rezidentům Andorry, Monaka, San Marina a Vatikánu/Svatého stolce, zejména jsou-li očkováni v členském státě.
- (18) Je nutno zohlednit, že dohody o volném pohybu osob uzavřené mezi Unií a jejími členskými státy na jedné straně a některými třetími zeměmi na straně druhé stanoví možnost omezit volný pohyb z důvodů veřejného zdraví. Pokud tyto dohody neobsahují mechanismus začlenění aktů Evropské unie, certifikáty vydané osobám, na něž se tyto dohody vztahují, by měly být uznávány za podmínek stanovených tímto nařízením. Podmíněno by to mělo být tím, že Komise přijme prováděcí akt stanovící, že třetí země vydává certifikáty v souladu s tímto nařízením a poskytla formální ujištění, že bude uznávat certifikáty vydané členskými státy.
- (19) Nařízení (EU) 2021/XXXX se vztahuje na státní příslušníky třetích zemí, kteří nespadají do oblasti působnosti tohoto nařízení, pobývají nebo se oprávněně zdržují na území státu, na nějž se uvedené nařízení vztahuje, a jsou oprávněni cestovat do jiných států v souladu s právem Unie.
- (20) Rámec vytvořený pro účely tohoto nařízení by měl dbát na zajištění soudržnosti s celosvětovými iniciativami, zejména těmi, jichž se účastní WHO. Součástí toho by měla pokud možno být interoperabilita mezi technologickými systémy zřízenými na celosvětové úrovni a systémy zřízenými pro účely tohoto nařízení s cílem usnadnit volný pohyb v Unii, mimo jiné prostřednictvím zapojení do infrastruktury veřejných klíčů nebo dvoustranné výměny veřejných klíčů. Aby se usnadnilo uplatňování práv občanů Unie, kteří byli očkováni třetími zeměmi, na volný pohyb, mělo by toto nařízení stanovit uznávání certifikátů vydaných třetími zeměmi občanům Unie a jejich rodinným příslušníkům, jestliže Komise shledá, že tyto certifikáty jsou vydány podle norem rovnocenných normám stanoveným podle tohoto nařízení.
- (21) Aby se usnadnil volný pohyb a mohla být koordinovaným způsobem na základě nejnovějších dostupných vědeckých důkazů zrušena omezení volného pohybu, která v současné době platí během pandemie COVID-19, měl by být zaveden interoperabilní certifikát o očkování. Tento certifikát o očkování by měl sloužit jako potvrzení, že jeho držiteli byla v členském státě podána očkovací látka proti COVID-19. Certifikát by měl obsahovat pouze informace nezbytné k jasné identifikaci držitele a očkovací látky proti COVID-19, číslo, datum a místo očkování. Členské státy by měly vydat certifikáty o očkování osobám, jimž byly podány očkovací látky, kterým byla udělena registrace podle nařízení Evropského parlamentu a Rady (ES) č. 726/2004⁸, očkovací látky, kterým byla udělena registrace podle směrnice Evropského parlamentu a Rady 2001/83/ES⁹, nebo očkovací látky, jejichž distribuce byla dočasně povolena podle čl. 5 odst. 2 směrnice 2001/83/ES.

⁸ Nařízení Evropského parlamentu a Rady (ES) č. 726/2004 ze dne 31. března 2004, kterým se stanoví postupy Společenství pro registraci humánních a veterinárních léčivých přípravků a dozor nad nimi a kterým se zřizuje Evropská agentura pro léčivé přípravky (Úř. věst. L 136, 30.4.2004, s. 1).

⁹ Směrnice Evropského parlamentu a Rady 2001/83/ES ze dne 6. listopadu 2001 o kodexu Společenství týkajícím se humánních léčivých přípravků (Úř. věst. L 311, 28.11.2001, s. 67).

- (22) Osoby očkované před datem použitelnosti tohoto nařízení, a to i v rámci klinického hodnocení, by rovněž měly mít možnost získat certifikát o očkování proti COVID-19, který je v souladu s tímto nařízením. Zároveň by členské státy měly mít nadále možnost vydávat potvrzení o očkování v jiných formátech pro jiné účely, zejména pro účely lékařské.
- (23) Členské státy by měly vydávat tyto certifikáty o očkování rovněž občanům Unie a jejich rodinným příslušníkům, kteří byli očkováni v třetí zemi a předložili o tom spolehlivý doklad.
- (24) Dne 27. ledna 2021 přijala síť pro elektronické zdravotnictví pokyny k potvrzení o očkování pro lékařské účely, které aktualizovala dne 12. března 2021¹⁰. Uvedené pokyny, zejména upřednostňované normy pro kódy, by měly tvořit základ technických specifikací přijatých pro účely tohoto nařízení.
- Některé členské státy osvobozují již nyní očkované osoby od určitých omezení (25)volného pohybu v rámci Unie. Pokud členské státy uznají potvrzení o očkování, aby mohly zrušit omezení volného pohybu zavedená v souladu s právem Unie s cílem omezit šíření onemocnění COVID-19, např. požadavky podstoupit karanténu, domácí izolaci či test na infekci SARS-CoV-2, měly by být povinny uznat za týchž podmínek platné certifikáty o očkování vydané jinými členskými státy v souladu s tímto nařízením. Uznání by mělo probíhat za týchž podmínek, což znamená například, že pokud členský stát považuje za dostačující jednorázovou podanou dávku očkovací látky, měl by ji považovat za dostačující i v případě držitelů certifikátu o očkování, v němž je zaznamenána jednorázová dávka téže očkovací látky. Z důvodů veřejného zdraví by se tato povinnost měla týkat pouze osob, kterým byly podány očkovací látky proti COVID-19 s registrací podle nařízení (ES) č. 726/2004. Členským státům by to nemělo nijak bránit v rozhodnutí, že budou uznávat certifikáty o očkování vydané pro jiné očkovací látky proti COVID-19, například očkovací látky, kterým příslušný orgán členského státu udělil registraci podle směrnice 2001/83/ES, očkovací látky, jejichž distribuce byla dočasně povolena podle čl. 5 odst. 2 směrnice 2001/83/ES, nebo očkovací látky, které byly zařazeny na seznam WHO k nouzovému použití.
- (26) Je nezbytné zabránit diskriminaci osob, které nejsou očkovány, například z lékařských důvodů, protože nejsou součástí cílové skupiny, které se očkovací látka v současné době doporučuje, nebo protože dosud neměly příležitost se očkovat nebo se rozhodly nenechat očkovat. Výkon práv na volný pohyb by proto neměl být podmíněn držením certifikátu o očkování nebo držením certifikátu o očkování konkrétním očkovacím léčivým přípravkem, zejména jsou-li tyto osoby schopny prokázat dodržení zákonných požadavků veřejného zdraví jiným způsobem; držením certifikátu též nelze podmínit využívání přeshraničních služeb přepravy cestujících, jako je letecká, vlaková, autokarová nebo trajektová doprava.
- (27) Mnoho členských států požaduje, aby osoby cestující na jejich území podstoupily před příjezdem nebo po něm test na infekci SARS-CoV-2. Na počátku pandemie COVID-19 členské státy k diagnostice COVID-19 obvykle používaly test pomocí polymerázové řetězové reakce s reverzní transkripcí (RT-PCR), což je test založený na amplifikaci nukleové kyseliny (NAAT), který WHO i ECDC považují za "zlatý standard", tedy za nejspolehlivější metodiku testování případů a kontaktů¹¹. Jak pandemie postupuje, na evropském trhu je ve stále větší míře dostupná nová generace

¹⁰ K dispozici na této adrese: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

¹¹ https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

rychlejších a levnějších testů: tzv. rychlých testů na antigen, jež detekují přítomnost virových proteinů (antigenů) ke zjištění probíhající infekce. Dne 18. listopadu 2020 přijala Komise doporučení Komise (EU) 2020/1743 o použití rychlých testů na antigen při diagnostikování infekce SARS-CoV-2¹².

- (28) Dne 22. ledna 2021 přijala Rada doporučení Rady 2021/C 24/01 o společném rámci pro používání a validaci rychlých testů na antigen a o vzájemném uznávání výsledků testů na COVID-19 v EU¹³, které stanoví vytvoření společného seznamu rychlých testů na antigen COVID-19. Na základě toho se Výbor pro zdravotní bezpečnost shodl dne 18. února 2021 na společném seznamu rychlých testů na antigen na COVID-19, na výběru rychlých testů na antigen, jejichž výsledky budou členské státy vzájemně uznávat, a na společném standardizovaném souboru údajů, které mají být zahrnuty do certifikátů o výsledcích testů na COVID-19¹⁴.
- (29) Navzdory tomuto společnému úsilí se občané Unie a jejich rodinní příslušníci, kteří vykonávají své právo na volný pohyb, stále potýkají s problémy, když se snaží uplatnit výsledky testů získané v jednom členském státě v jiném členském státě. Tyto problémy často plynou z jazyka, v němž je potvrzení o výsledku testu vydáno, nebo z nedostatečné důvěry v pravost předkládaného dokumentu.
- (30) Aby se zlepšilo uznávání výsledků testů provedených v jiném členském státě v okamžiku, kdy jsou tyto výsledky předkládány pro účely výkonu práva na volný pohyb, měl by být zaveden interoperabilní certifikát o testu obsahující informace nezbytné k jasné identifikaci držitele a druh, datum a výsledek testu na infekci SARS-CoV-2. Aby byla zajištěna spolehlivost výsledku testu, měly by být pro certifikát o testu vydaný na základě tohoto nařízení používány pouze výsledky testů NAAT a rychlých testů na antigen uvedených na seznamu vypracovaném na základě doporučení Rady 2021/C 24/01. Základem technických specifikací přijatých pro účely tohoto nařízení by měl být společný standardizovaný soubor údajů, které mají být uváděny na certifikátech o výsledcích testů na COVID-19, schválený Výborem pro zdravotní bezpečnost na základě doporučení Rady 2021/C 24/01, zejména upřednostňované normy pro kódy.
- (31) Certifikáty o testu vydané členskými státy v souladu s tímto nařízením by měly být uznávány členskými státy, které vyžadují potvrzení o testu na infekci SARS-CoV-2 v kontextu omezení volného pohybu zavedených k omezení šíření onemocnění COVID-19.
- (32) Osoby, které se uzdravily z onemocnění COVID-19, mohou mít podle současných poznatků pozitivní test na SARS-CoV-2 ještě určitou dobu po nástupu příznaků¹⁵. Jestliže chtějí vykonávat své právo na volný pohyb, přičemž musí podstoupit test, může jim být fakticky znemožněno cestování, přestože již nejsou infekční. Aby se usnadnil volný pohyb a mohla být koordinovaným způsobem na základě nejnovějších dostupných vědeckých důkazů zrušena omezení volného pohybu, která v současné době platí během pandemie COVID-19, měl by být zaveden interoperabilní certifikát o uzdravení, který bude obsahovat informace nezbytné k jasné identifikaci dotčené osoby a datum absolvovaného pozitivního testu na infekci SARS-CoV-2. Certifikát o

¹² Úř. věst. L 392, 23.11.2020, s. 63.

¹³ Úř. věst. C 24, 22.1.2021, s. 1.

¹⁴ https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_commonlist_en.pdf

¹⁵ <u>https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf</u>

uzdravení by měl být vydán nejdříve jedenáctý den po prvním pozitivním testu a měl by platit nejvýše 180 dní. Podle ECDC z nejnovějších poznatků vyplývá, že ačkoli je životaschopný virus SARS-CoV-2 vylučován deset až dvacet dní od nástupu příznaků, přesvědčivým epidemiologickým studiím se nepodařilo prokázat další přenos nemoci po desátém dni. Komise by měla být zmocněna k úpravě tohoto období na základě pokynů Výboru pro zdravotní bezpečnost nebo ECDC, které pečlivě studuje poznatky ohledně doby trvání získané imunity po uzdravení.

- (33) Již nyní některé členské státy osvobozují uzdravené osoby od určitých omezení volného pohybu v Unii. Pokud členské státy uznají potvrzení o uzdravení, aby mohla být zrušena omezení volného pohybu zavedená v souladu s právem Unie s cílem zabránit šíření SARS-CoV-2, např. požadavky podstoupit karanténu, domácí izolaci či test na infekci SARS-CoV-2, měly by být povinny uznat za týchž podmínek platné certifikáty o uzdravení vydané jinými členskými státy v souladu s tímto nařízením. Síť pro elektronické zdravotnictví ve spolupráci s Výborem pro zdravotní bezpečnost rovněž pracuje na pokynech týkajících se certifikátů o uzdravení a příslušných souborů údajů.
- (34) Aby bylo možné rychle dosáhnout společného postoje, měla by mít Komise možnost požádat Výbor pro zdravotní bezpečnost zřízený článkem 17 rozhodnutí Evropského parlamentu a Rady č. 1082/2013/EU¹⁶ o vydání pokynů ohledně dostupných vědeckých důkazů o účincích zdravotních příhod zaznamenaných v certifikátech zavedených v souladu s tímto nařízením, včetně účinnosti očkovací látky proti COVID-19 a souvisejícího trvání imunity, toho, zda očkovací látky zamezují asymptomatické infekci a přenosu viru, stavu osob, které se z viru zotavily, a dopadu nových variant SARS-CoV-2 na osoby očkované či již nakažené.
- (35) Za účelem zajištění jednotných podmínek k uplatňování certifikátů zavedených v rámci pro důvěryhodnost podle tohoto nařízení by měly být Komisi svěřeny prováděcí pravomoci. Tyto pravomoci by měly být vykonávány v souladu s nařízením Evropského parlamentu a Rady (EU) č. 182/2011¹⁷.
- (36) Komise by měla přijmout okamžitě použitelné prováděcí akty, pokud to v řádně odůvodněných případech týkajících se technických specifikací nezbytných k zavedení interoperabilních certifikátů vyžadují závažné naléhavé důvody nebo jakmile budou k dispozici nové vědecké důkazy.
- (37) Zpracovávání osobních údajů při provádění tohoto nařízení se řídí nařízením Evropského parlamentu a Rady (EU) 2016/679¹⁸. Toto nařízení stanoví pro zpracování osobních údajů jako právní základ čl. 6 odst. 1 písm. c) a čl. 9 odst. 2 písm. g) nařízení (EU) 2016/679, nezbytné pro vydávání a ověřování interoperabilních certifikátů stanovených v tomto nařízení. Neupravuje ale zpracování osobních údajů týkajících se dokumentace o očkování, testování nebo uzdravení pro jiné účely, například pro účely farmakovigilance nebo vedení osobních zdravotních záznamů. Právní základ zpracování údajů pro jiné účely má být stanoven vnitrostátními právními předpisy, které musí být v souladu s právními předpisy Unie v oblasti ochrany údajů.

¹⁶ Rozhodnutí Evropského parlamentu a Rady č. 1082/2013/EU ze dne 22. října 2013 o vážných přeshraničních zdravotních hrozbách a o zrušení rozhodnutí č. 2119/98/ES (Úř. věst. L 293, 5.11.2013, s. 1).

¹⁷ Úř. věst. L 55, 28.2.2011, s. 13.

¹⁸ Nařízení Evropského parlamentu a Rady (EU) 2016/679 ze dne 27. dubna 2016 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů a o volném pohybu těchto údajů a o zrušení směrnice 95/46/ES (obecné nařízení o ochraně osobních údajů) (Úř. věst. L 119, 4.5.2016, s. 1).

- (38) V souladu se zásadou minimalizace osobních údajů by certifikáty měly obsahovat pouze osobní údaje nezbytné za účelem usnadnění výkonu práva na volný pohyb v Unii během pandemie COVID-19. V tomto nařízení by měly být stanoveny specifické kategorie osobních údajů a datová pole, které mají být v certifikátech obsaženy.
- (39) Pro účely tohoto nařízení platí, že osobní údaje lze předávat nebo vyměňovat přes hranice výlučně za účelem získání informací nezbytných k potvrzení a ověření stavu očkování, testování nebo uzdravení držitele. Zejména je třeba umožnit ověření pravosti certifikátu.
- (40) Toto nařízení nevytváří právní základ pro uchovávání osobních údajů získaných z certifikátu členským státem určení či provozovateli služeb přeshraniční přepravy cestujících, kteří jsou podle vnitrostátních právních předpisů povinni provádět během pandemie COVID-19 určitá opatření v oblasti veřejného zdraví.
- (41) V zájmu zajištění koordinace by členské státy a Komise měly být informovány, jestliže některý členský stát požaduje, aby držitelé certifikátů podstoupili po vstupu na jeho území karanténu, domácí izolaci nebo test na nákazu SARS-CoV-2, nebo pokud těmto osobám odepře vstup.
- V souladu s doporučením (EU) 2020/1475 by měla být veškerá omezení volného (42) pohybu osob v Unii zavedená za účelem omezení šíření viru SARS-CoV-2 zrušena, jakmile to epidemiologická situace dovolí. To platí i pro povinnosti předkládat jiné dokumenty než dokumenty požadované podle práva Unie, zejména podle směrnice 2004/38/ES, jako jsou certifikáty upravené tímto nařízením. Uplatňování ustanovení nařízení o rámci "digitálního zeleného certifikátu" pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19 by proto mělo být pozastaveno, jakmile generální ředitel WHO v souladu s Mezinárodními zdravotnickými předpisy prohlásí, že ohrožení veřejného zdraví mezinárodního významu způsobené vírem SARS-CoV-2 skončilo. Zároveň však platí, že uplatňování těchto ustanovení by mělo být obnoveno, pokud generální ředitel WHO vyhlásí další ohrožení veřejného zdraví mezinárodního významu v důsledku propuknutí nákazy virem SARS-CoV-2, jeho variantou nebo podobnými infekčními nemocemi s epidemickým potenciálem. Pokud tato situace nastane, měla by být příslušná ustanovení opět pozastavena, jakmile ohrožení veřejného zdraví mezinárodního významu skončí.
- (43) Komise by měla zveřejnit zprávu o poznatcích získaných při uplatňování tohoto nařízení, včetně jeho dopadu na usnadnění volného pohybu a ochranu údajů, jeden rok poté, co generální ředitel WHO prohlásí, že ohrožení veřejného zdraví mezinárodního významu způsobené virem SARS-CoV-2 skončilo.
- (44) Aby byla zohledněna epidemiologická situace a pokrok při zvládání pandemie COVID-19 a zajištěna interoperabilita s mezinárodními normami, měla by být na Komisi přenesena pravomoc přijímat akty v souladu s článkem 290 Smlouvy o fungování Evropské unie, pokud jde o uplatňování některých článků tohoto nařízení a seznam osobních údajů, které mají být obsaženy v certifikátech upravených tímto nařízením. Je nanejvýš důležité, aby Komise v rámci přípravné činnosti vedla odpovídající konzultace, i s odborníky, a aby tyto konzultace probíhaly v souladu se zásadami stanovenými v interinstitucionální dohodě o zdokonalení tvorby právních předpisů ze dne 13. dubna 2016¹⁹. Pro zajištění rovné účasti na vypracovávání aktů v přenesené pravomoci obdrží Evropský parlament a Rada veškeré dokumenty současně

¹⁹ Úř. věst. L 123, 12.5.2016, s. 1.

s odborníky z členských států a jejich odborníci mají automaticky přístup na zasedání skupin odborníků Komise, jež se věnují přípravě aktů v přenesené pravomoci.

- (45) Jelikož cílů tohoto nařízení, totiž usnadnění volného pohybu v Unii během pandemie COVID-19 zavedením interoperabilních certifikátů o stavu očkování, testování a uzdravení držitele, nemohou uspokojivě dosáhnout členské státy, ale spíše jich lze z důvodu rozsahu nebo účinků navrhované činnosti lépe dosáhnout na úrovni Unie, může Unie přijmout opatření v souladu se zásadou subsidiarity stanovenou v článku 5 Smlouvy o Evropské unii. V souladu se zásadou proporcionality stanovenou v uvedeném článku nepřekračuje toto nařízení rámec toho, co je nezbytné pro dosažení těchto cílů.
- (46) Toto nařízení ctí základní práva a dodržuje zásady uznané zejména Listinou základních práv, včetně práva na respektování soukromého a rodinného života, práva na ochranu osobních údajů, práva na rovnost před zákonem a zákazu diskriminace, práva na volný pohyb a práva na účinnou právní ochranu. Členské státy by měly při provádění tohoto nařízení Listinu základních práv dodržovat.
- (47) Evropský inspektor ochrany údajů byl konzultován podle čl. 42 odst. 1 nařízení (EU) 2018/1725²⁰,

PŘIJALY TOTO NAŘÍZENÍ:

Článek 1

Předmět

Toto nařízení stanoví rámec pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19 za účelem usnadnění výkonu práva jejich držitelů na volný pohyb během pandemie COVID-19 (dále jen "digitální zelený certifikát").

Stanoví právní základ pro zpracování osobních údajů nezbytných k vydávání těchto certifikátů a ke zpracování informací nezbytných k potvrzení a ověření pravosti těchto certifikátů a jejich platnosti.

Článek 2

Definice

Pro účely tohoto nařízení se rozumí:

- (1) "držitelem" občan Unie nebo jeho rodinní příslušníci, kterým byl vydán interoperabilní certifikát obsahující informace o jejich stavu očkování, testování nebo uzdravení v souladu s tímto nařízením;
- (2) "digitálním zeleným certifikátem" interoperabilní certifikáty obsahující informace o stavu očkování, testování nebo uzdravení držitele vydané v souvislosti s pandemií COVID-19;
- (3) "očkovací látkou proti COVID-19" imunologický léčivý přípravek určený k aktivní imunizaci za účelem prevence onemocnění COVID-19;

²⁰ Nařízení Evropského parlamentu a Rady (EU) 2018/1725 ze dne 23. října 2018 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů orgány, institucemi a jinými subjekty Unie a o volném pohybu těchto údajů a o zrušení nařízení (ES) č. 45/2001 a rozhodnutí č. 1247/2002/ES (Úř. věst. L 295, 21.11.2018, s. 39).

- (4) "testem NAAT" test založený na amplifikaci nukleových kyselin (NAAT), jako např. techniky polymerázové řetězové reakce s reverzní transkripcí (RT-PCR), izotermální amplifikace nukleových kyselin metodou LAMP a amplifikace zprostředkované transkripcí (TMA), který se používá ke zjištění přítomnosti ribonukleové kyseliny SARS-CoV-2 (RNA SARS-CoV-2);
- (5) "rychlým testem na antigen" zkušební metoda založená na detekci virových proteinů (antigenů) pomocí imunotestu na bázi laterálního proudu, jehož výsledek je k dispozici do 30 minut;
- (6) "interoperabilitou" schopnost ověřovacích systémů v členském státě používat údaje zakódované jiným členským státem;
- (7) "čárovým kódem" metoda ukládání a zobrazování údajů ve vizuálním, strojově čitelném formátu;
- "elektronickou pečetí" data v elektronické podobě, která jsou připojena k jiným datům v elektronické podobě nebo jsou s nimi logicky spojena s cílem zaručit jejich původ a integritu;
- (9) "jedinečným identifikátorem certifikátu" jedinečný identifikátor přidělený na základě společné struktury každému certifikátu vydanému v souladu s tímto nařízením;
- (10) "rámcem pro důvěryhodnost" pravidla, politická opatření, specifikace, protokoly, datové formáty a digitální infrastruktura, které upravují a umožňují spolehlivé a zabezpečené vydávání a ověřování certifikátů s cílem zaručit jejich důvěryhodnost potvrzením jejich pravosti, platnosti a integrity, včetně možného použití elektronických pečetí.

Článek 3

Digitální zelený certifikát

- 1. Interoperabilní digitální zelený certifikát umožňuje vydávání a přeshraniční ověřování a uznávání těchto certifikátů:
 - (a) certifikát potvrzující, že jeho držiteli byla podána očkovací látka proti COVID-19 v členském státě, který certifikát vydal (dále jen "certifikát o očkování");
 - (b) certifikát, v němž je uveden výsledek držitele a datum provedení testu NAAT nebo rychlého testu na antigen, který je zařazen do společného a aktualizovaného seznamu rychlých testů na antigen na COVID-19 zavedeného na základě doporučení Rady 2021/C 24/01²¹ (dále jen "certifikát o testu");
 - (c) certifikát potvrzující, že se jeho držitel uzdravil z infekce SARS-CoV-2 v návaznosti na pozitivní test NAAT nebo pozitivní rychlý test na antigen, který je zařazen do společného a aktualizovaného seznamu rychlých testů na antigen na COVID-19 zavedeného na základě doporučení Rady 2021/C 24/01 (dále jen "certifikát o uzdravení").
- 2. Členské státy vydávají certifikáty uvedené v odstavci 1 v digitálním nebo tištěném formátu nebo v obou formátech. Certifikáty vydávané členskými státy obsahují interoperabilní čárový kód umožňující ověření pravosti, platnosti a integrity certifikátu. Čárový kód splňuje technické specifikace stanovené v souladu s článkem 8. Informace v certifikátech jsou rovněž uvedeny ve formátu čitelném pro člověka a

²¹ Doporučení Rady o společném rámci pro používání a validaci rychlých testů na antigen a o vzájemném uznávání výsledků testů na COVID-19 v EU (2021/C 24/01) (Úř. věst. C 24, 22.1.2021, s. 1).

musí být alespoň v úředním jazyce nebo jazycích vydávajícího členského státu a v angličtině.

- 3. Certifikáty uvedené v odstavci 1 se vydávají bezplatně. Držitel je oprávněn požádat o vydání nového certifikátu, pokud osobní údaje obsažené v certifikátu nejsou nebo přestaly být správné či aktuální nebo již nemá certifikát k dispozici.
- 4. Vydáním certifikátů uvedených v odstavci 1 není dotčena platnost jiných potvrzení o očkování, testu nebo uzdravení vydaných před vstupem tohoto nařízení v platnost nebo pro jiné účely, zejména pro účely lékařské.
- 5. Pokud Komise přijala prováděcí akt podle druhého pododstavce, certifikáty vydané v souladu s tímto nařízením třetí zemí, s níž Evropská unie a její členské státy uzavřely dohodu o volném pohybu osob, která umožňuje smluvním stranám nediskriminačním způsobem omezit volný pohyb z důvodů veřejného zdraví a jež neobsahuje mechanismus začlenění aktů Evropské unie, se uznávají za podmínek uvedených v čl. 5 odst. 5.

Komise posoudí, zda třetí země vydává certifikáty v souladu s tímto nařízením a poskytla formální ujištění, že bude uznávat certifikáty vydané členskými státy. V takovém případě přijme prováděcí akt přezkumným postupem podle čl. 13 odst. 2.

6. Komise může požádat Výbor pro zdravotní bezpečnost zřízený článkem 17 rozhodnutí č. 1082/2013/EU o vydání pokynů ohledně dostupných vědeckých důkazů o účincích zdravotních událostí zaznamenaných v certifikátech uvedených v odstavci 1.

Článek 4

Rámec pro důvěryhodnost digitálního zeleného certifikátu

- 1. Komise a členské státy vytvoří a udržují digitální infrastrukturu rámce pro důvěryhodnost umožňující zabezpečené vydávání a ověřování certifikátů uvedených v článku 3.
- 2. Rámec pro důvěryhodnost zajistí tam, kde je to možné, interoperabilitu s technologickými systémy zřízenými na mezinárodní úrovni.
- 3. Pokud Komise přijala prováděcí akt podle druhého pododstavce, považují se certifikáty obsahující údaje uvedené v příloze a vydané třetími zeměmi občanům Unie a jejich rodinným příslušníkům podle mezinárodní normy a v technologickém systému, které jsou interoperabilní s rámcem pro důvěryhodnost zřízeným na základě tohoto nařízení a umožňují ověření pravosti, platnosti a integrity certifikátu, pro účely usnadnění výkonu práva jejich držitelů na volný pohyb v Evropské unii, za rovnocenné certifikátům vydaným členskými státy v souladu s tímto nařízením. Pro účely tohoto pododstavce uznávají členské státy certifikáty o očkování vydané třetími zeměmi za podmínek uvedených v čl. 5 odst. 5.

Komise posoudí, zda certifikáty vydané třetí zemí splňují podmínky stanovené v tomto odstavci. V takovém případě přijme prováděcí akt přezkumným postupem podle čl. 13 odst. 2.
Článek 5

Certifikát o očkování

- Každý členský stát vydá certifikát o očkování uvedený v čl. 3 odst. 1 písm. a) osobě, které byla podána očkovací látka proti COVID-19, a to buď automaticky, nebo na její žádost.
- 2. Certifikát o očkování obsahuje tyto kategorie osobních údajů:
 - (a) identifikační údaje držitele;
 - (b) informace o podaném očkovacím léčivém přípravku;
 - (c) metadata certifikátu, jako je vydavatel certifikátu nebo jedinečný identifikátor certifikátu.

Osobní údaje v certifikátu o očkování se uvedou ve specifických datových polích stanovených v bodě 1 přílohy.

Komisi je svěřena pravomoc přijímat akty v přenesené pravomoci v souladu s článkem 11 za účelem změny bodu 1 přílohy doplněním, změnou nebo odstraněním datových polí pro kategorie osobních údajů uvedené v tomto odstavci.

- 3. Certifikát o očkování se vydává v zabezpečeném a interoperabilním formátu podle čl. 3 odst. 2 a jasně uvádí, zda bylo očkovací schéma dokončeno, či nikoliv.
- 4. Pokud si to v případě nových vědeckých důkazů nebo v zájmu zajištění interoperability s mezinárodními normami a technologickými systémy vyžádají naprosto nezbytné a naléhavé důvody, použije se na akty v přenesené pravomoci přijaté podle tohoto článku postup stanovený v článku 12.
- 5. Pokud členské státy uznají potvrzení o očkování, aby mohly zrušit omezení volného pohybu zavedená v souladu s právem Unie s cílem omezit šíření onemocnění COVID-19, uznají za týchž podmínek rovněž platné certifikáty o očkování vydané jinými členskými státy v souladu s tímto nařízením pro očkovací látku proti COVID-19, jíž byla udělena registrace podle nařízení (ES) č. 726/2004.

Členské státy mohou za týmž účelem rovněž uznat platné certifikáty o očkování vydané jinými členskými státy v souladu s tímto nařízením pro očkovací látku proti COVID-19, jíž příslušný orgán členského státu udělil registraci podle směrnice 2001/83/ES, očkovací látku proti COVID-19, jejíž distribuce byla dočasně povolena podle čl. 5 odst. 2 směrnice 2001/83/ES, nebo očkovací látku proti COVID-19, která byla zařazena na seznam WHO k nouzovému použití.

6. Pokud byl občan Unie nebo rodinný příslušník občana Unie očkován v třetí zemi jedním z typů očkovacích látek proti COVID-19 uvedených v odstavci 5 tohoto článku a příslušným orgánům členského státu byly poskytnuty všechny nezbytné informace, včetně spolehlivého potvrzení o očkování, vydají příslušné orgány dotčené osobě certifikát o očkování podle čl. 3 odst. 1 písm. a).

Článek 6 Certifikát o testu

- 1. Každý členský stát vydá certifikát o testu uvedený v čl. 3 odst. 1 písm. b) osobě, která byla testována na COVID-19, a to buď automaticky, nebo na její žádost.
- 2. Certifikát o testu obsahuje tyto kategorie osobních údajů:
 - (a) identifikační údaje držitele;

- (b) informace o provedeném testu;
- (c) metadata certifikátu, jako je vydavatel certifikátu nebo jedinečný identifikátor certifikátu.

Osobní údaje v certifikátu o testu se uvedou ve specifických datových polích stanovených v bodě 2 přílohy.

Komisi je svěřena pravomoc přijímat akty v přenesené pravomoci v souladu s článkem 11 za účelem změny bodu 2 přílohy doplněním, změnou nebo odstraněním datových polí pro kategorie osobních údajů uvedené v tomto odstavci.

- 3. Certifikát o testu se vydává v zabezpečeném a interoperabilním formátu podle čl. 3 odst. 2.
- 4. Pokud si to v případě nových vědeckých důkazů nebo v zájmu zajištění interoperability s mezinárodními normami a technologickými systémy vyžádají naprosto nezbytné a naléhavé důvody, použije se na akty v přenesené pravomoci přijaté podle tohoto článku postup stanovený v článku 12.
- 5. Pokud členské státy vyžadují potvrzení o testu na infekci SARS-CoV-2 v rámci omezení volného pohybu zavedených v souladu s právem Unie s cílem omezit šíření onemocnění COVID-19, uznají rovněž platné certifikáty o testu vydané jinými členskými státy v souladu s tímto nařízením.

Článek 7

Certifikát o uzdravení

Každý členský stát vydá na požádání certifikát o uzdravení podle čl. 3 odst. 1 písm.
 c), a to nejdříve jedenáctý den poté, co daná osoba obdržela první pozitivní test na infekci SARS-CoV-2.

Komisi je svěřena pravomoc přijímat akty v přenesené pravomoci v souladu s článkem 11 za účelem úpravy počtu dní, po jejichž uplynutí může být certifikát o uzdravení vydán, na základě pokynů Výboru pro zdravotní bezpečnost v souladu s čl. 3 odst. 6 nebo vědeckých důkazů přezkoumaných střediskem ECDC.

- 2. Certifikát o uzdravení obsahuje tyto kategorie osobních údajů:
 - (a) identifikační údaje držitele;
 - (b) informace o prodělané infekci SARS-CoV-2;
 - (c) metadata certifikátu, jako je vydavatel certifikátu nebo jedinečný identifikátor certifikátu.

Osobní údaje v certifikátu o uzdravení se uvedou ve specifických datových polích stanovených v bodě 3 přílohy.

Komisi je svěřena pravomoc přijímat akty v přenesené pravomoci v souladu s článkem 11 za účelem změny bodu 3 přílohy doplněním, změnou nebo odstraněním datových polí pro kategorie osobních údajů uvedené v tomto odstavci, včetně doby platnosti certifikátu o uzdravení.

- 3. Certifikát o uzdravení se vydává v zabezpečeném a interoperabilním formátu podle čl. 3 odst. 2.
- 4. Pokud si to v případě nových vědeckých důkazů nebo v zájmu zajištění interoperability s mezinárodními normami a technologickými systémy vyžádají

naprosto nezbytné a naléhavé důvody, použije se na akty v přenesené pravomoci přijaté podle tohoto článku postup stanovený v článku 12.

5. Pokud členské uznávají potvrzení o uzdravení z infekce SARS-CoV-2 jako základ pro zrušení omezení volného pohybu zavedených v souladu s právem Unie s cílem omezit šíření onemocnění COVID-19, uznají za týchž podmínek platné certifikáty o uzdravení vydané jinými členskými státy v souladu s tímto nařízením.

Článek 8

Technické specifikace

K zajištění jednotných podmínek provádění rámce pro důvěryhodnost stanoveného tímto nařízením přijme Komise prováděcí akty obsahující technické specifikace a pravidla pro:

- (a) zabezpečené vydávání a ověřování certifikátů uvedených v článku 3;
- (b) zajištění bezpečnosti osobních údajů s přihlédnutím k jejich povaze;
- (c) vyplňování certifikátů uvedených v článku 3, včetně systému kódování a dalších relevantních prvků;
- (d) stanovení společné struktury jedinečného identifikátoru certifikátu;
- (e) vydání platného, zabezpečeného a interoperabilního čárového kódu;
- (f) zajištění interoperability s mezinárodními normami nebo technologickými systémy;
- (g) rozdělení povinností mezi správce a ve vztahu ke zpracovatelům.

Tyto prováděcí akty se přijímají přezkumným postupem podle čl. 13 odst. 2.

V řádně odůvodněných závažných a naléhavých případech, zejména s cílem zajistit včasné provedení rámce pro důvěryhodnost, přijme Komise okamžitě použitelné příslušné prováděcí akty postupem podle čl. 13 odst. 3.

Článek 9

Ochrana osobních údajů

- 1. Osobní údaje obsažené v certifikátech vydaných v souladu s tímto nařízením se zpracovávají pro účely přístupu k informacím uvedeným v certifikátu a jejich ověření, aby se usnadnil výkon práva na volný pohyb v Unii během pandemie COVID-19.
- 2. Osobní údaje uvedené v certifikátech podle článku 3 zpracovávají příslušné orgány členského státu určení nebo provozovatelé služeb přeshraniční přepravy cestujících, kteří jsou podle vnitrostátních právních předpisů povinni provádět během pandemie COVID-19 určitá opatření v oblasti veřejného zdraví, k tomu, aby potvrdili a ověřili stav očkování, testování nebo uzdravení držitele. Za tímto účelem se osobní údaje omezí na to, co je nezbytně nutné. Osobní údaje zpřístupněné podle tohoto odstavce se neuchovávají.
- 3. Osobní údaje zpracovávané za účelem vydání certifikátů podle článku 3, včetně vydání nového certifikátu, se neuchovávají po dobu delší, než je pro jejich účel nezbytné, a v žádném případě ne déle, než je doba, po niž mohou být použity k výkonu práva na volný pohyb.
- 4. Orgány odpovědné za vydávání certifikátů podle článku 3 se považují za správce ve smyslu čl. 4 odst. 7 nařízení (EU) 2016/679.

Článek 10

Oznamovací postup

- 1. Pokud členský stát požaduje, aby držitelé certifikátů uvedených v článku 3 po vstupu na jeho území podstoupili karanténu, domácí izolaci nebo test na infekci SARS-CoV-2, nebo pokud těmto osobám odepírá vstup, oznámí to ostatním členským státům a Komisi před plánovaným zavedením těchto omezení. Za tímto účelem členský stát poskytne tyto informace:
 - (a) důvody omezení, včetně všech příslušných epidemiologických údajů, které je odůvodňují;
 - (b) rozsah omezení s uvedením, na které cestující se vztahují, či kteří jsou od nich osvobozeni;
 - (c) datum a dobu trvání omezení.

Je-li to nezbytné, může si Komise od dotčeného členského státu vyžádat doplňující informace.

Článek 11 Výkon přenesené pravomoci

- 1. Pravomoc přijímat akty v přenesené pravomoci je svěřena Komisi za podmínek stanovených v tomto článku.
- Pravomoc přijímat akty v přenesené pravomoci uvedená v čl. 5 odst. 2, čl. 6 odst. 2, čl. 7 odst. 1 a 2 a v článku 15 se na Komisi přenese na dobu neurčitou, která začne plynout od [datum vstupu v platnost].
- 3. Evropský parlament nebo Rada mohou přenesení pravomoci uvedené v čl. 5 odst. 2, čl. 6 odst. 2, čl. 7 odst. 1 a 2 a v článku 15 kdykoli zrušit. Rozhodnutím o zrušení se ukončuje přenesení pravomoci v něm určené. Rozhodnutí nabývá účinku prvním dnem po zveřejnění v Úředním věstníku Evropské unie nebo k pozdějšímu dni, který je v něm upřesněn. Nedotýká se platnosti již platných aktů v přenesené pravomoci.
- 4. Před přijetím aktu v přenesené pravomoci vede Komise konzultace s odborníky jmenovanými jednotlivými členskými státy v souladu se zásadami stanovenými v interinstitucionální dohodě o zdokonalení tvorby právních předpisů ze dne 13. dubna 2016.
- 5. Přijetí aktu v přenesené pravomoci Komise neprodleně oznámí současně Evropskému parlamentu a Radě.
- 6. Akt v přenesené pravomoci přijatý podle čl. 5 odst. 2, čl. 6 odst. 2, čl. 7 odst. 1 a 2 a článku 15 vstoupí v platnost pouze tehdy, pokud proti němu Evropský parlament nebo Rada nevysloví námitky ve lhůtě dvou měsíců ode dne, kdy jim byl tento akt oznámen, nebo pokud Evropský parlament i Rada před uplynutím této lhůty informují Komisi o tom, že námitky nevysloví. Z podnětu Evropského parlamentu nebo Rady se tato lhůta prodlouží o dva měsíce.

Článek 12

Postup pro naléhavé případy

1. Akty v přenesené pravomoci přijaté podle tohoto článku vstupují v platnost bezodkladně a jsou použitelné, pokud proti nim není vyslovena námitka v souladu s

odstavcem 2. V oznámení aktu v přenesené pravomoci Evropskému parlamentu a Radě se uvedou důvody použití postupu pro naléhavé případy.

2. Evropský parlament nebo Rada mohou proti aktu v přenesené pravomoci vyslovit námitky postupem uvedeným v čl. 11 odst. 6. V takovém případě zruší Komise tento akt neprodleně poté, co jí Evropský parlament nebo Rada oznámí rozhodnutí o vyslovení námitek.

Článek 13 Postup projednávání ve výboru

- 1. Komisi je nápomocen výbor. Uvedený výbor je výborem ve smyslu nařízení (EU) č. 182/2011.
- 2. Odkazuje-li se na tento odstavec, použije se článek 5 nařízení (EU) č. 182/2011.
- 3. Odkazuje-li se na tento odstavec, použije se článek 8 nařízení (EU) č. 182/2011 ve spojení s článkem 5 uvedeného nařízení.

Článek 14

Podávání zpráv

Jeden rok poté, co generální ředitel Světové zdravotnické organizace v souladu s Mezinárodními zdravotnickými předpisy prohlásí, že ohrožení veřejného zdraví mezinárodního významu způsobené virem SARS-CoV-2 skončilo, předloží Komise Evropskému parlamentu a Radě zprávu o uplatňování tohoto nařízení.

Zpráva bude obsahovat zejména posouzení dopadu tohoto nařízení na usnadnění volného pohybu občanů Unie a jejich rodinných příslušníků, jakož i na ochranu osobních údajů během pandemie COVID-19.

Článek 15

Vstup v platnost a použitelnost

- 1. Toto nařízení vstupuje v platnost třetím dnem po vyhlášení v Úředním věstníku Evropské unie.
- 2. Komise přijme akt v přenesené pravomoci v souladu s článkem 11, v němž uvede datum, od něhož se pozastaví uplatňování článků 3, 4, 5, 6, 7 a 10, jakmile generální ředitel Světové zdravotnické organizace v souladu s Mezinárodními zdravotnickými předpisy prohlásí, že ohrožení veřejného zdraví mezinárodního významu způsobené virem SARS-CoV-2 skončilo.
- 3. Komisi je svěřena pravomoc přijmout akt v přenesené pravomoci v souladu s článkem 11, v němž se uvede datum, od kterého se znovu začnou uplatňovat články 3, 4, 5, 6, 7 a 10, pokud po pozastavení uvedeném v odstavci 2 tohoto článku generální ředitel Světové zdravotnické organizace vyhlásí ohrožení veřejného zdraví mezinárodního významu v souvislosti s virem SARS-CoV-2, jeho variantou nebo podobnými infekčními nemocemi s epidemickým potenciálem. Po přijetí tohoto aktu v přenesené pravomoci se použije odstavec 2 tohoto článku.
- 4. Pokud si to v případě nejnovějšího vývoje v souvislosti s ohrožením veřejného zdraví mezinárodního významu vyžádají naprosto nezbytné a naléhavé důvody, použije se na akty v přenesené pravomoci přijaté podle tohoto článku postup stanovený v článku 12.

Toto nařízení je závazné v celém rozsahu a přímo použitelné ve všech členských státech. V Bruselu dne

Za Evropský parlament předseda

Za Radu předseda/předsedkyně

<u>LEGISLATIVNÍ FINANČNÍ VÝKAZ</u>

1. RÁMEC NÁVRHU/PODNĚTU

- 1.1 Název návrhu/podnětu
- 1.2 Příslušné oblasti politik
- 1.3 Povaha návrhu/podnětu
- 1.4 Cíle
- 1.4.1 Obecné cíle
- 1.4.2 Specifické cíle
- 1.4.3 Očekávané výsledky a dopady
- 1.4.4 Ukazatele výkonnosti
- 1.5 Odůvodnění návrhu/podnětu

1.5.1 Potřeby, které mají být uspokojeny v krátkodobém nebo dlouhodobém horizontu, včetně podrobného harmonogramu pro zahajovací fázi provádění podnětu

- 1.5.2 Přidaná hodnota ze zapojení Unie
- 1.5.3 Závěry vyvozené z podobných zkušeností v minulosti

1.5.4 Slučitelnost s víceletým finančním rámcem a možné synergie s dalšími vhodnými nástroji

1.5.5 Posouzení různých dostupných možností financování, včetně prostoru pro přerozdělení prostředků

- 1.6 Doba trvání a finanční dopad návrhu/podnětu
- 1.7 Předpokládaný způsob řízení

2. SPRÁVNÍ OPATŘENÍ

- 2.1 Pravidla pro sledování a podávání zpráv
- 2.2 Systémy řízení a kontroly

2.2.1 Odůvodnění navrhovaných způsobů řízení, mechanismů provádění financování, způsobů plateb a kontrolní strategie

2.2.2 Informace o zjištěných rizicích a systémech vnitřní kontroly zřízených k jejich zmírnění

- 2.2.3 Odhad a odůvodnění nákladové efektivnosti kontrol
- 2.3 Opatření k zamezení podvodů a nesrovnalostí

3. ODHADOVANÝ FINANČNÍ DOPAD NÁVRHU/PODNĚTU

- 3.1 Okruhy víceletého finančního rámce a dotčené výdajové rozpočtové položky
- 3.2 Odhadovaný finanční dopad návrhu na prostředky
- 3.2.1 Odhadovaný souhrnný dopad na výdaje
- 3.2.2 Odhadovaný výstup financovaný z operačních prostředků
- 3.2.3 Odhadovaný souhrnný dopad na správní prostředky
- 3.2.4 Slučitelnost se stávajícím víceletým finančním rámcem
- 3.2.5 Příspěvky třetích stran
- 3.3 Odhadovaný dopad na příjmy

<u>LEGISLATIVNÍ FINANČNÍ VÝKAZ</u>

1. RÁMEC NÁVRHU/PODNĚTU

1.1. Název návrhu/podnětu

Návrh nařízení Evropského parlamentu a Rady o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení za účelem usnadnění volného pohybu během pandemie COVID-19 (digitální zelený certifikát).

1.2. Příslušné oblasti politik

Volný pohyb osob v Evropské unii

Oživení a odolnost

1.3. Povaha návrhu/podnětu

🗵 nová akce

🗆 nová akce následující po pilotním projektu / přípravné akci³⁴

□ prodloužení stávající akce

□ sloučení jedné či více akcí v jinou/novou akci nebo přesměrování jedné či více akcí na jinou/novou akci

1.4. Cíle

1.4.1. Obecné cíle

Obecným cílem tohoto nařízení je zajistit vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení s cílem usnadnit volný pohyb v EU během pandemie COVID-19.

1.4.2. Specifické cíle

Specifický cíl č. 1

Stanovit formát a obsah certifikátů o očkování, testování a uzdravení vydávaných členskými státy za účelem usnadnění volného pohybu.

Specifický cíl č. 2

Zajistit interoperabilitu, bezpečnost a ověřitelnost certifikátů vydávaných členskými státy.

Specifický cíl č. 3

Stanovit pravidla pro uznávání certifikátů o očkování, testování a uzdravení vydávaných členskými státy za účelem usnadnění volného pohybu.

1.4.3. Očekávané výsledky a dopady

Upřesněte účinky, které by návrh/podnět měl mít na příjemce / cílové skupiny.

Cílem návrhu je usnadnit výkon práva na volný pohyb v EU během pandemie COVID-19 zavedením společného rámce pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19. Tento rámec by měl občanům EU a jejich rodinným příslušníkům, kteří využívají svého práva na volný pohyb, umožnit, aby prokázali, že

³⁴ Uvedené v čl. 58 odst. 2 písm. a) nebo b) finančního nařízení.

splňují požadavky v oblasti veřejného zdraví uložené členským státem určení v souladu s právem EU. Cílem návrhu je rovněž zajistit, aby omezení volného pohybu, která jsou v současné době zavedena s cílem omezit šíření COVID-19, mohla být koordinovaně zrušena, jakmile bude k dispozici více vědeckých důkazů.

Členským státům bude poskytnuta podpora při zavádění nezbytné infrastruktury pro interoperabilní vydávání a ověřování certifikátů tvořících rámec "digitálního zeleného certifikátu". Komise a členské státy dále zřídí a budou udržovat technologickou infrastrukturu nezbytnou pro rámec "digitálního zeleného certifikátu".

1.4.4. Ukazatele výkonnosti

Upřesněte ukazatele pro sledování pokroku a dosažených výsledků.

<u>Příprava na vývoj</u>

Po schválení návrhu nařízení a přijetí technických specifikací rámce pro důvěryhodnost by na úrovni EU měla být navržena odpovídající bezpečná digitální infrastruktura mezi vnitrostátními systémy, která bude zajišťovat důvěryhodné ověřování certifikátů. Je-li to technicky možné, může tato infrastruktura využít návrh stávajících řešení usnadňujících výměnu informací mezi záložními řešeními v členských státech, která již fungují na úrovni EU.

Připraveno ke zprovoznění co nejdříve v roce 2021

Aby mohla fungovat digitální infrastruktura na úrovni EU, měla by Komise a členské státy provést komplexní testy zvládání očekávaného objemu transakcí.

Systém v provozu

Komise by měla zajistit, aby byla na úrovni EU zavedena podpůrná digitální infrastruktura a aby byla účinně provozována a monitorována.

1.5. Odůvodnění návrhu/podnětu

1.5.1. Potřeby, které mají být uspokojeny v krátkodobém nebo dlouhodobém horizontu, včetně podrobného harmonogramu pro zahajovací fázi provádění podnětu

K zajištění interoperability mezi různými technickými řešeními, která vyvíjejí členské státy, z nichž některé již začaly přijímat potvrzení o očkování s cílem osvobodit cestující od určitých omezení, jsou zapotřebí jednotné podmínky pro vydávání, ověřování a uznávání certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19.

Rámec "digitálního zeleného certifikátu" stanoví formát a obsah certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19. Tento rámec by měl zajistit vydávání těchto certifikátů v interoperabilním formátu a jejich spolehlivé ověřování při předložení držitelem v jiných členských státech, čímž by se usnadnil volný pohyb v EU.

Cílem návrhu je rovněž doplnit vnitrostátní iniciativy pro zavádění certifikátů o očkování, testování a uzdravení koordinovaným, soudržným a interoperabilním způsobem, aby se zabránilo zdvojování úsilí.

Rámec "digitálního zeleného certifikátu" se bude uplatňovat po dobu trvání pandemie COVID-19 jako opatření k usnadnění výkonu práv občanů na volný pohyb. Po vyhlášení konce pandemie bude rámec pozastaven a v případě budoucích pandemií může být obnoven.

1.5.2. Přidaná hodnota ze zapojení Unie (může být důsledkem různých faktorů, např. přínosů z koordinace, právní jistoty, vyšší účinnosti nebo doplňkovosti). Pro účely tohoto bodu se "přidanou hodnotou ze zapojení Unie" rozumí hodnota plynoucí ze zásahu Unie, jež doplňuje hodnotu, která by jinak vznikla činností samotných členských států.

Důvody pro akci na evropské úrovni (*ex ante*): Cílů tohoto nařízení, totiž usnadnění volného pohybu v EU během pandemie COVID-19 zřízením zabezpečených a interoperabilních certifikátů o stavu očkování, testování a uzdravení držitele, nemohou uspokojivě dosáhnout členské státy samostatně, nýbrž spíše jich lze z důvodu rozsahu a účinků navrhované činnosti lépe dosáhnout na úrovni EU. Je proto zapotřebí opatření na úrovni EU.

Očekávaná vytvořená přidaná hodnota na úrovni Unie (*ex post*): Absence opatření na úrovni EU by pravděpodobně vedla k tomu, že by členské státy zavedly různé systémy, v důsledku čehož by občané měli při výkonu svých práv na volný pohyb problémy s uznáváním svých dokumentů v jiných členských státech. Zejména je nezbytné se dohodnout na technických normách, které se použijí k zajištění interoperability, zabezpečení a ověřitelnosti vydávaných certifikátů.

1.5.3. Závěry vyvozené z podobných zkušeností v minulosti

Práce bude vycházet ze zkušeností získaných při zřizování digitální infrastruktury známé jako "evropská služba federační brány", která slouží pro přeshraniční výměnu údajů mezi vnitrostátními aplikacemi pro trasování kontaktů a mobilními aplikacemi pro varování v souvislosti s bojem proti pandemii COVID-19. Podpora propojení vnitrostátních koncových serverů na úrovni EU, jakož i pomoc při vývoji a zavádění řešení ve všech členských státech má zásadní význam pro zajištění bezproblémového a rovnoměrného přijetí navrhovaných řešení ve všech členských státech.

1.5.4. Slučitelnost s víceletým finančním rámcem a možné synergie s dalšími vhodnými nástroji

Komise má v úmyslu podpořit naléhavá opatření prostřednictvím nástroje pro mimořádnou podporu (ESI) a prověří, jakým způsobem by v pozdější fázi mohla být část finanční podpory poskytnuta z jiných programů, jako je Digitální Evropa. Financování bude v souladu s víceletým finančním rámcem na období 2021–2027. Iniciativa by mohla vyžadovat použití jednoho nebo několika zvláštních nástrojů, jak jsou definovány v nařízení o VFR. Komise podnikne odpovídající kroky, aby zajistila včasné uvolnění zdrojů.

1.5.5. Posouzení různých dostupných možností financování, včetně prostoru pro přerozdělení prostředků

Finanční podpora Unie může zahrnovat tyto akce:

1) Podpora technických specifikací pro rámec

a. specifikace týkající se celkové architektury vydávání a ověřování digitálního zeleného certifikátu a souvisejících datových struktur (bezpečnost, digitální certifikáty / pečeti pro digitální podpis certifikátů, které tvoří rámec "digitálního zeleného certifikátu", orgány pro zajištění důvěryhodnosti atd.);

b. specifikace, které musí členské státy dodržovat při vydávání a ověřování certifikátů tvořících rámec "digitálního zeleného certifikátu";

c. specifikace pro vhodný podpůrný systém ve všech členských státech, který může být provozován na úrovni EU (komunikace mezi systémy členských států).

2) <u>Ověření koncepce (Proof of Concept) a pilotní činnosti, včetně bezpečnostních kontrol, přičemž se jako referenční řešení provádí výše uvedený bod 1</u>.

3) Zavedení v některých pilotních členských státech

a. posouzení vlivu na ochranu osobních údajů (v případě potřeby);

b. bezpečnostní audit;

c. samotné zavedení systému a vytvoření postupu spouštění.

4) <u>Finanční podpora EU na pomoc členským státům a na vývoj vnitrostátních řešení pro vydávání a ověřování, která budou interoperabilní na úrovni EU a pokud možno i s technologickými systémy zřízenými na mezinárodní úrovni.</u>

5) Postup spouštění v členských státech.

6) Provoz a údržba systémů EU podporujících interoperabilitu.

Komise použije finanční prostředky z ESI, a jakmile vstoupí v platnost právní základ programu Digitální Evropa, prověří, jakým způsobem by některé výdaje mohly být vynaloženy v rámci tohoto programu.

Vzhledem k mimořádné zdravotní situaci se většina přípravných výdajů vynaloží v rámci ESI před tím, než právní základ "digitálního zeleného certifikátu" vstoupí v platnost. Jakýkoli systém na úrovni EU bude aktivován až poté, co vstoupí v platnost jeho právní základ.

1.6. Doba trvání a finanční dopad

⊠ Časově omezená doba trvání

- X s platností od data přijetí do data pozastavení rámce pro "digitální zelený certifikát" týkajícího se vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19, jakmile generální ředitel WHO v souladu s mezinárodními zdravotnickými předpisy prohlásí, že ohrožení veřejného zdraví mezinárodního významu způsobené virem SARS-CoV-2 skončilo.
- Imanční dopad od roku 2021 na prostředky na závazky a na platby. Závazky ESI budou muset být uzavřeny do 31. ledna 2022.

□ Časově neomezená doba trvání

1.7. Předpokládaný způsob řízení³⁵

🗵 Přímé řízení Komisí

- 🗵 prostřednictvím jejích útvarů, včetně jejích zaměstnanců v delegacích Unie,

□ Sdílené řízení s členskými státy

□ **Nepřímé řízení,** při kterém jsou úkoly souvisejícími s plněním rozpočtu pověřeny:

³⁵ Vysvětlení způsobů řízení spolu s odkazem na finanční nařízení jsou k dispozici na stránkách BudgWeb: <u>http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html</u>

- − □ třetí země nebo subjekty určené těmito zeměmi,
- − □ mezinárodní organizace a jejich agentury (upřesněte),
- − □ EIB a Evropský investiční fond,
- − □ subjekty uvedené v článcích 70 a 71 finančního nařízení,
- − □ veřejnoprávní subjekty,
- □ soukromoprávní subjekty pověřené výkonem veřejné služby v rozsahu, v jakém poskytují dostatečné finanční záruky,
- soukromoprávní subjekty členského státu pověřené uskutečňováním partnerství soukromého a veřejného sektoru a poskytující dostatečné finanční záruky,
- Pokud vyberete více způsobů řízení, upřesněte je v části "Poznámky".

Poznámky

Žádné.

2. SPRÁVNÍ OPATŘENÍ

2.1. Pravidla pro sledování a podávání zpráv

Upřesněte četnost a podmínky.

Opatření, na která se poskytuje finanční pomoc podle tohoto návrhu, se budou pravidelně monitorovat.

Komise předloží jeden rok poté, co WHO prohlásí, že pandemie SARS-CoV-2 skončila, zprávu o uplatňování nařízení, v níž nastíní zejména jeho dopad na volný pohyb a ochranu osobních údajů.

2.2. Systémy řízení a kontroly

2.2.1. Odůvodnění navrhovaných způsobů řízení, mechanismů provádění financování, způsobů plateb a kontrolní strategie

Způsob řízení

Opatření na podporu cílů nařízení budou prováděna přímo, jak stanoví finanční nařízení.

Komise poskytne veškerou požadovanou podporu řádně odůvodněnou členskými státy, a to prostřednictvím přímých grantů pro příslušná ministerstva nebo jimi pověřené a zmocněné subjekty, nebo zadá zakázky na vývoj a provoz jakékoli potřebné infrastruktury pro interoperabilitu na úrovni EU. Toto uspořádání se pro dosažení cílů nařízení považuje za nejvhodnější, jelikož plně zohledňuje zásady hospodárnosti, efektivnosti a nejlepšího zhodnocení vynaložených prostředků.

Nástroje financování

Na opatření, která mají být financována za účelem dosažení cílů nařízení, budou čerpány prostředky z ESI. Jakmile vstoupí v platnost právní základ programu Digitální Evropa, Komise prověří, jakým způsobem by některé výdaje mohly být provedeny v rámci tohoto programu.

Komise podpoří členské státy při zavádění technické infrastruktury potřebné k zajištění interoperability pomocí grantů v souladu s ustanoveními finančního nařízení.

Kontrolní strategie

Kontrolní strategie budou zohledňovat rizika spojená s příslušnými nástroji a mechanismy provádění financování.

U grantů bude odpovídajícím způsobem nastavena kontrolní strategie, která se v souladu s finančním nařízením zaměří na tři klíčové fáze poskytování grantu:

a. organizaci výzev k podávání návrhů a výběr návrhů, které odpovídají politickým cílům nařízení;

b. provozní kontroly, sledování a kontroly *ex ante* týkající se provádění projektu, zadávání veřejných zakázek, předběžného financování, průběžných a konečných plateb atd.,

c. kontroly projektů a plateb *ex post*.

2.2.2. Informace o zjištěných rizicích a systémech vnitřní kontroly zřízených k jejich zmírnění

Byla zjištěna tato rizika:

a. zpoždění při plnění specifikací rámce pro důvěryhodnost;

b. zpoždění při zavádění infrastruktur členských států pro interoperabilitu a/nebo brány provozované EU;

c. možné chyby nebo chybné řízení/zneužití finančních prostředků EU.

Při provádění budou využívány granty, které jsou méně náchylné k chybám.

Mezi klíčové kontrolní funkce plánované pro program patří zaměření na politické cíle při současném zohlednění cílů vnitřní kontroly (legalita a správnost, účinnost a nákladová efektivnost kontrol). Jejich účelem bude zajistit zapojení všech účastníků, odpovídající rozpočtovou pružnost a konzistentní kontroly *ex ante* a *ex post*, přičemž je možné diferencovat podle rizik.

Použije se stávající vnitřní kontrolní systém Komise, aby bylo zajištěno, že finanční prostředky dostupné v rámci ESI (a programu Digitální Evropa, až bude přijat) jsou využívány řádně a v souladu s příslušnými právními předpisy.

Současný systém je uspořádán takto:

a. Interní kontrolní tým GŘ CONNECT se zaměřuje na dodržování platných správních postupů a právních předpisů. Pro tento účel se používá rámec vnitřní kontroly Komise. Stejný kontrolní rámec dodržují i další útvary Komise zapojené do provádění tohoto nástroje.

b. Do ročního plánu auditů bude plně začleněn pravidelný audit grantů a zakázek, které budou přiděleny v rámci tohoto nařízení; budou jej provádět externí auditoři.

c. Hodnocení celkových činností externími hodnotiteli.

Prováděná opatření může kontrolovat Evropský úřad pro boj proti podvodům (OLAF) a Účetní dvůr.

2.2.3. Odhad a odůvodnění nákladové efektivnosti kontrol (poměr "náklady na kontroly ÷ hodnota souvisejících spravovaných finančních prostředků") a posouzení očekávané míry rizika výskytu chyb (při platbě a při uzávěrce)

Odhadovaná míra chyb

Cílem je pro všechny výdaje související s prováděním opatření za účelem dosažení cíle nařízení udržet zbytkovou chybovost pod 2% prahovou hodnotou a zároveň omezit kontrolní zátěž členských států, aby bylo dosaženo správné rovnováhy mezi cílem legality a správnosti a dalšími cíli, jako je účinnost rámce digitálního zeleného certifikátu.

2.3. Opatření k zamezení podvodů a nesrovnalostí

Upřesněte stávající či předpokládaná preventivní a ochranná opatření, např. opatření uvedená ve strategii pro boj proti podvodům.

GŘ CONNECT je odhodláno bojovat proti podvodům ve všech fázích procesu řízení. Vypracovalo a provádí komplexní strategii boje proti podvodům, která zahrnuje všechny hlavní prováděné činnosti a zjištěná rizika podvodů. To zahrnuje intenzivnější využívání zpravodajských informací pomocí pokročilých IT nástrojů (zejména při řízení grantů) a průběžnou odbornou přípravu a informování zaměstnanců. Cílem celého tohoto souboru navržených kontrolních opatření je obecně rovněž pozitivní dopad na boj proti podvodům.

Právní předpisy zajistí, že klíčové kontroly, jako jsou audity a/nebo kontroly na místě, budou moci provádět útvary Komise včetně úřadu OLAF na základě standardních ustanovení doporučených úřadem OLAF.

3. ODHADOVANÝ FINANČNÍ DOPAD NÁVRHU/PODNĚTU

3.1. Okruhy víceletého finančního rámce a dotčené výdajové rozpočtové položky

• Stávající rozpočtové položky

<u>V pořadí</u> okruhů víceletého finančního rámce a rozpočtových položek.

Okruh	Rozpočtová položka	Druh výdaje	Prichavel						
víceletého finančního rámce	Číslo	RP/NRP ³⁶ .	zemí ESVO ³⁷	kandidátsk ých zemí ³⁸	třetích zemí	ve smyslu čl. 21 odst. 2 písm. b) finančního nařízení			
2b	06 07 01 Mimořádná podpora v rámci Unie	RP	NE	NE	NE	NE			
01	02 04 Program Digitální Evropa	RP	ANO	ANO (je- li stanoven v ročním pracovní m programu)	část progra mu	NE			

Při počáteční podpoře nejnaléhavějších opatření této iniciativy použije Komise finanční prostředky z fondů ESI, a jakmile vstoupí v platnost právní základ programu Digitální Evropa, prověří, jakým způsobem by některé výdaje mohly být vynaloženy v rámci tohoto programu.

³⁶ RP = rozlišené prostředky / NRP = nerozlišené prostředky.

³⁷ ESVO: Evropské sdružení volného obchodu.

³⁸ Kandidátské země a případně potenciální kandidáti západního Balkánu.

3.2. Odhadovaný dopad na výdaje

- 3.2.1. Odhadovaný souhrnný dopad na výdaje
 - − □ Návrh/podnět nevyžaduje využití operačních prostředků.
 - ■ Návrh/podnět vyžaduje využití operačních prostředků, jak je vysvětleno dále:

v milionech EUR (zaokrouhleno na tři desetinná místa)

Okruh víceletého finančního rámce	02	Odolnost a hodnoty
--------------------------------------	----	--------------------

GŘ CONNECT			Rok 2021	Rok 2022	Rok 2023	Rok 2024	CELKEM
• Operační prostředky							
06 07 01 Mimořádná podpora v rámci	Závazky	(1a)	46 000	3 000			49 000
Unie	Platby	(2a)	37 900	11 100			49 000
Prostředky na GŘ CONNECT	Závazky	=1a	46 000	3 000			49 000
z okruhu 2b CELKEM	Platby	=2a	37 900	11 100			49 000

Operační prostředky CELKEM	Závazky	(4)	46 000	3 000		49 000
• Operacin prostredky CELKEM	Platby	(5)	37 900	11 100		49 000
Prostředky z okruhu 2b	Závazky	=4	46 000	3 000		49 000
víceletého finančního rámce CELKEM	Platby	=5	37 900	11 100		49 000

Okruh víceletého finančního rámce	01	Jednotný trh, inovace a digitální agenda
--------------------------------------	----	--

GŘ CONNECT			Rok 2021	Rok 2022	Rok 2023	Rok 2024	CELKEM
• Operační prostředky							
02 04 Program Digitální Evropa	Závazky	(1b)	p.m.	p.m.			p.m.
	Platby	(2b)	p.m.	p.m.			p.m.
Prostředky na GŘ CONNECT	Závazky	=1b	p.m.	p.m.			p.m.
z okruhu 01 CELKEM	Platby	=2b	p.m.	p.m.			p.m.
• On one žní prostřadly, CELKEM	Závazky	(4)	p.m.	p.m.			p.m.
Operační prostředky CELKEM	Platby	(5)	p.m.	p.m.			p.m.
Prostředky z OKRUHU 01	Závazky	=4	p.m.	p.m.			p.m.
víceletého finančního rámce CELKEM	Platby	=5	p.m.	p.m.			p.m.

Okruh víceletého finanči rámce	ıího	7	"Správní výdaje"						
					v milionech	EUR (zaokrouhlend	o na tři desetinná místa)		
			Rok 2021	Rok 2022	Rok 2023	Rok 2024	CELKEM		
GŘ CONNECT + JUST + SANTE + DIGIT									
• Lidské zdroje			2 214	2 518			4 732		
• Ostatní správní výdaje									
GŘ CONNECT + JUST + SANTE + DIGIT CELKEM	Prostředky		2 214	2 518			4 732		

Prostředky z OKRUHU 7 víceletého finančního rámce CELKEM	(Závazky celkem = platby celkem)	2 214	2 518			4 732	
--	----------------------------------	-------	-------	--	--	-------	--

v milionech EUR (zaokrouhleno na tři desetinná místa)

		Rok 2021	Rok 2022	Rok 2023	Rok 2024	CELKEM
Prostředky z OKRUHŮ 1 až 7	Závazky	48 214	5 518			53 732
víceletého finančního rámce CELKEM	Platby	40 114	13 618			53 732

3.2.2. Odhadovaný výstup financovaný z operačních prostředků

Uved'te cíle a			2	2021	2	022	20	023	20	24	V	ložit poče de	et let p padu	odle trván (viz bod 1	ú finanč 6)	éního	CEI	LKEM
výstupy									VÝST	UPY								
Û	Druh ³⁹	Průmě rné náklad y	Počet	Nákla dy	Počet	Nákla dy	Počet	Nákla dy	Počet	Náklad y	Počet	Nákla dy	Počet	Nákla dy	Počet	Nákla dy	Celko vý počet	Náklady celkem
	SPECIFICKÝ CÍL č. 1 Stanovit formát a obsah certifikátů o očkování, testování a uzdravení vydávaných členskými státy za účelem usnadnění volného pohybu.																	
Návrh a provádění rámce pro dů			1	2 000														
Mezisoučet za s	pecifický	cíl č. 1		2 000														
	SPECIFICKÝ CÍL č. 2 Zajistit interoperabilitu, bezpečnost a ověřitelnost certifikátů vydávaných členskými státy.																	
Zavádění řešení podpořených EU zbývajících členských státech	J ve		1	32 000														
Připojení k bráně EU a její nepře	tržitý provoz		1	2 000		3 000												
Mezisoučet za s	pecifický	cíl č. 2		34 000		3 000												
SPECIFICKÝ CÍI Stanovit pravidla		ání certifik	cátů o c	očkování, t	testovár	ní a uzdrav	ení vydáv	aných čle	nskými státy	za účelem	ı usnadı	nění volno	ého po	hybu.				
Úspěšné dokončení pilotního tes	tování		1	10 000														
Mezisoučet za s	pecifický	cíl č. 3		10 000														
CEL	KEM			46 000		3 000												

Prostředky na závazky v milionech EUR (zaokrouhleno na tři desetinná místa)

³⁹ Výstupy se rozumí produkty a služby, které mají být dodány (např. počet financovaných studentských výměn, počet vybudovaných kilometrů silnic atd.).

3.2.3. Odhadovaný souhrnný dopad na správní prostředky

- − □ Návrh/podnět nevyžaduje využití prostředků správní povahy.
- ■ Návrh/podnět vyžaduje využití prostředků správní povahy, jak je vysvětleno dále:

Rok Rok F		
	Rok Rok 2023 2024	

v milionech EUR (zaokrouhleno na tři desetinná místa)

OKRUH 7 víceletého finančního rámce				
Lidské zdroje	2 214	2 518		4 732
Ostatní správní výdaje				
Mezisoučet za OKRUH 7 víceletého finančního rámce	2 214	2 518		4 732

Mimo OKRUH 7 ⁴⁰ víceletého finančního rámce			
Lidské zdroje			
Ostatní výdaje správní povahy			
Mezisoučet mimo OKRUH 7 víceletého finančního rámce			

CELKEM 2 214	2 518	4 732
--------------	-------	-------

Potřebné prostředky na oblast lidských zdrojů a na ostatní výdaje správní povahy budou pokryty z prostředků GŘ, které jsou již vyčleněny na řízení akce a/nebo byly vnitřně přerozděleny v rámci GŘ a případně doplněny z dodatečného přídělu, který lze řídícímu GŘ poskytnout v rámci ročního přidělování a s ohledem na rozpočtová omezení.

⁴⁰ Technická a/nebo administrativní pomoc a výdaje na podporu provádění programů a/nebo akcí EU (bývalé položky "BA"), nepřímý výzkum, přímý výzkum.

3.2.3.1. Odhadované potřeby v oblasti lidských zdrojů

- Návrh/podnět nevyžaduje využití lidských zdrojů.
- − Návrh/podnět vyžaduje využití lidských zdrojů, jak je vysvětleno dále:

		1	naa vyjae	1	1	1 1		
				Rok 2023	Rok 2024	Vložit počet let podle trván finančního dopadu (viz boo 1.6)		
• Pracovní místa podle plánu pra	ncovních míst (místa úředníků a č	ločasných zar	něstnanců))				
20 01 02 01 (v ústředí a v zastou	peních Komise)	14	16					
20 01 02 03 (při delegacích)								
01 01 01 01(v přímém výzkumu))							
01 01 01 11 (v přímém výzkumu)							
Jiné rozpočtové položky (upřesněte)								
• Externí zaměstnanci (v přepočt	u na plné pracovní úvazky: FTE)	42						
20 02 01 (VNO)		1	1					
20 02 03 (SZ, MZ, VNO, ZAP a MOD při delegacích)								
XX 01 xx yy zz ⁴³	– v ústředí							
	– při delegacích							
01 01 01 02 (SZ, VNO, ZAP v přímém výzkumu)								
01 01 01 12 (SZ, VNO, ZAP v přímém výzkumu)								
Jiné rozpočtové položky (upřesněte)								
CELKEM		15	17					

Odhad vyjádřete v přepočtu na plné pracovní úvazky

XX je oblast politiky nebo dotčená hlava rozpočtu.

Potřeby v oblasti lidských zdrojů budou pokryty ze zdrojů GŘ, které jsou již vyčleněny na řízení akce a/nebo byly vnitřně přeobsazeny v rámci GŘ, a případně doplněny z dodatečného přídělu, který lze řídícímu GŘ poskytnout v rámci ročního přidělování a s ohledem na rozpočtová omezení.

Popis úkolů:

Úředníci a dočasní zaměstnanci	Zaměstnanci budou pověřeni vypracováním, sledováním a prováděním tohoto nařízení, technických specifikací přijatých na jeho základě, sledováním technického provádění (prostřednictvím rámcové smlouvy a grantů), jakož i podporou členských států při vývoji jejich vnitrostátních aplikací.
Externí zaměstnanci	

⁴¹ Do výpočtu pro rok 2021 je zahrnuto pouze deset měsíců.

⁴² SZ = smluvní zaměstnanec; MZ = místní zaměstnanec; VNO = vyslaný národní odborník; ZAP = zaměstnanec agentury práce; MOD = mladý odborník při delegaci.

⁴³ Dílčí strop na externí zaměstnance financované z operačních prostředků (bývalé položky "BA").

3.2.4. Slučitelnost se stávajícím víceletým finančním rámcem

Návrh/podnět:

– ■ může být financován přerozdělením prostředků v rámci příslušných okruhů víceletého finančního rámce (VFR).

Při počáteční podpoře použije Komise fondy ESI, a jakmile vstoupí v platnost právní základ programu Digitální Evropa, prověří, jakým způsobem by některé výdaje mohly být vynaloženy v rámci tohoto programu.

– ■ vyžaduje použití nepřiděleného rozpětí v rámci příslušného okruhu VFR a/nebo použití zvláštních nástrojů definovaných v nařízení o VFR.

Iniciativa by mohla vyžadovat použití jednoho nebo několika zvláštních nástrojů, jak jsou definovány v nařízení o VFR.

− □ vyžaduje revizi VFR.

3.2.5. Příspěvky třetích stran

Návrh/podnět:

- ■ nepočítá se spolufinancováním od třetích stran.
- − □ počítá se spolufinancováním od třetích stran podle následujícího odhadu:

prostředky v milionech EUR (zaokrouhleno na tři desetinná místa)

	Rok N ¹	Rok N+1	Rok N+2	Rok N+3	Vložit počet let podle trvání finančního dopadu (viz bod 1.6)		Celkem	
Upřesněte spolufinancující subjekt								
Spolufinancované prostředky CELKEM								

1

Rokem N se rozumí rok, kdy se návrh/podnět začíná provádět. Výraz "N" nahrad te předpokládaným prvním rokem provádění (například 2021). Totéž proved te u let následujících.

3.3. Odhadovaný dopad na příjmy

- ■ Návrh/podnět nemá žádný finanční dopad na příjmy.
- − □ Návrh/podnět má tento finanční dopad:
 - □ na vlastní zdroje
 - □ na jiné příjmy

uveď te, zda je příjem účelově vázán na výdajové položky 🗆

v milionech EUR (zaokrouhleno na tři desetinná místa)

Prostředky dostupné v	Dopad návrhu/podnětu ²							
Příjmová rozpočtová položka:	dostupné v běžném rozpočtovém roce	Rok N	Rok N+1	Rok N+2	Rok N+3	Vložit počet let podle trvání finančního dopadu (viz bod 1.6)		
Článek								

U účelově vázaných příjmů upřesněte dotčené výdajové rozpočtové položky.

Jiné poznámky (např. způsob/vzorec výpočtu dopadu na příjmy nebo jiné údaje).

² Pokud jde o tradiční vlastní zdroje (cla, dávky z cukru), je třeba uvést čisté částky, tj. hrubé částky po odečtení 20 % nákladů na výběr.



Brusel 18. března 2021 (OR. en)

7129/21

Interinstitucionální spis: 2021/0071 (COD)

COVID-19 91 JAI 286 AG 20 FRONT 98 FREMP 55 IPCR 31 VISA 51 MI 180 SAN 154 TRANS 154 COCON 14 COMIX 152 CODEC 406

NÁVRH

Odesílatel:	Martine DEPREZOVÁ, ředitelka, za generální tajemnici Evropské komise
Datum přijetí:	18. března 2021
Příjemce:	Jeppe TRANHOLM-MIKKELSEN, generální tajemník Rady Evropské unie
Č. dok. Komise:	COM(2021) 140 final
Předmět:	Návrh NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení během pandemie COVID-19 státním příslušníkům třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm na území členských států (digitální zelený certifikát)

Delegace naleznou v příloze dokument COM(2021) 140 final.

Příloha: COM(2021) 140 final



V Bruselu dne 17.3.2021 COM(2021) 140 final

2021/0071 (COD)

Návrh

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY

o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení během pandemie COVID-19 státním příslušníkům třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm na území členských států (digitální zelený certifikát)

DŮVODOVÁ ZPRÁVA

1. SOUVISLOSTI NÁVRHU

Odůvodnění a cíle návrhu

V souladu s Úmluvou k provedení Schengenské dohody se státní příslušníci třetích zemí s oprávněným bydlištěm nebo oprávněným pobytem v některém členském státě mohou volně pohybovat po území ostatních členských států, pokud splňují určité podmínky. Z politiky Unie, díky níž se při překračování vnitřních hranic neprovádějí kontroly osob, tudíž těží nejen občané Unie, ale také státní příslušníci třetích zemí, kteří mají právo cestovat v rámci EU. Některá z omezení přijatých členskými státy za účelem omezení šíření koronaviru 2 způsobujícího těžký akutní respirační syndrom (dále jen "SARS-CoV-2"), který je příčinou onemocnění koronavirem 2019 (dále jen "COVID-19"), však měla dopad na uplatňování tohoto práva. Tato opatření často spočívala v omezeních vstupu nebo jiných specifických požadavcích na přeshraniční cestující, jako je podstoupení karantény či domácí izolace nebo podstoupení testu na infekci SARS-CoV-2 před příjezdem a/nebo po příjezdu.

Aby byl zajištěn dobře koordinovaný, předvídatelný a transparentní přístup k přijímání omezení svobody pohybu, přijala Rada dne 13. října 2020 doporučení Rady (EU) 2020/1475 o koordinovaném přístupu k omezování volného pohybu v reakci na pandemii COVID-19¹, které se týká rovněž postavení státních příslušníků třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm v Unii. Podle bodu 17 doporučení Rady (EU) 2020/1475 by členské státy mohly vyžadovat, aby osoby cestující z rizikových oblastí v jiném členském státě EU před příjezdem a/nebo po příjezdu podstoupily karanténu / domácí izolaci nebo test na infekci SARS-CoV-2.

Na důkaz splnění příslušných požadavků mají lidé při cestách předkládat různé druhy písemných dokumentů, jako jsou lékařská osvědčení, výsledky testů nebo prohlášení. Kvůli neexistenci standardizovaných a zabezpečených formátů vznikají jejich držitelům problémy s přijímáním těchto dokumentů v jiných členských státech a je hlášeno i předkládání padělaných nebo pozměněných dokumentů². Tyto problémy, které mohou způsobit zbytečné prodlevy a překážky, budou pravděpodobně narůstat s tím, jak se stále více Evropanů nechává testovat na COVID-19 a očkovat proti tomuto viru a dostává o tom potvrzení. Evropská rada se touto záležitostí zabývá. Její členové ve svém prohlášení přijatém v návaznosti na neformální videokonference konané ve dnech 25. a 26. února 2021³ vyzvali k pokračování práce na společném přístupu k certifikátům o očkování.

Členské státy se shodují na nutnosti používat tyto certifikáty pro lékařské účely, například z důvodu zajištění řádných návazných kroků mezi první a druhou dávkou, jakož i případných nezbytných přeočkování. Členské státy pracují na vytvoření certifikátů o očkování, často s využitím informací dostupných v imunizačních registrech.

Komise spolupracuje na přípravě interoperability certifikátů o očkování s členskými státy v rámci sítě pro elektronické zdravotnictví – dobrovolné sítě spojující vnitrostátní orgány odpovědné za elektronické zdravotnictví. Dne 27. ledna 2021 přijala síť pro elektronické

¹ Úř. věst. L 337, 14.10.2020, s. 3.

² <u>https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates</u>

³ Prohlášení SN 2/21.

zdravotnictví pokyny k potvrzení o očkování pro lékařské účely, které aktualizovala dne 12. března 2021⁴. Tyto pokyny definují ústřední prvky interoperability, zejména minimální soubor údajů pro certifikáty o očkování a jedinečný identifikátor. Síť pro elektronické zdravotnictví a Výbor pro zdravotní bezpečnost zřízený článkem 17 rozhodnutí Evropského parlamentu a Rady č. 1082/2013/EU⁵ rovněž pracují na společném standardizovaném souboru údajů pro certifikáty o výsledcích testů na COVID-19⁶, pokynech pro certifikáty o uzdravení a souvisejících datových souborech, jakož i na konceptu interoperability zdravotních certifikátů⁷.

Na základě dosavadní technické práce navrhuje Komise ve svém návrhu nařízení o digitálním zeleném certifikátu (COM(2021)/xxx), který se předkládá zároveň s tímto návrhem, aby byl zřízen celounijní rámec pro vydávání, ověřování a uznávání certifikátů o očkování v rámci EU jako součást "digitálního zeleného certifikátu". Tento rámec by měl zároveň zahrnovat i další certifikáty vydané během pandemie COVID-19, konkrétně potvrzení o negativním výsledku testu na infekci SARS-CoV-2, jakož i potvrzení, že se držitel z infekce virem SARS-CoV-2 uzdravil. Tohoto interoperabilního rámce tak budou moci využít i lidé, kteří nejsou očkování nebo dosud neměli možnost nechat se naočkovat, čímž se jim usnadní cestování. Například děti v současné době nemohou být proti onemocnění COVID-19 očkovány, ale měly by mít možnost získat certifikát o testu nebo o uzdravení (který by jejich jménem mohli obdržet jejich rodiče).

Rámec stanovený v návrhu nařízení o digitálním zeleném certifikátu (COM(2021)/xxx) se vztahuje na občany Unie a jejich rodinné příslušníky, kteří mohou být státními příslušníky třetích zemí. Cílem tohoto návrhu je zajistit, aby se týž rámec vztahoval i na ostatní státní příslušníky třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm na území členského státu EU, kteří v souladu s právem Unie mohou cestovat do jiného členského státu.

Podle čl. 77 odst. 2 písm. c) Smlouvy o fungování Evropské unie (dále také jen "SFEU") rozvíjí Unie politiky, které stanoví podmínky, za kterých požívají státní příslušníci třetích zemí v Unii svobody pohybu. Některá opatření přijatá členskými státy s cílem omezit šíření onemocnění COVID-19 však měla dopad na svobodu pohybu v rámci Unie u státních příslušníků třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm. Tato opatření mnohdy spočívají v omezení vstupu nebo v jiných zvláštních požadavcích na přeshraniční cestující, přičemž nejvíce dopadají na obyvatelstvo žijící v pohraničních oblastech a překračující hranice v rámci svého běžného pracovního života, vzdělávání, zdravotní péče, nákupů, kulturních a volnočasových aktivit. Jedná se například o požadavek podrobit se karanténě či domácí izolaci nebo se před příjezdem a/nebo po něm nechat otestovat na infekci COVID-19.

Doporučení Rady (EU) 2020/1475 stanovilo koordinovaný přístup, který se skládá z těchto klíčových bodů: uplatňování společných kritérií a prahových hodnot při rozhodování o tom, zda omezení volného pohybu zavést, vytváření map rizika přenosu onemocnění COVID-19 na základě dohodnutého barevného kódu, jež zveřejňuje Evropské středisko pro prevenci a

⁴ <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

⁵ Rozhodnutí Evropského parlamentu a Rady č. 1082/2013/EU ze dne 22. října 2013 o vážných přeshraničních zdravotních hrozbách a o zrušení rozhodnutí č. 2119/98/ES (Úř. věst. L 293, 5.11.2013, s. 1).

⁶ K dispozici na adrese <u>https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19 rat_common-list_en.pdf</u>

⁷ K dispozici na adrese <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

kontrolu nemocí (ECDC)⁸, a koordinovaný přístup, pokud jde o případná opatření, která se mohou odpovídajícím způsobem uplatnit na osoby pohybující se mezi oblastmi, v závislosti na úrovni rizika přenosu v uvedených oblastech.

Dne 30. října 2020 přijala Rada doporučení Rady (EU) 2020/1632 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19 v schengenském prostoru, v němž doporučila členským státům, které jsou vázány schengenským *acquis*, aby uplatňovaly zásady, společná kritéria, společné prahové hodnoty a společný rámec opatření stanovené v doporučení Rady (EU) 2020/1475. K zajištění interoperability různých technických řešení certifikátů o očkování, která vyvíjejí členské státy, z nichž některé již začaly přijímat potvrzení o očkování s cílem osvobodit cestující od určitých omezení, jsou zapotřebí jednotné podmínky pro vydávání, ověřování a uznávání certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19.

Rámec "digitálního zeleného certifikátu", který má být vytvořen, by měl stanovit formát a obsah certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19. Komise rovněž navrhuje, aby rámec "digitálního zeleného certifikátu" zajišťoval, že se certifikáty budou vydávat v interoperabilním formátu a bude možné je spolehlivě ověřit při předložení držitelem v jiných členských státech, čímž by se usnadnilo cestování po území EU.

Tyto certifikáty by měly obsahovat pouze nezbytné osobní údaje. Vzhledem k tomu, že uváděné osobní údaje zahrnují citlivé lékařské údaje, měla by se zajistit vysoká úroveň ochrany údajů a dodržování zásad minimalizace údajů. Rámec "digitálního zeleného certifikátu" by především neměl vyžadovat, aby byla zřízena a udržována databáze na úrovni EU. Měl by naopak umožnit decentralizované ověřování digitálně podepsaných interoperabilních certifikátů.

Navrhované nařízení (EU) 2021/XXX zohledňuje probíhající úsilí na mezinárodní úrovni, například pod záštitou Světové zdravotnické organizace (WHO) a jiných specializovaných agentur OSN, o stanovení specifikací a pokynů pro používání digitálních technologií k dokumentaci stavu očkování. Třetí země by měly být vybízeny, aby při rušení omezení u cest, které nejsou nezbytně nutné, uznávaly "digitální zelený certifikát". Především by mohla být zajištěna interoperabilita mezi technologickými systémy zřízenými na celosvětové úrovni a systémy zřízenými pro účely tohoto nařízení k usnadnění cestování v rámci Evropské unie.

• Soulad s platnými předpisy v této oblasti politiky

Tímto návrhem nejsou dotčena schengenská pravidla, pokud jde o podmínky vstupu státních příslušníků třetích zemí. Navrhované nařízení by v žádném případě nemělo být chápáno tak, že podporuje nebo usnadňuje opětovné zavedení kontrol na vnitřních hranicích, které musí zůstat krajním opatřením, jež podléhá podmínkám stanoveným v nařízení (EU) 2016/399 (Schengenský hraniční kodex)⁹.

Návrh doplňuje další politické iniciativy přijaté během pandemie COVID-19 v oblasti volného pohybu a cestování, jako jsou doporučení Rady (EU) 2020/1475, (EU) 2021/119,

^{8 &}lt;u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

⁹ Nařízení Evropského parlamentu a Rady (EU) 2016/399 ze dne 9. března 2016, kterým se stanoví kodex Unie o pravidlech upravujících přeshraniční pohyb osob (Úř. věst. L 77, 23.3.2016, s. 1).

(EU) 2020/912 a (EU) 2021/132, a navazuje na ně¹⁰. Doporučení Rady (EU) 2020/1475 popisuje zejména obecné zásady, podle nichž by se členské státy měly koordinovat při přijímání a uplatňování opatření na ochranu veřejného zdraví v reakci na pandemii COVID-19. Doporučení Rady (EU) 2020/912 uvádí třetí země, ze kterých by měly být povoleny cesty, které nejsou nezbytně nutné, jakož i funkce a potřeby, v jejichž případě jsou povoleny nezbytně nutné cesty bez ohledu na třetí zemi původu. Komise bude v nejbližší budoucnosti provádět důkladný přezkum fungování posledně zmíněného doporučení a podle vývoje v této oblasti navrhne změny.

• Soulad s ostatními politikami Unie

Tento návrh je součástí balíčku opatření EU v reakci na pandemii COVID-19. Vychází zejména z předchozí technické práce v rámci Výboru pro zdravotní bezpečnost a sítě pro elektronické zdravotnictví, což je dobrovolná síť spojující orgány, které v členských státech odpovídají za elektronické zdravotnictví.

Tento návrh je v souladu s politikou Unie v oblasti přistěhovalectví státních příslušníků třetích zemí.

Stávající právní předpisy EU neobsahují žádná ustanovení o vydávání, ověřování a uznávání certifikátů potvrzujících zdravotní stav držitele, a to ani v případě, že předložení těchto certifikátů může být nezbytné ke zrušení určitých omezení práva cestovat, jež byla zavedena během pandemie. Je proto nezbytné vypracovat ustanovení, která zajistí interoperabilitu a bezpečnost těchto certifikátů.

Tento návrh zohledňuje probíhající úsilí na mezinárodní úrovni (například pod záštitou specializovaných agentur OSN včetně Světové zdravotnické organizace (WHO)) o stanovení specifikací a pokynů pro používání digitálních technologií k dokumentaci stavu očkování. Třetí země by měly být vybízeny, aby při rušení omezení u cest, které nejsou nezbytně nutné, uznávaly "digitální zelený certifikát".

2. PRÁVNÍ ZÁKLAD, SUBSIDIARITA A PROPORCIONALITA

Právní základ

V čl. 77 odst. 2 písm. c) SFEU se uvádí, že Unie stanoví podmínky, za kterých požívají státní příslušníci třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm v Unii po krátkou dobu svobody pohybu. Použije se řádný legislativní postup.

Cílem návrhu je usnadnit státním příslušníkům třetích zemí pohyb po území EU během pandemie COVID-19 zavedením společného rámce pro vydávání a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19. Státní příslušníci třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm v některém z členských států, kteří mohou cestovat do ostatních členských států, by tak měli možnost

¹⁰ Doporučení Rady (EU) 2021/119, ze dne 1. února 2021, kterým se mění doporučení (EU) 2020/1475 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19 (Text s významem pro EHP), (Úř. věst. L 36, 2.2.2021, s. 1) a doporučení Rady (EU) 2021/132 ze dne 2. února 2021, kterým se mění doporučení (EU) 2020/912 o dočasném omezení cest do EU, jež nejsou nezbytně nutné, a o možném zrušení tohoto omezení (Úř. věst. L 41, 4.2.2021, s. 1).

prokázat, že splňují požadavky v oblasti veřejného zdraví uložené v souladu s právem Unie členským státem, do něhož přijíždějí. Cílem návrhu je rovněž zajistit, aby omezení volného pohybu, která jsou v současné době zavedena s cílem omezit šíření COVID-19, mohla být koordinovaně zrušena, jakmile bude k dispozici více vědeckých důkazů.

Tento návrh nestanoví povinnost nechat se očkovat a nezakládá ani nárok na očkování. Očkovací strategie jsou v pravomoci členských států.

• Subsidiarita (v případě nevýlučné pravomoci)

Cílů tohoto nařízení, totiž usnadnění pohybu po území Unie za pandemie COVID-19 zřízením zabezpečených a interoperabilních certifikátů o stavu očkování, testování a uzdravení držitele, nemůže být uspokojivě dosaženo jednotlivými členskými státy, ale spíše jich z důvodu rozsahu a účinků navrhované činnosti může být lépe dosaženo na úrovni Unie.

Pokud by nebylo přijato opatření na úrovni EU, členské státy by pravděpodobně zavedly různé systémy, v jejichž důsledku by se státní příslušníci třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm mohli při uplatňování svého práva na volný pohyb setkávat s tím, že by jim v jiném členském státě nemusely být automaticky uznány dokumenty, které jim byly vystaveny. Zejména je nezbytné se dohodnout na technických normách, které se použijí k zajištění interoperability, zabezpečení a ověřitelnosti vydávaných certifikátů.

Proporcionalita

Opatření na úrovni EU může být při řešení výše uvedených komplikací značným přínosem a jedině tak lze vytvořit a udržet jednotný a kompatibilní rámec.

Přijetí jednostranných nebo nekoordinovaných opatření ve věci zdravotních certifikátů v souvislosti s COVID-19 může vyústit v opatření, jež by státním příslušníkům třetích zemí, kteří mají svobodu pohybu v Unii, omezila možnost cestovat.

V souladu s pravidly stanovenými v nařízení (EU) 2021/XXXX, která se v celém rozsahu vztahují na toto navrhované nařízení, by se používání tohoto nařízení mělo pozastavit, jakmile pandemie COVID-19 skončí, neboť od tohoto okamžiku již nebude důvod, aby státní příslušníci třetích zemí při cestování v rámci Unie předkládali zdravotní doklady. Zároveň však platí, že by se toto nařízení mělo znovu začít používat, pokud WHO vyhlásí další pandemii způsobenou rozšířením SARS-CoV2, jeho varianty nebo podobného infekčního onemocnění s epidemickým potenciálem.

• Volba nástroje

Nařízení zajišťuje přímé, okamžité a společné provedení práva EU ve všech členských státech.

3. VÝSLEDKY HODNOCENÍ *EX POST*, KONZULTACÍ SE ZÚČASTNĚNÝMI STRANAMI A POSOUZENÍ DOPADŮ

Konzultace se zúčastněnými stranami

Návrh zohledňuje pravidelné diskuse s členskými státy, odborné výměny v rámci Výboru pro zdravotní bezpečnost a sítě pro elektronické zdravotnictví, dostupné informace o vývoji epidemiologické situace a příslušné vědecké důkazy, které jsou k dispozici.

Sběr a využití výsledků odborných konzultací

Návrh vychází z odborných diskusí ve Výboru pro zdravotní bezpečnost a síti pro elektronické zdravotnictví, z informací o epidemiologické situaci v souvislosti s pandemií COVID-19 zveřejněných ECDC a z dostupných relevantních vědeckých důkazů.

• Posouzení dopadů

Vzhledem k naléhavosti situace neprovedla Komise posouzení dopadů.

• Základní práva

Tento návrh počítá se zpracováním osobních údajů, včetně údajů o zdravotním stavu. Potenciálně může mít dopady na základní práva jednotlivců, zejména podle článku 7 (respektování soukromého života) a článku 8 (právo na ochranu osobních údajů) Listiny. Zpracování osobních údajů jednotlivců, včetně shromažďování a používání osobních údajů a přístupu k nim, ovlivňuje právo na soukromí a právo na ochranu osobních údajů podle Listiny. Zásah do těchto základních práv musí být odůvodněn.

Pokud jde o právo na ochranu osobních údajů včetně zabezpečení údajů, použije se nařízení Evropského parlamentu a Rady (EU) 2016/679¹¹. Není stanovena žádná výjimka z režimu Unie pro ochranu údajů a členské státy musí zavést jasná pravidla, podmínky a spolehlivé záruky v souladu s pravidly EU pro ochranu údajů. Navrhované nařízení nezřizuje evropskou databázi týkající se očkování, testování nebo uzdravení v kontextu onemocnění COVID-19. Pro účely navrhovaného nařízení musí být osobní údaje zahrnuty pouze do vydaného certifikátu, který by měl být chráněn proti padělání a manipulaci.

4. ROZPOČTOVÉ DŮSLEDKY

Na financování opatření na podporu této iniciativy se bude vztahovat legislativní finanční výkaz předložený spolu s návrhem nařízení (EU) 2021/XXX.

5. OSTATNÍ PRVKY

• Plány provádění a způsob monitorování, hodnocení a podávání zpráv

Nevztahuje se na tento návrh.

11

Nařízení Evropského parlamentu a Rady (EU) 2016/679 ze dne 27. dubna 2016 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů a o volném pohybu těchto údajů a o zrušení směrnice 95/46/ES (obecné nařízení o ochraně osobních údajů) (Úř. věst. L 119, 4.5.2016, s. 1).

Podrobné vysvětlení konkrétních ustanovení návrhu

Článek 1 tohoto návrhu popisuje předmět navrhovaného nařízení.

<u>Článek 2</u> stanoví urychlený vstup nařízení v platnost.

2021/0071 (COD)

Návrh

NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY

o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení během pandemie COVID-19 státním příslušníkům třetích zemí s oprávněným pobytem nebo oprávněným bydlištěm na území členských států (digitální zelený certifikát)

EVROPSKÝ PARLAMENT A RADA EVROPSKÉ UNIE,

s ohledem na Smlouvu o fungování Evropské unie, a zejména na čl. 77 odst. 2 písm. c) této smlouvy,

s ohledem na návrh Evropské komise,

v souladu s řádným legislativním postupem,

vzhledem k těmto důvodům:

- (1) Podle schengenského *acquis* se státní příslušníci třetích zemí s oprávněným bydlištěm v Unii a státní příslušníci třetích zemí, kteří oprávněně vstoupili na území některého členského státu, mohou po dobu 90 dnů během jakéhokoliv období 180 dnů volně pohybovat na území všech ostatních členských států.
- (2) Dne 30. ledna 2020 vyhlásil generální ředitel Světové zdravotnické organizace (WHO) ohrožení veřejného zdraví mezinárodního významu z důvodu globální nákazy koronavirem 2 způsobujícím těžký akutní respirační syndrom (SARS-CoV-2), který způsobuje onemocnění koronavirem 2019 (COVID-19). Dne 11. března 2020 dospěla WHO k závěru, že COVID-19 lze označit za pandemii.
- (3) S cílem omezit šíření viru přijaly členské státy různá opatření, z nichž některá měla dopad na cesty do členských států i pohyb po jejich území, například omezení vstupu nebo požadavky na to, aby přeshraniční cestující podstoupili karanténu.
- (4) Dne 13. října 2020 přijala Rada doporučení (EU) 2020/1475 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19¹².
- (5) Dne 30. října 2020 přijala Rada doporučení (EU) 2020/1632¹³ o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19 v schengenském prostoru, v němž doporučila členským státům, které jsou schengenským *acquis*

¹² Úř. věst. L 337, 14.10.2020, s. 3.

¹³ Doporučení Rady (EU) 2020/1632 ze dne 30. října 2020 o koordinovaném přístupu k omezení volného pohybu v reakci na pandemii COVID-19 v schengenském prostoru (Úř. věst. L 366, 4.11.2020, s. 25).

vázány, aby uplatňovaly zásady, společná kritéria, společné prahové hodnoty a společný rámec opatření stanovené v doporučení Rady (EU) 2020/1475.

- (6) Mnoho členských států již zahájilo nebo plánuje zahájit iniciativy na vydávání certifikátů o očkování. Aby se však účinně uplatnily při přeshraničním pohybu v rámci Unie, musí být tyto certifikáty plně interoperabilní, zabezpečené a ověřitelné. Je nezbytné, aby se členské státy společně dohodly na obsahu, formátu a technických normách těchto certifikátů a zásadách jejich používání.
- (7) Již nyní některé členské státy osvobozují očkované osoby od určitých cestovních omezení. Pokud členské státy uznají potvrzení o očkování, aby mohly zrušit omezení cestování zavedená v souladu s právem Unie s cílem omezit šíření onemocnění COVID-19, např. požadavky podstoupit karanténu, domácí izolaci či test na infekci SARS-CoV-2, měly by být povinny uznat za týchž podmínek platné certifikáty o očkování vydané jinými členskými státy v souladu s navrhovaným nařízením o digitálním zeleném certifikátu (COM(2021)/xxx. Uznání by mělo probíhat za týchž podmínek, což znamená například, že považuje-li členský stát za dostačující podání jediné dávky očkovací látky, měl by je považovat za dostačující i v případě držitelů certifikátu o očkování, v němž je zaznamenáno podání jedné dávky téže očkovací látky. Z důvodů veřejného zdraví by se tato povinnost měla týkat pouze osob, kterým byly podány očkovací látky proti COVID-19 s registrací podle nařízení Evropského parlamentu a Rady (ES) č. 726/2004¹⁴. Členským státům by to nemělo nijak bránit v rozhodnutí, že budou uznávat certifikáty o očkování vydané pro jiné očkovací látky proti COVID-19, například očkovací látky, kterým příslušný orgán členského státu udělil registraci podle směrnice Evropského parlamentu a Rady 2001/83/ES¹⁵, očkovací látky, jejichž distribuce byla povolena dočasně podle čl. 5 odst. 2 uvedené směrnice, nebo očkovací látky, které byly zařazeny na seznam WHO k nouzovému použití. Nařízení (EU) 2021/xxxx ze dne xx xx 2021 stanoví rámec pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19 za účelem usnadnění volného pohybu během pandemie COVID-19. Vztahuje se na občany Unie a státní příslušníky třetích zemí, kteří jsou rodinnými příslušníky občanů Unie.
- (8) V souladu s články 19, 20 a 21 Úmluvy k provedení Schengenské dohody se mohou státní příslušníci třetích zemí, na něž se vztahují tato ustanovení, volně pohybovat na území ostatních členských států.
- (9) Aby se státním příslušníkům třetích zemí, kteří mají právo pohybovat se na území členských států, usnadnilo uplatňování tohoto jejich práva, měl by se rámec pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, testování a uzdravení v kontextu onemocnění COVID-19 stanovený nařízením (EU) 2021/xxxx vztahovat rovněž na státní příslušníky třetích zemí, na něž se uvedené nařízení dosud nevztahuje, a to za předpokladu, že mají na území některého z členských států oprávněný pobyt nebo bydliště a mohou v souladu s právem Unie cestovat do jiných členských států.

¹⁴ Nařízení Evropského parlamentu a Rady (ES) č. 726/2004 ze dne 31. března 2004, kterým se stanoví postupy Společenství pro registraci humánních a veterinárních léčivých přípravků a dozor nad nimi a kterým se zřizuje Evropská agentura pro léčivé přípravky (Úř. věst. L 136, 30.4.2004, s. 1).

¹⁵ Směrnice Evropského parlamentu a Rady 2001/83/ES ze dne 6. listopadu 2001 o kodexu Společenství týkajícím se humánních léčivých přípravků (Úř. věst. L 311, 28.11.2001, s. 67).
- (10) Aby se certifikáty účinně uplatnily při přeshraničních cestách, musí být plně interoperabilní.
- (11) Toto nařízení by nemělo být chápáno tak, že usnadňuje nebo podporuje přijímání omezení volného pohybu nebo omezení jiných základních práv, která byla zavedena v reakci na pandemii. Případnou potřebou ověření certifikátů stanovených nařízením (EU) 2021/xxx navíc nelze nijak odůvodnit dočasné znovuzavedení ochrany vnitřních hranic. Kontroly na vnitřních hranicích by měly zůstat krajním opatřením, jež podléhá zvláštním pravidlům stanoveným v nařízení (EU) 2016/399 (Schengenský hraniční kodex)¹⁶.
- (12) V souladu s články 1 a 2 Protokolu č. 22 o postavení Dánska, připojeného ke Smlouvě o Evropské unii a ke Smlouvě o fungování Evropské unie, se Dánsko neúčastní přijímání tohoto nařízení a toto nařízení pro ně není závazné ani použitelné. Vzhledem k tomu, že toto nařízení navazuje na schengenské *acquis*, rozhodne se Dánsko v souladu s článkem 4 uvedeného protokolu do šesti měsíců ode dne přijetí tohoto nařízení Radou, zda je provede ve svém vnitrostátním právu.
- (13) Toto nařízení rozvíjí ta ustanovení schengenského acquis, kterých se neúčastní Irsko v souladu s rozhodnutím Rady 2002/192/ES¹⁷; Irsko se tedy nepodílí na jeho přijímání a toto nařízení pro ně není závazné ani použitelné. Ačkoli toto nařízení není pro Irsko použitelné, v zájmu usnadnění cestování v Unii by Irsko rovněž mohlo státním příslušníkům třetích zemí s oprávněným bydlištěm nebo oprávněným pobytem na jeho území vydávat certifikáty splňující stejné požadavky, jaké se vztahují na digitální zelený certifikát, a členské státy by je mohly uznávat. Stejně tak by Irsko mohlo uznávat certifikáty vydané členskými státy státním příslušníkům třetích zemí, kteří mají na jejich území oprávněné bydliště nebo oprávněný pobyt.
- (14) Pokud jde o Bulharsko, Chorvatsko, Kypr a Rumunsko, představuje toto nařízení akt navazující na schengenské *acquis* nebo s ním jinak související ve smyslu čl. 3 odst. 1 aktu o přistoupení z roku 2003, čl. 4 odst. 1 aktu o přistoupení z roku 2005 a čl. 4 odst. 1 aktu o přistoupení z roku 2011.
- (15) Pokud jde o Island a Norsko, rozvíjí toto nařízení ta ustanovení schengenského *acquis* ve smyslu Dohody uzavřené mezi Radou Evropské unie a Islandskou republikou a Norským královstvím o přidružení těchto dvou států k provádění, uplatňování a rozvoji schengenského *acquis*, která spadají do oblasti uvedené v čl. 1 bodě C rozhodnutí Rady 1999/437/ES¹⁸.
- (16) Pokud jde o Švýcarsko, rozvíjí toto nařízení ta ustanovení schengenského acquis ve smyslu Dohody mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji

¹⁶ Nařízení Evropského parlamentu a Rady (EU) 2016/399 ze dne 9. března 2016, kterým se stanoví kodex Unie o pravidlech upravujících přeshraniční pohyb osob (Úř. věst. L 77, 23.3.2016, s. 1).

¹⁷ Rozhodnutí Rady ze dne 28. února 2002 o žádosti Irska, aby se na ně vztahovala některá ustanovení schengenského *acquis* (Úř. věst. L 64, 7.3.2002, s. 20).

¹⁸ Rozhodnutí Rady ze dne 17. května 1999 o některých opatřeních pro uplatňování dohody uzavřené mezi Radou Evropské unie a Islandskou republikou a Norským královstvím o přidružení těchto dvou států k provádění, uplatňování a rozvoji schengenského *acquis* (Úř. věst. L 176, 10.7.1999, s. 31).

schengenského *acquis*, která spadají do oblasti uvedené v čl. 1 bodě C rozhodnutí 1999/437/ES ve spojení s článkem 3 rozhodnutí 2008/146/ES¹⁹.

- (17) Pokud jde o Lichtenštejnsko, rozvíjí toto nařízení ta ustanovení schengenského *acquis* ve smyslu Protokolu mezi Evropskou unií, Evropským společenstvím, Švýcarskou konfederací a Lichtenštejnským knížectvím o přistoupení Lichtenštejnského knížectví k Dohodě mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji schengenského *acquis*, která spadají do oblasti uvedené v čl. 1 bodě C rozhodnutí 1999/437/ES ve spojení s článkem 3 rozhodnutí 2011/350/EU²⁰.
- (18) V souladu s článkem 42 nařízení Evropského parlamentu a Rady (EU) 2018/1725²¹ byli konzultováni evropský inspektor ochrany údajů a Evropský sbor pro ochranu osobních údajů, kteří vydali své stanovisko dne [...],

PŘIJALY TOTO NAŘÍZENÍ:

Článek 1

Členské státy použijí pravidla stanovená v nařízení (EU) 2021/XXXX [nařízení o digitálním zeleném certifikátu] na ty státní příslušníky třetích zemí, kteří nespadají do působnosti uvedeného nařízení, ale kteří mají na jejich území oprávněné bydliště nebo pobyt a mohou v souladu s právem Unie cestovat do jiných členských států.

Článek 2

Toto nařízení vstupuje v platnost třetím dnem po vyhlášení v Úředním věstníku Evropské unie.

Toto nařízení je závazné v celém rozsahu a přímo použitelné ve všech členských státech.

V Bruselu dne

Za Evropský parlament předseda

Za Radu předseda/předsedkyně

¹⁹ Rozhodnutí Rady ze dne 28. ledna 2008 o uzavření Dohody mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji schengenského *acquis* jménem Evropského společenství (Úř. věst. L 53, 27.2.2008, s. 1).

²⁰ Rozhodnutí Rady ze dne 7. března 2011 o uzavření Protokolu mezi Evropskou unií, Evropským společenstvím, Švýcarskou konfederací a Lichtenštejnským knížectvím o přistoupení Lichtenštejnského knížectví k dohodě mezi Evropskou unií, Evropským společenstvím a Švýcarskou konfederací o přidružení Švýcarské konfederace k provádění, uplatňování a rozvoji schengenského *acquis* jménem Evropské unie, pokud jde o zrušení kontrol na vnitřních hranicích a pohyb osob (Úř. věst. L 160, 18.6.2011, s. 19).

²¹ Nařízení Evropského parlamentu a Rady (EU) 2018/1725 ze dne 23. října 2018 o ochraně fyzických osob v souvislosti se zpracováním osobních údajů orgány, institucemi a jinými subjekty Unie a o volném pohybu těchto údajů a o zrušení nařízení (ES) č. 45/2001 a rozhodnutí č. 1247/2002/ES (Úř. věst. L 295, 21.11.2018, s. 39).



Brusel 11. června 2021 (OR. en)

9718/21

Interinstitucionální spis: 2021/0068 (COD)

> VOTE 54 INF 182 PUBLIC 60 CODEC 878

POZNÁMKA

Předmět:	 Výsledek hlasování
	 NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19 (digitální certifikát EU COVID) za účelem usnadnění volného pohybu během pandemie COVID-19 (první čtení)
	 přijetí legislativního aktu
	 3801. zasedání RADY EVROPSKÉ UNIE
	(Doprava, telekomunikace a energetika)
	Lucemburk 11. června 2021

V této poznámce naleznete výsledek hlasování o výše uvedeném legislativním aktu.

Referenční dokumenty:

9482/21 + ADD 1 + ADD 2 PE-CONS 25/21

schválil Coreper (část II) dne 9. června 2021

Veškerá prohlášení nebo odůvodnění hlasování jsou k dispozici na internetových stránkách Rady: <u>Transparentnost a přístup k dokumentům.</u>



General Secretariat of the Council

Institution:	Council of the European Union
Session:	3801
Configuration:	Transport, Telecommunications and Energy
Item:	2021/0068 (COD) (Document: 25/21)
Voting Rule:	qualified majority
Subject:	Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

Vote	Members	Population (%)	Sitting data: 11/06/2021
① Yes	27	100%	Sitting date: 11/06/2021 Final result
❶ No	0	0%	FinalTesuit
O Abstain	0	0%	
Not participating	0		
Total	27		

Member State	Weighting	Vote	Member State	Weighting	Vote
BELGIQUE/BELGIË	2,58		EIETUVA	0,62	$\overline{0}$
БЪЛГАРИЯ	1,55			0,14	\odot
CESKÁ REPUBLIKA	2,35	\odot	MAGYARORSZÁG	2,18	\odot
DANMARK	1,30	$\textcircled{\textbf{0}}$	MALTA	0,11	0
EUTSCHLAND	18,54			3,91	
EESTI	0,30	$\textcircled{\textbf{0}}$	ÖSTERREICH	1,98	0
	1,11		POLSKA	8,47	0
ΕΛΛΆΔΑ	2,39		PORTUGAL	2,30	•
S ESPAÑA	10,56	$\textcircled{\textbf{O}}$	ROMÂNIA	4,31	\odot
	14,97		SLOVENIJA	0,47	0
TT HRVATSKA	0,91	$\textcircled{\textbf{0}}$	SLOVENSKO	1,22	
	13,58		SUOMI/FINLAND	1,23	
🛫 ΚΎΠΡΟΣ	0,20	$\textcircled{\textbf{O}}$		2,30	•
	0,43				

* When acting on a proposal from the Commission or the High Representative, qualified majority is reached if at least 55 % of members vote in favour (15 MS) accounting for at least 65% of the population For information: http://www.consilium.europa.eu/public-vote



Rada Evropské unie

> Brusel 11. června 2021 (OR. en)

9720/21

Interinstitucionální spis: 2021/0071(COD)

> VOTE 55 INF 183 PUBLIC 61 CODEC 880

POZNÁMKA

Předmět:	 Výsledek hlasování
	 NAŘÍZENÍ EVROPSKÉHO PARLAMENTU A RADY o rámci pro vydávání, ověřování a uznávání interoperabilních certifikátů o očkování, o testu a o zotavení v souvislosti s onemocněním COVID-19 (digitální certifikát EU COVID) ve vztahu ke státním příslušníkům třetích zemí s oprávněným pobytem nebo bydlištěm na území členských států během pandemie COVID-19 (první čtení)
	 přijetí legislativního aktu
	 3801. zasedání Rady Evropské unie
	(Doprava, telekomunikace a energetika)
	Lucemburk 11. června 2021

V této poznámce naleznete výsledek hlasování o výše uvedeném legislativním aktu.

Referenční dokumenty:

9484/21 + ADD 1 + ADD 2 PE-CONS 26/21

schválil Coreper (část II) dne 9. června 2021.

Veškerá prohlášení nebo odůvodnění hlasování jsou k dispozici na internetových stránkách Rady: <u>Transparentnost a přístup k dokumentům.</u>



General Secretariat of the Council

Institution: Session:	Council of the European Union 3801
Configuration:	Transport, Telecommunications and Energy
Item:	2021/0071 (COD) (Document: 26/21)
Voting Rule:	qualified majority
Subject:	Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third- country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

Vote	Members	Population (%)	Citting data: 11/06/2021
• Yes	25	100%	Sitting date: 11/06/2021 Final result
€ No	0	0%	Final result
Abstain	0	0%	
Not participating	0		
Total	25		

Member State	Weighting	Vote	Member State	Weighting	Vote
📔 BELGIQUE/BELGIË	2,64		🚃 LIETUVA	0,64	\odot
БЪЛГАРИЯ	1,59	$\textcircled{\black}{\bullet}$		0,14	\odot
늘 CESKÁ REPUBLIKA	2,41	\odot	MAGYARORSZÁG	2,23	1
DANMARK		\odot		0,12	\odot
	18,99			4,01	0
EESTI	0,30		ÖSTERREICH	2,03	\odot
EIRE/IRELAND		\odot	POLSKA	8,68	•
ΕΛΛΆΔΑ	2,45	\bigcirc	PORTUGAL	2,35	•
S ESPAÑA	10,82	$\textcircled{\textbf{O}}$		4,42	\bigcirc
FRANCE	15,34		COVENIJA	0,48	0
The second secon	0,93	\odot	SLOVENSKO	1,25	0
	13,92			1,26	0
🛫 ΚΎΠΡΟΣ	0,20	\odot		2,36	•
	0,44	\bigcirc			\otimes

* When acting on a proposal from the Commission or the High Representative, qualified majority is reached if at least 55 % of members vote in favour (14 MS) accounting for at least 65% of the population

For information: http://www.consilium.europa.eu/public-vote



Brussels, 26 March 2021 (OR. en)

7191/21

Interinstitutional File: 2021/0071(COD)

Council of the European Union

LIMITE

COVID-19 94 TRANS 158 JAI 293 COCON 15 AG 21 **COMIX 158 FRONT 102 CODEC 413** FREMP 58 **SCHENGEN 16 IPCR 32 AVIATION 52** VISA 54 **PHARM 45** MI 187 **RELEX 227 SAN 158 TOUR 9**

NOTE

From:	Presidency
To:	Ad hoc Working Party on the propsals on Digital Green Certificate
No. Cion doc.:	7129/21
Subject:	Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable vaccination, testing and recovery certificates for third country nationals legally residing in the Schengen area to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

Delegations will find in the <u>Annex</u> a Presidency compromise text on the above-mentioned proposal for further discussion at the Ad Hoc Working Party on the proposals for a Digital Green Certificate on 29 March 2021.

Changes compared to the Commission proposal are marked in **<u>bold/underline</u>** for additions and in bold/strikethrough for deletions.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2)(c)thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Under the Schengen acquis, third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180-day period.
- (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.
- (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.

- (4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic¹.
- (5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632² on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen *acquis* to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.
- (6) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in connection with cross-border travel within the Union, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.
- (7)Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive travel restrictions put in place in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with the proposal for a Regulation on a Digital Green Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council³. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC of the European Parliament and the Council⁴, vaccines whose distribution has been temporarily authorised based on Article 5(2)of that Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.

JAI.1

¹ OJ L 337, 14.10.2020, p. 3.

² Council Recommendation (EU) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area (OJ L 366, 4.11.2020, p. 25).

³ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States.
- (9) To facilitate travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.
- (10) For certificates to be used effectively in connection with cross-border travel, such certificates need to be fully interoperable.
- (11) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code)⁵.

(11a) Since this Regulation applies to third country nationals already legally staying or residing in the territories of the Member States, it should not be understood as granting third country nationals wishing to travel to a Member State the right to request a Digital Green Certificate from that Member State before arrival on its territory.

- (12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.
- (13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC⁶; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. Although Ireland is not subject to this Regulation, for the purposes of facilitating travel within the Union, Ireland could also issue certificates, which comply with the same requirements as those applicable to the Digital Green Certificate, to third-country nationals legally residing or legally staying in its territory and Member States to third country nationals legally residing or legally staying in their territories.

Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

⁶ Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20).

- (14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.
- (15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC⁷.
- (16) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC⁸.
- (17) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen acquis within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU⁹.

⁸ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (OJ L 53, 27.2.2008, p. 1).

⁹ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation is confederation with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

⁷ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

The European Data Protection Supervisor and the European Data Protection Board have (18)been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the Council¹⁰ and delivered an opinion on [...],

HAVE ADOPTED THIS REGULATION:

Article 1

Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.

Article 2

This Regulation shall enter into force on, and apply from, the third day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament The President

For the Council The President

JAI.1

6

¹⁰ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).



Council of the European Union

Interinstitutional File: 2021/0068(COD)

Brussels, 26 March 2021 (OR. en)

7399/21

LIMITE

COVID-19 111	TRANS 175
JAI 334	COCON 19
AG 26	COMIX 170
FRONT 109	CODEC 458
FREMP 69	SCHENGEN 21
IPCR 38	AVIATION 56
VISA 58	PHARM 53
MI 213	RELEX 246
SAN 175	TOUR 13

NOTE

From:	Presidency
To:	Ad hoc Working Party on the propsals on Digital Green Certificate
No. Cion doc.:	7128/21
Subject:	Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

Delegations will find in the <u>Annex</u> a Presidency compromise text on the above-mentioned proposal for further discussion at the Ad Hoc Working Party on the proposals for a Digital Green Certificate on 29 March 2021.

Changes compared to the Commission proposal are marked in <u>bold/underline</u> for additions and in bold/strikethrough for deletions. New changes compared to the previous version are also grey shaded.

<u>ANNEX</u>

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Every citizen of the Union has the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council¹ lays down detailed rules as regards the exercise of that right.
- (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.

JALA

¹ Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

- (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection.
- (4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic². That Recommendation establishes a coordinated approach on the following key points: the application of common criteria and thresholds when deciding whether to introduce restrictions to free movement, a mapping of the risk of COVID-19 transmission based on an agreed colour code, and a coordinated approach as to the measures, if any, which may appropriately be applied to persons moving between areas, depending on the level of risk of transmission in those areas. In view of their specific situation, the Recommendation also emphasises that essential travellers, as listed in its point 19, and cross-border commuters, whose lives are particularly affected by such restrictions, in particular those exercising critical functions or essential for critical infrastructure, should in principle be exempted from travel restrictions linked to COVID-19.
- (5) Using the criteria and thresholds established in Recommendation (EU) 2020/1475, the European Centre for Disease Prevention and Control ('ECDC') has been publishing, once a week, a map of Member States, broken down by regions, in order to support Member States' decision-making³.
- (6) As emphasised by Recommendation (EU) 2020/1475 any, Member States may restrict free movement for public health reasons. Any restrictions to the free movement of persons within the Union put in place to limit the spread of COVID-19 should be based on specific and limited public interest grounds, namely the protection of public health as emphasised by Recommendation (EU) 2020/1475. It is necessary for such limitations to be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should thus not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and personnel through the so-called "Green Lane" border crossings referred to in the Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services⁴.
- (7) The free movement of persons who do not pose a risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective pursued.

² OJ L 337, 14.10.2020, p. 3.

³ Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

⁴ OJ C 96I, 24.3.2020, p. 1.

- (8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their free movement rights, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.
- (9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, as national authorities and passenger transport services, such as airlines, trains, coaches or ferries, are confronted with a wide array of diverging document formats, not only regarding a person's vaccination status but also on tests and possible recovery from COVID-19.
- (10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery, entitled "Digital Green Certificate" should be established.
- (11) This Regulation should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, the exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply. At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.

(11a) This Regulation should not cover Member States' decisions to impose or waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19. The use of the digital green certificate in view of lifting restrictions should remain the responsibility of Member States.

- (12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.
- (13) The risk posed by false COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative COVID-19 test certificates⁵. Given the available and easily accessible technological means, such as highresolution printers and various graphics editor software, fraudsters are able to produce highquality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online.



⁵ <u>https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates</u>

- To ensure interoperability and equal access, including for persons with disabilities, (14)Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both. This should allow the prospective holder to request and receive a paper copy of the certificate or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human-readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user-friendliness. To avoid obstacles to free movement, and although there may be a charge for related services, such as the tests carried out, the certificates themselves should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon request, ensuring that they can be obtained easily and providing, where needed, the necessary support to allow for equal access by all citizens.
- (15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. The outline on the interoperability of health certificates⁶ adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU⁷ should form the basis for the trust framework.
- (16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, by the Member State of vaccination or test, or where the recovered person is located. Where reference is made to issuance by Member States, this should be understood as also covering issuance by designated bodies on behalf of Member States. Where relevant or appropriate, the certificates should be issued on behalf of the vaccinated, tested or recovered person, for example on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or other similar formalities.
- (17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See. in particular where they are vaccinated by a Member State.



⁶ Available at: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

⁷ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

- (18) It is necessary to take into account that the agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be conditional on an implementing act to be adopted by the Commission establishing that such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it would accept certificates issued by the Member States.
- (19) Regulation (EU) 2021/XXXX applies to third-country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.
- (20) The framework to be established for the purpose of this Regulation should seek to ensure coherence with global initiatives, in particular involving the WHO. This should include, where possible, interoperability between technological systems established at global level and the systems established for the purpose of this Regulation to facilitate free movement within the Union, including through the participation in a public key infrastructure or the bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated by third countries, this Regulation should provide for the acceptance of certificates issued by third countries to Union citizens and their family members where the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.
- (21) To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates to for persons receiving vaccines that have been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council⁸, for-vaccines that have been granted marketing authorisation has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.

⁸ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

- (22) Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the possibility to obtain a certificate on COVID-19 vaccination that complies with this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.
- (23) Member States should also issue such vaccination certificates to Union citizens and their family members who have been vaccinated in a third country and provide reliable proof to that effect.
- (24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021¹⁰. These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.
- (25)Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.

MMA/cr

LIMITE

¹⁰ Available at : <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

- (25a)Regulation (EC) No 726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation (EC) No 726/2004, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all Member States. In addition, [efficacy follow-up and supervision procedures of medicinal products authorised pursuant to Regulation (EC) No 726/2004 are carried out centrally for all Member States. The assessment and approval of vaccines via the centralised procedure follows shared standards and is done in a consistent way on behalf of all Member States. Member States' participation in the review and endorsement of the assessment is ensured through various committees and groups, which also benefits from the expertise from across the EU Medicines Regulatory Network. The authorisation via the centralised procedure provides the confidence that all Member States can rely on the authorisation and data on efficacy as well as safety and on the consistency of the batches being used for vaccination of citizens. The obligation to accept, under the same conditions, valid vaccination certificates issued by other Member States should therefore coverCOVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.
- (26) It is necessary to prevent discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended <u>or allowed, such as children</u>, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public-health-related requirements, and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries.

MMA/cr

LIMITE

- (27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts¹¹. As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection¹².
- (28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU¹³, which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates¹⁴.
- (29) Despite these common efforts, Union citizens and their family members exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, or to lack of trust in the authenticity of the document shown. Such problems are compounded for persons who cannot be vaccinated yet, in particular children, for whom test results may be the only way to travel in case restrictions are in place.
- (30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.

¹¹ <u>https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf</u>

¹² OJ L 392, 23.11.2020, p. 63.

¹³ OJ C 24, 22.1.2021, p. 1.

^{14 &}lt;u>https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf</u>

- (31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.
- According to existing evidence, persons who have recovered from COVID-19 can continue (32)to test positive for SARS-CoV-2 for a certain period after symptom onset¹⁵. Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and the date of a previous positive test for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.
- (33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States accept proof of recovery in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS-CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.
- (33a) Taking into account the latest scientific and technological developments and in light of the epidemiological evolution of the COVID-19 pandemic, the Commission should be empowered to address, based on relevant guidance from the ECDC, Member States' need to further supplement the certificates making up the Digital Green Certificate by establishing a certificate confirming that the holder has immunity or is at low risk of reinfection with COVID-19 based on a reliable test, such as serological testing for antibodies against SARS-CoV-2.

MMA/cr

LIMITE

¹⁵ <u>https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-</u> ending-of-isolation-of-people-with-COVID-19.pdf

- (34) To be able to obtain a common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council¹⁶ to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the virus, the situation of people having recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated.
- (35) In order to ensure uniform conditions for the implementation of the trust framework certificates established by this Regulation, implementing powers should be conferred on the Commission. Those powers should be *exercised* in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁷.
- (36) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the technical specifications necessary to establish interoperable certificates, imperative grounds of urgency so require or when new scientific evidence becomes available.
- (37) Regulation (EU) 2016/679 of the European Parliament and of the Council¹⁸ applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. The legal basis for processing for other purposes is to be provided for in national law, which must comply with Union data protection legislation.
- (38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the certificates should be set out in this Regulation.
- (39) For the purposes of this Regulation, personal data may be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In particular, it should allow for the verification of the authenticity of the certificate.

JAI.A

¹⁶ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

¹⁷ OJ L 55, 28.2.2011, p. 13.

¹⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

- (40) This Regulation does not create a legal basis for retaining personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic.
- (41) To ensure coordination, the Member States and the Commission should be informed when a Member State requires holders of certificates to undergo, after entry into its territory, quarantine/self-isolation or a test for SARS-CoV-2 infection, or if it denies entry to such persons.
- (42)In accordance with Recommendation (EU) 2020/1475, any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2 should be lifted as soon as the epidemiological situation allows. This also applies to obligations to present documents other than those required by Union law, in particular Directive 2004/38/EC, such as the certificates covered by this Regulation. Therefore, the Regulation's provisions on the "Digital Green Certificate" framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery should be suspended once the Director-General of the WHO has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended. This Regulation should apply for [18] months from the date of its entry into force. (43) At the latest [Six] months before the end of the application of this Regulation, taking into account he evolution of the epidemiological situation on the pandemic, the Commission should publish a report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection. one year after the Director-General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended.
- (44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016¹⁹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

¹⁹ OJ L 123, 12.5.2016, p. 1.

- (45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non-discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.
- (47) The European Data Protection Supervisor has been consulted pursuant to Article 42(1) of Regulation (EU) 2018/1725²⁰,

HAVE ADOPTED THIS REGULATION:

Article 1 Subject matter

This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery in order to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green Certificate").

It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates.

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) "holder" means the Union citizen or their family members to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.
- (2) "Digital Green Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;
- (3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID-19;
- (4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA);
- (5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes;
- (6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;
- (7) "barcode" means a method of storing and representing data in a visual, machine-readable format;
- (8) "electronic seal" means data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity;
- (9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation;
- (10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.

Article 3 Digital Green Certificate

- 1. The interoperable Digital Green Certificate **framework** shall allow for the issuance and cross-border verification and acceptance of any of the following certificates:
 - (a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');
 - (b) a certificate indicating the holder's result, type and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01²¹ ('test certificate');
 - (c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01 ('certificate of recovery').

<u>The Commission shall publish the list of COVID-19 rapid antigen tests established on</u> <u>the basis of Council Recommendation 2021/C 24/01, including any updates.</u>

1a.The Commission is empowered to adopt delegated acts in accordance with Article 11to supplement the certificates referred to in paragraph 1 by adding provisions on the
issuance and cross-border verification and acceptance of a certificate confirming that
the holder has immunity or is at low risk of reinfection with COVID-19 based on a
reliable test, in particular serological testing for antibodies against SARS-CoV-2,
where the Commission has received guidance to this effect pursuant to paragraph 6
('immunity certificate').

This certificate shall contain the following categories of data:

(a)identification of the holder;

(b) information about the test carried out;

(c)certificate metadata, such as the certificate issuer or a unique certificate identifier.

Any such delegated act shall also set out the data fields on the categories of data to be included in the certificate. The acceptance of such certificates shall take place under the conditions referred to in Article 7(5).

²¹ Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).

- 2. Member States shall issue the certificates referred to in paragraph 1 in a digital or paperbased format, or both. The certificates issued by Member States shall contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English.
- 3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, or the certificate is no longer available to the holder. Appropriate fees may be charged in case of repeated loss.

<u>3a</u> <u>The certificate shall include the following text:</u>

"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before traveling, please check the applicable public health measures applied at the point of destination."

- 4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other purposes, in particular for medical purposes.
- 5. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Article 5(5).

The Commission shall assess whether such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

6. Where necessary, the Commission shall ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU, the European Center for Disease Prevention and Control or the European Medicines Agency to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1, in particular in view of newly emerging SARS-CoV-2 variants of concern.

Article 4 Digital Green Certificate trust framework

- 1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.
- 2. The trust framework shall <u>seek to</u> ensure, where possible, interoperability with technological systems established at international level.
- 3. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates issued by third countries to Union citizens and their family members according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which-contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this subparagraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article 5(5).

The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

Article 5 Vaccination certificate

- 1. Each Member State shall issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.
- 2. The vaccination certificate shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about the vaccine medicinal product administered;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, on the categories of personal data mentioned in this paragraph where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.

- 3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) and shall clearly indicate whether or not the vaccination course has been completed.
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.

Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID-19 vaccine having received a WHO Emergency Use Listing.

5a. <u>Possession of a vaccination certificate shall not be a precondition to exercise free</u> <u>movement rights.</u>

Article 6 Test certificate

hall issue test contificates as notermed to in

- 1. Each Member State shall issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.
- 2. The test certificate shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about the test carried out;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.

- 3. The test certificate shall be issued in a secure and interoperable format as provided for in Article 3(2).
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States require proof of a test for SARS-CoV-2 infection as part of the restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept<u>, under the same conditions</u>, valid test certificates issued by other Member States in compliance with this Regulation.

Article 7 Certificate of recovery

1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.

- 2. The certificate of recovery shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about past SARS-CoV-2 infection **following a positive test**;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph, including until when a certificate of recovery shall be valid, <u>where such amendment is necessary to confirm or verify the</u> <u>authenticity, validity and integrity of the certificate in case of scientific progress in</u> <u>containing the COVID-19 pandemic or to ensure interoperability with international</u> <u>standards.</u>

- 3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States accept proof of recovery from SARS-CoV-2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.

New Article 7a

COVID-19 certificates and other documentation issued by a third-country

- 1. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with a vaccine medicinal product that corresponds to one of the types of COVID-19 vaccines referred to in paragraph 5 of Article 5 and where the authorities in a Member State have been provided with all necessary information, including reliable proof of vaccination, they may, upon request, issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned. A Member State shall not be required to issue a certificate for a vaccine not authorised for use in its territory.
- 2. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates issued by third countries or Overseas Countries and Territories, to Union citizens and their family members according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union.

The Commission shall assess whether certificates issued by a third country or Overseas Countries and Territories fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2). 3. For the purposes of this article, the acceptance by the Member States of certificates issued pursuat to this Article, shall take place under the conditions referred to in Articles 5(5), 6(5) and 7(5).

4. If a Member State accepts a certificate for a COVID-19 vaccine referred to in Article 5 (5) second subparagraph issued pursuant to this Article, it shall also accept certificates for the same COVID-19 vaccine issued by a Member State.

Article 8 Technical specifications

To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:

- (a) securely issue and verify the certificates referred to Article 3;
- (b) ensure the security of the personal data, taking into account the nature of the data;
- (c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;
- (d) lay down the common structure of the unique certificate identifier;
- (e) issue a valid, secure and interoperable barcode;
- (f) ensure, where possible, interoperability with international standards and/or technological systems;
- (g) allocate responsibilities amongst controllers and as regards processors, <u>in accordance with</u> <u>Article 28(3) of Regulation 2016/679</u>.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2).

On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).

JAI.A

Article 9 Protection of personal data

0. <u>Regulation (EU) 2016/679 shall apply to the processing of personal data carried out</u> <u>when implementing this Regulation.</u>

- 1. The personal data contained in the certificates issued in accordance with this Regulation shall be processed **only** for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic.
- 2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.
- 3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new certificate, shall not be retained longer than is necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.
- 4. The authorities <u>or other designated bodies</u> responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.

Article 10 Notification procedure

- 1. Member States shall notify Member States and the Commission on the acceptance of the certificates referred to in Article 3 and the conditions thereof. Where a Member State requires holders of certificates referred to in Article 3 to undergo, after entry into its territory, quarantine, self-isolation or a test for SARS-CoV-2 infection, or if it imposes other restrictions on holders of such certificates denies entry to such persons, it shall notify the other Member States and the Commission thereof. before the planned introduction of such restrictions. To that end, the Member State shall supply the following information:
 - (a) the reasons for such restrictions including all relevant epidemiological data supporting such restrictions;
 - (b) the scope of such restrictions, specifying <u>the holders of which certificates</u> which travellers are subject to or exempt from such restrictions;
 - (c) the date and duration of the restrictions.

The Commission may make this information publicly available.

Where necessary, the Commission may request additional information from the Member State concerned.

Article 11 Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The power to adopt delegated acts referred to in Articles 5(2), 6(2), 7(1) <u>and</u>, 7(2) and 15 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force].
- 3. The delegation of power referred to in Articles 5(2), 6(2), 7(1) <u>and</u>, 7(2) and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
- 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.

- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1) and 7(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 12 Urgency procedure

- 1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
- 2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 11(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 13

Committee procedure

- The Commission shall be assisted by a committee. That committee shall be a committee 1. within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
- Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in 3. conjunction with Article 5 thereof, shall apply.

24
Article 14

Transitional provisions

Member States may issue the certificates referred to in Article 3 in a format which does not comply with the requirements of this Regulation until [1month] after the entry into force of this Regulation. During this period, certificates issued in accordance with this Article shall be accepted by the Member States in accordance with Articles 5(5), 6(5) and 7(5). *Reporting*

One year after the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.

The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID-19 pandemic.

Article 15 Entry into force, applicability and reporting

- 1. This Regulation shall enter into force on, and apply from, the third day following that of its publication in the *Official Journal of the European Union*.
- 2. <u>The Regulation shall apply for [18] months from the date of its entry into force.</u>

At the latest [six] months before the end of the application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.

The report shall contain, in particular, an assessment of the impact of this <u>Regulation</u> on the facilitation of free movement as well as on the protection of personal data during the COVID-19 pandemic.

This report may be accompanied with legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.

2. The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 4, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended.

- 3. The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director-General of the World Health Organization declares a public health emergency of international concern in relation to SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.
- 4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament The President For the Council The President



Council of the European Union

Interinstitutional Files: 2021/0068(COD)

2021/0071(COD)

Brussels, 6 April 2021 (OR. en)

7472/21

LIMITE

COVID-19 119 **TRANS 187 JAI 348** COCON 20 AG 28 **COMIX 180 FRONT 117 CODEC 472** FREMP 76 **SCHENGEN 22 AVIATION 58 IPCR 39** VISA 65 **PHARM 56** MI 219 **RELEX 257 SAN 183 TOUR 15**

NOTE

From:	Presidency
To:	Ad hoc Working Party on the proposals for a Digital Green Certificate
No. Cion doc.:	7128/21
Subject:	Digital Green Certificate (DGC)
	- Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic
	- Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable vaccination, testing and recovery certificates for third country nationals legally residing in the Schengen area to facilitate free movement during the COVID-19 pandemic
	= Examination of Presidency compromise text

Delegations will find in the Annex a Presidency compromise text on the above-mentioned proposals for further discussion at the Ad Hoc Working Party on the proposals for a Digital Green Certificate on 8 April 2021.

Changes compared to the Commission proposal are marked in **bold/underline** for additions and in bold/strikethrough for deletions. New changes compared to the previous version are also grey shaded.

1

MMA/MdL/cr

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Every citizen of the Union has the <u>fundamental</u> right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council¹ lays down detailed rules as regards the exercise of that right.
- (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.

¹ Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

- (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection.
- (4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic². That Recommendation establishes a coordinated approach on the following key points: the application of common criteria and thresholds when deciding whether to introduce restrictions to free movement, a mapping of the risk of COVID-19 transmission based on an agreed colour code, and a coordinated approach as to the measures, if any, which may appropriately be applied to persons moving between areas, depending on the level of risk of transmission in those areas. In view of their specific situation, the Recommendation also emphasises that essential travellers, as listed in its point 19, and cross-border commuters, whose lives are particularly affected by such restrictions, in particular those exercising critical functions or essential for critical infrastructure, should in principle be exempted from travel restrictions linked to COVID-19.
- (5) Using the criteria and thresholds established in Recommendation (EU) 2020/1475, the European Centre for Disease Prevention and Control ('ECDC') has been publishing, once a week, a map of Member States, broken down by regions, in order to support Member States' decision-making³.
- (6) As emphasised by Recommendation (EU) 2020/1475 any, Member States may limit the fundamental right of free movement for public health reasons. Any restrictions to the free movement of persons within the Union put in place to limit the spread of COVID-19 should be based on specific and limited public interest grounds, namely the protection of public health as emphasised by Recommendation (EU) 2020/1475. It is necessary for such limitations to be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should thus not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and personnel through the so-called "Green Lane" border crossings referred to in the Guidelines for border management measures to protect health and ensure the availability of goods and essential services⁴.
- (7) The free movement of persons who do not pose a risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective pursued.



² OJ L 337, 14.10.2020, p. 3.

³ Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

⁴ OJ C 96I, 24.3.2020, p. 1.

- (8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their free movement rights, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.
- (9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, as national authorities and passenger transport services, such as airlines, trains, coaches or ferries, are confronted with a wide array of diverging document formats, not only regarding a person's vaccination status but also on tests and possible recovery from COVID-19.
- (10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery, entitled "Digital Green Certificate" should be established.
- (11) This Regulation should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, the exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply. At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.

(11a) This Regulation should not cover Member States' decisions to impose or waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19. The use of the Digital Green Certificate in view of lifting restrictions should remain the responsibility of the Member States.

- (12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.
- (13) The risk posed by false COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative COVID-19 test certificates⁵. Given the available and easily accessible technological means, such as highresolution printers and various graphics editor software, fraudsters are able to produce highquality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online.

MMA/MdL/cr

⁵ <u>https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates</u>

- (14)To ensure interoperability and equal access, including for persons with disabilities, Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both. This should allow the prospective holder to request and receive a paper copy of the certificate or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human-readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user-friendliness. To avoid obstacles to free movement, and although there may be a charge for related services, such as for tests, the certificates themselves should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon request, ensuring that they can be obtained easily and providing, where needed, the necessary support to allow for equal access by all citizens.
- (15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. The outline on the interoperability of health certificates⁶ adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU⁷ should form the basis for the trust framework.
- (16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, by the Member State of vaccination or test, or where the recovered person is located. Where reference is made to issuance by Member States, this should be understood as also covering issuance by designated bodies on behalf of Member States, including when they are issued in Overseas Countries and Territories on behalf of a Member State. Where relevant or appropriate, the certificates should be issued on behalf of the vaccinated, tested or recovered person, for example on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or other similar formalities.
- (17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See. in particular where they are vaccinated by a Member State.

⁶ Available at: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

- (18) It is necessary to take into account that the agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be conditional on an implementing act to be adopted by the Commission establishing that such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it would accept certificates issued by the Member States.
- (19) Regulation (EU) 2021/XXXX applies to third-country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.
- (20) The framework to be established for the purpose of this Regulation should seek to ensure coherence with global initiatives, in particular involving the WHO and the International Civil Aviation Organisation (ICAO). This should include, where possible, interoperability between technological systems established at global level and the systems established for the purpose of this Regulation to facilitate free movement within the Union, including through the participation in a public key infrastructure or the bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated or tested by third countries or by Overseas Countries or Territories referred to in Article 355 paragraph 2 TFEU, this Regulation should provide for the acceptance of certificates issued by third countries or by Overseas Countries or Territories and their family members where the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.
- (21) To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates to for persons receiving vaccines that have been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council⁸, for-vaccines that have been granted marketing authorisation pursuant to Directive 2001/83/EC of the European Parliament and of the Council⁹, or vaccines whose distribution has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.

⁸ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

- (22) Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the <u>right possibility</u> to obtain a certificate on COVID-19 vaccination that complies with this Regulation. Where Union citizens or their family members are not in possession of a vaccination certificate that complies with the requirements of this Regulation, in particular because they have been vaccinated before the entry into force of this Regulation, they should be given every reasonable opportunity to corroborate or prove by other means that they should benefit from the waiving of relevant restrictions to free movement afforded by a Member State. This should not be understood as affecting the right of Union citizens or their family members to receive, from Member States, certificates that comply with the requirements of this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.
- (23) Member States <u>may</u> also issue <u>upon request</u> such vaccination certificates to Union citizens and their family members who have been vaccinated in a third country and provide reliable proof to that effect.
- (24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021¹⁰. These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.
- (25)Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.

¹⁰ Available at : <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

- (25a) Regulation (EC) No 726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation (EC) No 726/2004, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all Member States. In addition, efficacy followup and supervision procedures of medicinal products authorised pursuant to Regulation (EC) No 726/2004 are carried out centrally for all Member States. The assessment and approval of vaccines via the centralised procedure follows shared standards and is done in a consistent way on behalf of all Member States. Member States' participation in the review and endorsement of the assessment is ensured through various committees and groups, which also benefits from the expertise from the EU Medicines Regulatory Network. The authorisation via the centralised procedure provides the confidence that all Member States can rely on the authorisation and data on efficacy as well as safety and on the consistency of the batches being used for vaccination of citizens. The obligation to accept, under the same conditions, valid vaccination certificates issued by other Member States should therefore cover COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.
- (26) It is necessary to prevent discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended **or allowed, such as children**, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public-health-related requirements, and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries.

- (27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts¹¹. As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection¹².
- (28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU¹³, which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates¹⁴.
- (29) Despite these common efforts, Union citizens and their family members exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, or to lack of trust in the authenticity of the document shown. Such problems are compounded for persons who cannot be vaccinated yet, in particular children, for whom test results may be the only way to travel in case restrictions are in place.
- (30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.

¹¹ <u>https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf</u>

¹² OJ L 392, 23.11.2020, p. 63.

¹³ OJ C 24, 22.1.2021, p. 1.

^{14 &}lt;u>https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf</u>

- (31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.
- According to existing evidence, persons who have recovered from COVID-19 can continue (32)to test positive for SARS-CoV-2 for a certain period after symptom onset¹⁵. Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and the date of a previous positive test for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.
- (33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States accept proof of recovery in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS-CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.
- (34) To be able to obtain a common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council¹⁶ to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the virus, the situation of people having recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated.

¹⁵ <u>https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf</u>

¹⁶ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

- (35) In order to ensure uniform conditions for the implementation of the trust framework certificates established by this Regulation, implementing powers should be conferred on the Commission. Those powers should be *exercised* in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁷.
- (36) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the technical specifications necessary to establish interoperable certificates, imperative grounds of urgency so require or when new scientific evidence becomes available.
- (37) Regulation (EU) 2016/679 of the European Parliament and of the Council¹⁸ applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. The legal basis for processing for other purposes is to be provided for in national law, which must comply with Union data protection legislation.
- (38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the certificates should be set out in this Regulation.
- (39) For the purposes of this Regulation, personal data may be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In particular, it should allow for the verification of the authenticity of the certificate.
- (40) This Regulation does not create a legal basis for retaining personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic.
- (41) To ensure coordination, the Member States and the Commission should be informed when a Member State requires holders of certificates to undergo, after entry into its territory, quarantine/self-isolation or a test for SARS-CoV-2 infection, or if it denies entry to such persons.

¹⁷ OJ L 55, 28.2.2011, p. 13.

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

- (41a) Clear, comprehensive and timely communication to the public on the issuance and acceptance of each type of certificate making up the Digital Green Certificate is crucial to ensure predictability for travel and legal certainty. The Commission should support the Member States' efforts in this regard, for example by making available the information provided by Member States on the 'Re-open EU' web platform.
- (42)In accordance with Recommendation (EU) 2020/1475, any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2 should be lifted as soon as the epidemiological situation allows. This also applies to obligations to present documents other than those required by Union law, in particular Directive 2004/38/EC, such as the certificates covered by this Regulation. Therefore, the Regulation's provisions on the "Digital Green Certificate" framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery should be suspended once the Director-General of the WHO has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended. This Regulation should apply for 12 months from the date of its entry into force. (43)-At the **latest** [3] months before the end of the application of this Regulation, taking into account he evolution of the epidemiological situation on the pandemic, the Commission should publish a report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection. one year after the Director-General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended.
- (42a) A transitional period should be provided to give Member States the possibility to continue issuing certificates which are not yet in compliance with this Regulation. During the transitional period, such certificates as well as certificates issued before the entry into force of this Regulation should be accepted by Member States provided they contain the necessary data.
- (44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016¹⁹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

¹⁹ OJ L 123, 12.5.2016, p. 1.

- (45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non-discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.
- (47) The European Data Protection Supervisor has been consulted pursuant to Article 42(1) of Regulation (EU) 2018/1725²⁰,

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery. **It shall** in order to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green Certificate").

It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates.

Article 2 Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) "holder" means the Union citizen or their family members to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.
- (2) "Digital Green Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;
- (3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID-19;
- (4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA);
- (5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes;
- (6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;
- (7) "barcode" means a method of storing and representing data in a visual, machine-readable format;

- (8) "electronic seal" means data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity;
- (9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation;
- (10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.

Article 3 Digital Green Certificate

- 1. The interoperable Digital Green Certificate <u>framework</u> shall allow for the issuance and cross-border verification and acceptance of any of the following certificates:
 - (a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');
 - (b) a certificate indicating the holder's result, type and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01²¹ ('test certificate');
 - (c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01 ('certificate of recovery').

The Commission shall publish the list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01, including any updates.

- 2. Member States shall issue the certificates referred to in paragraph 1 in a digital or paperbased format, or both. The certificates issued by Member States shall contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English.
- 3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, or the certificate is no longer available to the holder. **Appropriate fees may be charged in case of repeated loss.**

15

EN

²¹ Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).

<u>3a</u> <u>The certificate shall include the following text:</u>

"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before traveling, please check the applicable public health measures applied at the point of destination."

<u>3b</u> <u>Possession of a Digital Green Certificate shall not be a precondition to exercise free</u> <u>movement rights.</u>

- 4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other purposes, in particular for medical purposes.
- 5. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Article 5(5).

The Commission shall assess whether such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

6. Where necessary, the Commission shall ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU, the European Center for Disease Prevention and Control or the European Medicines Agency to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1, in particular in view of newly emerging SARS-CoV-2 variants of concern.

16

EN

Article 4 Digital Green Certificate trust framework

- 1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.
- 2. The trust framework shall <u>seek to</u> ensure, where possible, interoperability with technological systems established at international level.
- 3. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates issued by third countries to Union citizens and their family members according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which-contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this subparagraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article 5(5).

The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

Article 5

Vaccination certificate

- 1. Each Member State shall issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.
- 2. The vaccination certificate shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about the vaccine medicinal product administered;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, on the categories of personal data mentioned in this paragraph where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.

- 3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) <u>after the administration of each dose</u> and shall clearly indicate whether or not the vaccination course has been completed.
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.

Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID-19 vaccine having received a WHO Emergency Use Listing.

6. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with one of the types of COVID-19 vaccines referred to in paragraph 5 of this Article, and where the authorities of a Member State have been provided with all necessary information, including reliable proof of vaccination, they shall issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned.

Article 6

Test certificate

- 1. Each Member State shall issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.
- 2. The test certificate shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about the test carried out;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

MMA/MdL/cr

The personal data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.

- 3. The test certificate shall be issued in a secure and interoperable format as provided for in Article 3(2).
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States require proof of a test for SARS-CoV-2 infection as part of the restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept<u>under the same conditions</u>, valid test certificates issued by other Member States in compliance with this Regulation.

Article 7 Certificate of recovery

1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.

- 2. The certificate of recovery shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about past SARS-CoV-2 infection <u>following a positive test;</u>
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields on the eategories of personal data mentioned in this paragraph, including until when a certificate of recovery shall be valid, where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.

- 3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).
- 3aBased on guidance received pursuant to Article 3(6), the Commission is empoweredto adopt delegated acts in accordance with Article 11 to amend the provisions in
Article 3(1)(c) and Article 7(1) to allow for the issuance of a certificate of recovery
also based on serological testing for antibodies against SARS-CoV-2. Any such
delegated act shall also set out the data fields on the categories of data to be included
in the certificate. The issuance and acceptance of a certificate of recovery based on
serological testing for antibodies against SARS-CoV-2 shall be optional.
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States accept proof of recovery from SARS-CoV-2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.

<u>New Article 7a</u>

COVID-19 certificates and other documentation issued by a third country

- 1. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with a vaccine medicinal product that corresponds to one of the COVID-19 vaccines referred to in paragraph 5 of Article 5 and where the authorities in a Member State have been provided with all necessary information, including reliable proof of vaccination, they may, upon request, issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned. A Member State shall not be required to issue a certificate for a vaccine not authorised for use on its territory.
- 2. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates referred to in Article 3 issued by third countries or Overseas Countries and Territories to Union citizens and their family members according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation, that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union.

MMA/MdL/cr

<u>The Commission shall assess whether certificates issued by a third country or</u> <u>Overseas Countries and Territories fulfil the conditions set out in this paragraph. In</u> <u>that case, it shall adopt an implementing act in accordance with the examination</u> <u>procedure referred to in Article 13(2).</u>

- 3. For the purposes of this article, the acceptance by the Member States of certificates issued pursuant to this Article, shall take place under the conditions referred to in Articles 5(5), 6(5) and 7(5).
- 4. If a Member State accepts a certificate for a COVID-19 vaccine referred to in Article 5(5) second subparagraph issued pursuant to this Article, it shall also accept certificates for the same COVID-19 vaccine issued by a Member State.

Article 8 Technical specifications

To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:

- (a) securely issue and verify the certificates referred to Article 3;
- (b) ensure the security of the personal data, taking into account the nature of the data;
- (c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;
- (d) lay down the common structure of the unique certificate identifier;
- (e) issue a valid, secure and interoperable barcode;
- (f) ensure<u>, where possible</u>, interoperability with international standards and/or technological systems;
- (g) allocate responsibilities amongst controllers and as regards processors, <u>in accordance with</u> <u>Article 28(3) of Regulation 2016/679</u>.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2).

On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).

Article 9 Protection of personal data

0. <u>Regulation (EU) 2016/679 shall apply to the processing of personal data carried out</u> <u>when implementing this Regulation.</u>

- 1. The personal data contained in the certificates issued in accordance with this Regulation shall be processed **only** for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic.
- 2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.
- 3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new certificate, shall not be retained longer than is necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.
- 4. The authorities <u>or other designated bodies</u> responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.

Article 10 <u>Information exchange Notification procedure</u>

- 1. Member States shall <u>inform other</u> notify Member States and the Commission on the **issuance and** acceptance of the certificates referred to in Article 3 and the conditions thereof, <u>including which vaccines they accept pursuant to Article 5(5) second</u> <u>subparagraph</u>.
- 2. Where a Member State requires holders of certificates referred to in Article 3 to undergo, after entry into its territory, quarantine, self-isolation or a test for SARS-CoV-2 infection, or if it **imposes other restrictions on holders of such certificates** denies entry to such persons, it shall **inform in a timely manner** notify the other Member States and the Commission <u>thereof.</u> before the planned introduction of such restrictions. To that end, the Member State shall supply the following information:
 - (a) the reasons for such restrictions including all relevant epidemiological data supporting such restrictions;
 - (b) the scope of such restrictions, specifying <u>the holders of which certificates</u> which travellers are subject to or exempt from such restrictions;
 - (c) the date and duration of the restrictions.

2a <u>Member States shall provide the public with clear, comprehensive and timely</u> <u>information on the topics covered by paragraphs 1 and 2. The information provided</u> <u>by the Member States may also be made publicly available by Commission in a</u> <u>centralised manner.</u>

Where necessary, the Commission may request additional information from the Member State concerned.

Article 11 Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The power to adopt delegated acts referred to in Articles 5(2), 6(2), 7(1) **and**, 7(2) **and** 15 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force].
- 3. The delegation of power referred to in Articles 5(2), 6(2), 7(1) <u>and</u>, 7(2) and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

- 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1) <u>and</u>, 7(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 12

Urgency procedure

- 1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
- 2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 11(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 13

Committee procedure

- 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
- 3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 14

Transitional provision

Member States may issue the certificates referred to in Article 3 in a format which does not comply with the requirements of this Regulation until [1 month] after the entry into force of this Regulation. During this period, certificates issued in accordance with this Article as well as certificates issued before the entry of force of this Regulation shall be accepted by the Member States in accordance with Articles 5(5), 6(5) and 7(5) where they contain the data fields set out in the Annex.

Reporting

One year after the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.

The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID-19 pandemic.

Article 15 Entry into force, applicability <u>and reporting</u>

- 1. This Regulation shall enter into force on, and apply from, the third day following that of its publication in the *Official Journal of the European Union*.
- 2. <u>The Regulation shall apply for 12 months from the date of its entry into force.</u>

At the latest 3 months before the end of the application of this Regulation, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.

<u>The report shall contain, in particular, an assessment of the impact of this</u> <u>Regulation</u> <u>on the facilitation of free movement as well as on the protection of personal data</u> <u>during the COVID-19 pandemic.</u>

This report may be accompanied with legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.

- 2. The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 4, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS CoV 2 has ended.
- 3. The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director-General of the World Health Organization declares a public health emergency of international concern in relation to SARS-CoV 2, a variant thereof, or similar infectious diseases with epidemic potential. Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.
- 4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament The President For the Council The President

<u>ANNEX</u> <u>Certificate datasets</u>

- 1. Data fields to be included in the vaccination certificate:
 - (a) name: surname(s) and forename(s), in that order;
 - (**b**) date of birth;
 - (c) disease or agent targeted;
 - (d) vaccine/prophylaxis;
 - (e) vaccine medicinal product;
 - (f) vaccine marketing authorization holder or manufacturer;
 - (g) number in a series of vaccinations/doses;
 - (h) date of vaccination, indicating the date of the latest dose received;
 - (i) Member State of vaccination;
 - (j) certificate issuer;
 - (k) a unique certificate identifier.
- 2. Data fields to be included in the test certificate:
 - (a) name: surname(s) and forename(s), in that order;
 - (**b**) date of birth;
 - (c) disease or agent targeted;
 - (d) the type of test;
 - (e) test name (optional for NAAT test);
 - (f) test manufacturer (optional for NAAT test);
 - (g) date and time of the test sample collection;
 - (h) date and time of the test result production (optional for rapid antigen test);
 - (i) result of the test;
 - (j) testing centre or facility;
 - (**k**) Member State of test;
 - (l) certificate issuer;
 - (m) a unique certificate identifier.

- 3. Data fields to be included in the certificate of recovery:
 - (a) name: surname(s) and forename(s), in that order;
 - (**b**) date of birth;
 - (c) disease or agent the citizen has recovered from;
 - (d) date of first positive test result;
 - (e) Member State of test;
 - (f) certificate issuer;
 - (g) certificate valid from;
 - (h) certificate valid until (not more than 180 days after the date of first positive test result);
 - (i) a unique certificate identifier.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2)(c)thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Under the Schengen acquis, third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180-day period.
- (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.
- (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.

- (4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic²².
- (5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632²³ on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen *acquis* to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.
- (6) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in connection with cross-border travel within the Union, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.
- (7)Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive travel restrictions put in place in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with the proposal for a Regulation on a Digital Green Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council²⁴. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC of the European Parliament and the Council²⁵, vaccines whose distribution has been temporarily authorised based on Article 5(2) of that Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.



²² OJ L 337, 14.10.2020, p. 3.

²³ Council Recommendation (EU) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area (OJ L 366, 4.11.2020, p. 25).

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

 ²⁵ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States.
- (9) To facilitate travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.
- (10) For certificates to be used effectively in connection with cross-border travel, such certificates need to be fully interoperable.
- (11) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code)²⁶.

(11a) Since this Regulation applies to third country nationals already legally staying or residing in the territories of the Member States, it should not be understood as granting third country nationals wishing to travel to a Member State the right to request a Digital Green Certificate from that Member State before arrival on its territory.

- (12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.
- (13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC²⁷; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. Although Ireland is not subject to this Regulation, for the purposes of facilitating travel within the Union, Ireland could also issue certificates, which comply with the same requirements as those applicable to the Digital Green Certificate, to third-country nationals legally residing or legally staying in its territory and Member States could accept such certificates. Ireland could also accept certificates issued by Member States to third country nationals legally residing or legally staying in their territories.

MMA/MdL/cr

Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

²⁷ Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20).

- (14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.
- (15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC²⁸.
- (16) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC²⁹.
- (17) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen acquis within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU³⁰.

³⁰ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

MMA/MdL/cr

²⁸ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

²⁹ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (OJ L 53, 27.2.2008, p. 1).

(18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the Council³¹ and delivered an opinion on [...],

HAVE ADOPTED THIS REGULATION:

Article 1

Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.

Article 2

This Regulation shall enter into force on, and apply from, the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament The President For the Council The President

MMA/MdL/cr

³¹ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).



Council of the European Union

Interinstitutional Files: 2021/0068(COD)

2021/0071(COD)

Brussels, 9 April 2021 (OR. en)

7673/21

LIMITE

COVID-19 130	TRANS 197
JAI 371	COCON 22
AG 30	COMIX 200
FRONT 133	CODEC 498
FREMP 84	SCHENGEN 27
IPCR 41	AVIATION 72
VISA 73	PHARM 58
MI 238	RELEX 285
SAN 192	TOUR 18

NOTE

NOTE	
From:	Presidency
To:	Ad hoc Working Party on the proposals for a Digital Green Certificate
No. Cion doc.:	7128/21 + ADD 1, 7129/21
Subject:	Digital Green Certificate (DGC)
	 Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic
	- Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable vaccination, testing and recovery certificates for third country nationals legally residing in the Schengen area to facilitate free movement during the COVID-19 pandemic
	= Examination of Presidency compromise text

Delegations will find in the <u>Annex</u> a Presidency compromise text on the above-mentioned proposals for further discussion at the Ad Hoc Working Party on the proposals for a Digital Green Certificate on 12 April 2021.

Changes compared to the Commission proposal are marked in <u>bold/underline</u> for additions and in strikethrough for deletions. New changes compared to the previous version are also grey shaded.

The Presidency kindly asks delegations to focus on main issues, in particular on newly introduced changes, in preparation for Coreper on 14 April 2021.
Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Every citizen of the Union has the <u>fundamental</u> right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council¹ lays down detailed rules as regards the exercise of that right.
- (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.

¹ Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

- (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection.
- (4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic². That Recommendation establishes a coordinated approach on the following key points: the application of common criteria and thresholds when deciding whether to introduce restrictions to free movement, a mapping of the risk of COVID-19 transmission based on an agreed colour code, and a coordinated approach as to the measures, if any, which may appropriately be applied to persons moving between areas, depending on the level of risk of transmission in those areas. In view of their specific situation, the Recommendation also emphasises that essential travellers, as listed in its point 19, and cross-border commuters, whose lives are particularly affected by such restrictions, in particular those exercising critical functions or essential for critical infrastructure, should in principle be exempted from travel restrictions linked to COVID-19.
- (5) Using the criteria and thresholds established in Recommendation (EU) 2020/1475, the European Centre for Disease Prevention and Control ('ECDC') has been publishing, once a week, a map of Member States, broken down by regions, in order to support Member States' decision-making³.
- (6) As emphasised by Recommendation (EU) 2020/1475 any, Member States may limit the fundamental right of free movement for public health reasons. Any restrictions to the free movement of persons within the Union put in place to limit the spread of COVID-19 should be based on specific and limited public interest grounds, namely the protection of public health <u>as emphasised by Recommendation (EU) 2020/1475</u>. It is necessary for such limitations to be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should thus not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and personnel through the so-called "Green Lane" border crossings referred to in the Guidelines for border management measures to protect health and ensure the availability of goods and essential services⁴.
- (7) The free movement of persons who do not pose a risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective pursued.

² OJ L 337, 14.10.2020, p. 3.

³ Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

⁴ OJ C 96I, 24.3.2020, p. 1.

- (8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their free movement rights, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.
- (9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, as national authorities and passenger transport services, such as airlines, trains, coaches or ferries, are confronted with a wide array of diverging document formats, not only regarding a person's vaccination status but also on tests and possible recovery from COVID-19.
- (10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery, entitled "Digital Green Certificate" should be established.
- (11) This Regulation should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, the exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply and the specific situation of cross border communities should be taken into account. At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.
- (11a) This Regulation should not cover Member States' decisions to impose or waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19. The use of the Digital Green Certificate in view of lifting restrictions should remain the responsibility of the Member States.
- (12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.
- (13) The risk posed by false COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative COVID-19 test certificates⁵. Given the available and easily accessible technological means, such as highresolution printers and various graphics editor software, fraudsters are able to produce highquality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online.

⁵ <u>https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates</u>

- To ensure interoperability and equal access, including for persons with disabilities, (14)Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both, depending on the choice of the prospective holder. This should allow the prospective holder to request and receive a paper copy of the certificate or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human-readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and userfriendliness. To avoid obstacles to free movement, and although there may be a charge for related services, such as for tests, the certificates themselves should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon request, ensuring that they can be obtained easily and providing, where needed, the necessary support to allow for equal access by all citizens.
- (15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. The outline on the interoperability of health certificates⁶ adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU⁷ should form the basis for the trust framework.
- (16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, by the Member State of vaccination or test, or where the recovered person is located. Where reference is made to issuance by Member States, this should be understood as also covering issuance by designated bodies on behalf of Member States, including when they are issued in Overseas Countries and Territories on behalf of a Member State. Where relevant or appropriate, the certificates should be issued on behalf of the vaccinated, tested or recovered person, for example on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or other similar formalities.
- (17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See. in particular where they are vaccinated by a Member State.

⁶ Available at: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-</u> <u>framework_interoperability_certificates_en.pdf</u>

Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

- (18) It is necessary to take into account that the agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be conditional on an implementing act to be adopted by the Commission establishing that such a third country issues certificates in accordance with this Regulation and has provided formal assurances that it would accept certificates issued by the Member States.
- (19) Regulation (EU) 2021/XXXX applies to third-country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.
- (20) The framework to be established for the purpose of this Regulation should seek to ensure coherence with global initiatives, in particular involving the WHO and the International Civil Aviation Organisation (ICAO). This should include, where possible, interoperability between technological systems established at global level and the systems established for the purpose of this Regulation to facilitate free movement within the Union, including through the participation in a public key infrastructure or the bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated or tested by third countries or by Overseas Countries or Territories referred to in Article 355 (2) TFEU, this Regulation should provide for the acceptance of certificates issued by third countries or by Overseas Countries or Territories and their family members where the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.
- (20a) If the technical solution chosen for verification requires a Member State to transfer personal data to a recipient in a third country to confirm and verify the vaccination, testing or recovery status of the holder of a certificate issued by a third country, such transfer should be limited to the data necessary for the verification of the authenticity, validity and integrity of the certificate and may only be carried out in compliance with the conditions set out in Chapter V of Regulation (EU) 2016/679.

- (21) To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates to for persons receiving vaccines that have been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council⁸, for-vaccines that have been granted marketing authorisation pursuant to Directive 2001/83/EC of the European Parliament and of the Council⁹, or vaccines whose distribution has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.
- (22)Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the right possibility to obtain a certificate on COVID-19 vaccination that complies with this Regulation given that the Digital Green Certificate provides the mutually accepted framework to facilitate free movement. Where Union citizens or their family members are not in possession of a certificate that complies with the requirements of this Regulation, in particular because they have been vaccinated before the entry into force of this Regulation, they should be given every reasonable opportunity to corroborate or prove by other means that they should benefit from the waiving of relevant restrictions to free movement afforded by a Member State. This should not be understood as affecting the obligation of Member States to issue certificates that comply with the requirements of this **Regulation nor the right of Union citizens or their family members to receive, from** Member States, certificates that comply with the requirements of this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.
- (23) Member States <u>may</u> also issue <u>upon request</u> such vaccination certificates to Union citizens and their family members who have been vaccinated in a third country and provide <u>all</u> <u>necessary information, including</u> reliable proof to that effect. <u>This is of particular</u> <u>importance to allow the persons concerned to make use of an interoperable and</u> <u>accepted vaccination certificate when exercising their right of free movement within the Union. Member States should not be obliged to issue such vaccination certificates <u>at consular posts</u>.</u>

⁸ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

- (24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021¹⁰. These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.
- (25)Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.

8

MMA/MdL/ml

¹⁰ Available at : <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

- (25a) Regulation (EC) No 726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation (EC) No 726/2004, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all Member States. In addition, efficacy followup and supervision procedures of medicinal products authorised pursuant to Regulation (EC) No 726/2004 are carried out centrally for all Member States. The assessment and approval of vaccines via the centralised procedure follows shared standards and is done in a consistent way on behalf of all Member States. Member States' participation in the review and endorsement of the assessment is ensured through various committees and groups, which also benefits from the expertise from the EU Medicines Regulatory Network. The authorisation via the centralised procedure provides the confidence that all Member States can rely on the authorisation and data on efficacy as well as safety and on the consistency of the batches being used for vaccination of citizens. The obligation to accept, under the same conditions, valid vaccination certificates issued by other Member States should therefore cover COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing.
- (26) It is necessary to prevent discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended **or allowed, such as children**, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public-health-related requirements, and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries.

- (27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts¹¹. As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection¹².
- (28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU¹³, which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates¹⁴.
- (29) Despite these common efforts, Union citizens and their family members exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, or to lack of trust in the authenticity of the document shown. Such problems are compounded for persons who cannot be vaccinated yet, in particular children, for whom test results may be the only way to travel in case restrictions are in place.
- (30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.

https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

¹² OJ L 392, 23.11.2020, p. 63.

¹³ OJ C 24, 22.1.2021, p. 1.

^{14 &}lt;u>https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf</u>

- (31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.
- According to existing evidence, persons who have recovered from COVID-19 can continue (32)to test positive for SARS-CoV-2 for a certain period after symptom onset¹⁵. Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and the date of a previous positive test for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.
- (33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States accept proof of recovery in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS-CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.
- (33a) Taking into account the latest scientific and technological developments, the Commission should be empowered to adapt the provisions on the certificate of recovery by providing for its issuance on the basis of a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically reliable method by means of a delegated act. This delegated act should include the necessary data fields on the categories of data to be included in the certificate. It should also contain specific provisions on the maximum validity period as it might depend on the type of the test carried out. The issuance and acceptance of the certificate of recovery based on the tests and methods mentioned above shall be optional.



¹⁵ <u>https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf</u>

- (34) To be able to obtain a common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council¹⁶ to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the virus, the situation of people having recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated.
- (35) In order to ensure uniform conditions for the implementation of the trust framework certificates established by this Regulation, implementing powers should be conferred on the Commission. Those powers should be *exercised* in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council¹⁷.
- (36) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to the technical specifications necessary to establish interoperable certificates, imperative grounds of urgency so require or when new scientific evidence becomes available.
- (37) Regulation (EU) 2016/679 of the European Parliament and of the Council¹⁸ applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. The legal basis for processing for other purposes is to be provided for in national law, which must comply with Union data protection legislation.
- (38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the certificates should be set out in this Regulation.

¹⁶ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

¹⁷ OJ L 55, 28.2.2011, p. 13.

¹⁸ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

- (39) For the purposes of this Regulation, personal data may be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In particular, it should allow for the verification of the authenticity of the certificate.
- (40) This Regulation does not create a legal basis for retaining personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic.
- (41) To ensure coordination, the Member States and the Commission should be informed when a Member State requires holders of certificates to undergo, after entry into its territory, quarantine/self-isolation or a test for SARS-CoV-2 infection, or if it <u>imposes other</u> <u>restrictions on holders of such certificates</u> denies entry to such persons.
- (41a) Clear, comprehensive and timely communication to the public on the issuance and acceptance of each type of certificate making up the Digital Green Certificate is crucial to ensure predictability for travel and legal certainty. The Commission should support the Member States' efforts in this regard, for example by making available the information provided by Member States on the 'Re-open EU' web platform.
- (42)In accordance with Recommendation (EU) 2020/1475, any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2 should be lifted as soon as the epidemiological situation allows. This also applies to obligations to present documents other than those required by Union law, in particular Directive 2004/38/EC, such as the certificates covered by this Regulation. Therefore, the Regulation's provisions on the "Digital Green Certificate" framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery should be suspended once the Director-General of the WHO has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended. This Regulation should apply for 12 months from the date of its entry into force. (43) At the latest 3 months before the end of the application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic, the Commission should publish a report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection. one year after the Director-General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended.
- (42a) A transitional period should be provided to give Member States the possibility to continue issuing certificates which are not yet in compliance with this Regulation. During the transitional period, such certificates as well as certificates issued before the entry into force of this Regulation should be accepted by Member States provided they contain the necessary data.

- (44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016¹⁹. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non-discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.
- (47) The European Data Protection Supervisor and the European Data Protection Board have has been consulted pursuant to in accordance with Article 42(1) of Regulation (EU) 2018/1725²⁰ and delivered a joint opinion on 31 March 2021,

¹⁹ OJ L 123, 12.5.2016, p. 1.

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

HAVE ADOPTED THIS REGULATION:

Article 1 Subject matter

This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery. <u>It shall</u> in order to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green Certificate").

It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates.

Article 2

Definitions

For the purposes of this Regulation, the following definitions apply:

- (1) "holder" means the Union citizen or their family members to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.
- (2) "Digital Green Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;
- (3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID-19;
- (4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA);
- (5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes;
- (6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;
- (7) "barcode" means a method of storing and representing data in a visual, machine-readable format;

- (8) "electronic seal" means data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity;
- (9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation;
- (10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.

Article 3 Digital Green Certificate

- 1. The interoperable Digital Green Certificate <u>framework</u> shall allow for the issuance and cross-border verification and acceptance of any of the following certificates:
 - (a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');
 - (b) a certificate indicating the holder's result, type and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01²¹ carried out in the Member State issuing the certificate ('test certificate');
 - (c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test <u>in the Member State issuing the certificate</u> or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01-('certificate of recovery').

<u>The Commission shall publish the list of COVID-19 rapid antigen tests established on</u> <u>the basis of Council Recommendation 2021/C 24/01, including any updates.</u>

2. Member States shall issue the certificates referred to in paragraph 1 in a digital or paperbased format, or both, **depending on the choice of the prospective holder**. The certificates issued by Member States shall contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English.

MMA/MdL/ml

²¹ Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).

3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, or the certificate is no longer available to the holder. Appropriate fees may be charged in case of repeated loss.

<u>3a</u> <u>The certificate shall include the following text:</u>

"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before traveling, please check the applicable public health measures and related restrictions applied at the point of destination."

<u>3b</u> <u>Possession of a Digital Green Certificate shall not be a precondition to exercise free</u> <u>movement rights.</u>

- 4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other purposes, in particular for medical purposes.
- 5. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates **equivalent to those** issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Articles 5(5), **6(5) and 7(5)**.

The Commission shall assess whether such a third country issues certificates **equivalent to those issued** in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

6. Where necessary, the Commission shall ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU, the European Center for Disease Prevention and Control or the European Medicines Agency to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1, in particular in view of newly emerging SARS-CoV-2 variants of concern.

Article 4 Digital Green Certificate trust framework

- 1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.
- 2. The trust framework shall <u>seek to</u> ensure, where possible, interoperability with technological systems established at international level.
- 3. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates issued by third countries to Union citizens and their family members according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which-contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this subparagraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article 5(5).

The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).

Article 5 Vaccination certificate

- 1. Each Member State shall issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.
- 2. The vaccination certificate shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about the vaccine medicinal product administered;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, on the categories of personal data mentioned in this paragraph where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.

- 3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) <u>after the administration of each dose</u> and shall clearly indicate whether or not the vaccination course has been completed.
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.

Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID-19 vaccine having received a WHO Emergency Use Listing.

6. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with one of the types of COVID-19 vaccines referred to in paragraph 5 of this Article, and where the authorities of a Member State have been provided with all necessary information, including reliable proof of vaccination, they shall issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned.

Article 6

Test certificate

- 1. Each Member State shall issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.
- 2. The test certificate shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about the test carried out;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph <u>where such amendment is</u> <u>necessary to confirm or verify the authenticity, validity and integrity of the certificate</u> <u>in case of scientific progress in containing the COVID-19 pandemic or to ensure</u> <u>interoperability with international standards.</u>

- 3. The test certificate shall be issued in a secure and interoperable format as provided for in Article 3(2).
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States require proof of a test for SARS-CoV-2 infection as part of the restrictions to free movement put in place, in compliance with Union law and taking into account the specific situation of cross-border communities, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid test certificates issued by other Member States in compliance with this Regulation.

Article 7 Certificate of recovery

1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.

- 2. The certificate of recovery shall contain the following categories of personal data:
 - (a) identification of the holder;
 - (b) information about past SARS-CoV-2 infection <u>following a positive test</u>;
 - (c) certificate metadata, such as the certificate issuer or a unique certificate identifier.

The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.

The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph, including until when a certificate of recovery shall be valid, <u>where such amendment is necessary to confirm or verify the</u> <u>authenticity, validity and integrity of the certificate in case of scientific progress in</u> <u>containing the COVID-19 pandemic or to ensure interoperability with international</u> <u>standards.</u>

- 3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).
- 3aBased on guidance received pursuant to Article 3(6), the Commission is empowered
to adopt delegated acts in accordance with Article 11 to amend the provisions in
Article 3(1)(c) and Article 7(1) to allow for the issuance of the certificate of recovery
also based on a positive rapid antigen test, serological testing for antibodies against
SARS-CoV-2 or any other scientifically reliable method. Any such delegated act shall
add, modify or remove the data fields on the categories of data included in the
certificate. The issuance and acceptance of the certificate of recovery based on the
tests and methods mentioned in this paragraph shall be optional.
- 4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
- 5. Where Member States accept proof of recovery from SARS-CoV-2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.

<u>New Article 7a</u> <u>COVID-19 certificates and other documentation issued by a third country</u>

1. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with a vaccine medicinal product that corresponds to one of the COVID-19 vaccines referred to in paragraph 5 of Article 5 and where the authorities in a Member State have been provided with all necessary information, including reliable proof of vaccination, they may, upon request, issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned. A Member State shall not be required to issue a certificate for a vaccine not authorised for use on its territory.

2. Where the Commission has adopted an implementing act pursuant to the second subparagraph, certificates referred to in Article 3 issued by third countries to Union citizens and their family members according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation, that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union.

<u>The Commission shall assess whether certificates issued by a third country fulfil the</u> <u>conditions set out in this paragraph. In that case, it shall adopt an implementing act</u> <u>in accordance with the examination procedure referred to in Article 13(2).</u>

- 3. For the purposes of this article, the acceptance by the Member States of certificates issued pursuant to this Article, shall take place under the conditions referred to in Articles 5(5), 6(5) and 7(5).
- 4. <u>If a Member State accepts a certificate for a COVID-19 vaccine referred to in Article</u> 5(5) second subparagraph issued pursuant to this Article, it shall also accept certificates for the same COVID-19 vaccine issued by a Member State.
- 4a.Where reference is made to third countries in this Article, this shall also coverOverseas Countries and Territories referred to in Article 355(2) TFEU.

Article 8 Technical specifications

To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:

- (a) securely issue and verify the certificates referred to Article 3;
- (b) ensure the security of the personal data, taking into account the nature of the data;
- (c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;
- (d) lay down the common structure of the unique certificate identifier;
- (e) issue a valid, secure and interoperable barcode;
- (f) ensure<u>, where possible</u>, interoperability with international standards and/or technological systems;
- (g) allocate responsibilities amongst controllers and as regards processors, <u>in accordance with</u> <u>Article 28(3) of Regulation 2016/679</u>.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2).

On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).

Article 9 Protection of personal data

0. <u>Regulation (EU) 2016/679 shall apply to the processing of personal data carried out</u> <u>when implementing this Regulation.</u>

- 1. The personal data contained in the certificates issued in accordance with this Regulation shall be processed **only** for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic.
- 2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination **or transit**, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.
- 3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new certificate, shall not be retained longer than is necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.
- 4. The authorities <u>or other designated bodies</u> responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.
- 4a.The natural or legal person, public authority, agency or other body that has
administered the vaccine or carried out the test for which a certificate is to be issued
shall transmit to the authorities or other designated bodies responsible for issuing the
certificates the categories of data referred to in Articles 5(2), 6(2) and 7(2) necessary
to complete the data fields set out in the Annex.

Article 10 <u>Information exchange Notification procedure</u>

- 1. Member States shall <u>inform other</u> notify Member States and the Commission on the <u>issuance and</u> acceptance of the certificates referred to in Article 3 and the conditions thereof, <u>including which vaccines they accept pursuant to Article 5(5) second</u> <u>subparagraph</u>.
- 2. Where a Member State requires holders of certificates referred to in Article 3 to undergo, after entry into its territory, quarantine, self-isolation or a test for SARS-CoV-2 infection, or if it imposes other restrictions on holders of such certificates denies entry to such persons, it shall inform, notify the other Member States and the Commission thereof, as a general rule 48 hours in advance of the introduction of new measures. before the planned introduction of such restrictions. To that end, the Member State shall supply the following information:
 - (a) the reasons for such restrictions including all relevant epidemiological data supporting such restrictions;
 - (b) the scope of such restrictions, specifying <u>the holders of which certificates</u> which travellers are subject to or exempt from such restrictions;
 - (c) the date and duration of the restrictions.

Where necessary, the Commission may request additional information from the Member State concerned.

2a <u>Member States shall provide the public with clear, comprehensive and timely</u> <u>information on the topics covered by paragraphs 1 and 2, as a general rule 48 hours</u> <u>in advance of the introduction of new measures. The information provided by the</u> <u>Member States may also be made publicly available by the Commission in a</u> <u>centralised manner.</u>

Article 11 Exercise of the delegation

- 1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2. The power to adopt delegated acts referred to in Articles 5(2), 6(2), 7(1) <u>and</u>, 7(2) and 15 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force].
- 3. The delegation of power referred to in Articles 5(2), 6(2), 7(1) <u>and</u>, 7(2) and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

MMA/MdL/ml

- 4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.
- 5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
- 6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1) <u>and</u>, 7(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 12

Urgency procedure

- 1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.
- 2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 11(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 13 Committee procedure

- 1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
- 2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
- 3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 14 Transitional provision

<u>Member States may issue the certificates referred to in Article 3 in a format which does not</u> comply with the requirements of this Regulation until [1 month] after the entry into force of this Regulation. During this period, certificates issued in accordance with this Article as well as certificates issued before the entry of force of this Regulation shall be accepted by the Member States in accordance with Articles 5(5), 6(5) and 7(5) where they contain the data fields set out in the Annex.

Reporting

One year after the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.

The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID-19 pandemic.

Article 15 Entry into force, applicability <u>and reporting</u>

- 1. This Regulation shall enter into force on, and apply from, the third day following that of its publication in the *Official Journal of the European Union*.
- 2. <u>The Regulation shall apply for 12 months from the date of its entry into force.</u>

<u>At the latest 3 months before the end of the application of this Regulation, the</u> <u>Commission shall present a report to the European Parliament and the Council on</u> <u>the application of this Regulation.</u>

<u>The report shall contain, in particular, an assessment of the impact of this</u> <u>Regulation</u> on the facilitation of free movement as well as on the protection of personal data during the COVID-19 pandemic.

This report may be accompanied with legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.

- 2. The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 4, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended.
- 3. The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director-General of the World Health Organization declares a public health emergency of international concern in relation to SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.
- 4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament The President For the Council The President

<u>ANNEX</u> <u>Certificate datasets</u>

- 1. Data fields to be included in the vaccination certificate:
 - (a) name: surname(s) and forename(s), in that order;
 - (b) date of birth;
 - (c) disease or agent targeted: <u>COVID-19</u>;
 - (d) vaccine/prophylaxis;
 - (e) vaccine medicinal product;
 - (f) vaccine marketing authorization holder or manufacturer;
 - (g) number in a series of vaccinations/doses and the overall number of doses in the series;
 - (h) date of vaccination, indicating the date of the latest dose received;
 - (i) Member State of vaccination;
 - (j) certificate issuer;
 - (k) a unique certificate identifier.
- 2. Data fields to be included in the test certificate:
 - (a) name: surname(s) and forename(s), in that order;
 - (b) date of birth;
 - (c) disease or agent targeted: <u>COVID-19</u>;
 - (d) the type of test;
 - (e) test name (optional for NAAT test);
 - (f) test manufacturer (optional for NAAT test);
 - (g) date and time of the test sample collection;
 - (h) date and time of the test result production (optional for rapid antigen test);
 - (i) result of the test;

- (j) testing centre or facility;
- (k) Member State of test;
- (l) certificate issuer;
- (m) a unique certificate identifier.
- 3. Data fields to be included in the certificate of recovery:
 - (a) name: surname(s) and forename(s), in that order;
 - (b) date of birth;
 - (c) disease or agent the citizen has recovered from: <u>COVID-19</u>;
 - (d) date of first positive test result;
 - (e) Member State of test;
 - (f) certificate issuer;
 - (g) certificate valid from;
 - (h) certificate valid until (not more than 180 days after the date of first positive test result);
 - (i) a unique certificate identifier.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 77(2)(c)thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Under the Schengen acquis, third country nationals lawfully residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180-day period.
- (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (*SARS-CoV-2*), which causes coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.
- (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.

- (4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic¹.
- (5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632² on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen *acquis* to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.
- (6) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in connection with cross-border travel within the Union, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.
- (7)Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive travel restrictions put in place in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with the proposal for a Regulation on a Digital Green Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council³. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19 vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC of the European Parliament and the Council⁴, vaccines whose distribution has been temporarily authorised based on Article 5(2)of that Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.

¹ OJ L 337, 14.10.2020, p. 3.

² Council Recommendation (EU) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area (OJ L 366, 4.11.2020, p. 25).

³ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

- (8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States.
- (9) To facilitate travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.
- (10) For certificates to be used effectively in connection with cross-border travel, such certificates need to be fully interoperable.
- (11) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code)⁵.
- (11a) Since this Regulation applies to third country nationals already legally staying or residing in the territories of the Member States, it should not be understood as granting third country nationals wishing to travel to a Member State the right to request a Digital Green Certificate from that Member State before arrival on its territory.
- (11b) On 30 June 2020, the Council adopted Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction. This Regulation does not cover the temporary restrictions on nonessential travel into the Union.
- (12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.

Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

- (13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC⁶; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. Although Ireland is not subject to this Regulation, for the purposes of facilitating travel within the Union, Ireland could also issue certificates, which comply with the same requirements as those applicable to the Digital Green Certificate, to third-country nationals legally residing or legally staying in its territory. and Member States could accept such certificates. Ireland could also accept certificates issued by Member States to third country nationals legally residing or legally staying in their territories. Ireland and the other Member States should mutually accept certificates issued to third country nationals legally residing or legally staying in their territories. Ireland and the other Member States should mutually accept certificates issued to third country nationals legally residing or legally staying in their territories.
- (14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.
- (15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC⁷.
- (16) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC⁸.

⁶ Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20).

⁷ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

⁸ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (OJ L 53, 27.2.2008, p. 1).

- (17) As regards Liechtenstein, this Regulation constitutes a development of provisions of the Schengen acquis within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU⁹.
- (18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the Council¹⁰ and delivered an joint opinion on <u>31 March 2021</u>,

HAVE ADOPTED THIS REGULATION:

Article 1

Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.

MMA/MdL/ml

⁹ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Article 1a

Once Ireland has notified the Council and the Commission that it accepts certificates issued by Member States to persons covered by this Regulation, Member States shall accept, under the conditions of the Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate], certificates making up the Digital Green Certificate issued by Ireland to third country nationals who may travel freely within the territory of the Member States.

Article 2

This Regulation shall enter into force on, and apply from, the third day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament The President For the Council The President



Council of the European Union

> Brussels, 2 October 2020 (OR. en)

11395/20

Interinstitutional File: 2020/0256(NLE)

LIMITE

FREMP 85 JAI 763 FRONT 272 MI 379 SAN 336 TRANS 439 IPCR 27

NOTE

NOIL	
From:	Presidency
On:	2 October 2020
То:	Delegations
Subject:	Proposal for a Council recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic:
	- Presidency compromise text

Delegations will find in the Annex a Presidency compromise text for a Council recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic which takes into account discussions held in the IPCR Round Table, Coreper as well as at the General Affairs Council on 22 September 2020.

The changes compared to the Commission proposal are marked in **bold** or when text is deleted in strikethrough.

ANNEX

Presidency compromise text on the

Proposal for a

COUNCIL RECOMMENDATION

on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2), Article 46, Article 52(2), Article 168(6) and Article 292, first and second sentence thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1)Citizenship of the Union confers on every citizen of the Union the right of free movement.

JAI.A

2
- (2) Pursuant to Article 21(1) of Treaty on the Functioning of the European Union (TFEU), every citizen of the Union shall have the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council¹ gives effect to that right. Article 45 of the Charter of Fundamental Rights of the European Union (the Charter) also provides for freedom of movement and residence. Since the action of Union proves necessary to attain the objective laid down in Article 21 TFEU, and the Treaties do not otherwise provide the necessary powers, the Council may adopt provisions with a view to facilitating the exercise of the rights to move and reside freely.
- (3) Pursuant to Article 45(1) TFEU, freedom of movement for workers shall be secured within the Union. The attainment of this objective entails the right of workers of the Member States to move freely within the Union in order to pursue activities as employed persons subject to any limitations justified on grounds of public policy, public security or public health.
- (4) Pursuant to Article 49(1) TFEU, restrictions on the freedom of establishment of nationals of a Member State in another Member State shall be prohibited.
- (5) Pursuant to Article 56(1) TFEU, restrictions on the freedom to provide services within the Union shall also be prohibited. This includes the right of service providers to cross the border in order to provide services and the right of service recipients to travel to the country of the service provider in order to receive the service. The attainment of these objectives justifies coordination of measures that Member States may consider adopting in respect of non-nationals on grounds of public health.
- (6) Pursuant to Article 168(1) TFEU, a high level of human health protection is to be ensured in the definition and implementation of all Union policies and activities.
- (7) On 30 January 2020, the Director-General of the World Health Organization (WHO) declared a public health emergency of international concern over the global outbreak of novel coronavirus, which causes Coronavirus disease 2019 (COVID-19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.

¹ Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

- (8) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on Union citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.
- (9) On 13 February 2020, the Council adopted Conclusions on COVID-19² in which it urged Member States to act together, in cooperation with the Commission, in a proportionate and appropriate manner to develop close and enhanced coordination between Member States to ensure effectiveness of all measures, including, if necessary, measures regarding travel, while safeguarding the free movement within the Union, to ensure optimal protection of public health.
- (10) On 10 March 2020, the Heads of State or Government of the European Union emphasised the need for a joint European approach with regard to COVID-19.
- (11) Since On 16-March 2020, the Commission adopted a number of Guidelines and Communications with the aim of supporting coordination efforts of Member States and safeguarding the free movement within the Union in times of the COVID-19 pandemic³. for border management measures to protect health and ensure the availability of goods and essential services⁴. On 17 March 2020, the Heads of State or Government of the European Union endorsed these Guidelines.

² OJ C 57, 20.2.2020, p. 4.

³ Commission Guidelines for border management measures to protect health and ensure the availability of goods and essential services (OJ C 86I, 16.3.2020, p. 1.), Commission Guidelines concerning the exercise of the free movement of workers during COVID-19 outbreak (OJ C 1021, 30.3.2020, p.12), 'Joint European Roadmap towards lifting COVID-19 containment measures' of the President of the European Commission and the President of the European Council, Commission Guidance on free movement of health professionals and minimum harmonisation of training in relation to COVID-19 emergency measures (OJ C 156, 8.5.2020, p. 1), Commission Communication towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls (OJ C 169, 15.5.2020, P. 30), Commission Communication on the third assessment of the application of the temporary restriction on non-essential travel to the EU, Commission Guidelines on seasonal workers in the EU in the context of the COVID-19 outbreak (OJ C 235I, 17.7.2020, p. 1.), Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services (OJ C 96I, 24.3.2020, p. 1.), Commission Guidelines on Facilitating Air Cargo Operations during COVID-19 outbreak (OJ C 100I, 27.3.2020, p. 1.), and Commission Guidelines on protection of health, repatriation and travel arrangements for seafarers, passengers and other persons on board ships (OJ C 119, 14.4.2020, p. 1).

⁴ OJ C 86I , 16.3.2020, p. 1.

- (12) On 30 March 2020, the Commission adopted Guidelines concerning the exercise of the free movement of workers during COVID-19 outbreak⁵ to ensure that mobile workers and self-employed persons within the Union, in particular those in critical occupations to fight the pandemic, can reach their workplace.
- (13) On 15 April 2020, the President of the European Commission and the President of the European Council set out a 'Joint European Roadmap towards lifting COVID-19 containment measures'⁶, according to which restrictions to free movement should be lifted once the epidemiological situation converges sufficiently and social distancing rules are widely and responsibly applied.
- (14) On 7 May 2020, the Commission adopted Guidance on free movement of health professionals and minimum harmonisation of training in relation to COVID-19 emergency measures recommendations regarding Directive 2005/36/EC⁷ to help Member States address immediate staff shortages.
- (15) On 13 May 2020, the Commission adopted, as part of a package of guidelines and recommendations, a Communication towards a phased and coordinated approach for restoring freedom of movement and lifting internal border controls⁸. The Communication proposes a phased and coordinated approach that should start by lifting restrictions between areas or Member States with sufficiently similar epidemiological situations. The approach should be flexible, including the possibility to reintroduce certain measures if the epidemiological situation requires. According to the Communication, Member States should act on the basis of epidemiological criteria, the ability to apply containment measures throughout the whole journey, and economic and social considerations.
- (16) On 11 June 2020, the Commission adopted a Communication to the European Parliament, the European Council and the Council on the third assessment of the application of the temporary restriction on non-essential travel to the EU⁹, in which it strongly encouraged Member States to finalise the process of lifting restrictions to free movement within the Union.

MMA/mc

LIMITE

⁵ OJ C 102I , 30.3.2020, p. 12.

⁶_____https://ec.europa.eu/info/sites/info/files/communication_-

<u>_a_european_roadmap_to_lifting_coronavirus_containment_measures_0.pdf</u>

⁷ OJ C 156, 8.5.2020, p. 1.

⁸ OJ C 169, 15.5.2020, p. 30

⁹------https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0399

- (17) On 16 July 2020, the Commission adopted Guidelines on seasonal workers in the EU in the context of the COVID-19 outbreak¹⁰, in which it provides guidance to national authorities, labour inspectorates, and social partners to guarantee the rights, health and safety of seasonal workers, and to ensure that seasonal workers are aware of their rights.
- (18) To facilitate the unhindered flow of goods within the Union, the Commission adopted a Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services¹¹, Guidelines on Facilitating Air Cargo Operations during COVID-19 outbreak¹², and Guidelines on protection of health, repatriation and travel arrangements for seafarers, passengers and other persons on board ships¹³.
- (19) In view of the reduction in the number of COVID-19 cases across the Union during the months of June and July 2020, many Member States lifted restrictions to free movement imposed during the first wave of infections.
- (20) As numbers of COVID-19 cases started to increase across much of the Union in August 2020, some Member States started reintroducing restrictions to free movement.

¹² OJ C 100I , 27.3.2020, p. 1.

¹⁰ OJ C 235I , 17.7.2020, p. 1.

¹¹ OJ C 96I , 24.3.2020, p. 1.

¹³ OJ C 119, 14.4.2020, p. 1

- (21)As the COVID-19 pandemic has caused an unprecedented health emergency, the protection of public health has become an overriding priority for both the Union and its Member States. On the basis of the protection of public health, Member States may take measures that restrict Restrictions to the free movement of persons within the Union. put in place to limit the spread of COVID-19 should be based on specific and limited public interest grounds, namely the protection of public health. They should be applied in compliance with the general principles of EU law, in particular proportionality and nondiscrimination. This Recommendation is intended to facilitate the application of these principles, in a coordinated manner, to the exceptional situation caused by the COVID-19 pandemic. Therefore, the mechanisms put in place by this Recommendation should be strictly limited in scope and time to restrictions adopted in response to this pandemic. According to Article 168(7) TFEU, the definition of national health policies, including the organisation and delivery of health services and medical care, are the responsibility of Member States and may therefore vary from one Member State to another. While Member States are competent to decide on the most appropriate measures to safeguard public health, such as for instance quarantine or testing requirements, it is appropriate to ensure the coordination of such measures, with a view to safeguarding the exercise of the right of free movement and combatting a serious cross-border threat to health such as Covid-19.
- (21a) When adopting and applying restrictions to free movement, Member States should respect principles of EU law, in particular proportionality and non-discrimination. This Recommendation is intended to facilitate the application of these principles, in a coordinated manner, to the exceptional situation caused by the COVID-19 pandemic. Therefore, the mechanisms put in place by this Recommendation should be strictly limited in scope and time to restrictions adopted in response to this pandemic.
- (22) Unilateral measures in this area have the potential to cause significant disruptions as businesses and citizens are confronted with a wide array of diverging and rapidly changing measures. This is particularly harmful in a situation where the European economy has already been significantly affected by the virus.
- (23) This Recommendation seeks to ensure increased coordination among Member States considering the adoption of measures restricting free movement on grounds of public health. To limit restrictions to what is strictly necessary, Member States should, in a non-discriminatory manner and as much as possible, apply those restrictions to persons coming from specific areas or regions particularly affected rather than to the entire territory of a Member State. A coordinated approach among Member States is required to reduce the impact of restrictions on Union citizens and the economy, enhancing transparency and predictability, while ensuring a high level of human health protection.

- (24) A coordinated approach among Member States requires joint efforts on the following key points: the application of common criteria and thresholds when deciding whether to introduce restrictions to free movement, a mapping of the risk of COVID-19 transmission based on an agreed colour code, and a coordinated approach as to the measures, if any, which may appropriately be applied to persons moving between areas, depending on the level of risk of transmission in those areas.
- (25) Six months into the crisis, more information is available as to the most effective measures to take, based on regular exchanges among Member States and the Commission. The criteria and thresholds outlined in this Recommendation are based on the data made available by Member States. A comprehensive data set and maps outlining the status of the common criteria for EU regions should be published and updated weekly by the European Centre for Disease Prevention and Control, using the data provided by the Member States.
- (26) In view of the evolving epidemiological situation, the Commission, supported by European Centre for Disease Prevention and Control, should regularly assess the criteria, data needs and thresholds outlined in this Recommendation, including whether to consider other criteria should be considered or the thresholds adapted, and transmit its findings to the Council for its consideration, together with a proposal to amend the Recommendation, where necessary such as hospitalisation rates or intensive care unit occupancy rates.
- (27) Member States should apply a coordinated set of indicators and methodology to the epidemiological classification of areas and regions.
- (28) This Recommendation should not be understood as facilitating or encouraging the adoption of restrictions to free movement put in place in response to the pandemic, but rather seeks to provide a coordinated approach in the event that a Member State were to decide to introduce such restrictions. The decision as to whether to introduce restrictions to free movement remain the responsibility of the Member States, which have to comply with the requirements of Union law. Equally, Member States retain the flexibility not to introduce restrictions even if the criteria and thresholds outlined in this Recommendation are met.
- (29) Restrictions on free movement should only be considered when Member States have sufficient evidence to justify such restrictions in terms of their benefit for public health and they have reasonable grounds to believe that the restrictions would be effective.
- (30) Maps outlining the status of the common criteria for EU regions should be published and updated weekly by the European Centre for Disease Prevention and Control, using data provided by the Member States.

- (31) To improve coordination among Member States and increase predictability for the public, Member States should use an agreed timeline when considering to impose restrictions on freedom of movement due to the COVID-19 outbreak.
- (32) To limit the disruption to the internal market and family life while the pandemic is ongoing, travellers with an essential function or need, such as workers or self-employed persons exercising critical occupations, cross-border workers, transport workers or transport service providers, seafarers, and persons travelling for imperative business or family reason, including members of cross-border families travelling on a regular basis, should not be required to undergo quarantine.
- (33) Clear, timely and comprehensive information to **other Member States and** the **general** public is crucial to limit the impacts of any restrictions to free movement put in place, ensuring predictability, legal certainty and compliance by citizens,

HAS ADOPTED THIS RECOMMENDATION:

General Principles

-1a. When adopting and applying measures to protect public health in response to COVID 19 pandemic, Member States should coordinate their actions based, to the extent possible, on the following principles:

- 1. Any restrictions to the free movement of persons within the Union put in place to limit the spread of COVID-19 should be based on specific and limited public interest grounds, namely the protection of public health. It is necessary for such limitations to be applied in compliance with the general principles of Union law, in particular proportionality and non-discrimination. Any measures taken should thus not extend beyond what is strictly necessary to safeguard public health.
- 2. Any such restrictions should be lifted as soon as the epidemiological situation allows it.
- 3. There may be no discrimination between Member States, for example by applying more generous rules to travel to and from a neighbouring Member State as compared to travel to and from other Member States in the same epidemiological situation.
- 4. Restrictions cannot be based on the nationality of the person concerned, but should be based on the location(s) of the person during the 14 days prior to arrival.
- 5. Member States should always admit their own nationals and Union citizens and their family members resident in their territory, and should facilitate swift transit through their territories.

- 6. Member States should pay particular attention to the specificities of cross-border regions and the need to cooperate at local and regional level.
- 7. Member States should regularly exchange information on all matters covered by the scope of this recommendation.

Common criteria

- 8. Member States should take the following **key** criteria into account when considering to restrict free movement in response to the COVID-19 pandemic:
 - (a) the '14-day cumulative COVID-19 case notification rate', that is, the total number of newly notified COVID-19 cases per 100 000 population in a given area in the last 14 days at regional level;
 - (b) the 'test positivity rate', that is, the percentage of positive tests among all tests for COVID-19 infection carried out in given area during the last week;
 - (c) the 'testing rate', that is, the number of tests for COVID-19 infection per 100 000 population carried out in a given area during the last week.

Data on the common criteria

9. To ensure that comprehensive and comparable data is available, Member States should, on a weekly basis, provide the European Centre for Disease Prevention and Control with data **available** on the criteria mentioned in point 8.

Member States should also provide this data at the regional level to ensure that any measures can be targeted to those regions where they are strictly necessary.

Member States should exchange information on any testing strategies which they pursue.

Mapping of risk areas when considering restrictions of free movement

9a. Based on the data provided by the Member States, the European Centre for Disease Prevention and Control should publish a map of EU Member States, broken down by regions, in order to support Member States' decision-making. This map should also include data from Iceland, Liechtenstein, Norway and the Swiss Confederation. In this map, an area should be marked in the following colours:

JAI.A

(a) green, if the 14-day cumulative COVID-19 case notification rate is less than 25 and the test positivity rate of tests for COVID-19 infection is less than 4%;

- (b) orange, if the 14-day cumulative COVID-19 case notification rate is less than 50 but the test positivity rate of tests for COVID-19 infection is 4% or more, or, if the 14-day cumulative COVID-19 case notification rate ranges from 25 to 150 but the test positivity rate of tests for COVID-19 infection is less than 4%;
- (c) red, if the 14-day cumulative COVID-19 case notification rate is 50 or more and the test positivity rate of tests for COVID-19 infection is 4% or more, or if the 14-day cumulative COVID-19 case notification rate is more than 150 per 100 000 population;
- (d) grey, if not sufficient information is available to assess the criteria in points (a) to (c) or if the testing rate is 350 or less COVID-19 tests for infection per 100 000 population.

The European Centre for Disease Prevention and Control should also publish separate maps for each key indicator contributing to the comprehensive map: the 14day notification rate at a regional level as well as the testing and test positivity rates at a national level. Once data is available at regional level all maps should be based on this data.

9b. Each week, the European Centre for Disease Prevention and Control should publish updated versions of the maps and the underlying data.

Common thresholds when considering restrictions of free movement

10. Member States should not restrict the free movement of persons travelling to or from another Member State with Member State's areas classified as 'green' pursuant to point 9a.

(a)a 14-day cumulative COVID-19 case notification rate of less than 50 new COVID-19 cases per 100 000 population; or

(b)a test positivity rate of tests for COVID-19 infection of less than 3%;

provided that the Member State concerned has a weekly testing rate of more than 250 COVID-19 tests for infection per 100 000 population.

By way of exception, in Member States where the 14-day cumulative COVID-19 case notification rate is more than 150 per 100 000 population, the criterion in letter (b) should not apply.

- 11. Member States should take into account the regional distribution of cases within other Member States. Wherever possible, restrictions to free movement should be circumscribed in the light of the situation of the affected regions of the Member State concerned. For this purpose, the thresholds mentioned in point 10 should be applied to the regional level, not limiting free movement to or from other regions of that Member State that meet the thresholds
- 11a. When considering whether to apply restrictions on an area classified other than 'green' pursuant to point 9a,

a) Member States could take into account additional criteria and trends. To this end, ECDC will provide data on the population size, the hospitalisation rate, the rate of ICU admission and the mortality rate, if available, on a weekly basis;

b) Member States should take into account the epidemiological situation in their own territory, including testing policies, the number of tests performed and test positivity rates, and other epidemiological indicators.

Mapping of risk areas when considering restrictions of free movement

- 12. Based on the data provided by the Member States, the European Centre for Disease Prevention and Control should publish a map of EU/EEA countries¹⁴, broken down by regions, in order to support Member States' decision making. In this map, an area should be marked in the following colours:
 - (a) green, if the 14-day cumulative COVID-19 case notification rate is less than 25 and the test positivity rate of tests for COVID-19 infection is less than 3%;

¹⁴ In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, OJ L 29, 31.1.2020, p. 7 ("Withdrawal Agreement"), this refers equally to the United Kingdom during the transition period referred to in Article 127(1) of the Withdrawal Agreement.

- (b) orange, if the 14-day cumulative COVID-19 case notification rate is less than 50 but the test positivity rate of tests for COVID-19 infection is 3% or more, or, if the 14day cumulative COVID-19 case notification rate ranges from 25 to 150 but the test positivity rate of tests for COVID-19 infection is less than 3%;
- (c) red, if the 14-day cumulative COVID-19 case notification rate is 50 or more and the test positivity rate of tests for COVID-19 infection is 3% or more, or if the 14-day cumulative COVID-19 case notification rate is more than 150 per 100 000 population;
- (d) grey, if not sufficient information is available to assess the criteria in point 10 or if the testing rate is 250 or less COVID-19 tests for infection per 100 000 population. Different shades of grey should be used to distinguish between the two cases.
- 13. Each week, the European Centre for Disease Prevention and Control should publish an updated version of the map.

Coordination among Member States and common timeline

14. Member States intending to apply restrictions to persons travelling to or from an area classified as 'red' or 'grey' other than 'green' pursuant to point 9a 12(c) and (d), based on its own decision-making processes, should inform the affected Member State first, prior to publication. Particular attention should be paid to cross-border cooperation. other Other Member States and the Commission should also be informed of its the intention prior to publication on a Thursday. If possible the information should be given 48 hours in advance.

For this purpose informing other Member States and the Commission, Member States should use the established network of the Integrated Political Crisis Response (IPCR). The IPCR contact points should ensure that the information is passed on to their competent authorities without delay.

Save for exceptional circumstances, the measures communicated by a Member State pursuant to this point should enter into force on the Monday of the following week.

15. When considering whether to apply restrictions, Member States should also take into account the epidemiological situation in their own territory, including testing policies, the number of tests performed and test positivity rates, and other epidemiological indicators.

- 16. Member States should not impose any restrictions on persons travelling to or from an area classified as 'red' pursuant to point 12(c) located in another Member State if they do not impose the same restrictions on an area classified as 'red' pursuant to point 12(c) located in their own territory.
- 17. Member States should immediately inform other Member States and the Commission of the lifting **or easing** of any previously introduced restrictive measures, which should enter into force as soon as possible.

Restrictions to free movement should be lifted when an area is again classified as 'orange' or 'green' pursuant to point 9a + 2, provided that at least 14 days have elapsed since their introduction.

18. At the latest 7 days after the adoption of this Recommendation, Member States should phase out restrictions applied on areas not classified as 'green''red' or 'grey' pursuant to point 9a 12 before the adoption of this Recommendation.

Common framework as regards possible measures for travellers coming from higher-risk areas

19. Member States should **in principle** not refuse the entry of persons travelling from other Member States.

Member States that **consider necessary to** introduce restrictions to free movement, based on their own decision-making processes, could require persons travelling from an area classified as 'red' or 'grey other than 'green' pursuant to point **9a** 12(c) and (d) to

- (a) undergo quarantine / self-isolation; and/or
- (b) undergo a test for COVID-19 infection after arrival.

Wherever possible, the possibility to undergo tests for COVID-19 infection instead of quarantine should be the preferred option.

Member States may offer travellers Travellers should be given the option to substitute the test mentioned in letter (b) by a test for COVID-19 infection carried out prior to departure.

Member States should continue coordination efforts on the length of quarantine/selfisolation and substitution possibilities.

20. Member States should mutually recognise the results of tests for COVID-19 infection carried out in other Member States by certified health bodies. Member States should enhance cooperation on different aspects related to testing taking into account research and advice of epidemiological experts as well as best-practices.

- 21. Travellers with an essential function or need should not be required to undergo quarantine, in particular:
 - (a) Workers or self-employed persons exercising critical occupations, frontier and posted workers as well as seasonal workers as referred to in the Guidelines concerning the exercise of the free movement of workers during the COVID-19 outbreak¹⁵;
 - (b) transport workers or transport service providers, including drivers of freight vehicles carrying goods for use in the territory as well as those merely transiting;
 - (c) pupils, students and trainees who travel abroad on a daily basis;
 - (d) persons travelling for imperative family or business reasons;
 - (e) diplomats, staff of international organisations and people invited by international organisations whose physical presence is required for the well-functioning of these organisations, military personnel and humanitarian aid workers and civil protection personnel in the exercise of their functions;
 - (f) passengers in transit;
 - (g) seafarers;
 - (h) journalists, when performing their duties.
- 22. Member States could require persons entering their territory arriving from an area classified as 'red', 'orange' or 'grey' pursuant to point 12(c), (b) and (d) to submit passenger locator forms, notably those arriving by airplane, in accordance with data protection requirements. A common European Passenger Locator Form should be developed for possible use by Member States. Wherever possible, a digital option for passenger locator information should be used in order to simplify processing, while ensuring equal access to all citizens.

22a. When considering measures, Member States should take into account the differences in the epidemiological situation between orange and red areas.

23. Where justified, Member States could consider recommending that persons travelling from an area classified as 'orange' pursuant to point 12(b) undergo at least a test for COVID-19 infection prior to departure or upon arrival.

¹⁵ OJ C 102I , 30.3.2020, p. 12.

- 24. Any measures applied to persons arriving from an area classified area as 'red', 'orange' or 'grey other than 'green' pursuant to point 9a 12(c), (b) and (d) may not be discriminatory, that is, should apply equally to returning nationals of the Member State concerned.
- 25. Member States should ensure that any formal requirements imposed on citizens and businesses provide a concrete benefit to the public health efforts to combat the pandemic and do not create an undue and unnecessary administrative burden.
- 26. If a person develops symptoms upon arrival at the destination, testing, diagnosis, isolation and contact tracing should take place in accordance with the local practice, and entry should not be refused. Information on cases detected on arrival should be immediately shared with the public health authorities of the countries the person concerned has resided in during the previous 14 days for contact tracing purposes, using the Early Warning and Response System.
- 27. Restrictions should not take the form of prohibitions on the operation of certain transport services.

Communication and information to the public

28. Member States should provide relevant stakeholders and the general public with clear, comprehensive and timely information about any restrictions to free movement, any accompanying requirements (for example negative tests for COVID-19 infection or passenger locator forms), as well as the measures applied to travellers travelling from higherrisk areas as early as possible before new measures come into effect. As a general rule, this information should be published 24 hours before the measures come into effect, taking into account that some flexibility is required for epidemiological emergencies.

In particular, Member States should, as quickly as possible, inform the public of any newly introduced or lifted restrictions, communicated to other Member States and the Commission pursuant to points 14 and 17.

This information should also be made available on the 'Re-open EU' web platform, which should contain a cross-reference to the map published regularly by the European Centre for Disease Prevention and Control pursuant to points **9a** and **9b**.

The substance of the measures, their geographical scope and the categories of persons to whom they apply should be clearly described.

Done at Brussels,

For the Council The President

JAI.A

MMA/mc



Council of the European Union General Secretariat

Brussels, 07 May 2021

WK 6177/2021 INIT

I IMITE

COVID-19	IPCR	COMIX
JAI	VISA	SCHENGEN
POLGEN	MI	AVIATION
FRONT	SAN	PHARM
FREMP	TRANS	RELEX
	COCON	TOUR

This is a paper intended for a specific community of recipients. Handling and further distribution are under the sole responsibility of community members.

MEETING DOCUMENT

From: To:	General Secretariat of the Council Ad hoc Working Party on the proposals for a Digital Green Certificate
N° Cion doc.:	7128/21 + ADD 1, 7129/21
Subject:	 Digital Green Certificate Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic Proposal for a Regulation of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable vaccination, testing and recovery certificates for third country nationals legally residing in the Schengen area to facilitate free movement during the COVID-19 pandemic - Examination of compromise suggestions

For the purpose of discussions at the ad hoc Working Party on DGC on Monday 10 May 2021, delegations will find in the Annex the four-column table on the above-mentioned proposals.

Delegations are invited to focus on the rows coloured in orange next to which letters C or P/C are indicated in the fifth column (C = endorsement required by Council and P = endorsement required by Parliament).

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate)

(Text with EEA relevance)

C: Endorsement required by Council

P: Endorsement required by Parliament

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
1.	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	
2.	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,	Functioning of the European Union,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,	
3.	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,		Having regard to the proposal from the European Commission,	
4.	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,		After transmission of the draft legislative act to the national parliaments,	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
5.	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,
6.	Whereas:	Whereas:	Whereas:	Whereas:
7.	(1) Every citizen of the Union has the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council ¹ lays down detailed rules as regards the exercise of that right.	(1) Every citizen of the Union has the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council ² lays down detailed rules as regards the exercise of that right.	(1) Every citizen of the Union has the <u>fundamental</u> right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council ³ lays down detailed rules as regards the exercise of that right.	(1) Every citizen of the Union has the <u>fundamental</u> right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council ⁴ lays down detailed rules as regards the exercise of that right.
8.		(1a) Facilitating freedom of movement is one of the key preconditions for starting an economic recovery.		[Row 19]

¹ Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

² Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

³ Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

⁴ Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC (OJ L 158, 30.4.2004, p. 77).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
9.	(2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (<i>SARS-CoV-2</i>), which causes coronavirus disease 2019 (COVID- 19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.		(2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (<i>SARS-CoV-2</i>), which causes coronavirus disease 2019 (COVID- 19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.	(2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (<i>SARS-CoV-2</i>), which causes coronavirus disease 2019 (COVID- 19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.	
10.	(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on Union citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection.	(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on Union citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection. Such restrictions have detrimental effects on citizens and businesses, especially cross-border workers and commuters or seasonal workers.	(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on Union citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection.	 (3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on Union citizens' right to move and reside freely within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine/self-isolation or a test for SARS-CoV-2 infection. [EP position in row 11 (main regulation) and Row 9 (twin regulation)] 	
11.	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475	

Commission proposa COM (2021) 130 fin			ncil position 7796/21	Compromise text
on a coordinated approach restriction of free mover	n to the on a coordinated ap ment in restriction of free DVID-19 response to the endation pandemic ⁶ . That Re establishes a coordin nts: the on the following ke eria and application of commen- hether to thresholds when decid o free introduce restriction e risk of movement, a mapping ased on COVID-19 transmiss and a an agreed colour to the coordinated approact measures, if any, persons appropriately be appl ppending moving between are smission on the level of risk of of their in those areas. In the specific situat phasises Recommendation als listed in that essential travelle s-border its point 19, and es are commuters, whose	proach to the on a coordin movement in restriction of cOVID-19 response to pandemic ⁷ . T establishes a optication of ding whether to on criteria and ding whether to on s to free g of the risk of sion based on code, and a ch as to the which may lied to persons as, depending of their sion, the so emphasises ers, as listed in l cross-border e lives are coventation of thresholds whi introduce response coventation coventation pandemic ⁷ . T establishes a on the follow application of thresholds whi introduce response coventation cove	ated approach to the on rest free movement in rest of the COVID-19 resp that Recommendation pan coordinated approach esta wing key points: the on common criteria and app en deciding whether to three estrictions to free intra- mapping of the risk of consmission based on CO colour code, and a an approach as to the coo colour code, and a	demic ⁸ . That Recommendation ablishes a coordinated approach the following key points: the dication of common criteria and esholds when deciding whether to oduce restrictions to free vement, a mapping of the risk of VID-19 transmission based on agreed colour code, and a ordinated approach as to the asures, if any, which may propriately be applied to persons ving between areas, depending the level of risk of transmission those areas. In view of their cific situation, the commendation also emphasises t essential travellers, as listed in point 19, and cross-border nmuters whose lives are
restrictions, in particular exercising critical function essential for critical infras	ons or exercising critical tructure, essential for critical	functions or exercising c infrastructure, essential for	ritical functions or exercitical infrastructure, esse	rictions, in particular those reising critical functions or ential for critical infrastructure,
should in principle be e	xempted should in principle	be exempted should in pr	inciple be exempted sho	uld in principle be exempted

- OJ L 337, 14.10.2020, p. 3. OJ L 337, 14.10.2020, p. 3. OJ L 337, 14.10.2020, p. 3. OJ L 337, 14.10.2020, p. 3.

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	from travel restrictions linked to COVID-19.	from travel restrictions linked to COVID-19.	from travel restrictions linked to COVID-19.	from travel restrictions linked to COVID-19.
12.	(5) Using the criteria and	(5) Using the criteria and	(5) Using the criteria and	(5) Using the criteria and
	thresholds established in	thresholds established in	thresholds established in	thresholds established in
	Recommendation (EU) 2020/1475,	Recommendation (EU) 2020/1475,	Recommendation (EU) 2020/1475,	Recommendation (EU) 2020/1475,
	the European Centre for Disease	the European Centre for Disease	the European Centre for Disease	the European Centre for Disease
	Prevention and Control ('ECDC')	Prevention and Control ('ECDC')	Prevention and Control ('ECDC')	Prevention and Control ('ECDC')
	has been publishing, once a week, a	has been publishing, once a week, a	has been publishing, once a week, a	has been publishing, once a week, a
	map of Member States, broken	map of Member States, broken	map of Member States, broken	map of Member States, broken
	down by regions, in order to support	down by regions, in order to support	down by regions, in order to support	down by regions, in order to support
	Member States' decision-making ⁹ .	Member States' decision-making ¹⁰ .	Member States' decision-making ¹¹ .	Member States' decision-making ¹² .
13.	(6) As emphasised by	(6) As emphasised by	(6) As emphasised by	(6) As emphasised by
	Recommendation (EU) 2020/1475,	Recommendation (EU) 2020/1475,	Recommendation (EU) 2020/1475	Recommendation (EU) 2020/1475
	any restrictions to the free	any restrictions to the free	any, Member States may limit the	any, Member States may limit the
	movement of persons within the	movement of persons within the	fundamental right of free	fundamental right of free
	Union put in place to limit the spread	Union put in place to limit the spread	movement for public health	movement for public health
	of COVID-19 should be based on	of COVID-19 should be based on	reasons. Any restrictions to the free	reasons. Any restrictions to the free
	specific and limited public interest	specific and limited public interest	movement of persons within the	movement of persons within the
	grounds, namely the protection of	grounds, namely the protection of	Union put in place to limit the spread	Union put in place to limit the spread
	public health. It is necessary for such	public health. It is necessary for such	of COVID-19 should be based on	of COVID-19 should be based on
	limitations to be applied in	limitations to be applied in	specific and limited public interest	specific and limited public interest
	compliance with the general	compliance with the general	grounds, namely the protection of	grounds, namely the protection of
	principles of Union law, in	principles of Union law, in	public health <u>as emphasised by</u>	public health <u>as emphasised by</u>
	particular proportionality and non-	particular proportionality and non-	<u>Recommendation (EU) 2020/1475</u> .	<u>Recommendation (EU) 2020/1475</u> .
	discrimination. Any measures taken	discrimination. Any measures taken	It is necessary for such limitations to	It is necessary for such limitations to
	should thus not extend beyond what	should thus <i>be strictly limited in</i>	be applied in compliance with the	be applied in compliance with the
	is strictly necessary to safeguard	<i>scope and time in line with the</i>	general principles of Union law, in	general principles of Union law, in
	public health. Furthermore, they	<i>effort to restore a fully functioning</i>	particular proportionality and non-	particular proportionality and non-

⁹ Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

¹⁰ Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

¹¹ Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

¹² Available at: <u>https://www.ecdc.europa.eu/en/covid-19/situation-updates/weekly-maps-coordinated-restriction-free-movement</u>

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and personnel through the so-called "Green Lane" border crossings referred to in the Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services ¹³ .	Schengen area without internal border controls and should not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and <i>medical and healthcare</i> personnel through the so-called "Green Lane" border crossings referred to in the Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services ¹⁴ .	discrimination. Any measures taken should thus not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and personnel through the so-called "Green Lane" border crossings referred to in the Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services ¹⁵ .	discrimination. Any measures taken should thus <i>be strictly limited in</i> <i>scope and time and should</i> not extend beyond what is strictly necessary to safeguard public health. Furthermore, they should be consistent with measures taken by the Union to ensure seamless free movement of goods and essential services across the Single Market, including those of medical supplies and <i>medical and healthcare</i> personnel through the so-called "Green Lane" border crossings referred to in the Commission Communication on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services ¹⁶ .	
14.	(7) The free movement of persons who do not pose a risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions	(7) People who are vaccinated, have a negative NAAT test that is less than [72 hours] old or have a negative rapid antigen test that is less than [24 hours] old, and people who have tested positive for specific antibodies to the spike protein within the last [6 months], have a	(7) The free movement of persons who do not pose a risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions	(7) <u>Persons who are vaccinated</u> or <u>have a recent negative</u> diagnostic test or persons who have recovered from COVID-19 within the last 6 months, have a reduced risk of infecting people with SARS- CoV-2, according to current medical knowledge. The free	

- OJ C 96I, 24.3.2020, p. 1. OJ C 96I, 24.3.2020, p. 1.

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	would not be necessary to achieve the objective pursued.	significant reduced risk of infecting people with SARS-CoV-2, according to current medical knowledge. The free movement of persons who based on sound scientific evidence do not pose a significant risk to public health, for example because they are immune to and cannot transmit SARS-CoV- 2, should not be restricted, as such restrictions would not be necessary to achieve the objective pursued.	would not be necessary to achieve the objective pursued.	movement of persons who <i>based on</i> <i>sound scientific evidence</i> do not pose a <i>significant</i> risk to public health, for example because they are immune to and cannot transmit SARS-CoV-2, should not be restricted, as such restrictions would not be necessary to achieve the objective pursued.
15.		(7a) To ensure harmonised use of the certificates, the duration of their respective validity should be set in this Regulation. However, at this stage, it is still unclear whether vaccines prevent transmission of COVID-19. Similarly, there is insufficient evidence on the duration of effective protection against COVID-19 following recovery from a prior infection. Therefore, it should be possible to adjust the duration of validity based on technical and scientific progress.		
16.	(8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their	(8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their	(8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their	(8) Many Member States have launched or plan to launch initiatives to issue vaccination certificates. However, for these to be used effectively in a cross-border context when citizens exercise their

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	free movement rights, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.	free movement rights, such <i>vaccination</i> certificates need to be fully interoperable, <i>compatible</i> , secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles, technical standards <i>and level of protection</i> of such certificates.	certificates need to be fully interoperable, secure and verifiable.	free movement rights, such <i>vaccination</i> certificates need to be fully interoperable, <i>compatible</i> , secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards <i>and level of protection</i> of such certificates.	
17.	(9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, as national authorities and passenger transport services, such as airlines, trains, coaches or ferries, are confronted with a wide array of diverging document formats, not only regarding a person's vaccination status but also on tests and possible recovery from COVID- 19.	(9) Unilateral measures in this area have the potential to cause significant disruptions to the exercise of free movement rights, and to hinder the proper functioning of the internal market, including the tourism sector, as national authorities and passenger transport services, such as airlines, trains, coaches or ferries, are confronted with a wide array of diverging document formats, not only regarding a person's vaccination status but also on tests and possible recovery from COVID- 19.	area have the potential to cause significant disruptions to the exercise of free movement rights, as national authorities and passenger transport services, such as airlines,	significant disruptions to the exercise of free movement rights,	
18.		(9a) The European Parliament called in its resolution of 3 March 2021 on establishing an EU strategy for sustainable tourism for a harmonised approach across the EU on tourism, both implementing common criteria for safe travel, with an EU Health Safety protocol		(9a) The European Parliament called in its resolution of 3 March 2021 on establishing an EU strategy for sustainable tourism for a harmonised approach across the EU on tourism, both implementing common criteria for safe travel, with an EU Health Safety protocol	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
		for testing and quarantine requirements and calling for a common vaccination certificate, once there is sufficient evidence that vaccinated persons do not transmit the virus, or mutual recognition of vaccination procedures.		for testing and quarantine requirements and calling for a common vaccination certificate, once there is sufficient evidence that vaccinated persons do not transmit the virus, or mutual recognition of vaccination procedures. (9b) In their statement of 25 March 2021, the Members of the European Council called for preparations to start on a common approach to the gradual lifting of restrictions, to ensure that efforts are coordinated when the epidemiological situation allows for an easing of current measures, and for the legislative and technical work on COVID-19 interoperable and non-discriminatory digital certificates to be taken forward as a matter of urgency.
19.	(10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery,	(10) Without prejudice to the common measures on the crossing of internal borders by persons as laid down in the Schengen acquis, in particular in Regulation (EU) 2016/399 of the European Parliament and of the Council ¹⁷ , and for the purpose of facilitating	(10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery,	(10) To facilitate the exercise of the right to move and reside freely within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery,

¹⁷ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code) (OJ L 77, 23.3.2016, p. 1).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	entitled "Digital Green Certificate" should be established.	To facilitate the exercise of the right to move and reside freely-within the territory of the Member States, a common framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery, entitled "EU COVID-19 Digital Green Certificate" should be established which should be binding and directly applicable in all Member States. All Union transport hubs, such as airports, ports, railway and bus stations, where the certificate is being verified, should apply standardised and common criteria and procedures for the verification of the EU COVID-19 certificate on the basis of guidance developed by the Commission.	entitled "Digital Green Certificate" should be established.	entitled "Digital Green Certificate" should be established, which should be binding and directly applicable in all Member States. Facilitating freedom of movement is one of the key preconditions for starting an economic recovery. [Transport hubs - Row 160]	
20.		(10a) Member States, when applying this Regulation, should accept every type of certificate issued in accordance with this Regulation. The interoperable certificates should have equal value during the duration of their validity.			
21.	(11) This Regulation should not be understood as facilitating or encouraging the adoption of	(11) This Regulation <i>is intended</i> to facilitate the application of the principles of proportionality and	(11) This Regulation should not be understood as facilitating or encouraging the adoption of	(11) This Regulation is intended to facilitate the application of the principles of proportionality and	

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, the exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply. At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.	non-discrimination with regard to possible restrictions to free movement and other fundamental rights as a result of the COVID-19 pandemic, while pursuing a high level of public health protection and should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, The exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply. Any need for verification of certificates established by this Regulation should not be able as such to justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.	restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, the exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply <u>and the specific situation of cross border communities should be taken into account. At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.</u>	non-discrimination with regard to possible restrictions to free movement during the COVID-19 pandemic, while pursuing a high level of public health protection, and should not be understood as facilitating or encouraging the adoption of restrictions to free movement, or other fundamental rights, in response to the pandemic. In particular, The exemptions to the restriction of free movement in response to the COVID-19 pandemic referred to in Recommendation (EU) 2020/1475 should continue to apply <u>and the specific situation of cross border communities should be taken into account. At the same time, the "Digital Green Certificate" framework will ensure that interoperable certificates are also available to essential travellers.</u>
22.		(11a) This Regulation should not cover Member States' decisions to impose or waive restrictions to free movement put in place, in	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			compliance with Union law, to limit the spread of COVID-19.The use of the Digital Green Certificate in view of lifting restrictions should remain the responsibility of the Member States.		
23.	(12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.	(12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.	approach for the issuance,	(12) The foundation of a common approach for the issuance, verification and acceptance of such interoperable certificates hinges upon trust. False COVID-19 certificates may pose a significant risk to public health. Authorities in one Member State need assurance that the information included in a certificate issued in another Member State is trustworthy, that it has not been forged, that it belongs to the person presenting it, and that anyone verifying this information only has access to the minimum amount of information necessary.	
24.	(13) The risk posed by false COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative COVID-19 test certificates ¹⁸ . Given	(13) The risk posed by false COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative COVID-19 test certificates ¹⁹ . Given	COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the	(13) The risk posed by false P COVID-19 certificates is real. On 1 February 2021, Europol issued an Early Warning Notification on the illicit sales of false negative	P/C

¹⁸ https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates

¹⁹ https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates

²⁰ https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	the available and easily accessible technological means, such as high- resolution printers and various graphics editor software, fraudsters are able to produce high-quality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online.	the available and easily accessible technological means, such as high- resolution printers and various graphics editor software, fraudsters are able to produce high-quality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online.	certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised	COVID-19 test certificates ²¹ . Given the available and easily accessible technological means, such as high- resolution printers and various graphics editor software, fraudsters are able to produce high-quality forged, faked or counterfeit certificates. Cases of illicit sales of fraudulent test certificates have been reported, involving more organised forgery rings and individual opportunistic scammers selling false certificates offline and online. (13a) It is important that sufficient resources are made available to implement this Regulation and to prevent, detect, investigate and prosecute fraud and illicit practices regarding the issuance and use of the Digital Green Certificate.	
25.	(14) To ensure interoperability and equal access, Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both. This should allow the prospective holder to request and receive a paper copy of the certificate or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally	(14) To ensure interoperability and equal access, <i>including for</i> <i>vulnerable persons such as persons</i> <i>with disabilities and for persons</i> <i>with limited access to digital</i> <i>technologies</i> , Member States should issue the certificates making up the <i>EU COVID-19</i> Digital Green Certificate in a digital or paper- based format, or both <i>as chosen by</i> <i>the holder</i> . This should allow the	(14) To ensure interoperability and equal access, including for persons with disabilities , Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both, depending on the choice of the prospective holder . This should allow the prospective holder to request and receive a paper copy of the certificate or to store and display	(14) To ensure interoperability and equal access, <i>including for</i> <i>vulnerable persons such as persons</i> <i>with disabilities and for persons</i> <i>with limited access to digital</i> <i>technologies</i> , Member States should issue the certificates making up the Digital Green Certificate in a digital or paper-based format, or both, <u>depending on the choice of the</u> prospective holder . This should	

²¹ <u>https://www.europol.europa.eu/early-warning-notification-illicit-sales-of-false-negative-covid-19-test-certificates</u>

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
readable barcode containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human- readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user-friendliness. To avoid obstacles to free movement, the certificates should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon request, ensuring that they can be obtained easily and providing, where needed, the necessary support to allow for equal access by all citizens.	prospective holder to request and receive a paper copy of the certificate and/or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode only containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human- readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user-friendliness. The information and layout should be presented in an accessible manner for persons with disabilities following the accessibility requirements for information, laid down in Directive (EU) 2019/882 of the European Parliament and of the Council ²² . To avoid obstacles to free movement, the certificates should be issued free of charge, and persons eitizens should have a right to have them issued. Member States	the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. The information on the certificate should also be included in human-readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user- friendliness. To avoid obstacles to free movement, <u>and although there</u> <u>may be a charge for related</u> <u>services, such as for tests</u> , the certificates <u>themselves</u> should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon request, ensuring that they can be obtained easily and providing, where needed, the necessary support to allow for equal access by all citizens.	allow the prospective holder to request and receive a paper copy of the certificate <i>and</i> /or to store and display the certificate on a mobile device. The certificates should contain an interoperable, digitally readable barcode <i>only</i> containing the relevant data relating to the certificates. Member States should guarantee the authenticity, validity and integrity of the certificates by electronic seals or similar means. <u>To</u> <u>ensure a high level of confidence in</u> <u>the authenticity of certificates,</u> <u>Member States should consider the</u> <u>use of advanced electronic seals as</u> <u>defined in Regulation (EU)</u> <u>910/2014.</u> The information on the certificate should also be included in human-readable format, either printed or displayed as plain text. The layout of the certificates should be easy to understand and ensure simplicity and user-friendliness. To avoid obstacles to free movement, the certificates should be issued free of charge, and citizens should have a right to have them issued. Member States should issue the certificates making up the Digital Green Certificate automatically or upon	
	should <i>automatically</i> issue the		request, ensuring that they can be obtained easily <i>and swiftly</i> and	

²² Directive (EU) 2019/882 of the European Parliament and of the Council of 17 April 2019 on the accessibility requirements for products and services (OJ L 151, 7.6.2019, p. 70).

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	certificates making up the EU COVID-19 Digital Green Certificate automatically, or in the case of the certificate of recovery only upon request, ensuring that they can be obtained easily and swiftly and providing, where needed, the necessary support to ensure allow for equal access by all persons. Any additional technical, digital and transport infrastructure expenses needed to put in place the vaccination certificates should be eligible under Union funds and programmes.		providing, where needed, the necessary support to allow for equal access by all citizens. <u>Where a</u> <u>certificate is not issued</u> <u>automatically, citizens should thus</u> <u>be able to request it quickly and</u> <u>easily, for example by submitting a</u> <u>request in an online patient portal.</u> <u>A separate certificate should be</u> <u>issued for each vaccination, test or</u> <u>recovery, which should not contain</u> <u>data on any previous certificates,</u> <u>except where explicitly provided.</u> (14a) Authentic certificates making <u>up the Digital Green Certificate</u> <u>should be individually identifiable</u> <u>by means of a unique certificate</u> <u>identifier, taking into account that</u> <u>citizens might be issued more than</u> <u>one certificate during the course of</u> <u>the COVID-19 pandemic. The</u> <u>unique certificate identifier is</u> <u>composed of an alphanumeric</u> <u>string, and Member States should</u> <u>ensure that it does not contain any</u> <u>data linking it to other documents</u> <u>or identifiers, such as to passport or</u> <u>identifier may only be used for its</u> <u>intended purpose, including for</u> <u>requests for the issuance of a new</u> <u>certificate if the certificate is no</u>	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
				longer available to the holder, and the revocation of certificates. The unique certificate identifier also avoid the need to process other personal data that would otherwise be necessary to identify individual certificates.	
26.		(14a) The vaccines should be considered as global public goods available to the general population, hence Member States should ensure fair and free of charge access for all citizens. Member States should also ensure universal, accessible, timely and free of charge access to COVID-19 testing possibilities, including making these available in all transport hubs. Issuance of certificates pursuant to Article 3(1) should not lead to differential treatment and discrimination based on vaccination status or the possession of a specific certificate referred to in Articles 5, 6 and 7.			
27.	(15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their	(15) The security, authenticity, integrity and validity of the certificates making up the <i>EU</i> <i>COVID-19</i> Digital Green Certificate and their compliance with Union data protection	(15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their	(15) The security, authenticity, integrity and validity of the certificates making up the Digital Green Certificate and their compliance with Union data protection legislation are key to their	

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. The outline on the interoperability of health certificates ²³ adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU ²⁴ should form the basis for the trust framework.	legislation are key to their acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. <i>The infrastructure</i> <i>should be developed, with a strong</i> <i>preference for the use of Union</i> <i>technology, to function on all</i> <i>electronic devices while ensuring</i> <i>that that infrastructure is protected</i> <i>from cybersecurity threats. The</i> <i>trust framework should ensure that</i> <i>the verification of a certificate can</i> <i>happen offline and without</i> <i>informing the issuer about the</i> <i>verification and should therefore</i> <i>ensure that no issuer of certificates,</i> <i>nor any other third party, is</i> <i>informed when a holder presents a</i> <i>certificate.</i> The outline on the interoperability of health certificates ²⁵ adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU ²⁶ should form the basis for the trust framework. <i>The trust</i>	acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. The outline on the interoperability of health certificates ²⁷ adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU ²⁸ should form the basis for the trust framework.	acceptance in all Member States. It is therefore necessary to establish a trust framework laying out the rules on and infrastructure for the reliable and secure issuance and verification of certificates. <u>The infrastructure</u> <u>should be developed, with a strong</u> <u>preference for the use of open</u> <u>source technology, to function on</u> <u>different major operating systems</u> <u>while ensuring that that</u> <u>infrastructure is protected from</u> <u>cybersecurity threats. The trust</u> <u>framework should ensure that the</u> <u>verification of a certificate can</u> <u>happen offline and without</u> <u>informing the issuer or any other</u> <u>third party about the verification.</u> <u>The trust framework should be</u> <u>based on a public-key</u> <u>infrastructure with a trust chain</u> <u>from Member States' health</u> <u>authorities to the individual entities</u> <u>issuing the certificates. The trust</u> <u>framework should allow for</u> <u>detection against fraud, in</u> <u>particular forgery.</u> The outline on	

²³ Available at: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

²⁴ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

²⁵ Available at: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

²⁶ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

²⁷ Available at: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u>

²⁸ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
		framework should therefore be based on a public-key infrastructure with a trust chain from Member States' health authorities to the individual entities issuing the certificates. The trust framework should allow for detection against fraud, in particular forgery. A separate independent certificate should be issued for each vaccination, test or recovery, and no history of the previous certificates of the holder should be stored on the certificate.		the interoperability of health certificates ²⁹ adopted, on 12 March 2021, by the eHealth Network set up under Article 14 of Directive 2011/24/EU ³⁰ should form the basis for the trust framework. [EP amendments on new certificate – row 25] EP amendment on separate certificate – row 95]
28.	(16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, whatever their nationality, by the Member State of vaccination or test, or where the recovered person is located. Where relevant or appropriate, the certificates should be issued on behalf of the vaccinated, tested or recovered person, for example on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates	(16) Pursuant to this Regulation, any of the certificates making up the EU COVID-19 Digital Green Certificate should be issued to persons as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, including citizens from Overseas Countries and Territories as referred to in Article 355.2 Treaty on the functioning of European Union (TFEU), whatever their nationality, by the Member State of vaccination or test, or where the recovered person is located. Where relevant or appropriate, the certificates should be issued to	(16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, whatever their nationality, by the Member State of vaccination or test, or where the recovered person is located. Where reference is made to issuance by Member States, this should be understood as also covering issuance by designated bodies on behalf of Member States, including when they are issued in Overseas Countries and	(16) Pursuant to this Regulation, the certificates making up the Digital Green Certificate should be issued to beneficiaries as referred to in Article 3 of Directive 2004/38/EC, that is, Union citizens and their family members, whatever their nationality, by the Member State of vaccination or test, or where the recovered person is located. Where reference is made to issuance by Member States, this should be understood as also covering issuance by designated bodies on behalf of Member States, including when they are issued in Overseas Countries and

Available at: <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf</u> Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	should not require legalisation or other similar formalities.	<i>another person</i> on behalf of the vaccinated, tested or recovered person, for example <i>to the legal guardian</i> on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or <i>any</i> other similar formalities.	Territories or the Faroe Islands on behalf of a Member State. Where relevant or appropriate, the certificates should be issued on behalf of the vaccinated, tested or recovered person, for example on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or other similar formalities.	Territories or the Faroe Islands on behalf of a Member State. Where relevant or appropriate, the certificates should be issued to another person on behalf of the vaccinated, tested or recovered person, for example to the legal guardian on behalf of legally incapacitated persons or to parents on behalf of their children. The certificates should not require legalisation or any other similar formalities.	
29.		(16a) Restrictions linked to cross- border travel are particularly disruptive for persons who cross them daily or frequently to go to work or school, visit close relatives, seek medical care, or to take care of loved ones. The EU COVID-19 Certificate should facilitate the free movement of border residents, seasonal cross-border workers, temporary cross-border workers and transport workers.		[Rows 11 and 21]	
		(16b) Underlining Recital (14a) and paragraphs 6 and 19 of Council Recommendation (EU) 2020/1475, Member States should pay particular attention to the specificities of cross-border regions, outermost regions, exclaves and geographically			

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
		isolated areas and the need to cooperate at local and regional level as well as to persons who are considered to be frontier workers, cross-border workers and border residents and who reside in another Member State to which they return as a rule daily or at least once a week.		
30.	(17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See, in particular where they are vaccinated by a Member State.	(17) The certificates making up the <i>EU COVID-19</i> Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See , in particular where they are vaccinated by a Member State.	(17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See. in particular where they are vaccinated by a Member State.	(17) The certificates making up the Digital Green Certificate could also be issued to nationals or residents of Andorra, Monaco, San Marino and the Vatican/Holy See , in particular where they are vaccinated by a Member State .
31.	(18) It is necessary to take into account that the agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be	(18) It is necessary to take into account that the Agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be	(18) It is necessary to take into account that the agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be	(18) <u>It is necessary to take into</u> account that Agreements on free movement of persons concluded by the Union and its Member States, of the one part, and certain third countries, of the other part, provide for the possibility to restrict free movement for public health reasons. Where such an agreement does not contain a mechanism of incorporation of European Union acts, certificates issued to beneficiaries of such agreements should be accepted under the conditions laid down in this Regulation. This should be

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	conditional on an implementing act	conditional on an implementing act	conditional on an implementing act	conditional on an implementing act	
	to be adopted by the Commission	to be adopted by the Commission	to be adopted by the Commission	to be adopted by the Commission	
	establishing that such a third country	establishing that such a third country	establishing that such a third country	establishing that such a third country	
	issues certificates in accordance	issues certificates in accordance	issues certificates in accordance	issues certificates in accordance	
	with this Regulation and has	with this Regulation and has	with this Regulation and has	with this Regulation and has	
	provided formal assurances that it	provided formal assurances that it	provided formal assurances that it	provided formal assurances that it	
	would accept certificates issued by	would accept certificates issued by	would accept certificates issued by	would accept certificates issued by	
	the Member States.	the Member States.	the Member States.	the Member States.	
32.	(19) Regulation (EU) 2021/XXXX applies to third- country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.	(19) Regulation (EU) 2021/XXXX applies to third- country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.	2021/XXXX applies to third-	(19) Regulation (EU) 2021/XXXX applies to third- country nationals who do not fall within the scope of this Regulation and who reside or stay legally in the territory of a State to which that Regulation applies and who are entitled to travel to other States in accordance with Union law.	
33.	(20) The framework to be	(20) The framework to be	(20) The framework to be	(20) The framework to be	
	established for the purpose of this	established for the purpose of this	established for the purpose of this	established for the purpose of this	
	Regulation should seek to ensure	Regulation should seek to ensure	Regulation should seek to ensure	Regulation should seek to ensure	
	coherence with global initiatives, in	coherence with global initiatives or	coherence with global initiatives, in	coherence with global initiatives, in	
	particular involving the WHO. This	similar initiatives with third	particular involving the WHO <u>and</u>	particular involving the WHO and	
	should include, where possible,	countries with which the European	<u>the International Civil Aviation</u>	the International Civil Aviation	
	interoperability between	Union has close partnerships, in	<u>Organisation (ICAO)</u> . This should	Organisation (ICAO). This should	
	technological systems established at	particular involving the WHO and	include, where possible,	include, where possible,	
	global level and the systems	the International Civil Aviation	interoperability between	interoperability between	
	established for the purpose of this	Organisation. This should include,	technological systems established at	technological systems established at	
	Regulation to facilitate free	where possible, interoperability	global level and the systems	global level or by third countries	
	movement within the Union,	between technological systems	established for the purpose of this	with which the European Union	
	including through the participation	established at global level and the	Regulation to facilitate free	has close links and the systems	
	in a public key infrastructure or the	systems established for the purpose	movement within the Union,	established for the purpose of this	
	bilateral exchange of public keys.	of this Regulation to facilitate free	including through the participation	Regulation to facilitate free	
	To facilitate the free movement	movement within the Union,	in a public key infrastructure or the	movement within the Union,	
	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
-----	---	---	--	---	--
	rights of Union citizens vaccinated by third countries, this Regulation should provide for the acceptance of certificates issued by third countries to Union citizens and their family members where the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.	including through the participation in a public key infrastructure or the bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated or tested by third countries or by Overseas Countries or Territories referred to in Article 355 (2) TFEU or listed in Annex II thereto or the Faroe Islands, this Regulation should provide for the acceptance of certificates issued by third countries or by Overseas Countries or Territories or the Faroe Islands to Union citizens and their family members where, the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.	bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated or tested by third countries or by Overseas Countries or Territories referred to in Article 355 (2) TFEU or listed in its annex II or the Faroe Islands, this Regulation should provide for the acceptance of certificates issued by third countries or by Overseas Countries or Territories or the Faroe Islands to Union citizens and their family members where the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.	including through the participation in a public key infrastructure or the bilateral exchange of public keys. To facilitate the free movement rights of Union citizens vaccinated or tested by third countries or by Overseas Countries or Territories referred to in Article 355 (2) TFEU or listed in Annex II thereto or the Faroe Islands, this Regulation should provide for the acceptance of certificates issued by third countries or by Overseas Countries or Territories or the Faroe Islands to Union citizens and their family members where, the Commission finds that these certificates are issued according to standards equivalent to those established pursuant to this Regulation.	
34.			(20a) If the technical solution chosen for verification requires a Member State to transfer personal data to a recipient in a third country to confirm and verify the vaccination, testing or recovery status of the holder of a certificate issued by a third country, such transfer should be limited to the data necessary for the verification of the authenticity, validity and integrity of the certificate and may only be carried out in compliance with the		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
			<u>conditions set out in Chapter V of</u> <u>Regulation (EU) 2016/679.</u>	
35.	(21) To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates for persons receiving vaccines that have been granted marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council ³¹ , for vaccines that have been granted marketing authorisation pursuant to Directive 2001/83/EC of the	(21) For the purpose of facilitating To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence and guidance made available by the Health Security Committee, ECDC and the European Medicines Agency (EMA), an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State and should allow for the waiving of travel restrictions. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates for persons receiving vaccines that have been granted	and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable vaccination certificate should be established. This vaccination certificate should serve to confirm that the holder has received a COVID-19 vaccine in a Member State. The certificate should contain only the necessary information to clearly identify the holder as well as the COVID-19 vaccine, number, date and place of vaccination. Member States should issue vaccination certificates <u>to</u> for persons receiving vaccines that have been granted marketing	

³¹ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

³⁵ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	European Parliament and of the Council ³² , or vaccines whose distribution has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.	marketing authorisation pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council ³³ , for vaccines that have been granted marketing authorisation pursuant to Directive 2001/83/EC of the European Parliament and of the Council ³⁴ , or vaccines whose distribution has been temporarily authorised pursuant to Article 5(2) of Directive 2001/83/EC.	Council ³⁶ , or vaccines whose	
36.	(22) Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the possibility to obtain a certificate on COVID-19 vaccination that complies with this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.	(22) Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should <i>be entitled</i> also have the possibility to obtain a certificate on COVID-19 vaccination that complies with this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.	vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the <u>right</u> <u>possibility</u> to obtain a certificate on COVID-19 vaccination that complies with this Regulation <u>given</u> <u>that the Digital Green Certificate</u>	(22) Persons who have been vaccinated before the date of application of this Regulation, including as part of a clinical trial, should also have the <u>right</u> <u>possibility</u> to obtain a certificate on COVID-19 vaccination that complies with this Regulation <u>given</u> <u>that the Digital Green Certificate</u> <u>provides the mutually accepted</u> <u>framework to facilitate free</u> <u>movement. Where Union citizens</u> <u>or their family members are not in</u>

³² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

³³ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

³⁴ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

³⁶ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p.67).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			possession of a certificate that complies with the requirements of this Regulation, in particular because they have been vaccinated before the entry into force of this Regulation, they should be given every reasonable opportunity to corroborate or prove by other means that they should benefit from the waiving of relevant restrictions to free movement afforded by a Member State. This should not be understood as affecting the obligation of Member States to issue certificates that comply with the requirements of this Regulation nor the right of Union citizens or their family members to receive, from Member States, certificates that comply with the requirements of this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.	possession of a certificate that complies with the requirements of this Regulation, in particular because they have been vaccinated before the entry into force of this Regulation, they should be given every reasonable opportunity to corroborate or prove by other means that they should benefit from the waiving of relevant restrictions to free movement afforded by a Member State. This should not be understood as affecting the obligation of Member States to issue certificates that comply with the requirements of this Regulation nor the right of Union citizens or their family members to receive, from Member States, certificates that comply with the requirements of this Regulation. At the same time, Member States should remain free to issue proofs of vaccination in other formats for other purposes, in particular for medical purposes.	
37.	(23) Member States should also issue such vaccination certificates to Union citizens and their family members who have been vaccinated in a third country and provide reliable proof to that effect.	(23) In line with the principle of non-discrimination, Member States should also issue such vaccination certificates to Union citizens and their family members who have been vaccinated with a COVID-19 vaccine having been granted	(23) Member States should <u>may</u> also issue <u>upon request</u> such vaccination certificates to Union citizens and their family members who have been vaccinated in a third country and provide <u>all necessary</u> <u>information, including</u> reliable		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		market authorisation pursuant to Regulation (EC) No 726/2004 in a third country and provide reliable proof to that effect. Member States should also be able to issue vaccine certificates to Union citizens and their family members who have been vaccinated with a vaccine that has received a WHO Emergency Use Listing, and where they provide reliable proof to that effect.	proof to that effect. <u>This is of</u> <u>particular importance to allow the</u> <u>persons concerned to make use of</u> <u>an interoperable and accepted</u> <u>vaccination certificate when</u> <u>exercising their right of free</u> <u>movement within the Union.</u> <u>There is no requirement for</u> <u>Member States to issue such</u> <u>vaccination certificates at</u> <u>consular posts.</u>		
38.	(24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021 ³⁷ . These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	(24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021 ³⁸ . These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	(24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021 ³⁹ . These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	(24) On 27 January 2021, the eHealth Network adopted guidelines on proof of vaccination for medical purposes, which it updated on 12 March 2021 ⁴⁰ . These guidelines, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	
39.	(25) Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union	(25) Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States <i>should</i> accept proof of vaccination in order to waive restrictions to free movement put in place, in	(25) Already now, several Member States exempt vaccinated persons from certain restrictions to free movement within the Union. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union		

³⁷ Available at : <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof</u> interoperability-guidelines en.pdf

³⁸ Available at : <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

³⁹ Available at : <u>https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf</u>

⁴⁰ Available at : https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
COM (2021) 130 final law, to limit the spread of COVID- 19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-	compliance with Union law, to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, <i>and</i> they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination	7796/21 law, to limit the spread of COVID- 19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation. This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single dose of a vaccine administered, it should do so also for holders of a vaccination certificate indicating a single dose of the same vaccine. On grounds of public health, this obligation should be limited to persons having received COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-		
19 vaccines, such as vaccines having been granted marketing outhorization by the competent	certificates issued for other COVID- 19 vaccines, such as vaccines having hear marketing	19 vaccines, such as vaccines having been granted marketing outhorization by the competent		
authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC,	been granted marketing authorisation by the competent authority of a Member State	authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC,		
vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive	pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based	vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive		
2001/83/EC, or vaccines having	on Article 5(2) of Directive	2001/83/EC, or vaccines having		

received a WHO Emergency Use Listing. 2001/33/EC; or vaccines having received a WHO Emergency Use Listing. received a WHO Emergency Use Existing. 40. (25a) Regulation (EC) No 726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation of the medicinal product concerned in terms of quality, safety and effeacy, are valid in all Member States. In addition. efficacy follow-up and supervision procedures of medicinal products of the procedures of medicinal products of the medicinal product concerned in terms of quality, safety and effeacy, are valid in all Member States. The assessment and approval of vaccines via the centralised procedures of and proval of vaccines via the centralised procedure follows shared standards and is done in a		Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation (EC) No Regulation (EC) No quality, safety and efficacy, are valid in all Member States. In addition, efficacy follow-up and supervision procedures pursuant to Regulation (EC) No 726/2004 are carried out centrally for all Member States. In addition, efficacy follow-up and supervision products authorised pursuant to Regulation f(EC) No 726/2004 are carried out centrally for all Member States. The sasessment and approval of vaccines via the centralised procedure follows shared standards and is done in a		. .	received a WHO Emergency Use	6,		
<u>Consistent way on behalf of all</u> <u>Member States. Member States'</u> participation in the review and	40.			726/2004 puts in place harmonised procedures, involving all Member States, for the authorisation and surveillance of medicinal products at Union level, ensuring that only high quality medicinal products are placed on the market and administered to persons throughout the Union. As a result, the marketing authorisations granted by the Union pursuant to Regulation (EC) No 726/2004, including the underlying evaluation of the medicinal product concerned in terms of quality, safety and efficacy, are valid in all Member States. In addition, efficacy follow-up and supervision procedures of medicinal products authorised pursuant to Regulation (EC) No 726/2004 are carried out centrally for all Member States. The assessment and approval of vaccines via the centralised procedure follows shared standards and is done in a consistent way on behalf of all Member States. Member States'		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
			endorsement of the assessment is ensured through various committees and groups, which also benefits from the expertise from the EU Medicines Regulatory Network. The authorisation via the centralised procedure provides the confidence that all Member States can rely on the authorisation and data on efficacy as well as safety and on the consistency of the batches being used for vaccination of citizens. The obligation to accept, under the same conditions, valid vaccination certificates issued by other Member States should therefore cover COVID-19 vaccines having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004. In order to support the work of WHO and to strive for better global interoperability, Member States are in particular encouraged to accept vaccination certificates issued for other COVID-19 vaccines having received a WHO Emergency Use Listing.	
41.			(25b) This should not prevent Member States from deciding to accept vaccination certificates issued for other COVID-19	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			vaccines, such as vaccines having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, vaccines whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing. Where one of these COVID-19 vaccines is subsequently granted marketing authorisation pursuant to Regulation (EC) No 726/2004, the obligation to accept, under the same conditions, would also cover valid vaccination certificates issued by a Member States for that COVID-19 vaccine, regardless whether the certificates were issued before or after the authorisation via the centralised procedure.		
42.	(26) It is necessary to prevent discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended, or because they have not yet had the opportunity or chose not to be vaccinated. Therefore, possession of a vaccination	(26) It is necessary to prevent <i>any</i> <i>kind</i> of discrimination <i>(direct or</i> <i>indirect)</i> against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently <i>administered</i> recommended, or because they have not yet had the opportunity or chose not to be	(26) It is necessary to prevent discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended <u>or allowed, such as children</u> , or because they have not yet had the opportunity or chose not to be vaccinated. Therefore,	(26) It is necessary to prevent <i>direct or indirect</i> discrimination against persons who are not vaccinated, for example because of medical reasons, because they are not part of the target group for which the vaccine is currently recommended <i>administered</i> or <u>allowed</u> , such as children, or because they have not yet had the	

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public- health-related requirements, and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries.	vaccinated, or where there is no vaccine available yet for certain age categories, like children. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public-health-related requirements, and cannot be a pre- condition to free movement within the Union and to use cross-border passenger transport services such as airlines, trains, coaches, ferries or any other means of transport.	possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public- health-related requirements, and cannot be a pre-condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries.	opportunity or chose not to be vaccinated. Therefore, possession of a vaccination certificate, or the possession of a vaccination certificate indicating a specific vaccine medicinal product, should not be a pre-condition to exercise free movement rights, in particular where those persons are, by other means, able to show compliance with lawful, public-health-related requirements, <u>in particular where</u> those persons are, by other means, able to show compliance with lawful, <u>public health related</u> requirements, and cannot be a pre- condition to use cross-border passenger transport services such as airlines, trains, coaches or ferries or
	(26c) COVID-19 vaccines need to be produced at scale, priced affordably, allocated globally so that they are available where needed, and widely deployed in local communities.		any other means of transport. In addition, this Regulation cannot be interpreted as establishing an obligation or right to be vaccinated.
	(26d) Tackling the pandemic is a prerequisite for social and economic recovery and for the effectiveness of the recovery efforts. The development of COVID-19 vaccines is essential. The problems with serious cases of non-compliance with production		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		and delivery schedules are very concerning.			
43.	(27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts ⁴¹ . As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for	(27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts ⁴³ . As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for	(27) Many Member States have been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts ⁴⁵ . As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743 on the use of rapid antigen tests for	been requiring persons travelling to their territory to undergo a test for SARS-CoV-2 infection before or after arrival. At the beginning of the COVID-19 pandemic, Member States typically relied on reverse transcription polymerase chain reaction (RT-PCR), which is a nucleic acid amplification test (NAAT) for COVID-19 diagnostics considered by the WHO and ECDC as the 'gold standard', that is, the most reliable methodology for testing of cases and contacts ⁴⁷ . As the pandemic has progressed, a new generation of faster and cheaper tests has become available on the European market, the so-called rapid antigen tests, which detect the presence of viral proteins (antigens) to detect an ongoing infection. On 18 November 2020, the Commission adopted Commission Recommendation (EU) 2020/1743	

⁴¹ <u>https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf</u>

⁴³ https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

⁴⁵ https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

⁴⁷ https://www.ecdc.europa.eu/sites/default/files/documents/TestingStrategy_Objective-Sept-2020.pdf

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	the diagnosis of SARS-CoV-2 infection ⁴² .	the diagnosis of SARS-CoV-2 infection ⁴⁴ .	the diagnosis of SARS-CoV-2 infection ⁴⁶ .	the diagnosis of SARS-CoV-2 infection ⁴⁸ .	
44.	(28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID- 19 test results in the EU ⁴⁹ , which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates ⁵⁰ .	(28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID- 19 test results in the EU ⁵¹ , which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates ⁵² .	(28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID- 19 test results in the EU ⁵³ , which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates ⁵⁴ .	(28) On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID- 19 test results in the EU ⁵⁵ , which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates ⁵⁶ .	

- 42 OJ L 392, 23.11.2020, p. 63.
- 44 OJ L 392, 23.11.2020, p. 63.
- 46 OJ L 392, 23.11.2020, p. 63.
- 48 OJ L 392, 23.11.2020, p. 63.
- 49 OJ C 24, 22.1.2021, p. 1.
- https://ec.europa.eu/health/sites/health/files/preparedness response/docs/covid-19 rat common-list en.pdf 50 51
- OJ C 24, 22.1.2021, p. 1.
- 52 https://ec.europa.eu/health/sites/health/files/preparedness response/docs/covid-19 rat common-list en.pdf 53
- OJ C 24, 22.1.2021, p. 1.
- https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf OJ C 24, 22.1.2021, p. 1. 54
- 55
- 56 https://ec.europa.eu/health/sites/health/files/preparedness response/docs/covid-19 rat common-list en.pdf

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
45.	(29) Despite these common efforts, Union citizens and their family members exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, or to lack of trust in the authenticity of the document shown.	(29) Despite these common efforts, <i>persons</i> Union citizens exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, Θr to lack of trust in the authenticity of the document shown, <i>and to the costs of tests</i> .	(29) Despite these common efforts, Union citizens and their family members exercising their free movement right still face problems when trying to use a test result obtained in one Member State in another. These problems are often linked to the language in which the test result is issued, or to lack of trust in the authenticity of the document shown. <u>Such problems are</u> <u>compounded for persons who</u> <u>cannot be vaccinated yet, in</u> <u>particular children, for whom test</u> <u>results may be the only way to</u> <u>travel in case restrictions are in</u> <u>place.</u>		
46.	(30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for	(30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for	(30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for	(30) To improve the acceptance of test results carried out in another Member State when presenting such results for the purposes of exercising free movement, an interoperable test certificate should be established, containing the necessary information to clearly identify the holder as well as the type, date and result of the test for SARS-CoV-2 infection. To ensure the reliability of the test result, only the results of NAAT tests and rapid antigen tests featured in the list established on the basis of Council Recommendation 2021/C 24/01 should be eligible for	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	a test certificate issued on the basis of this Regulation. The common standardised set of data to be included in COVID-19 test result certificates agreed by the Health Security Committee on the basis of Council Recommendation 2021/C 24/01, in particular the preferred code standards, should form the basis for the technical specifications adopted for the purpose of this Regulation.	
47.	(31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.	(31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in <i>order to waive</i> restrictions to free movement put in place to limit the spread of COVID-19.	(31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.	(31) Test certificates issued by Member States in compliance with this Regulation should be accepted by Member States requiring proof of a test for SARS-CoV-2 infection in the context of the restrictions to free movement put in place to limit the spread of COVID-19.	
48.		(31a) Antibodies to SARS-CoV-2 are produced either after a natural infection – either with or without a clinical disease – and after vaccination. While we do not have definitive data yet on the persistence of those antibodies after vaccination, there is abundant evidence that naturally induced antibodies are detectable for several months after the infection. Testing for antibodies therefore allows to identify persons who have			

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		been previously infected and who may have developed immune response and therefore have a very low likelihood to get infected again or infect others.			
49.	(32) According to existing evidence, persons who have recovered from COVID-19 can continue to test positive for SARS- CoV-2 for a certain period after symptom onset ⁵⁷ . Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and the date of a previous positive test	(32) According to existing evidence, persons who have recovered from COVID-19 can continue to test positive for SARS- CoV-2 for a certain period after symptom onset ⁵⁸ . Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. <i>For the purpose of</i> <i>facilitating</i> To facilitate free movement, and <i>of ensuring</i> to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and	(32) According to existing evidence, persons who have recovered from COVID-19 can continue to test positive for SARS- CoV-2 for a certain period after symptom onset ⁵⁹ . Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and the date of a previous positive test	(32) According to existing evidence, persons who have recovered from COVID-19 can continue to test positive for SARS- CoV-2 for a certain period after symptom onset ⁶⁰ . Where such persons are required to undergo a test when seeking to exercise free movement, they may thus be effectively prevented from travelling despite no longer being infectious. <i>For the purpose of</i> <i>facilitating</i> To facilitate free movement, and to ensure that restrictions of free movement currently in place during the COVID-19 pandemic can be lifted in a coordinated manner based on the latest scientific evidence available, an interoperable certificate of recovery should be established, containing the necessary information to clearly identify the person concerned and	

⁵⁷ https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf

⁵⁸ https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf

⁵⁹ https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf

⁶⁰ https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.	the date of a previous positive test for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. <i>The</i> <i>precautionary principle should,</i> <i>however, still apply</i> . The Commission should be empowered to change <i>the validity</i> this period, <i>both the starting and ending points,</i> on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery. <i>In addition, individuals should</i> <i>have the option to undergo a highly</i> <i>specific test for the spike antigen in</i> <i>case they are asymptomatic.</i>	for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.	the date of a previous positive test for SARS-CoV-2 infection. A certificate of recovery should be issued at the earliest from the eleventh day after the first positive NAAT test and should be valid for not more than 180 days. According to ECDC, recent evidence shows that despite shedding of viable SARS-CoV-2 between ten and twenty days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten. The Commission should be empowered to change this period on the basis of guidance from the Health Security Committee or from ECDC, which is closely studying the evidence base for the duration of acquired immunity after recovery.	
50.	(33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States accept proof of recovery in order to waive	(33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States <i>should</i> accept proof of recovery in order to	(33) Already now, several Member States exempt recovered persons from certain restrictions to free movement within the Union. Where Member States accept proof of recovery in order to waive		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS- CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.	waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS-CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, <i>and</i> they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.	restrictions to free movement put in place, in compliance with Union law, to limit the spread of SARS- CoV-2, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation. The eHealth Network, in collaboration with Health Security Committee, is also working on guidelines on recovery certificates and respective datasets.		
51.			(33a) Taking into account the latest scientific and technological developments, the Commission should be empowered to adapt the provisions on the certificate of recovery by providing for its issuance on the basis of a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically reliable method by means of a delegated act. This delegated act should include the necessary data fields on the categories of data to be included in the certificate. It should also contain specific provisions on the maximum validity period as it	(33a) Taking into account the latest scientific and technological developments, the Commission should be empowered to adapt the provisions on the certificate of recovery by providing for its issuance on the basis of a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically reliable method by means of a delegated act. This delegated act should include the necessary data fields on the categories of data to be included in the certificate. It should also contain specific provisions on the maximum validity period as it	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
			might depend on the type of the test carried out. The issuance and acceptance of the certificate of recovery based on the tests and methods mentioned above should be optional.	might depend on the type of the test carried out. The issuance and acceptance of the certificate of recovery based on the tests and methods mentioned above should be optional.
52.	(34) To be able to obtain a common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ⁶¹ to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the virus, the situation of people having	common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ⁶² to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the	(34) To be able to obtain a common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ⁶³ to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19 vaccines, whether vaccines prevent asymptomatic infection and transmission of the virus, the situation of people having	common position quickly, the Commission should be able to ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU of the European Parliament and of the Council ⁶⁴ , <u>the European Center for</u> <u>Disease Prevention and Control or</u> <u>the European Medicines Agency</u> to issue guidance about the available scientific evidence concerning the effects of medical events documented in the certificates established in accordance with this Regulation, including the effectiveness and duration of the immunity conferred by COVID-19

⁶¹ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

⁶² Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

⁶³ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

⁶⁴ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated.	recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated infected. Such information could also form the basis for Council Recommendations to enable a coordinated approach for lifting restrictions on the free movement of holders of certificates.	recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already contaminated.	asymptomatic infection and transmission of the virus, the situation of people having recovered from the virus, and the impacts of the new SARS-CoV-2 variants on people having been vaccinated or already-contaminated <i>infected</i> .
53.	(35) In order to ensure uniform	(35) In order to ensure uniform	(35) In order to ensure uniform	(35) In order to ensure uniform
	conditions for the implementation of	conditions for the implementation of	conditions for the implementation of	conditions for the implementation of
	the trust framework certificates	the trust framework certificates	the trust framework certificates	the trust framework certificates
	established by this Regulation,	established by this Regulation,	established by this Regulation,	established by this Regulation,
	implementing powers should be	implementing powers should be	implementing powers should be	implementing powers should be
	conferred on the Commission.	conferred on the Commission.	conferred on the Commission.	conferred on the Commission.
	Those powers should be <i>exercised</i> in	Those powers should be exercised in	Those powers should be <i>exercised</i> in	Those powers should be exercised in
	accordance with Regulation (EU)	accordance with Regulation (EU)	accordance with Regulation (EU)	accordance with Regulation (EU)
	No 182/2011 of the European	No 182/2011 of the European	No 182/2011 of the European	No 182/2011 of the European
	Parliament and of the Council ⁶⁵ .	Parliament and of the Council ⁶⁶ .	Parliament and of the Council ⁶⁷ .	Parliament and of the Council ⁶⁸ .
54.	(36) The Commission should	(36) The Commission should	(36) The Commission should	(36) The Commission should
	adopt immediately applicable	adopt immediately applicable	adopt immediately applicable	adopt immediately applicable
	implementing acts where, in duly	implementing acts where, in duly	implementing acts where, in duly	implementing acts where, in duly
	justified cases relating to the	justified cases relating to the	justified cases relating to the	justified cases relating to the
	technical specifications necessary to	technical specifications necessary to	technical specifications necessary to	technical specifications necessary to
	establish interoperable certificates,	establish interoperable certificates,	establish interoperable certificates,	establish interoperable certificates,
	imperative grounds of urgency so	imperative grounds of urgency so	imperative grounds of urgency so	imperative grounds of urgency so

- OJ L 55, 28.2.2011, p. 13. OJ L 55, 28.2.2011, p. 13.

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	require or when new scientific evidence becomes available.	require or when new scientific evidence becomes available.	require or when new scientific evidence becomes available.	require or when new scientific evidence becomes available.	
55.	(37) Regulation (EU) 2016/679 of the European Parliament and of the Council ⁶⁹ applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. The legal basis for processing for other purposes is to be provided for in	(37) Regulation (EU) 2016/679 of the European Parliament and of the Council ⁷⁰ applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. The legal basis for processing for other purposes is to be provided for in	(37) Regulation (EU) 2016/679 of the European Parliament and of the Council ⁷¹ applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. <u>Member</u> <u>States may process such data for</u> other purposes, if T the legal basis	(37) Regulation (EU) 2016/679 of the European Parliament and of the Council ⁷² applies to the processing of personal data carried out when implementing this Regulation. This Regulation establishes the legal ground for the processing of personal data, within the meaning of Articles 6(1)(c) and 9(2)(g) of Regulation (EU) 2016/679, necessary for the issuance and verification of the interoperable certificates provided for in this Regulation. It also does not regulate the processing of personal data related to the documentation of a vaccination, test or recovery event for other purposes, such as for the purposes of pharmacovigilance or for the maintenance of individual personal health records. <u>Member</u> <u>States may process such data for</u> other purposes, if T the legal basis	

⁶⁹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁷¹ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁷² Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	national law, which must comply with Union data protection legislation.	national law, which must comply with Union data protection legislation.	for processing <u>of such data</u> for other purposes, <u>including the related</u> <u>retention periods</u> , is to be provided for in national law, which must comply with Union data protection legislation.	for processing <u>of such data</u> for other purposes, <u>including the related</u> <u>retention periods</u> , is to be provided for in national law, which must comply with Union data protection legislation. (37a) <u>Where a Member State</u> <u>requires, based on national law, to</u> <u>use COVID-19 certificates for</u> <u>domestic purposes, it is encouraged</u> to ensure that certificates making <u>up the Digital Green Certificate are</u> <u>accepted for these purposes in</u> <u>order to avoid that persons</u> <u>travelling to another Member State</u> <u>using a certificate making up the</u> <u>Digital Green Certificate would</u> <u>need to obtain an additional</u> <u>national certificate.</u> [EP amendment on Article 8a and 8b, Rows 173 and 175]
56.	(38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the certificates should be set out in this Regulation.	(38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data <i>strictly</i> necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the	minimisation of personal data, the certificates should only contain the personal data necessary for the purpose of facilitating the exercise of the right to free movement within	(38) In line with the principle of minimisation of personal data, the certificates should only contain the personal data <i>strictly</i> necessary for the purpose of facilitating the exercise of the right to free movement within the Union during the COVID-19 pandemic. The specific categories of personal data and data fields to be included in the

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		certificates should be set out in this Regulation.		certificates should be set out in this Regulation.	
57.	(39) For the purposes of this Regulation, personal data may be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In particular, it should allow for the verification of the authenticity of the certificate.	(39) For the purposes of this Regulation, personal data <i>do not</i> <i>need to</i> may <i>be</i> transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In line with the public-key infrastructure approach, only the public keys of the issuers need to be transferred or accessed across borders, which will be ensured by an interoperability gateway set up and maintained by the Commission. In particular, the presence of the certificate combined with the public key of the issuer it should allow for the verification of the authenticity and integrity of the certificate and for the detection of fraud. In line with the principle of data protection by default, verification techniques not requiring transmission of personal data should be employed.	(39) For the purposes of this Regulation, personal data may be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In particular, it should allow for the verification of the authenticity of the certificate.	(39) For the purposes of this Regulation, personal data <u>on</u> <u>individual certificates</u> do not need to be transmitted/exchanged across borders with the sole purpose of obtaining the information necessary to confirm and verify the holder's vaccination, testing or recovery status. In line with the public-key infrastructure approach, only the public keys of the issuers need to be transferred or accessed across borders, which will be ensured by an interoperability gateway set up and maintained by the Commission. In particular, the presence of the certificate combined with the public key of the issuer should allow for the verification of the authenticity and integrity of the certificate. For the prevention and detection of fraud, Member States may exchange lists of revoked certificates. In line with the principle of data protection by default, verification techniques not requiring transmission of personal data <u>on individual certificates</u> should be employed.	
58.	(40) This Regulation does not create a legal basis for retaining	(40) This Regulation <i>prohibits retention of</i> does not create a legal	(40) This Regulation does not create a legal basis for retaining		

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic.	basis for retaining personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic. This Regulation does not create a legal basis for the establishment of any repository of data base at Member State or Union level or through the trust framework digital infrastructure.	personal data obtained from the certificate by the Member State of destination or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic.	basis for retaining personal data obtained from the certificate by the Member State of destination or transit or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic. This Regulation does not provide a legal basis for setting up or maintaining a centralised database at Union level containing personal data. (40a) In accordance with Regulation (EU) 2018/1725, the Commission is to consult the European Data Protection Supervisor when preparing delegated acts or implementing acts that impact on the protection of individuals' rights and freedoms with regard to the processing of personal data. <u>The Commission may also consult the European</u> Data Protection Board where such acts are of particular importance for the protection of individuals' rights and freedoms with regard to the processing of personal data. (40b) In accordance with Regulation 2016/679, the data controllers and processors of personal data are to take adequate technical and organisational

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
				measures to ensure a level of security appropriate to the risk of the processing
59.	(41) To ensure coordination, the Member States and the Commission should be informed when a Member State requires holders of certificates to undergo, after entry into its territory, quarantine/self-isolation or a test for SARS-CoV-2 infection, or if it denies entry to such persons.	Deleted	(41) To ensure coordination, the Member States and the Commission should be informed when a Member State requires holders of certificates to undergo, after entry into its territory, quarantine/self-isolation or a test for SARS-CoV-2 infection, or if it imposes other restrictions on holders of such certificates denies entry to such persons.	
60.		(41a) Clear, comprehensive and timely communication to the public on the issuance, use and acceptance of each type of certificate making up the EU COVID-19 Certificate is crucial to ensure predictability for travel and legal certainty. The Commission should support the Member States' efforts in this regard, for example by making available the information provided by Member States on the 'Re-open EU' web platform.	(41a) Clear, comprehensive and timely communication to the public on the issuance and acceptance of each type of certificate making up the Digital Green Certificate is crucial to ensure predictability for travel and legal certainty. The Commission should support the Member States' efforts in this regard, for example by making available the information provided by Member States on the 'Re-open EU' web platform.	(41a) Clear, comprehensive and timely communication to the public on the issuance and acceptance of each type of certificate making up the Digital Green Certificate is crucial to ensure predictability for travel and legal certainty. The Commission should support the Member States' efforts in this regard, for example by making available the information provided by Member States on the 'Re-open EU' web platform.
61.			(41b) A transitional period should be provided to give Member States the possibility to continue issuing certificates which are not yet in compliance with this	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			Regulation.Duringthetransitionalperiod,suchcertificates as well as certificatesissued before the entry into forceofthisRegulationshouldbeacceptedbyMemberStatesprovidedtheycontainthenecessarydata.		
62.	(42) In accordance with Recommendation (EU) 2020/1475, any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2 should be lifted as soon as the epidemiological situation allows. This also applies to obligations to present documents other than those required by Union law, in particular Directive 2004/38/EC, such as the certificates covered by this Regulation. Therefore, the Regulation. Therefore, the Regulation's provisions on the "Digital Green Certificate" framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery should be suspended once the Director-General of the WHO has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by	(42) In accordance with Recommendation (EU) 2020/1475, any restrictions to the free movement of persons within the Union put in place to limit the spread of SARS-CoV-2 should be lifted as soon as the epidemiological situation allows. This also applies to obligations to present documents other than those required by Union law, in particular Directive 2004/38/EC, such as the certificates covered by this Regulation. Therefore, the Regulation. Therefore, the Regulation. Therefore, the Regulation and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery should be suspended once the Director General of the WHO has declared, in accordance with the International Health Regulations, that the public health emergency of international concern caused by			

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended.	SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended.	SARS-CoV-2 has ended. At the same time, their application should resume if the Director-General of the WHO declares another public health emergency of international concern due to an outbreak of SARS-CoV-2, a variant thereof, or similar infectious diseases with epidemic potential. Where this is the case, the provisions concerned should again be suspended once that public health emergency of international concern has ended. This Regulation should apply for 12 months from the date of its entry into force. (43)-At the latest 3 months before the end of the application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic, the Commission		
63.	(43) The Commission should publish a report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection, one year after the Director-General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended.	(43) This Regulation should apply for 12 months from the date of its entry into force. Four months after the entry into force of this Regulation and at the latest 3 months before the end of its application, the Commission should present publish a report to the European Parliament and the Council on the application of this Regulation, including on its impact on free movement, fundamental rights, the protection of personal	should publish a report on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection. one year after the Director General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended .		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		data, as well as an assessment of the most up-to-date vaccine and testing technologies, and uses by the Member States of the EU COVID-19 Certificate for purposes, based on national law, not provided for in this Regulation on the lessons learned from the application of this Regulation, including on its impact on the facilitation of free movement and data protection, one year after the Director General of the WHO has declared that the public health emergency of international concern caused by SARS-CoV-2 has ended.			
64.	(44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work,	(44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work,	(44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the list of personal data to be included in the certificates covered by this Regulation. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work,	(44) In order to take into account the epidemiological situation and the progress in containing the COVID-19 pandemic and to ensure interoperability with international standards, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the application of certain Articles of this Regulation as well as the <u>list of personal data data fields</u> to be included in the certificates based on the categories of data defined by this Regulation. It is of particular importance that the Commission carry out appropriate	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁷³ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁷⁴ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁷⁵ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016 ⁷⁶ . In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.	
65.	(45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union	(45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union	(45) Since the objectives of this Regulation, namely to facilitate the free movement within the Union during the COVID-19 pandemic by establishing interoperable certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union	certificates on the holder's vaccination, testing and recovery status, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better	

OJ L 123, 12.5.2016, p. 1.

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.	
66.	(46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non- discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.	(46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non- discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.	(46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non- discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.	(46) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights ('Charter'), including the right to respect for private life and family life, the right to the protection of personal data, the right to equality before the law and non- discrimination, the right to free movement and the right to an effective remedy. Member States should comply with the Charter when implementing this Regulation.	
67.		(46a) As far as Member States decide to require national digital certificates for other purposes than free movement at a national level, those should be interoperable with the EU COVID-19 Certificate and respect its safeguards as defined in this regulation, in particular to ensure non-discrimination between different nationalities, non-		[Row 55]	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		discrimination between different certificates, high standards of data protection and to avoid fragmentation.			
68.		(46b) Member States should not introduce restrictions to access to public services with respect to those who do not hold the certificates covered by this Regulation.			
69.		(46c) A list of all the entities foreseen to be acting as controllers, processors and recipients of the data in that Member State shall be made public within a period of one month after the date of entry into force of this Regulation in order to allow the Union citizens making use of the EU COVID-19 Certificate to know the identity of the entity to whom they may turn to for the exercise of their data protection rights under Regulation (EU) 2016/679, including in particular the right to receive transparent information on the ways in which data subject's rights may be exercised with respect to the processing of personal data.			
70.	(47) The European Dat Protection Supervisor has bee		 (47) The European Data Protection Supervisor and the European Data Protection Board have has been consulted pursuant to 	 (47) The European Data Protection Supervisor and the European Data Protection Board have has been consulted pursuant to 	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	consulted pursuant to Article 42(1) of Regulation (EU) 2018/1725 ⁷⁷ ,	pursuant to Article 42(2+) of Regulation (EU) 2018/1725 ⁷⁸ ,	in accordance with Article 42(1) of Regulation (EU) 2018/1725 ⁷⁹ and delivered a joint opinion on 31 March 2021,	in accordance with Article 42(1) of Regulation (EU) 2018/1725 ⁸⁰ and delivered a joint opinion on 31 March 2021,
71.	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:
72.	Article 1 Subject matter	Article 1 Subject matter	Article 1 Subject matter	Article 1 Subject matter
73.	This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery in order to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green Certificate").	This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery in order to facilitate for the <i>purpose of facilitating</i> the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green EU COVID-19 Certificate").	This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery. <u>It shall</u> in order to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic ("Digital Green Certificate").	This Regulation lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery <i>for the purpose of facilitating</i> in order to facilitate the holders' exercise of their right to free movement during the COVID-19 pandemic (<i>"Digital Green Certificate"</i>).

⁷⁷ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁷⁸ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁷⁹ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
				[Mention of "Digital Green Certificate" in the fourth column does not prejudge negotiations on the name of the certificate]	
74.	It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates.	It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates <i>in</i> <i>full compliance with Regulation</i> <i>(EU) 2016/679.</i>	It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates.	It provides for the legal ground to process personal data necessary to issue such certificates and to process the information necessary to confirm and verify the authenticity and validity of such certificates <i>in</i> <i>full compliance with Regulation</i> <i>(EU) 2016/679</i> .	С
75.		It cannot be interpreted as establishing a direct or indirect right or obligation for persons to be vaccinated. This Regulation does not introduce or establish any additional formality or requirement for the exercise of the right to free movement or the right of entry in the territory of the Member States pursuant to Directive 2004/38/EC and Regulation (EU) 2016/399.		[EP amd 2a incorporated in Row 42]	
76.	Article 2 Definitions	Article 2 Definitions	Article 2 Definitions	<i>Article 2</i> <i>Definitions</i>	
77.	For the purposes of this Regulation, the following definitions apply:	For the purposes of this Regulation, the following definitions apply:	For the purposes of this Regulation, the following definitions apply:	For the purposes of this Regulation, the following definitions apply:	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
78.	(1) "holder" means the Union citizen or their family members to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.	(1) "holder" means the Union eitizen or their family members <i>person</i> to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.	(1) "holder" means the person Union citizen or their family members to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.	(1) "holder" means the person Union citizen or their family members to whom an interoperable certificate containing information about his or her vaccination, testing and/or recovery status has been issued in accordance with this Regulation.	
79.	(2) "Digital Green Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;	(2) "Digital Green EU COVID- 19 Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;	(2) "Digital Green Certificate" means interoperable certificates containing information about the vaccination, testing and/or recovery status of the holder issued in the context of the COVID-19 pandemic;		Р
80.	(3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID- 19;	(3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19;	(3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID- 19;	(3) "COVID-19 vaccine" means an immunological medicinal product indicated for active immunisation to prevent COVID-19 caused by severe acute respiratory syndrome coronavirus 2 (SARS- CoV-2);	Р
81.	(4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the	(4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the	(4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the	(4) "NAAT test" means a molecular nucleic acid amplification test (NAAT), such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	SARS-CoV-2 ribonucleic acid (RNA);	SARS-CoV-2 ribonucleic acid (RNA);	SARS-CoV-2 ribonucleic acid (RNA);	SARS-CoV-2 ribonucleic acid (RNA);
82.	(5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes;	(5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes <i>conducted by a trained healthcare professional or other trained operator</i> ;	(5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes;	 (5) "rapid antigen test" means a testing method that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes; [EP position covered in row 93]
83.		(5a) "serology or antibody test" means a laboratory-based test performed on blood samples (serum, plasma, or whole blood) aiming to detect if a person has developed antibodies against SARS-CoV-2, thus indicating that the holder has been exposed to SARS-CoV-2 and has developed antibodies, regardless of whether he or she was symptomatic or not;		(5a) "antibody test" means a laboratory-based test aiming to detect if a person has developed antibodies against SARS-CoV-2, thus indicating that the holder has been exposed to SARS-CoV-2 and has developed antibodies, regardless of whether he or she was symptomatic or not;
84.	(6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;	(6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;	(6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;	(6) "interoperability" means the capability of verifying systems in a Member State to use data encoded by another Member State;
85.	(7) "barcode" means a method of storing and representing data in a visual, machine-readable format;	(7) "barcode" means a method of storing and representing data in a visual, machine-readable format;	(7) "barcode" means a method of storing and representing data in a visual, machine-readable format;	(7) "barcode" means a method of storing and representing data in a visual, machine-readable format;

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
86.	(8) "electronic seal" means data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity;	(8) "electronic seal" means data in electronic form "advanced electronic seal" as defined in Regulation (EU) 910/2014 of the European Parliament and of the Council, which is attached to or and logically associated with other data in electronic form to ensure the latter's origin and integrity;	(8) "electronic seal" means data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity;	 (8) "electronic seal" means electronic seal as defined in Article 3(25) of Regulation (EU) 910/2014 of the European Parliament and of the Council data in electronic form, which is attached to or logically associated with other data in electronic form to ensure the latter's origin and integrity; [EP amd incorporated in row 25] 	Р
87.	(9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation;	Deleted	(9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation;	(9) "unique certificate identifier" means a unique identifier given, in accordance with a common structure, to each certificate issued in accordance with this Regulation; <i>[EP amd incorporated in row 25]</i>	Р
88.	(10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.	(10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.	(10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.	(10) "trust framework" means the rules, policies, specifications, protocols, data formats and digital infrastructure regulating and allowing for the reliable and secure issuance and verification of certificates to guarantee the certificates' trustworthiness by confirming their authenticity, validity and integrity, including by the possible use of electronic seals.	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
89.	Article 3 Digital Green Certificate	Article 3 EU COVID-19 Digital Green Certificate	Article 3 Digital Green Certificate	Article 3 Digital Green Certificate	
90.	1. The interoperable Digital Green Certificate shall allow for the issuance and cross-border verification and acceptance of any of the following certificates:	1. Without prejudice to Article 22 of Regulation (EU) 2016/399 the interoperable Digital Green EU COVID-19 Certificate shall allow for the issuance and cross-border verification and acceptance of any of the following certificates:	1. The interoperable Digital Green Certificate <u>framework</u> shall allow for the issuance and cross- border verification and acceptance of any of the following certificates:	1. The interoperable Digital Green Certificate <u>framework</u> shall allow for the issuance and cross- border verification and acceptance of any of the following certificates: [Council to reflect on EP amendment "Without prejudice to Article 22 of Regulation (EU) 2016/399"]	P/C
91.	(a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');	(a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');	(a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');	(a) a certificate confirming that the holder has received a COVID-19 vaccine in the Member State issuing the certificate ('vaccination certificate');	
92.	(b) a certificate indicating the holder's result and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01 ⁸¹ ('test certificate');	(b) a certificate indicating the holder's result, <i>type</i> and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01 ('test certificate');	(b) a certificate indicating the holder's result, type and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01 ⁸² carried out by health	(b) a certificate indicating the holder's result, type and date of a NAAT test or a rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Council	

⁸¹ Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).

⁸² Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).
	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			professionals in the Member State issuing the certificate ('test certificate');	Recommendation2021/C24/0183carriedoutbyhealthprofessionalsor by skilled testingpersonnelintheMemberStateStateStateissuingthecertificate('testcertificate');StateState	
93.	(c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01 ('certificate of recovery').	(c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01 or having confirmation of an immune response against SARS-CoV-2 by means of a serology or antibody test, including the date of the first positive NAAT test or the date of serological testing for antibodies against SARS-CoV-2 ('certificate of recovery').	(c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test or a positive rapid antigen test listed in the common and updated list of COVID-19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01 ('certificate of recovery').	(c) a certificate confirming that the holder has recovered from a SARS-CoV-2 infection following a positive NAAT test <u>carried out by</u> <u>health professionals or by skilled</u> <u>testing personnel</u> or a positive rapid antigen test listed in the common and updated list of COVID 19 rapid antigen tests established on the basis of Recommendation 2021/C 24/01 ('certificate of recovery'). [Related to the issue of serological tests]	P/C
94.		The Commission shall publish the list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01, including any updates.	The Commission shall publish the list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01, including any updates.	The Commission shall publish the list of COVID-19 rapid antigen tests established on the basis of Council Recommendation 2021/C 24/01, including any updates.	

⁸³ Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU (2021/C 24/01) (OJ C 24, 22.1.2021, p. 1).

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
95.	2. Member States shall issue the certificates referred to in paragraph 1 in a digital or paper-based format, or both. The certificates issued by Member States shall contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English.	2. Member States shall issue the certificates referred to in paragraph 1 in a digital of and a paper-based format, or both. The prospective holders shall be entitled to receive the certificates in the format of their choice. The certificates issued by Member States shall be user-friendly and contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form, shall be accessible to persons with disabilities, and shall be, at least, in the official language or languages of the issuing Member State and English.	designated bodies acting on behalf of Member States, shall issue the certificates referred to in paragraph 1 in a digital or paper-based format, or both. The certificates issued by Member States shall contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English.	 Member States, or designated bodies acting on behalf of Member States, shall issue the certificates referred to in paragraph 1 in a digital or paper-based format, or both. The prospective holders shall be entitled to receive the certificates in the format of their choice. The certificates issued by Member States shall be user- friendly and contain an interoperable barcode allowing for the verification of the authenticity, validity and integrity of the certificate. The barcode shall comply with the technical specifications established in accordance with Article 8. The information contained in the certificates shall also be shown in human-readable form and shall be, at least, in the official language or languages of the issuing Member State and English. 2a. A separate certificate shall not contain data on any previous certificates, except where explicitly provided. 	Р

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
				[Reference to persons with disabilities in row 168 and 25 in Council position] EP am row 179 and 27]	
96.	3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, or the certificate is no longer available to the holder.	3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, <i>including with regard to the</i> <i>vaccination, test or recovery status</i> <i>of the holder</i> , or <i>if</i> the certificate is no longer available to the holder.	3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, or the certificate is no longer available to the holder. <u>Appropriate fees</u> <u>may be charged in case of</u> <u>repeated loss.</u>	3. The certificates referred to in paragraph 1 shall be issued free of charge. The holder shall be entitled to request the issuance of a new certificate if the personal data contained in the certificate is not or no longer accurate or up to date, <i>including with regard to the</i> <i>vaccination, test or recovery status</i> <i>of the holder</i> , or <i>if</i> the certificate is no longer available to the holder. <u>Appropriate fees may be charged</u> <u>in case of repeated loss.</u>	P/C
97.		<i>3a The certificate shall include the following text:</i>	<u>3a</u> The certificate shall include the following text:	<i>3a The certificate shall include the following text:</i>	
98.		"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before travelling, please check the applicable public health measures and related restrictions applied at the point of destination."	"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before traveling, please check the applicable public health measures and related restrictions applied at the point of destination."	"This certificate is not a travel document. The scientific evidence on COVID-19 vaccination, testing and recovery continues to evolve, also in view of new variants of concern of the virus. Before travelling, please check the applicable public health measures and related restrictions applied at the point of destination."	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
99.		The Member State shall provide the holder with clear, comprehensive and timely information on the use of the vaccination certificate, test certificate, and/or recovery certificate for the purposes of this Regulation.		[Article 10 - Row 192] [To be discussed with restrictions]
100.		3b. Possession of a EU COVID- 19 Certificate shall not be a precondition to exercise free movement rights.	3bPossessionofaDigitalGreenCertificateshallnotbeapreconditiontoexercisefreemovementrights.	3b. Possession of a Digital Green Certificate shall not be a precondition to exercise free movement rights.
101.		3c. Issuance of certificates pursuant to paragraph 1 shall not lead to differential treatment and discrimination based on vaccination status or the possession of a specific certificate referred to in Articles 5, 6 and 7. Member States shall ensure universal, accessible, timely and free of charge testing possibilities in order to guarantee the right to free movement inside the Union without discrimination on grounds of economic or financial possibilities.		
102.	4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other	4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other	4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other	4. Issuance of the certificates referred to in paragraph 1 shall not affect the validity of other proofs of vaccination, test or recovery issued before the entry into application of this Regulation or for other

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	purposes, in particular for medical purposes.	purposes, in particular for medical purposes.	purposes, in particular for medical purposes.	purposes, in particular for medical purposes.	
103.		4a. Union transport hubs, such as airports, ports, and railway and bus stations, where the certificates referred to in paragraph 1 are verified shall apply standardised and common criteria and procedures for their verification, on the basis of guidance developed by the Commission.		Member States shall ensure that the verification of the certificates is seamlessly integrated into the operation of transport infrastructure such as airports, ports, and railway and bus stations. [Row 160]	P/C
104.	5. Where the Commission has adopted an implementing act pursuant to the second sub- paragraph, certificates issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non- discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Article 5(5).	5. Where the Commission has adopted an implementing act pursuant to the second sub- paragraph, certificates issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non- discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Article 5(5).	5. Where the Commission has adopted an implementing act pursuant to the second sub- paragraph, certificates <u>equivalent to</u> <u>those</u> issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Articles $5(5)$, <u>6(5) and</u> $7(5)$.	5. Where the Commission has adopted an implementing act pursuant to the second sub- paragraph, certificates <u>equivalent to</u> <u>those</u> issued in accordance with this Regulation by a third country with which the European Union and its Member States have concluded an agreement on free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of European Union acts shall be accepted under the conditions referred to in Articles $5(5)$, <u>6(5) and</u> $7(5)$.	Р
105.	The Commission shall assess whether such a third country issues	The Commission shall assess whether such a third country issues	The Commission shall assess whether such a third country issues	The Commission shall assess whether such a third country issues	Р

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	certificates in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).	certificates in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).	certificates <u>equivalent to those</u> <u>issued</u> in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).	certificates <u>equivalent to those</u> <u>issued</u> in accordance with this Regulation and has provided formal assurances that it will accept certificates issued by the Member States. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).	
106.	6. The Commission may ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1.	6. The Commission may shall ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU, the ECDC and the EMA to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1.		6. <u>Where necessary</u> , the Commission may shall ask the Health Security Committee established by Article 17 of Decision No 1082/2013/EU, the <u>European Center for Disease</u> <u>Prevention and Control or the</u> <u>European Medicines Agency</u> to issue guidance on the available scientific evidence on the effects of medical events documented in the certificates referred to in paragraph 1, <u>in particular in view of newly</u> <u>emerging SARS-CoV-2 variants</u> <u>of concern</u> .	Р
107.		6a. Member States shall make available sufficient resources to implement this Regulation, including to prevent, detect, investigate and prosecute fraud and illicit practices regarding the issuance and use of the EU COVID-19 Certificate.		[Row 24]	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
108	. Article 4 Digital Green Certificate trust framework	Article 4 EU COVID-19 Digital Green Certificate trust framework	Article 4 Digital Green Certificate trust framework	Article 4 Digital Green Certificate trust framework	
109	1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.	1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.	1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3.	1. The Commission and the Member States shall set up and maintain a trust framework digital infrastructure allowing for the secure issuance and verification of the certificates referred to in Article 3. <u>Ia. The trust framework shall be based on a public key</u> infrastructure to verify the integrity and the authenticity of the certificates referred to in Article 3. <u>The trust framework shall allow for</u> detection against fraud, in particular forgery, and may also support the bilateral exchange of certificate revocation lists containing the unique certificate identifiers of revoked certificates. <u>Such certificate revocation lists</u> shall not contain any other personal data. The verification of certificates referred to in Article 3, and where applicable, certificate revocation lists shall not result in the notification of the issuer about the verification. [EP amendment in row 171]	P/C

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
110.	2. The trust framework shall ensure, where possible, interoperability with technological systems established at international level.	2. The trust framework shall ensure, where possible, interoperability with technological systems established at international level.	2. The trust framework shall <u>seek to</u> ensure, where possible, interoperability with technological systems established at international level.	2. The trust framework shall <u>seek to</u> ensure, where possible, interoperability with technological systems established at international level.	Р
111.	3. Where the Commission has adopted an implementing act pursuant to the second sub- paragraph, certificates issued by third countries to Union citizens and their family members according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this sub-paragraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article 5(5).	3. Where the Commission has adopted an implementing act pursuant to the second sub- paragraph, certificates issued by third countries to Union citizens and their family members, <i>as well as to</i> <i>nationals or residents of Andorra,</i> <i>Monaco, San Marino and the</i> <i>Vatican/Holy See</i> , according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this sub-paragraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under	3. Where the Commission has adopted an implementing act pursuant to the second sub- paragraph, certificates issued by third countries to Union citizens and their family members according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this sub-paragraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article $\frac{5(5)}{}$.	[moved to row 153]	

	Commission proposal COM (2021) 130 final	EP position the conditions referred to in Article 5(5).	Council position 7796/21	Compromise text	
112.	The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).	The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2). The Commission shall also keep a publicly accessible register of those third countries that fulfil the conditions of issuing certificates within the meaning of this Regulation.	The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).	[Taking up in Article 7a]	P/C
113.	<i>Article 5</i> <i>Vaccination certificate</i>	<i>Article 5</i> Vaccination certificate	<i>Article 5</i> <i>Vaccination certificate</i>	<i>Article 5</i> Vaccination certificate	
114.	1. Each Member State shall issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.	1. Each Member State shall <i>automatically</i> issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.	1. Each Member State shall issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered, either automatically or upon request by that person.	1. Each Member State shall automatically issue vaccination certificates as referred to in Article 3(1)(a) to a person to whom a COVID-19 vaccine has been administered., either automatically or upon request by that person. <u>A</u> certificate may also be issued upon request, provided that the person concerned is informed about its right to receive such a certificate	P/C

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
				and that it can be obtained easily and swiftly.	
115.	2. The vaccination certificate shall contain the following categories of personal data:	2. The vaccination certificate shall contain the following categories of personal data:	2. The vaccination certificate shall contain the following categories of personal data:	2. The vaccination certificate shall contain the following categories of personal data:	С
116.	(a) identification of the holder;	(a) identification of the holder;	(a) identification of the holder;	(a) identification of the holder;	
117.	(b) information about the vaccine medicinal product administered;	(b) information about the vaccine medicinal product administered <i>and</i> <i>information about the number of</i> <i>doses and dates</i> ;	(b) information about the vaccine medicinal product administered;	(b) information about the vaccine medicinal product administered <i>and</i> <i>information about the number of</i> <i>doses and dates</i> ;	С
118.	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier .	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.[EP amd - row 25]	Р
119.	The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.	The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.	The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.	The personal data shall be included in the vaccination certificate in accordance with the specific data fields set out in point 1 of the Annex.	С
120.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, or by adding data fields falling under on—the categories of personal data	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, on the categories of personal data mentioned in this paragraph where such amendment is necessary to confirm or verify the authenticity,	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 1 of the Annex by adding, modifying or removing data fields, or by adding data fields falling under on—the categories of personal data mentioned in <i>points (b) and (c) of</i> this paragraph, where such	P/C

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		mentioned in <i>points (b) and (c) of</i> this paragraph.	validityandintegrityofthecertificate,incaseofscientificprogressincontainingtheCOVID-19pandemic or to ensureinteroperabilitywithinternational standards.	amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate, in case of scientific progress in containing the COVID-19 pandemic, or to ensure interoperability with international standards.	
121.	3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) and shall clearly indicate whether or not the vaccination course has been completed.	3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) and shall clearly indicate whether or not the vaccination course <i>for that specific vaccine</i> has been completed.	3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) <u>after the</u> <u>administration of each dose</u> and shall clearly indicate whether or not the vaccination course has been completed.	3. The vaccination certificate shall be issued in a secure and interoperable format as provided for in Article 3(2) <u>after the</u> <u>administration of each dose</u> and shall clearly indicate whether or not the vaccination course has been completed.	Р
122.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	
123.	5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid	5. Where Member States <i>shall</i> accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, <i>and</i> they shall also accept, under the same	5. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept, under the same conditions, valid		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	vaccination certificates issued by other Member States in compliance with this Regulation for a COVID- 19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.	conditions, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.	vaccination certificates issued by other Member States in compliance with this Regulation for a COVID- 19 vaccine having been granted marketing authorisation pursuant to Regulation (EC) No 726/2004.		
124.	Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID- 19 vaccine having received a WHO Emergency Use Listing.	Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID- 19 vaccine having received a WHO Emergency Use Listing.	Member States may also accept, for the same purpose, valid vaccination certificates issued by other Member States in compliance with this Regulation for a COVID-19 vaccine having been granted marketing authorisation by the competent authority of a Member State pursuant to Directive 2001/83/EC, a COVID-19 vaccine whose distribution has been temporarily authorised based on Article 5(2) of Directive 2001/83/EC, or a COVID- 19 vaccine having received a WHO Emergency Use Listing. <u>Where</u> <u>Member States accept valid</u> <u>vaccination certificates issued in</u> <u>compliance with this Regulation</u> <u>for a COVID-19 vaccine having</u> <u>been granted marketing</u> <u>authorisation by the competent</u> <u>authoristion by the competent</u> <u>authoristion has been temporarily</u> <u>authorised based on Article 5(2) of</u> <u>Directive 2001/83/EC, or a</u>		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			COVID-19vaccinehavingreceived a WHO Emergency UseListing they shall also accept,under the same conditions, validvaccination certificates issued byother Member States.		
125.	6. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with one of the types of COVID-19 vaccines referred to in paragraph 5 of this Article, and where the authorities of a Member State have been provided with all necessary information, including reliable proof of vaccination, they shall issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned.	6. Where a Union citizen or a family member of a Union citizen or a national or resident of Andorra, Monaco, San Marino and the Vatican/Holy See, has been vaccinated in a third country with one of the types of COVID-19 vaccines referred to in paragraph 5 of this Article, and where the authorities of a Member State have been provided with all necessary information, including reliable proof of vaccination certificate as referred to in Article 3(1)(a) to the person concerned.	6. Where a Union citizen or a family member of a Union citizen has been vaccinated in a third country with one of the types of COVID-19 vaccines referred to in paragraph 5 of this Article, and where the authorities of a Member State have been provided with all necessary information, including reliable proof of vaccination, they shall issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned.	[Moved to Row 152]	
126.	<i>Article 6</i> <i>Test certificate</i>	Article 6 Test certificate	Article 6 Test certificate	<i>Article 6</i> <i>Test certificate</i>	
127.	1. Each Member State shall issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.	1. Each Member State shall <i>automatically</i> issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.	1. Each Member State shall issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person.	1. Each Member State shall <i>automatically</i> issue test certificates as referred to in Article 3(1)(b) to persons tested for COVID-19, either automatically or upon request by that person. <u>A certificate may also be issued upon request, provided</u>	P/C

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
				that the person concerned is informed about its right to receive such a certificate and that it can be obtained easily and swiftly.	
128.	2. The test certificate shall contain the following categories of personal data:	2. The test certificate shall contain the following categories of personal data:	2. The test certificate shall contain the following categories of personal data:	2. The test certificate shall contain the following categories of personal data:	C
129.	(a) identification of the holder;	(a) identification of the holder;	(a) identification of the holder;	(a) identification of the holder;	
130.	(b) information about the test carried out;	(b) information about the test carried out;	(b) information about the test carried out;	(b) information about the test carried out;	
131.	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier .	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.	 (c) certificate metadata, such as the certificate issuer or a unique certificate identifier. [EP amd - row 25] 	Р
132.	The personal data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.	The personal data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.	The personal data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.	The personal data shall be included in the test certificate in accordance with the specific data fields set out in point 2 of the Annex.	С
133.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields, or by adding data fields falling under on the categories of personal data mentioned in points (b) and (c) of this paragraph.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields on the categories of personal data mentioned in this paragraph where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 2 of the Annex by adding, modifying or removing data fields, or by adding data fields falling under on the categories of personal data mentioned in points (b) and (c) of this paragraph, where such amendment is necessary to	P/C

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			certificate, in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.	confirm or verify the authenticity, validity and integrity of the certificate, in case of scientific progress in containing the COVID-19 pandemic, or to ensure interoperability with international standards.	
134.	3. The test certificate shall be issued in a secure and interoperable format as provided for in Article $3(2)$.	3. The test certificate shall be issued in a secure and interoperable format as provided for in Article $3(2)$.	3. The test certificate shall be issued in a secure and interoperable format as provided for in Article $3(2)$.	3. The test certificate shall be issued in a secure and interoperable format as provided for in Article $3(2)$.	
135.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	
136.	5. Where Member States require proof of a test for SARS-CoV-2 infection as part of the restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, they shall also accept valid test certificates issued by other Member States in compliance with this Regulation.	5. Where Member States shall accept proof of a negative test for SARS-CoV-2 infection in order to waive restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, and they shall also accept valid test certificates issued by other Member States in compliance with this Regulation.	5. Where Member States require proof of a test for SARS-CoV-2 infection as part of the restrictions to free movement put in place, in compliance with Union law <u>and</u> <u>taking into account the specific</u> <u>situation of cross-border</u> <u>communities</u> , to limit the spread of COVID-19, they shall also accept <u>,</u> <u>under the same conditions</u> , valid test certificates issued by other		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21 Member States in compliance with this Regulation.	Compromise text
137.	<i>Article 7</i> <i>Certificate of recovery</i>	<i>Article 7</i> <i>Certificate of recovery</i>	<i>Article 7</i> <i>Certificate of recovery</i>	<i>Article 7</i> <i>Certificate of recovery</i>
138.	1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.	1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection, or after submission of a subsequent negative NAAT test. It shall also be possible to issue a certificate of recovery through the detection of antibodies by a serological test.	1. Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c) at the earliest from the eleventh day after a person has received his or her first positive test for SARS-CoV-2 infection.	 Each Member State shall issue, upon request, certificates of recovery as referred to in Article 3(1)(c). <u>The certificate of recovery shall be</u> issued at the earliest from the eleventh day after a person has received his or her first positive NAAT test for SARS-CoV-2 infection. [Amendment linked to the possibility to issuing recovery certificate on the basis of antibodies test – political]
139.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the number of days as of which a certificate of recovery may be issued, based on guidance received from the Health Security Committee in accordance with Article 3(6) or on scientific evidence reviewed by ECDC.
140.		The Commission is empowered to adopt delegated acts in accordance with Article 11 to establish and		[Row 148]

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		amend the types of serological tests for antibodies against SARS-CoV-2 in respect of which a certificate of recovery may be issued, based on scientific evidence reviewed by ECDC.			
141.	2. The certificate of recovery shall contain the following categories of personal data:	2. The certificate of recovery shall contain the following categories of personal data:	2. The certificate of recovery shall contain the following categories of personal data:	2. The certificate of recovery shall contain the following categories of personal data:	С
142.	(a) identification of the holder;	(a) identification of the holder;	(a) identification of the holder;	(a) identification of the holder;	
143.	(b) information about past SARS-CoV-2 infection;	(b) information about past SARS-CoV-2 infection documented by a positive NAAT test, or outcome of serology test;	(b) information about past SARS-CoV-2 infection <u>following a</u> <u>positive test</u> ;	(b) information about past SARS-CoV-2 infection <u>following a</u> <u>positive test</u> ;	Р
144.	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.	(c) certificate metadata, such as the certificate issuer-or a unique certificate identifier.	(c) certificate metadata, such as the certificate issuer or a unique certificate identifier.	 (c) certificate metadata, such as the certificate issuer or a unique certificate identifier. [EP amd - row 25] 	Р
145.	The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.	The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.	The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.	The personal data shall be included in the certificate of recovery in accordance with the specific data fields set out in point 3 of the Annex.	С
146.	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields on the categories of personal data	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields on the categories of personal data	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields on the categories of personal data	The Commission is empowered to adopt delegated acts in accordance with Article 11 to amend point 3 of the Annex by adding, modifying or removing data fields, or by adding data fields falling under on-the	P/C

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	mentioned in this paragraph, including until when a certificate of recovery shall be valid.	mentioned in this paragraph, including until when a certificate of recovery shall be valid, or by adding data fields falling under the categories of personal data mentioned in points (b) and (c) of this paragraph.	mentioned in this paragraph, including until when a certificate of recovery shall be valid, where such amendment is necessary to confirm or verify the authenticity, validity and integrity of the certificate, in case of scientific progress in containing the COVID-19 pandemic or to ensure interoperability with international standards.	categories of personal data mentioned in <i>points (b) and (c) of</i> this paragraph, <u>where such</u> <u>amendment is necessary to</u> <u>confirm or verify the authenticity,</u> validity and integrity of the <u>certificate, in case of scientific</u> <u>progress in containing the</u> <u>COVID-19 pandemic, or to ensure</u> <u>interoperability with</u> <u>international standards.</u>	
147.	3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).	3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).	3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).	3. The certificate of recovery shall be issued in a secure and interoperable format as provided for in Article 3(2).	
148.			<u>3a</u> Based on guidance received pursuant to Article 3(6), the Commission is empowered to adopt delegated acts in accordance with Article 11 to amend the provisions in Article 3(1)(c) and Article 7(1) to allow for the issuance of the certificate of recovery also based on a positive rapid antigen test, serological testing for antibodies against SARS-CoV-2 or any other scientifically validated method. Any such delegated act shall add, modify or remove the data fields on the categories of data included in the certificate. The issuance and acceptance of the certificate of	3a Based on guidance <u>received pursuant to Article</u> 3(6), the Commission is <u>empowered to adopt delegated</u> <u>acts in accordance with Article</u> 11 to amend the provisions in <u>Article 3(1)(c) and Article 7(1)</u> <u>to allow for the issuance of the</u> <u>certificate of recovery also</u> <u>based on a positive rapid</u> <u>antigen test, serological testing</u> <u>for antibodies against SARS-</u> <u>CoV-2 or any other</u> <u>scientifically validated method.</u> <u>Any such delegated act shall</u> <u>add, modify or remove the data</u>	Ρ

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			recovery based on the tests and methods mentioned in this paragraph shall be optional.	fields on the categories of data included in the certificate. The issuance and acceptance of the certificate of recovery based on the tests and methods mentioned in this paragraph shall be optional. 3b. Following the adoption of the delegated act described in paragraph 3a, the Commission shall establish and maintain a list of antibody tests on the basis of which a certificate of recovery may be issued, based on guidance received from ECDC.	
149.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of newly emerging scientific evidence or to ensure interoperability with international standards and technological systems, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	
150.	5. Where Member States accept proof of recovery from SARS-CoV- 2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID- 19, they shall accept, under the same	5. Where Member States <i>shall</i> accept proof of recovery from SARS-CoV-2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID-19, <i>and</i> they	5. Where Member States accept proof of recovery from SARS-CoV- 2 infection as a basis for waiving restrictions to free movement put in place, in compliance with Union law, to limit the spread of COVID- 19, they shall accept, under the same		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.	shall accept, under the same conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.	conditions, valid certificates of recovery issued by other Member States in compliance with this Regulation.		
151.			<u>New Article 7a</u> <u>COVID-19 certificates and other</u> <u>documentation issued by a third</u> <u>country</u>	<u>New Article 7a</u> <u>COVID-19 certificates and other</u> <u>documentation issued by a third</u> <u>country</u>	
152.		6. Where a Union citizen or a family member of a Union citizen or a national or resident of Andorra, Monaco, San Marino and the Vatican/Holy See, has been vaccinated in a third country with one of the types of COVID-19 vaccines referred to in paragraph 5 of this Article, and where the authorities of a Member State have been provided with all necessary information, including reliable proof of vaccination, they shall issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned. [Moved from row 125 for reference purposes]	1. Where a vaccination certificate has been issued in a third country for a vaccine medicinal product that corresponds to one of the COVID- 19 vaccines referred to Article 5(5) and where the authorities in a Member State have been provided with all necessary information, including reliable proof of vaccination, they may, upon request, issue a vaccination certificate as referred to in Article 3(1)(a) to the person concerned. A Member State shall not be required to issue a certificate for a vaccine not authorised for use on its territory.		
153.		3. Where the Commission has adopted an implementing act pursuant to the second sub-	2. Where the Commission has adopted an implementing act pursuant to the second sub-	2. Where the Commission has adopted an implementing act pursuant to the second sub-	

Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	paragraph, certificates issued by third countries to Union citizens and their family members, <i>as well as to</i> <i>nationals or residents of Andorra,</i> <i>Monaco, San Marino and the</i> <i>Vatican/Holy See</i> , according to an international standard and technological system that are interoperable with the trust framework established on the basis of this Regulation and that allows for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union. For the purposes of this sub-paragraph, the acceptance, by the Member States, of vaccination certificates issued by third countries shall take place under the conditions referred to in Article 5(5). <i>[Moved from row 111 for</i> <i>reference purposes]</i>	paragraph, certificates referred to in Article 3 issued by third countries according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation that allow for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union.	paragraph, certificates referred to in Article 3 issued by third countries according to a standard and technological system that are interoperable with the trust framework established on the basis of this Regulation that allow for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex shall be treated like certificates issued by Member States in accordance with this Regulation, for the purpose of facilitating the holders' exercise of their right to free movement within the European Union.	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
154.		The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2). The Commission shall also keep a publicly accessible register of those third countries that fulfil the conditions of issuing certificates within the meaning of this Regulation. [Moved from row 112 for reference purposes]	The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2).	The Commission shall assess whether certificates issued by a third country fulfil the conditions set out in this paragraph. In that case, it shall adopt an implementing act in accordance with the examination procedure referred to in Article 13(2). The Commission shall make available the list of implementing acts adopted pursuant to this subparagraph.	Р
155.			3. For the purposes of this article, the acceptance by the Member States of certificates issued pursuant to this Article, shall take place under the conditions referred to in Articles 5(5), 6(5) and 7(5).	3. For the purposes of this article, the acceptance by the Member States of certificates issued pursuant to this Article, shall take place under the conditions referred to in Articles 5(5), 6(5) and 7(5).	Р
156.			4. If a Member State accepts a certificate for a COVID-19 vaccine referred to in Article 5(5) second subparagraph issued pursuant to this Article, it shall also accept certificates for the same COVID-19 vaccine issued by a Member State.	4. If a Member State accepts a certificate for a COVID-19 vaccine referred to in Article 5(5) second subparagraph issued pursuant to this Article, it shall also accept certificates for the same COVID-19 vaccine issued by a Member State.	Р

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
157.			5. This Article shall also apply to COVID-19 certificates and other documentation issued by Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and by the Faroe Islands. It shall not apply to COVID-19 certificates and other documentation issued in Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and in the Faroe Islands, issued on behalf of a Member State.	5. This Article shall also apply to COVID-19 certificates and other documentation issued by Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and by the Faroe Islands. It shall not apply to COVID-19 certificates and other documentation issued in Overseas Countries and Territories referred to in Article 355(2) TFEU and listed in its Annex II, and in the Faroe Islands, issued on behalf of a Member State.	Р
158.	Article 8 Technical specifications	Article 8 Technical specifications	Article 8 Technical specifications	Article 8 Technical specifications	
159.	To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:	To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:	To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:	To ensure uniform conditions for implementation of the trust framework established by this Regulation, the Commission shall adopt implementing acts containing the technical specifications and rules to:	
160.	(a) securely issue and verify the certificates referred to Article 3;	(a) securely issue and verify the certificates referred to Article 3;	(a) securely issue and verify the certificates referred to Article 3;	(a) securely issue and verify the certificates referred to Article 3;	
161.	(b) ensure the security of the personal data, taking into account the nature of the data;	(b) ensure the security of the personal data, taking into account the nature of the data;	(b) ensure the security of the personal data, taking into account the nature of the data;	(b) ensure the security of the personal data, taking into account the nature of the data;	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
162.	(c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;	(c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;	(c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;	(c) populate the certificates referred to Article 3, including the coding system and any other relevant elements;	
163.	(d) lay down the common structure of the unique certificate identifier;	(d) lay down the common structure of the unique certificate identifier;	(d) lay down the common structure of the unique certificate identifier;	(d) lay down the common structure of the unique certificate identifier;[<i>EP amd – row 25</i>]	Р
164.	(e) issue a valid, secure and interoperable barcode;	(e) issue a valid, secure and interoperable barcode;	(e) issue a valid, secure and interoperable barcode;	(e) issue a valid, secure and interoperable barcode;	
165.	(f) ensure interoperability with international standards and/or technological systems;	(f) ensure interoperability with international standards and/or technological systems;	(f) ensure, where possible, interoperability with international standards and/or technological systems;	(f) <u>seek to</u> ensure interoperability with international standards and/or technological systems;	Р
166.	(g) allocate responsibilities amongst controllers and as regards processors.	(g) allocate responsibilities amongst controllers and as regards processors <i>in accordance with</i> <i>Chapter IV of Regulation</i> 2016/679;	(g) allocate responsibilities amongst controllers and as regards processors, <u>in accordance with</u> <u>Article 28(3) of Regulation</u> <u>2016/679</u> .	(g) allocate responsibilities amongst controllers and as regards processors, <i>in accordance with</i> <i>Chapter IV of Regulation</i> 2016/679.	С
167.		(ga) establish processes for a regular testing, assessment and evaluation of the effectiveness of the data protection and security measures adopted.			
168.		(gb) ensure accessibility for persons with disabilities to the human-readable information contained in the digital certificate		(gb) ensure accessibility for persons with disabilities to the human-readable information contained in the digital certificate	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		and in the paper-based certificate, in line with Union harmonised accessibility requirements.		and in the paper-based certificate in line with the accessibility requirements included in Union law legislation.	
169.	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2). When the envisaged implementing act concerns the processing of personal data, the Commission shall consult the EDPS, and, where applicable, may consult the EDPB.	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 13(2). [EP amd. Row 58]	Р
170.	On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).	On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).	On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3).	On duly justified imperative grounds of urgency, in particular to ensure a timely implementation of the trust framework, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 13(3). <u>Implementing acts</u> <u>adopted on the basis of this sub- paragraph shall remain in force for the duration of the applicability of this Regulation.</u>	Р
171.		The trust framework shall be based on a public key infrastructure to verify the integrity of the EU COVID-19 Certificates and the authenticity of the electronic seals. The trust framework shall allow for		[Row 109]	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		detection against fraud, in particular forgery, and shall ensure that the verification of EU COVID- 19 Certificates and electronic seals does not inform the issuer about the verification.			
172.		Article 8a National digital certificates and interoperability with the EU COVID-19 Certificate trust framework		[Row 55]	
173.		Where a Member State has adopted or adopts a national digital certificate for purely domestic purposes, it shall ensure that it is fully interoperable with the EU COVID-19 Certificate trust framework. The same safeguards as in this Regulation shall apply.		[Row 55]	
174.		Article 8b Further use of the EU COVID-19 Certificate framework			
175.		Where a Member State seeks to implement the EU COVID-19 Certificate for any possible use other than the intended purpose of facilitating free movement between Member States, that Member State shall create a legal basis under national law, complying with the		[Row 55]	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		principles of effectiveness, necessity, and proportionality, including specific provisions clearly identifying the scope and extent of the processing, the specific purpose involved, the categories of entities that can verify the certificate as well as the relevant safeguards to prevent discrimination and abuse, taking into account the risks to the rights and freedoms of data subjects. No data shall be retained in the context of the verification process.			
176.	Article 9 Protection of personal data	Article 9 Protection of personal data	Article 9 Protection of personal data	Article 9 Protection of personal data	
177.			0. <u>Regulation (EU) 2016/679</u> <u>shall apply to the processing of</u> <u>personal data carried out when</u> <u>implementing this Regulation.</u>	0. <u>Regulation (EU) 2016/679</u> <u>shall apply to the processing of</u> <u>personal data carried out when</u> <u>implementing this Regulation.</u>	
178.	1. The personal data contained in the certificates issued in accordance with this Regulation shall be processed for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic.	1. Regulation (EU) 2016/679 shall apply to the processing of personal data carried out when implementing this Regulation. The personal data contained in the certificates issued in accordance with this Regulation shall be processed only for the purpose of accessing and verifying the information included in the certificate in order to facilitate the	1. The personal data contained in the certificates issued in accordance with this Regulation shall be processed <u>only</u> for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic.	1. <u>For the purpose of this</u> <u>Regulation</u> , the personal data contained in the certificates issued in accordance with this Regulation shall be processed <u>only</u> for the purpose of accessing and verifying the information included in the certificate in order to facilitate the exercise of the right of free movement within the Union during the COVID-19 pandemic. <u>After the</u>	P/C

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		exercise of the right of free movement within the Union during the COVID-19 pandemic as provided for in this Regulation and until it ceases to apply.		end of applicability of this Regulation, no further processing shall occur.	
179.	2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.	2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, <i>only</i> to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained <i>or processed by</i> <i>the verifier for other purposes. A</i> <i>separate independent certificate</i> <i>shall be issued for each</i> <i>vaccination, test or recovery, and</i> <i>no history of the previous</i> <i>certificates of the holder shall be</i> <i>stored on the certificate.</i>	2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination <u>or</u> <u>transit</u> , or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained.	2. The personal data included in the certificates referred to in Article 3 shall be processed by the competent authorities of the Member State of destination <u>or</u> transit, or by the cross-border passenger transport services operators required by national law to implement certain public health measures during the COVID-19 pandemic, <i>only</i> to confirm and verify the holder's vaccination, testing or recovery status. For this purpose, the personal data shall be limited to what is strictly necessary. The personal data accessed pursuant to this paragraph shall not be retained. [EP addition – row 95]	Р
180.	3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new	3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new	3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new	3. The personal data processed for the purpose of issuing the certificates referred to in Article 3, including the issuance of a new	Р

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
	certificate, shall not be retained longer than is necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.	certificate, shall not be retained by the issuer longer than is strictly necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement, after which the personal data shall be erased immediately and irrevocably. There shall be no centralised processing or retention of the personal data included in the certificate at Member State or Union level.	certificate, shall not be retained longer than is necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement.	certificate, shall not be retained <i>by</i> <i>the issuer</i> longer than is <i>strictly</i> necessary for its purpose and in no case longer than the period for which the certificates may be used to exercise the right to free movement. <i>[Row 58]</i>	
181.	4. The authorities responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.	4. The authorities or other designated bodies responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679. By [one month after the date of entry into force of this Regulation], the Member States shall make public the entities foreseen to be acting as controllers, processors and recipients of the data and communicate this information to the Commission and any modifications thereto regularly after that date. By [two months after the entry into force of this Regulation], the Commission shall publish the collected information in	4. The authorities <u>or other</u> <u>designated bodies</u> responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.	4. The authorities <u>or other</u> <u>designated bodies</u> responsible for issuing the certificates referred to in Article 3 shall be considered as controllers referred to in Article 4(7) of Regulation (EU) 2016/679.	Р

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		a publicly accessible list and keep that public list up to date.			
182.			4a. The natural or legal person, public authority, agency or other body that has administered the vaccine or carried out the test for which a certificate is to be issued shall transmit to the authorities or other designated bodies responsible for issuing the certificates the categories of data referred to in Articles 5(2), 6(2) and 7(2) necessary to complete the data fields set out in the Annex.	4a. The natural or legal person, public authority, agency or other body that has administered the vaccine or carried out the test for which a certificate is to be issued shall transmit to the authorities or other designated bodies responsible for issuing the certificates the categories of data referred to in Articles 5(2), 6(2) and 7(2) necessary to complete the data fields set out in the Annex.	
183.		5. The data controllers and processors shall take adequate technical and organisational measures to ensure a level of security appropriate to the risk of the processing.		[Row 58]	Р
184.		6. Where a controller referred to in paragraph 4 enlists a processor, in application of Article 28(3) of Regulation (EU) 2016/679, no transfer of personal data by the processor to a third country may take place.		6. Where a controller referred to in paragraph 4 enlists a processor, in application of Article 28(3) of Regulation (EU) 2016/679, no transfer of personal data by the processor to a third country may take place.	С
185.	<i>Article 10</i> <i>Notification procedure</i>	Article 10	Article 10 <u>Information exchange Notification</u> procedure		

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
		EU COVID-19 Certificate and travel restrictions		
186.		Member States shall not introduce and implement additional travel restrictions such as quarantine, self-isolation or a test for SARS- CoV-2 infection, or any discriminatory measures for holders of certificates referred to in Article 3, upon the introduction of the EU COVID-19 Certificate.	0. <u>Member States shall inform</u> other Member States and the <u>Commission on the issuance and</u> acceptance of the certificates referred to in Article 3 and the conditions thereof, including which vaccines they accept pursuant to Article 5(5) second subparagraph.	
187.	1. Where a Member State requires holders of certificates referred to in Article 3 to undergo, after entry into its territory, quarantine, self-isolation or a test for SARS-CoV-2 infection, or if it denies entry to such persons, it shall notify the other Member States and the Commission before the planned introduction of such restrictions. To that end, the Member State shall supply the following information:	Deleted	1. Where a Member State requires holders of certificates referred to in Article 3 to undergo, after entry into its territory, quarantine, self-isolation or a test for SARS-CoV-2 infection, or if it imposes other restrictions on holders of such certificates denies entry to such persons, it shall inform , notify the other Member States and the Commission thereof, if possible 48 hours in advance of the introduction of new measures. before the planned introduction of such restrictions. To that end, the Member State shall supply the following information:	
188.	(a) the reasons for such restrictions, including all relevant	Deleted	(a) the reasons for such restrictions including all relevant	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	epidemiological data supporting such restrictions;		epidemiological data supporting such restrictions;	
189.	(b) the scope of such restrictions, specifying which travellers are subject to or exempt from such restrictions;	Deleted	(b) the scope of such restrictions, specifying <u>the holders of which</u> <u>certificates</u> which travellers are subject to or exempt from such restrictions;	
190.	(c) the date and duration of the restrictions.	Deleted	(c) the date and duration of the restrictions.	
191.	Where necessary, the Commission may request additional information from the Member State concerned.	Deleted	Where necessary, the Commission may request additional information from the Member State concerned.	
192.			1a.MemberStatesshallprovidethepublicwithclear,comprehensiveandtimelyinformationonthetopicscoveredbyparagraphs1and2.Asgeneralrule,thisinformationshouldbepublished24hoursbeforethemeasurescomeintoeffect,takingintoaccountthatsomeflexibilityisrequiredforepidemiologicalemergences.TheinformationinformationprovidedbytheMemberStatesmay also bemadepubliclyavailablebytheCommissioninacentralisedmanner.	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
193.	<i>Article 11</i> <i>Exercise of the delegation</i>	<i>Article 11</i> <i>Exercise of the delegation</i>	<i>Article 11</i> <i>Exercise of the delegation</i>	Article 11 Exercise of the delegation
194.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
195.	2. The power to adopt delegated acts referred to in Articles 5(2), 6(2), 7(1), 7(2) and 15 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force].	2. The power to adopt delegated acts referred to in Articles $5(2)$, $6(2)$, $7(1)$ and $7(2)$ and 15 shall be conferred on the Commission for <i>a</i> period of <i>12 months</i> from [date of entry into force].	2. The power to adopt delegated acts referred to in Articles $5(2)$, $6(2)$, $7(1)$ and, $7(2)$ and 15 shall be conferred on the Commission for an indeterminate period of time from [date of entry into force].	2. The power to adopt delegated acts referred to in Articles $5(2)$, $6(2)$, $7(1)$ and $7(2)$ and 15 shall be conferred on the Commission for <i>a</i> period of <i>12 months</i> from [date of entry into force].
196.	3. The delegation of power referred to in Articles 5(2), 6(2), 7(1), 7(2) and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the <i>Official Journal of the European Union</i> or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles $5(2)$, $6(2)$, $7(1)$ and $7(2)$ and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles $5(2)$, $6(2)$, $7(1)$ and, $7(2)$ and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the <i>Official Journal of the European Union</i> or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles $5(2)$, $6(2)$, $7(1)$ and, $7(2)$ and 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the <i>Official Journal of the European Union</i> or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
197.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member	4. Before adopting a delegated P act, the Commission shall consult experts designated by each Member

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.	State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. When such a delegated act concerns the processing of personal data, the Commission shall consult the EDPS and, where applicable, may consult the EDPB.	State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.	State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016. [EP position recital 58]
198.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	
199.	6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1), 7(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1) and 7(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to Articles 5(2), 6(2), 7(1) and, 7(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to Articles $5(2)$, $6(2)$, $7(1)$ and , $7(2)$ and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
200.	Article 12	Article 12	Article 12	Article 12
	Urgency procedure	Urgency procedure	Urgency procedure	Urgency procedure
201.	1. Delegated acts adopted under	1. Delegated acts adopted under	1. Delegated acts adopted under	1. Delegated acts adopted under
	this Article shall enter into force	this Article shall enter into force	this Article shall enter into force	this Article shall enter into force
	without delay and shall apply as	without delay and shall apply as	without delay and shall apply as	without delay and shall apply as
	long as no objection is expressed in	long as no objection is expressed in	long as no objection is expressed in	long as no objection is expressed in
	accordance with paragraph 2. The	accordance with paragraph 2. The	accordance with paragraph 2. The	accordance with paragraph 2. The
	notification of a delegated act to the	notification of a delegated act to the	notification of a delegated act to the	notification of a delegated act to the
	European Parliament and to the	European Parliament and to the	European Parliament and to the	European Parliament and to the
	Council shall state the reasons for	Council shall state the reasons for	Council shall state the reasons for	Council shall state the reasons for
	the use of the urgency procedure.	the use of the urgency procedure.	the use of the urgency procedure.	the use of the urgency procedure.
202.	2. Either the European	2. Either the European	2. Either the European	2. Either the European
	Parliament or the Council may	Parliament or the Council may	Parliament or the Council may	Parliament or the Council may
	object to a delegated act in	object to a delegated act in	object to a delegated act in	object to a delegated act in
	accordance with the procedure	accordance with the procedure	accordance with the procedure	accordance with the procedure
	referred to in Article 11(6). In such	referred to in Article 11(6). In such	referred to in Article 11(6). In such	referred to in Article 11(6). In such
	a case, the Commission shall repeal	a case, the Commission shall repeal	a case, the Commission shall repeal	a case, the Commission shall repeal
	the act immediately following the	the act immediately following the	the act immediately following the	the act immediately following the
	notification of the decision to object	notification of the decision to object	notification of the decision to object	notification of the decision to object
	by the European Parliament or by	by the European Parliament or by	by the European Parliament or by	by the European Parliament or by
	the Council.	the Council.	the Council.	the Council.
203.	Article 13	<i>Article 13</i>	<i>Article 13</i>	Article 13
	Committee procedure	<i>Committee procedure</i>	<i>Committee procedure</i>	Committee procedure
204.	1. The Commission shall be	1. The Commission shall be	1. The Commission shall be	1. The Commission shall be
	assisted by a committee. That	assisted by a committee. That	assisted by a committee. That	assisted by a committee. That
	committee shall be a committee	committee shall be a committee	committee shall be a committee	committee shall be a committee
	within the meaning of Regulation	within the meaning of Regulation	within the meaning of Regulation	within the meaning of Regulation
	(EU) No 182/2011.	(EU) No 182/2011.	(EU) No 182/2011.	(EU) No 182/2011.

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
205.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	
206.	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.	3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.	
207.	Article 14 Reporting	Article 14 Reporting	Article 14 Reporting Transitional provision		
208.	One year after the Director-General of the World Health Organization has declared, in accordance with the	1. One year after the Director- General of the World Health Organization has declared, in accordance with the International Health Regulations, that the public	Member States may issue the certificates referred to in Article 3 in a format which does not comply with the requirements of this Regulation until 6 weeks after the entry into force of this Regulation. During this period, certificates issued in accordance with this Article as well as certificates issued before the entry of force of this Regulation shall be accepted by the Member States in accordance with Articles 5(5), 6(5) and 7(5) where they contain the data fields set out in the Annex. One year after the Director General of the World Health Organization has declared, in accordance with the International Health Regulations,		
	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
------	---	---	---	-----------------	--
	International Health Regulations, that the public health emergency of international concern caused by SARS-CoV-2 has ended, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.	health emergency of international concern caused by SARS-CoV-2 has ended, By [4 months after the date of entry into force of this Regulation], the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.	that the public health emergency of international concern caused by SARS-CoV-2 has ended, the Commission shall present a report to the European Parliament and the Council on the application of this Regulation.		
209.	The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID- 19 pandemic.	2. The report shall contain, in particular, include an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID-19 pandemic, including on travel and tourism, on fundamental rights and in particular non-discrimination, on the protection of personal data, as well as information on the most up to date vaccine and testing technologies, based, inter alia, on information provided by the ECDC. The report shall also include an assessment of uses by the Member States of the EU COVID-19 Certificate for purposes, based on national law, not provided for in this Regulation.	The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement of Union citizens and their family members as well as on the protection of personal data during the COVID- 19 pandemic.	[Row 215]	
210.		3. At the latest three months before the end of the application of this Regulation, the Commission shall present a report to the		[Row 214]	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		European Parliament and the Council on the application of this Regulation. This report shall carry out an assessment in accordance with paragraph 2. It may be accompanied by legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation and based on the principles of necessity, proportionality and effectiveness.			
211.	. Article 15 Entry into force and applicability	<i>Article 15</i> <i>Entry into force and applicability</i>	Article 15 Entry into force, applicability <u>and</u> <u>reporting</u>		
212.	1. This Regulation shall enter into force on the third day following that of its publication in the <i>Official</i> <i>Journal of the European Union</i> .	1. This Regulation shall enter into force on <i>and apply from</i> the third day following that of its publication in the <i>Official Journal of</i> <i>the European Union</i> .	1. This Regulation shall enter into force on, and apply from, the third day following that of its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on, and apply from, the third day following that of its publication in the <i>Official Journal of</i> <i>the European Union</i> .	
213.		2. The Regulation shall cease to apply 12 months from [date of entry into force of this Regulation].	2. <u>The Regulation shall apply</u> <u>for 12 months from the date of its</u> <u>entry into force.</u>	2. <u>The Regulation shall apply</u> <u>for 12 months from the date of its</u> <u>entry into force.</u>	
214.			<u>At the latest 3 months before the</u> <u>end of the application of this</u> <u>Regulation, the Commission shall</u>	<u>At the latest 3 months before the</u> <u>end of the application of this</u> Regulation, the Commission shall	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
			present a report to the European Parliament and the Council on the application of this Regulation.	present a report to the European Parliament and the Council on the application of this Regulation.	
215.			The report shall contain, in particular, an assessment of the impact of this Regulation on the facilitation of free movement, including the acceptance of the different types of vaccines, as well as on the protection of personal data during the COVID-19 pandemic.	<u>The report shall contain, in</u> particular, an assessment of the impact of this Regulation on the facilitation of free movement, including on travel and tourism and the acceptance of the different types of vaccines, fundamental rights and non-discrimination, as well as on the protection of personal data during the COVID- 19 pandemic.	Ρ
216.			This report may be accompanied with legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.	Link to row 210 EP text This report may be accompanied with legislative proposals, in particular to extend the date of application of this Regulation, taking into account the evolution of the epidemiological situation on the pandemic.	Р
217.	2. The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 4, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations,	Deleted	 The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations, 	2. The Commission shall adopt a delegated act in accordance with Article 11 specifying the date from which the application of Articles 3, 4, 5, 6, 7 and 10 is to be suspended once the Director-General of the World Health Organization has declared, in accordance with the International Health Regulations,	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
	that the public health emergency of international concern caused by SARS-CoV-2 has ended.		that the public health emergency of international concern caused by SARS-CoV-2 has ended.	that the public health emergency of international concern caused by SARS-CoV-2 has ended.
218.	3. The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director-General of the World Health Organization declares a public health emergency of international concern in relation to <i>SARS-CoV-2, a variant thereof, or</i> <i>similar</i> infectious diseases with epidemic potential. Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.	Deleted	3. The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director General of the World Health Organization declares a public health emergency of international concern in relation to <i>SARS-CoV-2, a variant thereof, or</i> <i>similar</i> infectious diseases with epidemic potential. Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.	3. The Commission is empowered to adopt a delegated act in accordance with Article 11 specifying the date from which Articles 3, 4, 5, 6, 7 and 10 are to apply again if, after the suspension referred to in paragraph 2 of this Article, the Director General of the World Health Organization declares a public health emergency of international concern in relation to <i>SARS-CoV 2, a variant thereof, or</i> <i>similar</i> infectious diseases with epidemic potential. Following the adoption of such a delegated act, paragraph 2 of this Article shall apply.
219.	4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	Deleted	4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.	4. Where, in the case of developments regarding public health emergencies of international concern, imperative grounds of urgency so require, the procedure provided for in Article 12 shall apply to delegated acts adopted pursuant to this Article.
220.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
221.	ANNEX Certificate datasets	ANNEX Certificate datasets	ANNEX Certificate datasets	ANNEX Certificate datasets	
222.	1. Data fields to be included in the vaccination certificate:	1. Data fields to be included in the vaccination certificate:	1. Data fields to be included in the vaccination certificate:	1. Data fields to be included in the vaccination certificate:	
223.	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	
224.	(b) date of birth;	(b) date of birth;	(b) date of birth;	(b) date of birth;	
225.	(c) disease or agent targeted;	(c) disease or agent targeted <i>be it</i> COVID-19 or SARS-CoV-2 or one of its variants;	(c) disease or agent targeted <u>:</u> <u>COVID-19</u> ;	(c) disease or agent targeted: H <u>COVID-19 (meaning also SARS-</u> <u>CoV-2 or one of its variants)</u> ;	Р
226.	(d) vaccine/prophylaxis;	(d) vaccine/prophylaxis;	(d) vaccine/prophylaxis;	(d) vaccine/prophylaxis;	
227.	(e) vaccine medicinal product;	(e) vaccine medicinal product;	(e) vaccine medicinal product;	(e) vaccine medicinal product;	
228.	(f) vaccine marketing authorization holder or manufacturer;	(f) vaccine marketing authorization holder or manufacturer;	(f) vaccine marketing authorization holder or manufacturer;	(f) vaccine marketing authorization holder or manufacturer;	
229.	(g) number in a series of vaccinations/doses;	(g) number in a series of vaccinations/doses;	(g) number in a series of vaccinations/doses <u>and the</u> <u>overall number of doses in</u> <u>the series</u> ;	(g) number in a series of H vaccinations/doses <u>and the overall</u> <u>number of doses in the series</u> ;	Р
230.	 (h) date of vaccination, indicating the date of the latest dose received; 	(h) date of vaccination, indicating the date of <i>each dose</i>	 (h) date of vaccination, indicating the date of the latest dose received; 	(h) date of vaccination, indicating the date of <i>each dose</i>	

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
		<i>received and of</i> the latest dose received;		<i>received and of</i> the latest dose received;	
231.	(i) Member State of vaccination;	(i) Member State of vaccination;	(i) Member State of vaccination;	(i) Member State of vaccination;	
232.	(j) certificate issuer;	(j) certificate issuer;	(j) certificate issuer;	(j) certificate issuer;	
233.	(k) a unique certificate identifier.	(k) a unique certificate identifier valid until (not more than [1 year] after the date of vaccination);	(k) a unique certificate identifier.	(k) a unique certificate identifier.[EP amd – row 25]	Р
234.	2. Data fields to be included in the test certificate:	2. Data fields to be included in the test certificate:	2. Data fields to be included in the test certificate:	2. Data fields to be included in the test certificate:	
235.	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	
236.	(b) date of birth;	(b) date of birth;	(b) date of birth;	(b) date of birth;	
237.	(c) disease or agent targeted;	(c) disease or agent targeted, <i>be it</i> COVID-19 or SARS-CoV-2 or one of its variants;	(c) disease or agent targeted <u>:</u> <u>COVID-19</u> ;	(c) disease or agent targeted: <u>COVID-19 (meaning also SARS-</u> <u>CoV-2 or one of its variants)</u> ;	Р
238.	(d) the type of test;	(d) the type of test;	(d) the type of test;	(d) the type of test;	Р
239.		(da) the type of sample (e.g. nasopharyngeal; oropharyngeal);			

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
240.	(e) test name (optional for NAAT test);	(e) test name (optional for NAAT test);	(e) test name (optional for NAAT test);	(e) test name (optional for NAAT test);	
241.	(f) test manufacturer (optional for NAAT test);	(f) test manufacturer (optional for NAAT test);	(f) test manufacturer (optional for NAAT test);	(f) test manufacturer (optional for NAAT test);	
242.	(g) date and time of the test sample collection;	(g) date and time of the test sample collection;	(g) date and time of the test sample collection;	(g) date and time of the test sample collection;	
243.	(h) date and time of the test result production (optional for rapid antigen test);	(h) date and time of the test result production (optional for rapid antigen test);	(h) date and time of the test result production (optional for rapid antigen test);	(h) date and time of the test result production (optional for rapid antigen test);	Р
244.	(i) result of the test;	(i) result of the test;	(i) result of the test;	(i) result of the test;	
245.	(j) testing centre or facility;	(j) testing centre or facility;	(j) testing centre or facility;	(j) testing centre or facility (optional for rapid antigen test);	Р
246.	(k) Member State of test;	(k) Member State of test;	(k) Member State of test;	(k) Member State of test;	
247.	(l) certificate issuer;	(l) certificate issuer;	(l) certificate issuer;	(l) certificate issuer;	
248.	(m) a unique certificate identifier.	(m) a unique certificate identifier.	(m) a unique certificate identifier.	(m) a unique certificate identifier.[EP amd – row 25]	Р
249.		(n) certificate valid until (not more than [72 hours] from the sample collection for NAAT test			

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text
		and [24 hours] from the sample collection for rapid antigen test);		
250.	3. Data fields to be included in the certificate of recovery:	3. Data fields to be included in the certificate of recovery:	3. Data fields to be included in the certificate of recovery:	3. Data fields to be included in the certificate of recovery:
251.	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;	(a) name: surname(s) and forename(s), in that order;
252.	(b) date of birth;	(b) date of birth;	(b) date of birth;	(b) date of birth;
253.	(c) disease or agent the citizen has recovered from;	(c) disease or agent, be it COVID-19 or SARS-CoV-2 or one of its variants, from which the citizen has recovered;	 (c) disease or agent the citizen has recovered from: <u>COVID-19</u>; 	(c) disease or agent the citizen P has recovered from: <u>COVID-19</u> (meaning also SARS-CoV-2 or one of its variants);
254.	(d) date of first positive test result;	(d) date of first positive NAAT test result;	(d) date of first positive test result;	(d) date of first positive <i>NAAT</i> test result;
255.		(da) date of the serological or antibody test;		
256.	(e) Member State of test;	(e) Member State of test;	(e) Member State of test;	(e) Member State of test;
257.	(f) certificate issuer;	(f) certificate issuer;	(f) certificate issuer;	(f) certificate issuer;
258.	(g) certificate valid from;	(g) certificate valid from;	(g) certificate valid from;	(g) certificate valid from;

	Commission proposal COM (2021) 130 final	EP position	Council position 7796/21	Compromise text	
259	. (h) certificate valid until (not more than 180 days after the date of first positive test result);		 (h) certificate valid until (not more than 180 days after the date of first positive test result); 		
260	. (i) a unique certificate identifier.	deleted	(i) a unique certificate identifier.	(i) a unique certificate identifier.[EP amd - row 25]	Р

•

• Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to third-country nationals legally staying or legally residing in the territories of Member States during the COVID-19 pandemic (Digital Green Certificate)

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
1.	THE EUROPEAN PARLIAMENT	THE EUROPEAN PARLIAMENT	THE EUROPEAN PARLIAMENT	THE EUROPEAN PARLIAMENT
	AND THE COUNCIL OF THE			
	EUROPEAN UNION,	EUROPEAN UNION,	EUROPEAN UNION,	EUROPEAN UNION,
2.	Having regard to the Treaty on the			
	Functioning of the European Union,			
	and in particular Article			
	77(2)(c)thereof,	77(2)(c)thereof,	77(2)(c)thereof,	77(2)(c)thereof,
3.	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,
4.	After transmission of the draft			
	legislative act to the national			
	parliaments,	parliaments,	parliaments,	parliaments,
5.	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,
6.	Whereas:	Whereas:	Whereas:	Whereas:
7.	(1) Under the Schengen acquis,			
	third country nationals lawfully			

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
	residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180- day period.	residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180- day period.	residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180- day period.	residing in the Union and third country nationals who have legally entered the territory of a Member State may move freely within the territories of all other Member States during a period of 90 days in any 180- day period.
8.	 (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (<i>SARS-CoV-</i> 2), which causes coronavirus disease 2019 (COVID- 19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic. 	 (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV- 2), which causes coronavirus disease 2019 (COVID- 19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic. 	 (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (<i>SARS-CoV-</i> 2), which causes coronavirus disease 2019 (COVID- 19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic. 	 (2) On 30 January 2020, the Director-General of the World Health Organization ('WHO') declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (<i>SARS-CoV-2</i>), which causes coronavirus disease 2019 (COVID- 19). On 11 March 2020, the WHO made the assessment that COVID-19 can be characterized as a pandemic.
9.	(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.	(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine. Such restrictions have detrimental effects on citizens and businesses, especially cross-border workers and commuters or seasonal workers.	(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine.	(3) To limit the spread of the virus, the Member States have adopted various measures, some of which have had an impact on travel to and within the territory of the Member States, such as restrictions on entry or requirements for cross-border travellers to undergo quarantine. <i>Such restrictions have detrimental effects on persons and businesses, especially cross-border workers, commuters and seasonal workers.</i>

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
10.	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic ⁸⁴ .	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic .	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic ⁸⁵ .	(4) On 13 October 2020, the Council adopted Council Recommendation (EU) 2020/1475 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic ⁸⁶ .
11.	(5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632 ⁸⁷ on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen <i>acquis</i> to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.	(5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen acquis to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.	(5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632 ⁸⁸ on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen <i>acquis</i> to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.	(5) On 30 October 2020, the Council adopted Council Recommendation (EU) 2020/1632 ⁸⁹ on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area, in which it recommended Member States that are bound by the Schengen <i>acquis</i> to apply the principles, common criteria, common thresholds and common framework of measures, set out in Council Recommendation (EU) 2020/1475.
12.	(6) Many Member States have launched or plan to launch initiatives	(6) Many Member States have launched or plan to launch initiatives	(6) Many Member States have launched or plan to launch initiatives	(6) Many Member States have launched or plan to launch initiatives

⁸⁴ OJ L 337, 14.10.2020, p. 3.

⁸⁸ Council Recommendation (EU) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area (OJ L 366, 4.11.2020, p. 25).

⁸⁵ OJ L 337, 14.10.2020, p. 3.

⁸⁶ OJ L 337, 14.10.2020, p. 3.

⁸⁷ Council Recommendation (EU) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area (OJ L 366, 4.11.2020, p. 25).

⁸⁹ Council Recommendation (EU) 2020/1632 of 30 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic in the Schengen area (OJ L 366, 4.11.2020, p. 25).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
	to issue vaccination certificates. However, for these to be used effectively in connection with cross- border travel within the Union, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.	to issue vaccination certificates. However, for these to be used effectively in connection with cross- border travel within the Union, such <i>vaccination</i> certificates need to be fully interoperable, <i>compatible</i> , secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles, and technical standards <i>and level of protection</i> of such certificates.	to issue vaccination certificates. However, for these to be used effectively in connection with cross- border travel within the Union, such certificates need to be fully interoperable, secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles and technical standards of such certificates.	to issue vaccination certificates. However, for these to be used effectively in connection with cross- border travel within the Union, such <i>vaccination</i> certificates need to be fully interoperable, <i>compatible</i> , secure and verifiable. A commonly agreed approach is required among Member States on the content, format, principles, and technical standards <i>and level of protection</i> of such certificates.
13.	(7) Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive travel restrictions put in place in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with the proposal for a Regulation on a Digital Green Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, it should do so also	(7) Already now, several Member States exempt vaccinated persons from certain travel restrictions to free movement within the Union. Where Member States should accept proof of vaccination in order to waive travel restrictions to free movement put in place, in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, and they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with the proposal for a this Regulation on a Digital Green Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers sufficient a single	(7) Already now, several Member States exempt vaccinated persons from certain travel restrictions. Where Member States accept proof of vaccination in order to waive travel restrictions put in place in compliance with Union law to limit the spread of COVID-19, such as requirements to undergo quarantine/self-isolation or be tested for SARS-CoV-2 infection, they should be required to accept, under the same conditions, valid vaccination certificates issued by other Member States in compliance with the proposal for a Regulation on a Digital Green Certificate (COM(2021)/xxx). This acceptance should take place under the same conditions, meaning that, for example, where a Member State considers a single dose of an administered vaccine to be sufficient, it should do so also	

Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
for holders of a vaccination certificate	dose of an administered <i>a</i> vaccine	for holders of a vaccination certificate	
indicating a single dose of the same	administered to be sufficient, it	indicating a single dose of the same	
vaccine. On grounds of public health,	should do so also for holders of a	vaccine. On grounds of public health,	
this obligation should be limited to	vaccination certificate indicating a	this obligation should be limited to	
persons having received COVID-19	single dose of the same vaccine. On	persons having received COVID-19	
vaccines having been granted	grounds of public health, this	vaccines having been granted	
marketing authorisation pursuant to	obligation should be limited to	marketing authorisation pursuant to	
Regulation (EC) No 726/2004 of the	persons having received COVID-19	Regulation (EC) No 726/2004 of the	
European Parliament and of the	vaccines having been granted	European Parliament and of the	
Council ⁹⁰ . This should not prevent	marketing authorisation pursuant to	Council ⁹⁴ . This should not prevent	
Member States from deciding to	Regulation (EC) No 726/2004 the	Member States from deciding to	
accept vaccination certificates issued	European Parliament and of the	accept vaccination certificates issued	
for other COVID-19 vaccines, such as	Council ⁹² . This should not prevent	for other COVID-19 vaccines, such as	
vaccines having been granted	Member States from deciding to	vaccines having been granted	
marketing authorisation by the	accept vaccination certificates issued	marketing authorisation by the	
competent authority of a Member	for other COVID-19 vaccines, such as	competent authority of a Member	
State pursuant to Directive	vaccines having been granted	State pursuant to Directive	
2001/83/EC of the European	marketing authorisation by the	2001/83/EC of the European	
Parliament and the Council ⁹¹ , vaccines	competent authority of a Member	Parliament and the Council ⁹⁵ , vaccines	
whose distribution has been	State pursuant to Directive	whose distribution has been	
temporarily authorised based on	2001/83/EC of the European	temporarily authorised based on	
Article $5(2)$ of that Directive	Parliament and the Council ⁹³ , vaccines	Article $5(2)$ of that Directive	
2001/83/EC, or vaccines having	whose distribution has been	2001/83/EC, or vaccines having	

90 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

⁹¹ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁹² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

⁹³ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

⁹⁴ Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

⁹⁵ Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
	received a WHO Emergency Use Listing. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID- 19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.	temporarily authorised based on Article 5(2) of that Directive 2001/83/EC, or vaccines having received a WHO Emergency Use Listing. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID- 19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.	received a WHO Emergency Use Listing. Regulation (EU) No 2021/xxxx of xx xx 2021 lays down a framework for the issuance, verification and acceptance of interoperable certificates on COVID- 19 vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic. It applies to Union citizens and third-country nationals who are family members of Union citizens.	
14.	 (8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States. 	 (8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States. 	 (8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States. 	 (8) In accordance with Articles 19, 20 and 21 of the Convention implementing the Schengen Agreement, the third-country nationals covered by these provisions may travel freely within the territories of the other Member States.
15.	(9) To facilitate travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered	(9) Without prejudice to the common measures on the crossing of internal borders by persons as laid down in the Schengen acquis, in particular in Regulation (EU) 2016/399, and for the purpose of facilitating To facilitate travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and	(9) To facilitate travel within the territories of the Member States by third country nationals who have the right to such travel, the framework for the issuance, verification and acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered	

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
	by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.	acceptance of interoperable certificates on COVID-19 vaccination, testing and recovery established by Regulation (EU) No 2021/xxxx should also apply to third-country nationals who are not already covered by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.	by that Regulation, provided that they are legally staying or legally residing in the territory of a Member State and are entitled to travel to other Member States in accordance with Union law.	
16.	(10) For certificates to be used effectively in connection with cross- border travel, such certificates need to be fully interoperable.	(10) For certificates to be used effectively in connection with cross- border travel, such certificates need to be fully interoperable. <i>All Union</i> <i>transport hubs, such as airports,</i> <i>ports, railways and bus stations,</i> <i>where the certificate is being verified,</i> <i>should apply standardised and</i> <i>common criteria and procedures for</i> <i>the verification of the EU COVID-19</i> <i>certificate on the basis of guidance</i> <i>developed by the Commission.</i>	(10) For certificates to be used effectively in connection with cross- border travel, such certificates need to be fully interoperable.	
17.	(11) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at	(11) This Regulation is intended to facilitate the application of the principles of proportionality and non-discrimination with regard to possible restrictions to free movement and other fundamental rights as a result of the pandemic, while pursuing a high level of public health protection and should not be understood as facilitating or	(11) This Regulation should not be understood as facilitating or encouraging the adoption of travel restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at	(11) This Regulation <i>is intended to</i> <i>facilitate the application of the</i> <i>principles of proportionality and</i> <i>non-discrimination with regard to</i> <i>possible travel restrictions during the</i> <i>COVID-19 pandemic, while pursuing</i> <i>a high level of public health</i> <i>protection, and</i> should not be understood as facilitating or encouraging the adoption of

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
	internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code) ⁹⁶ .	encouraging the adoption of travel restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code) ⁹⁷ .	internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code) ⁹⁸ .	restrictions to free movement, or other fundamental rights, in response to the pandemic. In addition, any need for verification of certificates established by Regulation (EU) 2021/xxx cannot as such justify the temporary reintroduction of border controls at internal borders. Checks at internal borders should remain a measure of last resort, subject to specific rules set out in Regulation (EU) 2016/399 (Schengen Borders Code) ⁹⁹ .
18.			(11a) Since this Regulation applies to third country nationals already legally staying or residing in the territories of the Member States, it should not be understood as granting third country nationals wishing to travel to a Member State the right to request a Digital Green Certificate from that Member State before arrival on its territory.	

⁹⁶ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

⁹⁷ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

⁹⁸ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

⁹⁹ Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (OJ L 77, 23.3.2016 p.1).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
19.			(11b) On 30 June 2020, the <u>Council adopted Recommendation</u> (EU) 2020/912 on the temporary <u>restriction on non-essential travel</u> <u>into the EU and the possible lifting</u> <u>of such restriction. This Regulation</u> <u>does not cover the temporary</u> <u>restrictions on non-essential travel</u> <u>into the Union.</u>	
20.	(12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.	(12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.	(12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.	(12) In accordance with Articles 1 and 2 of Protocol No 22 on the position of Denmark annexed to the Treaty on European Union and to the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of the said Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it.
21.	(13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ¹⁰⁰ ;	(13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC ¹⁰¹ ;	(13) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with	

Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20). Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20).

Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. Although Ireland is not subject to this Regulation, for the purposes of facilitating travel within the Union, Ireland could also issue certificates, which comply with the same requirements as those applicable to the Digital Green Certificate, to third- country nationals legally residing or legally staying in its territory and Member States could accept such certificates. Ireland could also accept certificates issued by Member States to third country nationals legally residing or legally staying in their territories.	Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. Although Ireland is not subject to this Regulation, for the purposes of facilitating travel within the Union, Ireland could also issue certificates, which comply with the same requirements as those applicable to the <i>EU COVID-19 Certificate</i> Digital Green Certificate, to third-country nationals legally residing or legally staying in its territory and Member States could accept such certificates. Ireland could also accept certificates issued by Member States to third country nationals legally residing or legally staying in their territories.	Council Decision 2002/192/EC ¹⁰² ; Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application. <u>In order to</u> <u>allow Member States to accept,</u> <u>under the conditions of the</u> <u>Regulation (EU) 2021/XXXX</u> <u>[Regulation on a Digital Green Certificate], certificates issued by</u> <u>Ireland to third country nationals</u> <u>legally residing or legally staying in</u> its territory for the purposes of <u>facilitating travel within the Union,</u> <u>Ireland should issue these third- country nationals with certificates</u> <u>that comply with the requirements</u> <u>of the Digital Green Certificate</u> <u>trust framework. Although Ireland is</u> not subject to this Regulation, for the purposes of facilitating travel within the Union, Ireland could also issue certificates, which comply with the same requirements as those applicable to the Digital Green Certificate, to third-country nationals legally residing or legally staying in its territory. and Member States could accept such certificates issued by Member States to third country nationals legally residing or legally staying in their territories. Ireland and the other Member States	

¹⁰² Council Decision of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (OJ L 64, 7.3.2002, p. 20).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
			should mutually accept certificates issued to third country nationals covered by this Regulation based on reciprocity.	
22.	 (14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession. 	 (14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession. 	 (14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession. 	 (14) As regards Bulgaria, Croatia, Cyprus and Romania, this Regulation constitutes a development of the Schengen acquis within, respectively, the meaning of Article 3(1) of the 2003 Act of Accession, Article 4(1) of the 2005 Act of Accession and Article 4(1) of the 2011 Act of Accession.
23.	(15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC ¹⁰³ .	(15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC.	(15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1, point C, of Council Decision 1999/437/EC ¹⁰⁴ .	(15) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis which fall within the area referred to

Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

¹⁰⁴ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
				in Article 1, point C, of Council Decision 1999/437/EC ¹⁰⁵ .
24.	(16) As regards Switzerland, this	(16) As regards Switzerland, this	(16) As regards Switzerland, this	(16) As regards Switzerland, this
	Regulation constitutes a development	Regulation constitutes a development	Regulation constitutes a development	Regulation constitutes a development
	of the provisions of the Schengen	of the provisions of the Schengen	of the provisions of the Schengen	of the provisions of the Schengen
	acquis within the meaning of the	acquis within the meaning of the	acquis within the meaning of the	acquis within the meaning of the
	Agreement between the European	Agreement between the European	Agreement between the European	Agreement between the European
	Union, the European Community and	Union, the European Community and	Union, the European Community and	Union, the European Community and
	the Swiss Confederation on the Swiss	the Swiss Confederation on the Swiss	the Swiss Confederation on the Swiss	the Swiss Confederation on the Swiss
	Confederation's association with the	Confederation's association with the	Confederation's association with the	Confederation's association with the
	implementation, application and	implementation, application and	implementation, application and	implementation, application and
	development of the Schengen acquis	development of the Schengen acquis	development of the Schengen acquis	development of the Schengen acquis
	which fall within the area referred to	which fall within the area referred to	which fall within the area referred to	which fall within the area referred to
	in Article 1, point C, of Decision	in Article 1, point C, of Decision	in Article 1, point C, of Decision	in Article 1, point C, of Decision
	1999/437/EC read in conjunction with	1999/437/EC read in conjunction with	1999/437/EC read in conjunction with	1999/437/EC read in conjunction with
	Article 3 of Council Decision	Article 3 of Council Decision	Article 3 of Council Decision	Article 3 of Council Decision
	2008/146/EC ¹⁰⁶ .	2008/146/EC .	2008/146/EC ¹⁰⁷ .	2008/146/EC ¹⁰⁸ .
25.	(17) As regards Liechtenstein, this	(17) As regards Liechtenstein, this	(17) As regards Liechtenstein, this	(17) As regards Liechtenstein, this
	Regulation constitutes a development	Regulation constitutes a development	Regulation constitutes a development	Regulation constitutes a development
	of provisions of the Schengen acquis	of provisions of the Schengen acquis	of provisions of the Schengen acquis	of provisions of the Schengen acquis
	within the meaning of the Protocol	within the meaning of the Protocol	within the meaning of the Protocol	within the meaning of the Protocol
	between the European Union, the	between the European Union, the	between the European Union, the	between the European Union, the
	European Community, the Swiss	European Community, the Swiss	European Community, the Swiss	European Community, the Swiss

¹⁰⁵ Council Decision of 17 May 1999 on certain arrangements for the application of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the association of those two States with the implementation, application and development of the Schengen acquis (OJ L 176, 10.7.1999, p. 31).

¹⁰⁶ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (OJ L 53, 27.2.2008, p. 1).

¹⁰⁷ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (OJ L 53, 27.2.2008, p. 1).

¹⁰⁸ Council Decision of 28 January 2008 on the conclusion, on behalf of the European Community, of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (OJ L 53, 27.2.2008, p. 1).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
	Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU ¹⁰⁹ .	Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU.	Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU ¹¹⁰ .	Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis which fall within the area referred to in Article 1 point C, of Decision 1999/437/EC read in conjunction with Article 3 of Decision 2011/350/EU ¹¹¹ .
26.	(18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the	(18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the Council and delivered an opinion on [],	(18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the	(18) The European Data Protection Supervisor and the European Data Protection Board have been consulted in accordance with Article 42 of Regulation (EU) 2018/1725 of the European Parliament and of the

¹⁰⁹ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

¹¹⁰ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

¹¹¹ Council Decision of 7 March 2011 on the conclusion, on behalf of the European Union, of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis, relating to the abolition of checks at internal borders and movement of persons (OJ L 160, 18.6.2011, p. 19).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
	Council ¹¹² and delivered an opinion on [],		Council ¹¹³ and delivered an joint opinion on <u>31 March 2021</u> ,	Council ¹¹⁴ and delivered an joint opinion on <u>31 March 2021</u> ,
27.	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS
28.	Article 1	Article 1	Article 1	Article 1
29.	Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.	Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green EU COVID-19 Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.	Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.	Member States shall apply the rules laid down in Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate] to those third country nationals who do not fall within the scope of that Regulation but who reside or stay legally in their territory and are entitled to travel to other Member States in accordance with Union law.
30.			<u>Article 1a</u>	
31.			Provided that Ireland has notified the Council and the Commission that it accepts certificates issued by Member States to persons covered	

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

	Commission proposal COM (2021) 140 final	EP position	Council position 7796/21	Compromise text
			by this Regulation, Member States shall accept, under the conditions of Regulation (EU) 2021/XXXX [Regulation on a Digital Green Certificate], certificates making up the Digital Green Certificate issued by Ireland to third country nationals who may travel freely within the territory of the Member States.	
32.	Article 2	Article 2	Article 2	Article 2
33.	This Regulation shall enter into force on the third day following that of its publication in the <i>Official Journal of</i> <i>the European Union</i> .	This Regulation shall enter into force on, <i>and apply from</i> , the third day following that of its publication in the <i>Official Journal of the European</i> <i>Union</i> .	This Regulation shall enter into force on <u>, and apply from</u> , the third day following that of its publication in the Official Journal of the European Union.	This Regulation shall enter into force on <u>, and apply from</u> , the third day following that of its publication in the Official Journal of the European Union.
34.	This Regulation shall be binding in its entirety and directly applicable in all Member States.		This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.