

Draft

GOVERNMENT REGULATION

of ... 2025

on the list of psychomodulatory substances

The Government hereby orders § 44c(3)(a) to implement § 33k(6) of Act No 167/1998 on addictive substances and amending certain other acts, as amended by Act No 321/2024:

§ 1

Subject matter

This Regulation establishes the list of psychomodulatory substances set out in the Annex to this Regulation.

§ 2

Notification of a technical regulation

This Regulation has been notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of standards and technical regulations and of rules on Information Society services.

§ 3

Effective date

This Regulation comes into effect on 2025.

Prime Minister:

Deputy Prime Minister and Minister for Health

List of psychomodulatory substances

International Nonproprietary Name (INN)	Other International Nonproprietary Name or generic name	The name of the active substances [International Nonproprietary Name (INN)]	Chemical name of the active substances according to IUPAC	Description	Comment
Kratom	Mitragyna speciosa	Mitragynine 7-hydroxymitragynine	methyl (16E)-9,17-dimethoxy-16,17-didehydro-20 β -corynan-16-carboxylate) methyl (2E)-2-[(2S,3S,7aS,12bS)-3-ethyl-7a-hydroxy-8-methoxy-1,2,3,4,6,7,7a,12b-octahydroindol[2,3-a]quinolizine-2-yl]-3-methoxyprop-2-enoate	Vegetable mixture originating from the leaves of the plant <i>Mitragyna speciosa</i> , containing the alkaloids mitragynine or 7-hydroxymitragynine	
Kratom Extract	-	Mitragynine 7-hydroxymitragynine	methyl (16E)-9,17-dimethoxy-16,17-didehydro-20 β -corynan-16-carboxylate) methyl (2E)-2-[(2S,3S,7aS,12bS)-3-ethyl-7a-hydroxy-8-methoxy-1,2,3,4,6,7,7a,12b-octahydroindol[2,3-a]quinolizine-2-yl]-3-methoxyprop-2-enoate	Preparation made from kratom	
Cannabis up to 1%	Cannabis containing	Substances of the	$\Delta^{6a(10a)}$ -, $\Delta^{6\alpha(7)}$ -, Δ^7 -, Δ^8 -, Δ^{10} -,	The flowering or	May contain the

THC	no more than 1% of substances from the tetrahydrocannabinol group	tetrahydrocannabinol group	$\Delta^{9(11)}$ -tetrahydrocannabinols, their stereoisomers	fruiting top of a cannabis plant or the above-ground part of a cannabis plant, the part of which is a top containing the sum of substances from the tetrahydrocannabinol group and their acids up to a maximum of 1% of the substance content, intended for human consumption or for processing for human consumption, except for source material for processing into food or cosmetics.	substance hexahydrocannabinol in natural form at a concentration of less than 0.3%.
Cannabis extract and tincture up to 1% THC.	Cannabis extract and tincture containing not more than 1% of substances belonging to the tetrahydrocannabinol group	Substances of the tetrahydrocannabinol group	$\Delta^{6a(10a)}$ -, $\Delta^{6\alpha(7)}$ -, Δ^7 -, Δ^8 -, Δ^{10} -, $\Delta^{9(11)}$ -tetrahydrocannabinols, their stereoisomers	Extract or leachate obtained from cannabis with up to 1% THC, containing the sum of substances from the tetrahydrocannabinol group and their acids at a level of 1% of the substance content, intended for human consumption or for processing for human consumption, except for source	May contain the substance hexahydrocannabinol in natural form at a concentration of less than 0.3%.

				material for processing into food or cosmetics, and preparations thereof.	
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