

Regulatory framework for “psychomodulatory substances” in Czechia

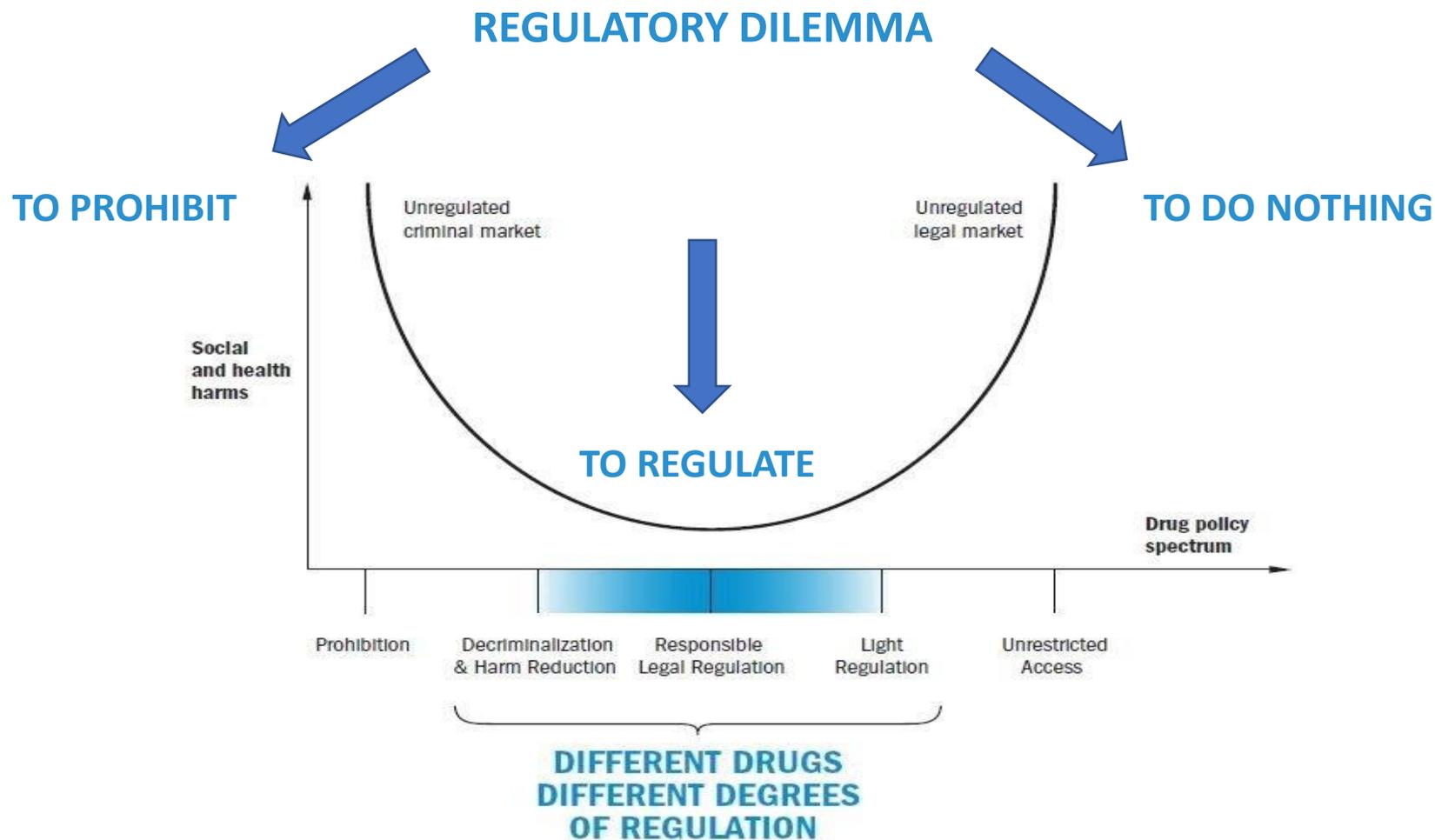
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Affiliations and disclosure

Viktor Mravčík

- Head of research and innovations in the NGO Společnost Podané ruce, Brno, Czechia.
- Scientific Advisor to the National Drug Coordinator, Office of the Government, Czechia.
- Associate professor and researcher at the Department of Addictology, 1st Medical Faculty, Charles University, Prague, Czechia.
- Researcher in the National Institute of Mental Health, Klecany, Czechia.
- Senior researcher of the think tank Institute for Rational Addiction Policies, Brno, Czechia
- Vice-chairman of the board of the Society for Addiction Medicine of the Czech Medical Association.
- Chairman of the scientific board of the Responsible Gaming Project of the Institute for Gambling Regulation, Prague, Czechia.
- Chairman of the scientific board of the Institute for European Legislation, Brno, Czechia

Responsible Regulation Model



Mravčík, V., Chomynová, P., & Grohmannová, K. (2019). Koncept problémového užívání návykových látek. *Psychiatrie*, 23 (3), 121-128. https://www.tigis.cz/images/stories/psychiatrie/2019/Psychiatrie_3_2019/Mravcik_Psychiatrie_3_2019_web.pdf

Global Commission on Drug Policy: "Time to end prohibition", Annual 2021 Report. <https://www.drogy-info.cz/publikace/zaostreno-na-drogy/2022-zaostreno/03-22-jak-regulovat-konopi-prakticky-pruvodce/>

COORDINATION

National Strategy to Prevent and Reduce the Harm Associated with Addictive Behaviour 2019-2027



Prague
January 2022

Addictions:

- In addressing the issue of addiction, we will apply a policy based on a scientifically proven and balanced concept of **risk prevention and harm reduction**, while ensuring sufficient funding for both prevention programmes and services and **the regulation of addictive substances corresponding to their degree of harmfulness.**

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> [Cas Lek Cesk.](#) 2023;162(6):231-237.

FULL TEXT LINKS

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Decriminalisation and smart regulation of psychoactive substances: a modern alternative to prohibition

Viktor Mravčík

PMID: 38981723

<https://pubmed.ncbi.nlm.nih.gov/38981723/>

Psychomodulatory substances

- new legislative framework in Czechia effective since 1 January 2025
- allows for the new category of substances to be marketed for human non-medical use

Process

- Development of the concept started in Autumn 2021
- Adopted by the Chamber of Deputies of the Parliament on 3 May 2024
- Notified by European commission on 21 August 2024
- Adopted by the Senate on 9 October 2024
- Authorised by the President 17 October 2024
- Effective by 1st January 2025
- Subordinate implementing legislation (2 governmental decrees and 2 ministerial regulations) effective progressively during 2025

EU and national legislative basis of the new framework

- **Council Framework Decision 2004/757/JHA (Article 1b)**

National control measures

*Without prejudice to the obligations imposed on the Member States under this Framework Decision, **Member States may maintain or introduce** in their territories, with regard to new psychoactive substances, **any national control measures that they consider appropriate.***

- **Law on Addictive Substances (167/1998 Coll. as ammended by 321/2024 Coll.)**

 Two new categories of substances:

I. Listed Psychoactive Substances

- New, unknown substances - ‚Quarantine Schedule‘
- Research only
- Small amounts for personal use – exempt from prosecution

II. Psychomodulatory Substances

- Available to adults in non-medical context
- Regulated market with strict conditions

What are Psychomodulatory Substances?



Psychoactive effects



Known and acceptable (low) health and social risks



**Scheduled on a list of Psychomodulatory Substances
(Government Decree)**

What are (not) Psychomodulatory Substances?

X Substances controlled as „drugs“(illicit substances)

X Food

X Cosmetics

X Medicines



New type of psychoactive product marketed for human consumption

We had to overcome two paradigms:

- psychoactive substances in non-medical context should be prohibited
- anything that is intended to be ingested (and is not medicine) is a food

Market regulation:

- Only licensed vendors: sale/ manufacture/ distribution
- Specialised shops
- On-line sales: special license, sophisticated age verification process
- Regulation of safety profile of the product (amount, potency, contaminants)
- Unit packing
- Information for consumers (effects, risks, recommended dose)
- Mandatory labelling including health warning, safety warning
- Ban to sale psychomodulatory substances in a form of smokable products
- Ban on sale to minors, vending machines, advertising and sponsoring

Handling and possession rules

- The „handling“ of psychomodulatory substances requires a permit (licence), unless defined otherwise
- „Handling“ excludes (i.e. licence is not needed):
 - possession of psychomodulatory substances by natural persons for personal use
 - handling of small quantities of psychomodulatory substances by a natural persons
- Administrative offence:
 - handling the psychomodulatory substance in quantities greater than small
 - handling a small amount of a listed psychoactive substance without permission

Crime offences

- Psychomodulatory substances are considered „addictive substances“ for the purposes of crimes committed „under influence“ (such as „drug driving“)
- New articles on „handling“ of psychomodulatory substances and listed psychomodulatory substances distinct from „drug crimes“
- Unauthorised handling of psychomodulatory substances punishable from „greater extent“
- Illicit production and other handling of scheduled psychoactive substances punishable from quantities „greater than small“

Role of regions and municipalities

- Psychomodulatory substances become integral part of addiction policies
- Municipality may
 - prohibit smoking, the use of electronic cigarettes, **psychomodulatory substances or scheduled psychoactive substances** in a public space located near a school, educational facility or other space reserved for the activities of persons under 18 years of age.
 - prohibit the consumption of alcoholic beverages, the use of **psychomodulatory substances or scheduled psychoactive substances** in a place or event open to the public if the place or event is open to persons under 18 years of age
 - restrict or prohibit the sale, serving and consumption of alcoholic beverages, the use of **psychomodulatory substances or scheduled psychoactive substances** on certain days or hours or in certain places when a cultural, sporting or other social event open to the public is held.

Scheduling scheme

- NPS is briefly scheduled as listed psychoactive substances (prohibited, but not as „illicit drugs“)
- Risk assessment within maximum of two years
- Rescheduling based on risk assessment
- Factors considered in the risk assessment (as defined by the law):
 - Toxicological properties
 - Addictive potential
 - Prevalence and patterns of use
 - Incidence of intoxications, death and other health and social consequences
 - Information on legitimate use
 - International findings and recommendations

Psychomodulatory substances – candidates

- Kratom

- Low-THC cannabis ?

- ~~• Hexahydrocannabinol (HHC)~~



Notification Detail

Draft Government Regulation on the List of Psychomodulatory Substances

Notification Number: 2025/0093/CZ (Czechia)
Date received: 17/02/2025
End of Standstill: 19/05/2025 (18/08/2025)

Issue of detailed opinion by: European Commission

Draft Text: [CS](#) [BG](#) [HR](#) [DA](#) [NL](#) [EN](#) [ET](#) [FI](#) [FR](#) [GA](#) [DE](#) [EL](#) [HU](#) [IT](#) [LV](#) [LT](#) [MT](#) [PL](#) [PT](#) [RO](#) [SK](#) [SL](#) [ES](#) [SV](#)

Impact assessment: [CS](#) [EN](#)



EVROPSKÁ KOMISE

Brusel, 12.5.2025
C(2025) 3077 final

Jeho Excelence
Mr Jan Lipavský
Ministr zahraničních věcí
Ministerstvo zahraničních věcí
Loretánské náměstí 5
118 00 Praha 1
Česká republika

Věc: Oznámení 2025/93/CZ

Návrh nařízení vlády o seznamu psychomodulačních látek

**Dodání podrobného stanoviska dle čl. 6 odst. 2 směrnice (EU)
2015/1535 ze dne 9. září 2015**

References / more info

> [Int J Drug Policy](#). 2024 Oct 9;133:104603. doi: 10.1016/j.drugpo.2024.104603. Online ahead of print.

FULL TEXT LINKS



Psychomodulatory substances: New legislative framework for control of psychoactive substances in Czechia

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🔖 Collections

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<https://www.sciencedirect.com/science/article/abs/pii/S0955395924002871>



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Psychomodulační látka

🌐 Přidat jazyky ▾

https://cs.wikipedia.org/wiki/Psychomodula%C4%8Dn%C3%AD_l%C3%A1tka

Link to the Collection of Laws (PDF in Czech for download), law No. 321/2024 Coll.: <https://www.e-sbirka.cz/sb/2024/321?zalozka=text>

Thank you for your attention!

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