

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 $\beta$ -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 $\beta$ -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	$\Delta^{6a(10a)}$ -, $\Delta^{6a(7)}$ -, $\Delta^7$ -, $\Delta^8$ -, $\Delta^{10}$ -,	The flowering or fruiting top	May contain the

THC	no more than 1% of substances from the tetrahydrocannabinol group	tetrahydrocannabinol group	$\Delta^{9(11)}$ -tetrahydrocannabinols, their stereoisomers	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	$\Delta^{6a(10a)}$ -, $\Delta^{6a(7)}$ -, $\Delta^7$ -, $\Delta^8$ -, $\Delta^{10}$ -, $\Delta^{9(11)}$ -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 material for processing into food or cosmetics, and preparations thereof.	May contain the substance hexahydrocannabinol in natural form at a concentration of less than 0.3%.