DRAFT

DECREE

of ……. 2025,

on psychomodulatory substances

Pursuant to § 44c(7), in order to implement § 33e(2) and (4) and § 33f(1) and (8) of Act No 167/1998 on addictive substances and amending certain other acts, as amended by Act No 273/2013, Act No 366/2021 and Act No 321/2024 (hereinafter the 'Act'), the Ministry of Health, in cooperation with the Office of the Government, lays down the following:

PART ONE

GENERAL PROVISIONS

§ 1

Subject matter

This Decree provides for

a) the manner in which the particulars on the unit packet and the outside packaging of psychomodulatory substances shall be indicated,

b) the manner in which the consumer information notice, the safety warning on the risks of use of the product by minors, and the health warning shall be indicated,

c) the technical requirements for the composition, appearance, quality, and properties of psychomodulatory substances, including the maximum permitted quantity of psychomodulatory substances in a unit packet, the maximum permitted quantity of active substances in a unit packet, the maximum permitted concentrations of active substances, the elements and features prohibited when placing psychomodulatory substances on the market, and the maximum permissible levels of chemical and microbiological contamination,

d) the good manufacturing practice requirements for manufacturers of psychomodulatory substances.

§ 2

Definitions

For the purposes of this Decree,

a) active substance means the psychoactive component of a psychomodulatory substance,

b) consumer information means the consumer information notice on the effects and risks, and the recommended dosage information,

c) safety warning on the risks of use of the product by minors means the warning information, in both graphic and textual form, alerting to the unsuitability and risks of use of psychomodulatory substances by persons under 18 years of age,

d) health warning means the warning information alerting to the harmful effects of psychomodulatory substances on human health,

e) distribution for the purpose of placing on the market means the purchase and sale of a product intended to be placed on the market for resale purposes,

f) manufacturing facility means the premises operated by a manufacturer of psychomodulatory substances in which psychomodulatory substances are manufactured, prepared, stored and handled unpackaged or packaged,

g) manufacturing equipment means tools, equipment, instruments, containers, machinery and technological equipment, handling packaging, and other aids and articles which come into direct or indirect contact with psychomodulatory substances when being handled,

h) establishment means the part of the manufacturer's undertaking in which the manufacturing facility, warehouse of packaged products or other service or office premises are located,

i) operational hygiene means all measures relating to the manufacturing facility, manufacturing equipment, or establishment that are necessary to ensure the health safety of psychomodulatory substances,

j) personal hygiene means the principles of conduct and the working practices of persons working in a manufacturing facility aimed at ensuring health safety in the manufacture of psychomodulatory substances,

k) quality verification means verification that the psychomodulatory substance meets the requirements for maximum concentration of active substances and the requirements for the maximum permissible chemical and microbiological contamination,

l) product intended to be placed on the market means a psychomodulatory substance in a unit packet intended to be placed on the market,

m) single dose means an individually packaged or otherwise separated quantity of a psychomodulatory substance in a unit packet,

n) good manufacturing practice means a set of rules and guidelines to ensure that products intended to be placed on the market comply with the legal requirements for quality and safety.

PART TWO

TECHNICAL REQUIREMENTS

§ 3

Requirements for the quality and composition of psychomodulatory substances

(1) Only psychomodulatory substances that meet the quality and composition requirements set out in Annexes 1 to 6 to this Decree may be distributed for the purpose of placing them on the market or placed on the market.

(2) Products intended to be placed on the market may contain, in addition to the active substances and ingredients naturally occurring in a psychomodulatory substance, only ingredients which do not pose a risk to human health at the concentration used, provided that the psychomodulatory substance is used in accordance with the consumer information, including the instructions for use under § 8. The list of active substances for each psychomodulatory substance is set out in Annex 1 to this Decree.

(3) Ingredients not posing a risk to human health as referred to in paragraph (2) are

a) additives listed in Annex II, Part B to Regulation (EU) No 1333/2008 of the European Parliament and of the Council[1)],

b) sugars[2)],

c) oils, fats and

d) alcohol-, fat- and oil-based solvents as referred to in the implementing act concerning the requirements for extraction solvents used in the manufacture of food products[3)].

(4) Ingredients other than those referred to in paragraph (3) may be contained in a product intended to be placed on the market in trace quantities, only where it is technically impossible to avoid the presence of that trace quantity during the manufacture of the product intended to be placed on the market.

(5) The product intended to be placed on the market must not contain ingredients harmful to human health, in particular contaminating chemicals and microorganisms; a list of chemical and microbiological indicators and their permissible values set out in Annex 3 to this Decree.

(6) A unit packet of a psychomodulatory substance shall not contain active substances in a concentration exceeding that laid down in Annex 1 to this Decree, nor shall it contain a psychomodulatory substance and active substances in a quantity exceeding that laid down in Annex 1 to this Decree.

§ 4

(1) A psychomodulatory substance contained in a unit packet may be divided into multiple single doses with the same composition.

(2) If a single dose is provided with packaging, such packaging must be safe for human health in accordance with the requirements of Article 3(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[4)], or the requirements of Article 4(a) and (e) of Commission Regulation (EU) No 10/2011[5)] in the part concerning the composition requirements, and the requirements of § 3(1) of the Decree on hygiene requirements for products intended to come into contact with food and meals[6)]; the use of ingestible or impregnated packaging is not permitted.

[1)] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, as amended.

[2)] Annex I, point 8 of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, as amended.

[3)] Decree No 253/2018 on requirements for extraction solvents used in the manufacture of foodstuffs, as amended.

[4)] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, as amended.

[5)] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, as amended.

[6)] Decree No 38/2001 on hygiene requirements for products intended to come into contact with food and meals, as amended.

§ 5

Properties and appearance of the unit packet of a psychomodulatory substance

(1) The unit packet of a psychomodulatory substance shall be secured against any undesirable handling that could, in particular, compromise the integrity of the product and be contrary to the purpose for which the psychomodulatory substance is intended, especially against the handling of the unit packets by children, in accordance with Part 3 of Annex II to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[7)].

(2) The packaging of the unit packet and any outside packaging shall be labelled with the name of the psychomodulatory substance, as well as its form and subtype as set out in Annex 2 to this Decree. The name of the psychomodulatory substance shall be indicated on one line only. The designation of the form shall be indicated on one line only and placed directly under the name of the psychomodulatory substance. The designation of the subtype shall be indicated on one line only and placed directly under the designation of the form of the psychomodulatory substance. The text containing the name of the psychomodulatory substance and, where applicable, its form or subtype, shall be indicated in parallel with the text of the health warning. The characteristic appearance and properties of the psychomodulatory substance are set out in Annex 2 to this Decree.

(3) On outside packaging containing more than one unit packet of a psychomodulatory substance, the number of unit packets contained in the outside packaging shall be indicated.

(4) If a unit packet contains single doses, the number of single doses shall be indicated on the unit packet. All single doses shall contain the same quantity of the psychomodulatory substance and have the same active substance content and organoleptic properties.

(5) The unit packet may, without dividing its contents into single doses, be adapted to indicate or designate smaller portions of the psychomodulatory substance which, during normal handling of the unit packet, may serve to determine the recommended dosage (hereinafter referred to as 'dosage portion').

(6) If the unit packet contains a psychomodulatory substance in liquid form, it shall be fitted with a dropper or other dispensing mechanism which, during normal handling of the unit packet, shall allow the recommended single dose to be determined safely and shall prevent the contents of the unit packet from being emptied all at once.

§ 6

Unit packet labelling

(1) If the packaging of a unit packet and the outside packaging is labelled with the brand name, that name shall appear on one line only.

(2) The packaging of the unit packet and the outside packaging of the psychomodulatory substance may bear a single barcode or QR code if

a) it is in black on a white background and

[7)] Annex II, Part 3 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended.

b) it does not represent an image, pattern or symbol that resembles anything other than a barcode or QR code; the consumer information contained in the barcode or QR code shall not supplement, modify, comment on or paraphrase the consumer information referred to in § 8(1).

§ 7

(1) The information referred to in § 33e (1) of the Act

a) shall be indicated on or attached to the unit packet and the outside packaging,

b) shall be visible, easily legible and indelible,

c) shall not be obscured or interrupted when distributed for the purpose of placing on the market or when placed on the market, and

d) shall, as regards textual information, be in Czech.

(2) The net quantity of the psychomodulatory substance in the unit packet and in the single dose, if the unit packet contains single doses, shall be indicated in milligrams (mg) or grams (g) for substances of powdery, solid or semi-solid consistency, or in millilitres (ml) for substances of liquid consistency.

(3) The concentration of the active substances in a psychomodulatory substance shall be indicated as a percentage by weight of the net weight of the psychomodulatory substance using the symbol '%'. If the concentration of the active substance exceeds 1.0 %, it may be indicated in whole numbers. The concentration of the active substance may be indicated as a range that includes the actual concentration value of the active substance and does not exceed one third of the average of that range.

(4) The ingredients referred to in § 3(2) contained in the psychomodulatory substance shall be indicated in descending order by weight.

§ 8

(1) Each unit packet and any outside packaging of a psychomodulatory substance shall bear consumer information consisting of

a) the heading reading 'Consumer information',

b) the text of the consumer information notice as set out in Annex 4 to this Decree,

c) instructions for use pursuant to the Act governing consumer protection[8)], which shall include a description of the method of use of the product, and

d) information on the recommended dosage, which means information on the value of the recommended single dose of the psychomodulatory substance and the recommended daily dose of the psychomodulatory substance, specifically for each method of use of the product.

[8)] Act No 634/1992 on consumer protection, as amended.

(2) The heading referred to in paragraph 1(a) shall be in larger or more prominent font than the other text of the consumer information.

(3) The instructions for use referred to in paragraph 1(c) shall be preceded by the heading reading ‘Instructions for use’, which shall be placed immediately below the text of the consumer information. The instructions for use shall contain a description of the method of use of the product, showing how the product is to be prepared for use and how the psychomodulatory substance is to be used. The instructions for use referred to in paragraph 1(c) shall also contain instructions for storage and preservation of the psychomodulatory substance.

(4) The instructions for use referred to in paragraph 1(c) shall not contain instructions encouraging the consumer to use the product by

a) smoking,

b) transdermal application,

c) a method that would breach the integrity of the skin or mucous membranes,

d) inhaling an aerosol not produced by combustion, if the psychomodulatory substance contains oils or fats.

(5) The recommended dosage value referred to in paragraph 1(d) shall be indicated in milligrams (mg) or grams (g) for substances of powdery, solid or semi-solid consistency, or in millilitres (ml) for substances of liquid consistency. The recommended dosage may be indicated as the number of tablespoon units, teaspoon units or droplet units, where the package is equipped with an appropriate dispensing mechanism; the recommended dosage shall be converted to these volume units, with the volume unit of one tablespoon set at 17 ml, the volume unit of one teaspoon set at 7 ml, and the volume unit of one droplet set at 0.05 ml. The recommended dosage may be indicated as the number of single doses of the psychomodulatory substance if the unit packet contains single doses. The recommended dosage may be indicated in dosage portions if the contents of the unit packet are provided with dosage portions.

(6) The recommended dosage shall not exceed a value representing the quantity of the psychomodulatory substance that contains the maximum permitted single dose of the active substance for the recommended single dose of the psychomodulatory substance and the maximum permitted daily dose of the active substance for the recommended daily dose. The maximum permitted single doses and the maximum permitted daily doses of active substances are set out in Annex 5 to this Decree.

§ 9

Neither the instructions for use referred to in § 8(1)(c) nor the information on the recommended dosage referred to in § 8(1)(d) shall diminish, supplement, alter, comment on or paraphrase the text of the consumer information referred to in § 8(1)(a) and (b).

§ 10

(1) The consumer information referred to in § 8(1) or the packaging of a psychomodulatory substance shall not contain any other text or graphic element which in any way diminishes, supplements, alters, comments on, paraphrases or refers to that information.

(2) The consumer information referred to in § 8(1) may be indicated directly on the packaging, on a label, or in another manner, but shall always form part of the unit packet; where indicated on a label, it must be an adhesive, peel-off, multi-layer or sandwich label.

§ 11

(1) A numerical code consisting of 8 digits shall be used for lot marking.

(2) The lot marking shall be preceded by the letter 'L', except in cases where it is clearly distinguishable from other information and cannot be confused with any other indication.

(3) The lot marking shall be easily visible, clearly legible and indelible.

§ 12

(1) The safety warning on the risks of use of the product by minors referred to in § 33e(1)(n) of the Act shall consist of a graphic sign together with the text 'Not intended for persons under 18 years of age.' and 'Keep out of reach of persons under 18 years of age.'; the design of the graphic sign is set out in Annex 6 to this Decree; the text of the safety warning shall be placed in close proximity to the graphic sign and on a white background; no other text or graphic element which in any way diminishes, comments on, paraphrases or refers to the safety warning may appear on the packaging.

(2) The health warning referred to in § 33e(1)(o) of the Act shall read as follows: 'Use of this product may harm your health. Follow the consumer information.'; no other text or graphic element which in any way diminishes, comments on, paraphrases or refers to this health warning may appear on the packaging.

(3) Information on the presence of substances that may cause allergies or intolerances in certain persons pursuant to § 33e(1)(n) of the Act means the particulars referred to in Article 9(1)(c) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council[9)].

§ 13

The health warning referred to in § 12(2) shall

[9)] Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, as amended.

a) be printed in black, bold Helvetica font while preserving the default character spacing, i.e. 100 %, and normal spaces on a white background; the point size of the letters shall be such that the relevant text covers as much of the surface reserved for it as possible,

b) be centred on the area reserved for it,

c) be positioned parallel to the main text on the area reserved for this warning,

d) be parallel to the lateral edge of the unit packet or of the outside packaging,

e) be indicated on the largest surface of the unit packet and of any outside packaging,

f) cover at least 30 % of the area of the largest surface of the unit packet and of any outside packaging, on which the health warning has been printed, and

g) remain intact when the unit packet is opened in the usual manner.

§ 14

Prohibited elements and features

(1) No packaging of a psychomodulatory substance, contents of a unit packet of a psychomodulatory substance, or form of a single dose, nor the labelling or presentation of the psychomodulatory substance may contain any element or feature that

a) promotes the psychomodulatory substance or encourages its consumption with reference to its properties and health effects,

b) suggests that the psychomodulatory substance has vitalising, energetic, healing, rejuvenating, natural, or organic effects or properties, or other health or lifestyle benefits,

c) indicates that the psychomodulatory substance does not contain any additives or flavourings,

d) promotes naturally occurring substances or additives with reference to their properties and health effects.

(2) No packaging of a psychomodulatory substance, contents of a unit packet of a psychomodulatory substance, or form of a single dose, nor the labelling or presentation of the psychomodulatory substance may

a) suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one type offers or other similar offers,

b) encourage the use of the psychoactive substance in a way that increases the health or other risks of its use,

c) contain any elements typical of substances whose placing on the market is prohibited or elements that encourage socially undesirable behaviour,

d) suggesting an increased possibility of personal or social achievement,

e) contain any elements which may be particularly attractive to persons under 18 years of age or which directly or indirectly target persons under 18 years of age, or are derived from the culture of persons under 18 years of age,

f) contain elements identifying flavours and aromas other than elements in the form of text which is preceded by the word ‘flavour’.

(3) An element or feature prohibited under paragraphs (1) and (2) means any form of representation, in particular text, symbol, name, trademark, figurative or other sign.

(4) A single dose of a psychomodulatory substance intended for oral administration and having a semi-solid or solid consistency shall be of a neutral form in the shape of a simple geometric shape.

§ 15

Technical requirements for quality verification of a psychomodulatory substance lot

Manufacturers or distributors of psychomodulatory substances shall verify the quality of a lot of psychomodulatory substances intended to be placed on the market in accordance with the technical requirements set out in Annex 7 to this Decree.

PART THREE

GOOD MANUFACTURING PRACTICE

§ 16

Good manufacturing practice requirements

The requirements for good manufacturing practice comprise

a) rules for operating the quality management system,

b) principles of operational and personal hygiene,

c) requirements for the manufacturing facility,

d) requirements for manufacturing equipment,

e) requirements for manufacturing processes and technology,

f) rules for documentation management,

g) packaging requirements,

h) storage requirements, and

i) requirements for the management of production waste.

§ 17

Quality management system

(1) In the course of production, the manufacturer shall act in a manner that ensures the resulting product meets the quality requirements for psychomodulatory substances set out in Part Two of this Decree.

(2) In order to achieve the required quality of a psychomodulatory substance intended to be placed on the market, the manufacturer shall, through internal regulations, establish and implement a quality assurance system meeting the minimum requirements for a quality assurance system set out in this Decree. The manufacturer shall continuously monitor the effectiveness of the quality assurance system, keep and maintain records of such monitoring, and modify or update the system where deficiencies are identified.

(3) The quality assurance system includes repeated internal checks that monitor compliance with the rules of good manufacturing practice and that allow for subsequent corrective action if necessary. The manufacturer shall keep and maintain records of such internal checks and any subsequent corrective action taken for a minimum period of 5 years.

§ 18

Principles of operational and personal hygiene

(1) All persons working in a manufacturing facility at sites where psychomodulatory substances are handled shall adhere to the principles of personal hygiene; at a minimum, they shall

a) maintain sanitary facilities, such as changing rooms, washrooms, showers and toilets, and ancillary facilities, such as facilities for washing working footwear, drying working clothes, warming rooms, rest rooms, first aid rooms and storage areas for cleaning supplies and equipment, in a clean and serviceable condition,
b) not keep objects unrelated to the performance of work activities in the manufacturing facility,
c) not allow unauthorised persons to enter the manufacturing facility,
d) store personal belongings, clothes and footwear only in the changing room or in a designated area of the manufacturing establishment outside the manufacturing facility,
e) use for cleaning only detergents, cleaning agents and disinfectants that are intended for use in the food industry,
f) not smoke or inhale any other aerosol in the manufacturing facility,
g) store cleaning agents and preparations for routine protective disinfection, disinsection and rodent control in their original packaging outside the manufacturing facility, and
h) not use containers and packaging intended for psychomodulatory substances or foodstuffs to store cleaning agents or preparations for routine protective disinfection, disinsection or rodent control.

(2) In addition, the following personal hygiene principles shall apply to persons working in a manufacturing facility at sites where psychomodulatory substances are handled; they shall

a) maintain personal hygiene and wash their hands in warm water using a suitable detergent or disinfectant before starting work, when switching from dirty to clean work, after using the toilet, after handling waste, and whenever hands become soiled,

b) wear clean personal protective equipment appropriate to the nature of the work, in particular working clothes, working footwear and a head covering when manufacturing psychomodulatory substances; keep working clothes clean and change them during the shift as needed; for tasks requiring a high level of cleanliness or where there is a higher risk of contamination, wear disposable protective gloves and mouth masks,
c) not leave the manufacturing facility during working hours in working clothes and footwear,
d) avoid any unhygienic behaviour in the manufacturing facility,
e) ensure proper hand care, keep fingernails short, clean and unpainted, and refrain from wearing decorative or other items on the hands, and
f) store used working clothes and personal clothes in a designated place outside the manufacturing facility; store working clothes separately from personal clothes.

(3) The manufacturer of psychomodulatory substances shall ensure that no person who is suffering from or carrying a food-borne illness, or who is affected by, for example, infected wounds, skin infections, ulcers or diarrhoea, works in any area where psychomodulatory substances are handled. This applies to any job role involving the possibility of direct or indirect contamination of the psychomodulatory substance with pathogenic microorganisms.

§ 19

Manufacturing facility

(1) In the manufacturing facility,

a) floor surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary to ensure operational hygiene, disinfect; impervious, non-absorbent, washable, non-slippery and non-toxic materials must be used; where necessary to ensure operational hygiene, floors must allow surface drainage,

b) wall surfaces must be maintained in a sound condition and they must be easy to clean and, where necessary to ensure operational hygiene, disinfect; impervious, non-absorbent, washable, and non-toxic materials must be used, and the surface must be smooth up to a height appropriate for the operations,

c) ceilings and overhead fixtures must be designed, constructed and finished to prevent the accumulation of dirt and to reduce condensation, the growth of undesirable moulds and the shedding of particles,

d) windows and other openings must be constructed to prevent the accumulation of dirt; windows and openings which can be opened to the outside environment must, where necessary to ensure operational hygiene, be fitted with insect-proof screens which can be easily removed for cleaning; where open windows would result in contamination of psychomodulatory substances, windows must remain closed and fixed during production,

e) doors must be easy to clean and, where necessary to ensure operational hygiene, disinfect; smooth and non-absorbent surfaces must be used,

f) surfaces, including surfaces of manufacturing equipment, in contact with psychomodulatory substances must be maintained in a sound condition and be easy to clean and, where necessary to ensure operational hygiene, disinfect; smooth, washable and non-toxic materials must be used.

(2) Where necessary to ensure operational hygiene, adequate facilities must be provided for the cleaning and disinfecting of work tools and manufacturing equipment. These facilities must be constructed of materials resistant to corrosion and must be easy to clean and have a supply of hot and cold water.

(3) Separate washing of psychomodulatory substances must be ensured so that when washing the psychomodulatory substance, the washing water does not come into contact with already washed psychomodulatory substances. Every sink or other such facility provided for the washing of psychomodulatory substances must have a supply of hot or cold potable water and be kept clean.

§ 20

Manufacturing equipment

All manufacturing equipment with which psychomodulatory substances come into contact must be kept clean,

a) be so constructed, be of such materials safe for contact with foodstuffs and be kept in such good order, repair and technical condition as to minimise any risk of contamination of the psychomodulatory substance,

b) with the exception of disposable packaging, be so constructed, be of such materials and be kept in such good order and technical condition as to enable them to be kept thoroughly cleaned and, where necessary to ensure operational hygiene, disinfected, and

c) be installed in such a manner as to allow adequate cleaning of the surrounding area.

§ 21

Manufacturing processes and technology

(1) When extracting the active substance of a psychomodulatory substance, only extraction solvents listed in the Decree concerning the requirements for extraction solvents used in the manufacture of foodstuffs[10)] may be used.

(2) In addition to the psychomodulatory substance, only the ingredients referred to in § 3(3) may be used in the manufacture of a psychomodulatory substance intended for oral administration.

(3) The ingredients referred to in § 3(3)(a) and (c) may be added to a psychomodulatory substance if their addition improves the safety of the product intended to be placed on the market or if this is necessary from a technological standpoint.

§ 22

Documentation

[10)] Decree No 253/2018 on requirements for extraction solvents used in the manufacture of foodstuffs, as amended.

(1) The manufacturer shall ensure that all activities related to the manufacture and processing of psychomodulatory substances and the disposal of waste generated during manufacture are logged.
(2) The manufacturer shall create, maintain and regularly update a system of controlled documentation governing the method and scope of record-keeping of activities related to the manufacture and processing of psychomodulatory substances and the disposal of waste generated during manufacture, as well as the keeping of other records. The manufacturer shall establish a clear and comprehensible system which leaves no doubt as to which particular persons are required to log and keep records.
(3) Records of specific activities shall be taken immediately after the relevant activity has been carried out, so that each individual activity can be traced retrospectively.
(4) All documents relating to the manufacture and processing of psychomodulatory substances and the disposal of waste arising from manufacture shall be retained in paper or electronic form for a period of at least five years from the date the document was created or the date of the last entry therein, whichever is later. The documentation shall be retained in such a way as to prevent deterioration, loss, damage, destruction, misuse or theft of documents, while allowing the documents to be presented without delay to supervisory authorities.
(5) At least the following information shall be documented

a) the name(s) and surname or company name of the manufacturer,

b) the place of manufacture, namely the address and the designation of the room,

c) the lot number,

d) the type, origin and quantity of the starting psychomodulatory substance or other substance which is not a psychomodulatory substance but which is the starting material for its production and the treatment of which produces the psychomodulatory substance,

e) the conditions of manufacture,

f) incidents occurring during manufacture or processing which could affect the chemical composition of the product,

g) the date and time of manufacture,

h) a record for each individual lot confirming that manufacture has taken place in accordance with the requirements of good manufacturing practice,

i) the date, designation and quantity of waste generated by manufacture, and

j) the date, designation and quantity of manufacture waste disposed of.

§ 23

Packaging

(1) The material used to store or package psychomodulatory substances must not be a source of contamination and must comply with the requirements of Article 3(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council[4)], or the requirements of Article 4(a) and (e) of Commission Regulation (EU) No 10/2011[5)] in the part concerning the

composition requirements, and the requirements of § 3(1) of the Decree on hygiene requirements for products intended to come into contact with food and meals[6)].

(2) Packaging intended for the storage or packaging of psychomodulatory substances must be stored in such a way as to avoid the risk of contamination and it must be ensured that it is intact and clean.

(3) The procedure for the packaging of psychomodulatory substances shall be such as to avoid contamination of the psychomodulatory substance.

§ 24

Storage

(1) Psychomodulatory substances ready for packaging shall be stored by the manufacturer at the manufacturing facility.

(2) Products intended to be placed on the market shall be stored by the manufacturer in dry and well-ventilated premises that have a constant temperature and are protected from pests. Storage conditions shall be monitored and recorded.

§ 25

Manufacturing waste

(1) Wastes generated in the manufacture of psychomodulatory substances shall be segregated and separately collected at the point of generation. Separate waste collection facilities appropriate to the type and nature of the waste shall be used for sorted waste. All collection facilities shall be tightly sealable, leak-proof and labelled, and shall conform to the relevant standards or be certified for the given purpose. Waste sorting shall be carried out within the meaning of the Waste Catalogue[11)] according to individual types and categories. Mixing hazardous waste is prohibited. The collection of waste in manufacturing premises shall be limited to the time necessary. The waste collection point shall be equipped with a hazardous waste identification sheet[12)].

(2) The collection point or storage facility for waste shall comply with the technical requirements of other legislation[11).] The period of collection before disposal shall be determined on the basis of the nature of the waste and, in the case of bio-waste, shall be a maximum of three days.

(3) Legal persons or sole traders who are the producer of waste resulting from the manufacture of psychomodulatory substances shall draw up instructions for the management of that waste at the establishment. The instructions shall be part of the manufacturing facility's operating rules.

[11)] Decree No 8/2021 on the Waste Catalogue and the assessment of properties of waste (Waste Catalogue).

[12)] Decree No 273/2021 on details of waste management, as amended.
Act No 541/2020 on waste, as amended.

(4) Unusable psychomodulatory substances and waste contaminated by them shall be disposed of in accordance with the type and nature of the waste. An official record of the disposal shall be made by the manufacturer.

PART FOUR

TRANSITIONAL AND FINAL PROVISIONS

§ 26

Transitional provisions

Psychomodulatory substances that do not comply with the requirements laid down in this Decree and that have been manufactured or placed on the market and labelled before the effective date of this Decree may be offered for sale and sold for no longer than two months after the effective date of this Decree.

§ 27

Technical regulation

This Decree was 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 technical regulations and of rules on Information Society services.

§ 28

Effective date

This Decree shall come into effect on 1 July 2025.

Minister of Health:

Maximum quantity of a psychomodulatory substance in a unit packet, list of active substances and their maximum quantity in a unit packet, and the maximum concentration of active substances in a psychomodulatory substance

Psychomodulatory substance	Maximum quantity of a psychomodulatory substance in a unit packet	Active substance	Maximum quantity of an active substance in a unit packet	Maximum concentration of an active substance in % by weight of the psychomodulatory substance
Kratom	50 g	Mitragynine	1250 mg	2.5
		7-hydroxymitragynine	50 mg	0.1
Kratom extract	10 g or 10 ml	Mitragynine	1250 mg	12.5
		7-hydroxymitragynine	50 mg	0.5
Cannabis containing no more than 1 % of substances of the tetrahydrocannabinol group	15 g	Substances of the tetrahydrocannabinol group	150 mg*)	1.0
Cannabis extract and tincture containing no more than 1 % of substances of the tetrahydrocannabinol group	10 g or 10 ml	Substances of the tetrahydrocannabinol group	100 mg*)	1.0

*) The value represents the combined weight of all substances of the tetrahydrocannabinol group

Names, forms and subtypes of psychomodulatory substances and their characteristic appearance and properties

Psychomodulatory substance	Name	Form	Subtype	Characteristic appearance and properties
Kratom	Kratom	Powder	Green	Finely crushed or ground mixture of dried leaves of the plant *Mitragyna speciosa* predominantly green in colour.
			White	Finely crushed or ground mixture of dried leaves of the plant *Mitragyna speciosa* predominantly white in colour.
			Yellow	Finely crushed or ground mixture of dried leaves of the plant *Mitragyna speciosa* predominantly yellow in colour.
			Red	Finely crushed or ground mixture of dried leaves of the plant *Mitragyna speciosa* predominantly red in colour.
			Brown	Finely crushed or ground mixture of dried leaves of the plant *Mitragyna speciosa* predominantly brown in colour.
			Golden	Finely crushed or ground mixture of dried leaves of the plant *Mitragyna speciosa* predominantly golden in colour.
Kratom extract	Kratom	Extract	Concentrated powder	Powdery substance made from the psychomodulatory substance Kratom.
			Alcohol tincture	Liquid substance containing an alcohol-based solvent, made from the psychomodulatory substance Kratom.
			Oil tincture	Liquid substance containing an oil-based solvent, made from the psychomodulatory

				substance Kratom.
			Fat paste	Paste-like substance containing a fat- or oil-based solvent, made from the psychomodulatory substance Kratom.
			Paste	Paste-like substance containing other than a fat- or oil-based solvent, made from the psychomodulatory substance Kratom.
			Jelly	Semi-solid substance containing a jelly-based solvent, made from the psychomodulatory substance Kratom.
			Compressed substance	Semi-solid to solid substance containing a solvent, made from the psychomodulatory substance Kratom.
Cannabis containing no more than 1 % of substances of the tetrahydrocannabinol group	Cannabis up to 1 % THC	Plant top	-	Whole dried cymose inflorescence of the plant *Cannabis sativa* that is dark-green, grey-green to brown-green in colour and crowded into dense spikes. Tiny flowers are wrapped in bracts covered with glandular hairs on the upper side.
Cannabis containing no more than 1 % of substances of the tetrahydrocannabinol group	Cannabis up to 1 % THC	Plant top	Decarboxylated	Heat-decarboxylated whole dried cymose inflorescence of the plant *Cannabis sativa* that is dark-green, grey-green to brown-green in colour and crowded into dense spikes. Tiny flowers are wrapped in bracts covered with glandular hairs on the upper side.

Cannabis extract and tincture containing no more than 1 % of substances of the tetrahydrocannabinol group	Cannabis up to 1 % THC	Extract	Alcohol tincture	Liquid substance containing an alcohol-based solvent, made from Cannabis containing up to 1 % THC.
			Oil tincture	Liquid substance containing an oil-based solvent, made from Cannabis containing up to 1 % THC.
			Fat paste	Paste-like substance containing a fat- or oil-based solvent, made from Cannabis containing up to 1 % THC.
			Paste	Paste-like substance containing a semi-solid solvent other than a fat- or oil-based one, made from Cannabis containing up to 1 % THC.
			Jelly	Semi-solid substance containing a jelly-based solvent, made from Cannabis up to 1 % THC.
			Compressed substance	Solid substance containing a solid-based solvent, made from Cannabis up to 1 % THC.

Chemical and microbiological requirements for psychomodulatory substances

1) This Annex sets out the indicators for contaminating chemicals and microorganisms and their permissible values (PV).

2) If the permissible values set out in this Annex are exceeded for a psychomodulatory substance, that psychomodulatory substance shall be considered unfit for placing on the market.

3) The permissible values for chemical indicators are given in mg per 1 kg or l of the sample.

4) Method of expressing the permissible values for microbiological indicators:

a) the permissible amount of microorganisms in 1 g or in 1 ml of the sample; colony-forming units (CFU) are counted as microorganisms, for example, 105 indicates a permissible amount of 1.105 microorganisms in 1 g or in 1 ml of the sample, 5.10 indicates a permissible amount of 5.10 microorganisms in 1 g or in 1 ml of the sample,

b) requirement for the absence of microorganisms in the weighed portion or volume of the sample, expressed in grams (g) or millilitres (ml) designated for testing, as indicated after the slash following the term ‘negat’.

5) The procedures for sampling and for chemical and microbiological testing shall follow the applicable technical procedures for the chemical and microbiological testing of foodstuffs.

Indicator	Permissible values (PV)
Chemical indicators	
Metals and metalloids	
Arsenic (As)	0.50
Heavy metals	
Lead (Pb)	3.0
Cadmium (Cd)	1.0
Mercury (Hg)	0.10
Mycotoxins	
Aflatoxin B_1	0.005
Total content of aflatoxins B_1, B_2, G_1 and G_2	0.01
Other chemical indicators	
Polycyclic aromatic hydrocarbons	0.05
Microbiological indicators	
Total plate count	10^7
Total yeast/mould count	10^5
Escherichia coli	10^2
Salmonella spp.	‘negat/25’

Explanatory notes:

The polycyclic aromatic hydrocarbons (PAHs) indicator includes the sum of PAHs comprising benzo(α)anthracene, benzo(b)fluoranthene, chrysene, and benzo(a)pyrene.

Text of the consumer information notice

1) The text of the information notice for the psychomodulatory substance Kratom and the psychomodulatory substance Kratom extract reads as follows:

‘This product has psychoactive effects. This product is not a food. This product is not a medicinal product and has not been clinically tested. If you are unsure whether this product is suitable for you, consult your physician.

Effects:

At the recommended dosage, this product has stimulating effects. If the recommended dosage is exceeded, this product has sedative effects.

The use of this product may affect alertness, movement coordination, speech coordination, balance, sensory perception, pain perception, sleep, mood, and immune system function.

Prolonged use of high doses may lead to addiction. This product should not be used every day; there should be a three-day break between each use. Long-term effects on human health have not been sufficiently documented, especially for uses other than oral use of the dried plant itself.

Warning:

Do not use this product while, immediately before, or within eight hours before driving a motor vehicle or performing activities requiring increased attention, concentration, or motor coordination. If you feel under the influence of this product, do not drive or engage in such activities even after this period.

This product is not intended for persons under 18 years of age. Do not use this product in combination with other psychoactive substances, alcohol, nicotine, medicines, or during pregnancy or breastfeeding, or if you suffer from mental health illness or physical illness involving impaired kidney, liver, heart, or vascular function.

There have been reports of suspected kratom poisoning and subsequent death.

Use in accordance with the instructions for use. Do not exceed the recommended daily dose. Keep out of reach of persons under 18 years of age.’.

2) The text of the information notice for the psychomodulatory substance Cannabis containing no more than 1 % of substances of the tetrahydrocannabinol group and the psychomodulatory substance Cannabis extract and tincture containing no more than 1 % of substances of the tetrahydrocannabinol group reads as follows:

‘This product has psychoactive effects. This product is not a food. This product is not a medicinal product and has not been clinically tested. If you are unsure whether this product is suitable for you, consult your physician.

Effects:

This product has sedative effects. Use of this product may cause fatigue and drowsiness.

Prolonged use of high doses of substances of the tetrahydrocannabinol group may lead to addition. Be mindful of the content of substances of the tetrahydrocannabinol group in the dose being used. The use of substances of the tetrahydrocannabinol group may cause psychiatric and psychological changes affecting mental and physical health, such as schizophrenia, development of psychosis, reduced intellectual ability, or impaired cognitive function.

Warning:

Do not use this product while, immediately before, or within eight hours before driving a motor vehicle or performing activities requiring increased attention, concentration, or motor coordination. If you feel under the influence of this product, do not drive or engage in such activities even after this period.

This product is not intended for persons under 18 years of age. Do not use this product in combination with other psychoactive substances, alcohol, nicotine, medicines, or during pregnancy or breastfeeding, or if you suffer from any mental health illness or physical illness involving impaired kidney, liver, heart, or vascular function.

Use in accordance with the instructions for use. Do not exceed the recommended daily dose. Keep out of reach of persons under 18 years of age.’.

Maximum permitted single doses and maximum permitted daily doses of the active substance

Psychomodulatory substance	Active substance	Maximum permitted single dose of the active substance	Maximum permitted daily dose of the active substance
Kratom Kratom extract	Mitragynine	125 mg	375 mg
	7-hydroxymitragynine	5 mg	15 mg
Cannabis containing no more than 1 % of substances of the tetrahydrocannabinol group Cannabis extract and tincture containing no more than 1 % of substances of the tetrahydrocannabinol group	Substances of the tetrahydrocannabinol group*)	2.5 mg	5 mg

*) The values represent the combined weight of all substances of the tetrahydrocannabinol group

1) The values given in the table are intended for oral administration, i.e. administration involving the swallowing of the substance, where absorption occurs predominantly in the lower parts of the digestive tract and not exclusively or almost exclusively in the oral cavity.

2) If the method of use indicated in the product's instructions for use includes administration other than oral, the permitted single dose and the permitted daily dose shall not exceed 30 % of the value indicated in the table.

Safety warning on the risks of use of the product by minors

The safety warning on the risks of use of the product by minors consists of a graphic symbol in the form of a prohibition sign, which is circular in shape, with a diameter of at least 1 cm, a white background, a circle with a thick red border, and a red diagonal stripe crossing the black number 18 on a white background (Figure 1).

Figure 1

Technical requirements for quality verification of a psychomodulatory substance lot

1. Microbiological analyses

Sampling for microbiological analysis must be carried out with the utmost care and in accordance with established hygiene standards to avoid contamination of the sample during collection.

1.1. Sampling techniques

The general principles for the sampling of psychomodulatory substances for microbiological analysis were compiled on the basis of the preliminary standard ČSN P CEN ISO/TS 17728: Microbiology of the food chain — Sampling techniques for microbiological analysis of food and feed samples, and the technical standard ČSN EN ISO 7218: General requirements and guidance for microbiological examinations.

A packaged product in a unit packet stored at ambient temperature shall be sampled without damaging the packaging, labelled with sample identification data (name, subtype and form of psychomodulatory substance, lot marking, manufacturer, and brand name, if given) and transported to the laboratory at the storage temperature indicated on the product label or at room temperature (18 °C to 27 °C – see ISO 7218).

Sampling plan

It is not specified in the Decree on psychomodulatory substances; therefore, n = 1 is taken, and the sample is not composed of subsamples.

Method of selection of packaged products for the sample

Random (spot) or systematic

Minimum size of a single sample of packaged products

If a sample is taken to determine **all five microorganisms** (MOs) listed in Annex 3 (microbiological indicators), the size of the aggregate sample consisting of at least two packages shall be at least 200 g (ml).

If a sample is taken to determine **one species of microorganisms** listed in Annex 3 (microbiological indicators), the size of the aggregate sample consisting of at least two units of packaging shall be as follows:

Salmonella spp. – min. 80 g

Total plate count – min. 40 g

Yeasts and moulds: min. 40 g for both MOs

Escherichia coli – min. 40 g.

Transport of the sample to the laboratory

Cross-contamination of samples, leakage, or loss or gain of moisture must be prevented during storage and transport of the sample. During transport, the samples must be kept under conditions as close as possible to their original storage conditions and these conditions must be maintained throughout the entire period of transport.

Unless otherwise specified (e.g. by the manufacturer or applicable legislation), the following temperatures are recommended for the transport of samples:
- stable products: ambient temperature (18 °C to 27 °C),
- other products not stable at ambient temperature: 1 °C to 8 °C (ideally not more than 4 °C),

The duration of transport must be as short as possible and take place under controlled temperature conditions to ensure the preservation of the samples' integrity and analytical properties (which is in the manufacturer's interest).

1.2. Analytical methods

The analyses must be started within 24 hours of sampling.
The microbiological requirements set out in Annex 3 shall be checked in accordance with the Czech technical standards, which shall be used as the reference test methods:

Microorganism	**Reference test methods**
Total number of microorganisms (aerobic mesophilic microorganisms)	ČSN EN ISO 4833-1 or 2
Yeasts and moulds	ČSN ISO 21527-1 or 2
Escherichia coli	ČSN ISO 16649-1 o 2
Salmonella	ČSN EN ISO 6579-1

The use of alternative analytical methods is acceptable provided they are:
a) validated against the specific reference method provided for in the table in accordance with the protocol set out in standard ČSN ISO 16140-2, and
b) validated for a broad range of food as referred to in standard ČSN EN ISO 16140-2

Measurement uncertainty and evaluation

In the case of microbiological requirements for psychomodulatory substances, measurement uncertainty must not be considered as an additional tolerance when evaluating compliance of the measured value with the permissible value under the microbiological requirements for psychomodulatory substances set out in Annex 3.

2. Chemical analyses

2.1. Metals and metalloids, heavy metals (As, Pb, Cd, Hg)

2.1.1. Sampling

Minimum size of aggregate sample: 100 g or 100 ml.

and, at the same time:

Minimum number and size of subsamples of the psychomodulatory substance

Lot size (number of	**Aggregate sample – Number of packages to**	**Size of laboratory sample**

packages)	be taken for sample	
1–250	2	Whole content of the package
251–1 000	4	From each retail package taken for sample, half of the content of the package
> 1 000	4 packages + 1 package for every additional 1 000 retail packages maximum 25 retail packages	≤ 10 packages: half of the content of each retail package > 10 packages: an equal quantity is taken from each package to result in a sample with the equivalent of the content of five packages

Method of sampling: Incremental samples shall be taken from different locations within the lot or sublot

2.1.2. Requirements for analyses:

Each laboratory sample shall be thoroughly mixed (and finely ground, if necessary).

Parameter	Characteristics	
Specificity	Free from matrix or spectral interferences	
Repeatability (RSD_r)	HORRAT $_r$ less than 2	
Reproducibility (RSD_R)	HORRAT $_R$ less than 2	
Recovery	If an extraction step is applied in the analytical method, the analytical result shall be corrected for recovery. If this is the case, the recovery rate shall be reported. In case no extraction step is applied in the analytical method (e.g. in the case of metals), the result may be reported uncorrected for recovery if evidence is provided by ideally making use of suitable certified reference material that the certified concentration allowing for the measurement uncertainty is achieved (i.e. high accuracy of the measurement) and thus that the method is not biased. In case the result is reported uncorrected for recovery this shall be mentioned.	
LOD	= three tenths of LOQ	
LOQ	Lead, cadmium, mercury	≤ one fifth of the permissible value
	Arsenic	≤ two thirds of the

		permissible value

2.2. Mycotoxins (Aflatoxin B1, Total content of aflatoxins B1, B2, G1 and G2)

2.2.1. Sampling

Minimum size of aggregate sample: 100 g or 100 ml.
and, at the same time:

Minimum number and size of subsamples of the psychomodulatory substance

Lot size (number of packages)	Aggregate sample – Number of packages to be taken for sample	Size of laboratory sample
1–250	2	Whole content of the package
251–1 000	4	From each retail package taken for sample, half of the content of the package
> 1 000	4 packages + 1 package for every additional 1 000 retail packages maximum 25 retail packages	≤ 10 packages: half of the content of each retail package > 10 packages: an equal quantity is taken from each package to result in a sample with the equivalent of the content of five packages

Method of sampling: Incremental samples shall be taken from different locations within the lot or sublot
Samples shall be placed in light-impermeable packaging immediately after sampling (unless already in light-impermeable packaging).

2.2.2. Requirements for analyses:

Each laboratory sample shall be thoroughly mixed (and finely ground, if necessary).

Recovery: the average recovery should be between 70 % and 120 %.

Average recovery is the mean value from replicate samples obtained during validation when determining the precision parameters RSD_r and RSD_{wR}.

Precision

The RSD_r shall be ≤ 20 %.

The RSD_{wR} shall be ≤ 20 %.

The RSD_R should be ≤ 25 %.

These criteria apply to all concentrations.

In case a laboratory provides the evidence that the RSD_{wR} criterion is complied with, there is no need to provide evidence for the RSD_r criterion as compliance with RSD_{wR} guarantees compliance with the RSD_r criterion.

Limit of quantification

The method must meet the limit of quantification (LOQ) requirement for each individual substance (Aflatoxin B1, B2, G1, G2) of 0.001 mg/kg or lower.

Identification

For identification, the criteria as laid down in the Guidance document on identification of mycotoxins and plant toxins in food and feed of 1 January 2023, published by the Network of National Reference Laboratories cooperating with the European Union Reference Laboratory for mycotoxins and plant toxins in food and feed, and available on the European Commission's website, shall be applied.

Note:
a) Repeatability relative standard deviation (RSDr) means the relative standard deviation (in %) calculated from results generated under repeatability conditions (repeatability precision): using the same method on the same sample material in one laboratory by the same operator, with the same instrument, within a short interval of time (one day or one sequence).
b) Within-laboratory reproducibility relative standard deviation (RSDwR) means the relative standard deviation (in %) calculated from results generated under within-laboratory reproducibility conditions (intermediate precision): using the same method on the same sample material in one laboratory but on different days (preferably a longer time interval) and may include other conditions, such involving different operators and/or different (equivalent) instruments.
c) Reproducibility relative standard deviation (RSDR) means the relative standard deviation (in %) calculated from results generated under reproducibility conditions (interlaboratory precision), meaning the same material is analysed by different laboratories. The RSDR can be derived from, in particular, collaborative studies and proficiency tests.
d) Limit of quantification (LOQ) means the lowest content of the analyte which can be measured with reasonable statistical certainty. In the context of this regulation this means the lowest successfully validated level: the lowest tested concentration of analyte in a sample material, for which it has been demonstrated that the criteria for recovery, precision, and identification are met.

2.3. PAHs (sum of PAHs comprising benzo(α)anthracene, benzo(b)fluoranthene, chrysene, and benzo(a)pyrene)

2.3.1. Sampling

Minimum size of aggregate sample: 100 g or 100 ml.
and, at the same time:

Minimum number and size of subsamples of the psychomodulatory substance

Lot size	Aggregate sample –	Size of laboratory sample

(number of packages)	Number of packages to be taken for sample	
1–250	2	Whole content of the package
251–1 000	4	From each retail package taken for sample, half of the content of the package
> 1 000	4 packages + 1 package for every additional 1 000 retail packages maximum 25 retail packages	≤ 10 packages: half of the content of each retail package > 10 packages: an equal quantity is taken from each package to result in a sample with the equivalent of the content of five packages

Method of sampling: Incremental samples shall be taken from different locations within the lot or sublot

2.3.2. Requirements for analyses:

Each laboratory sample shall be thoroughly mixed (and finely ground, if necessary).

Parameter	Characteristics
Specificity	Free from matrix or spectral interferences, verification of positive detection
Repeatability (RSD_r)	HORRAT $_r$ less than 2
Reproducibility (RSD_R)	HORRAT $_R$ less than 2
Recovery	50-120 %
LOD	≤ 0.30 µg/kg for each of the four substances
LOQ	≤ 0.90 µg/kg for each of the four substances

2.4. Analysis of the content of active substances in the psychomodulatory substance

These analyses shall be carried out for the purposes of verifying compliance with the requirements for the maximum concentration of active substances in psychomodulatory substances.

2.4.1. Sampling

Minimum size of aggregate sample: 100 g or 100 ml.
and, at the same time:

Minimum number and size of subsamples of the psychomodulatory substance

Lot size (number of packages)	Aggregate sample – Number of packages to be taken for sample	Size of laboratory sample
1–250	2	Whole content of the package
251–1 000	4	From each retail package taken for sample, half of the content of the package
> 1 000	4 packages + 1 package for every additional 1 000 retail packages maximum 25 retail packages	≤ 10 packages: half of the content of each retail package > 10 packages: an equal quantity is taken from each package to result in a sample with the equivalent of the content of five packages

Method of sampling: Incremental samples shall be taken from different locations within the lot or sublot

2.4.2. Requirements for analyses

Each laboratory sample shall be thoroughly mixed (and finely ground, if necessary).

The method of liquid chromatography with mass spectrometric detection (LC-MS/MS) shall be used for the determination.

Recovery: the average recovery should be between 70 % and 120 %.

Average recovery is the mean value from replicate samples obtained during validation when determining the precision parameters RSD_r and RSD_{wR}.

Precision

The RSD_r shall be ≤ 20 %.

The RSD_{wR} shall be ≤ 20 %.

The RSD_R should be ≤ 25 %.

These criteria apply to all concentrations.

In case a laboratory provides the evidence that the RSD_{wR} criterion is complied with, there is no need to provide evidence for the RSD_r criterion as compliance with RSD_{wR} guarantees compliance with the RSD_r criterion.

Limit of quantification

The method must meet the limit of quantification (LOQ) requirement for each analyte at max. 1 mg/kg

Identification

For identification, the criteria as laid down in the Guidance document on identification of mycotoxins and plant toxins in food and feed of 1 January 2023, published by the Network of National Reference Laboratories cooperating with the European Union Reference Laboratory for mycotoxins and plant toxins in food and feed, and available on the European Commission's website, shall be applied.

2.5. Approach to sampling for chemical analyses (elements, aflatoxins, PAHs and active substances)

2.5.1. Sampling for chemical analyses (elements, aflatoxins, PAHs and active substances)

The sample sizes referred to in points 2.1.1, 2.2.1, 2.3.1 and 2.4.1 must be complied with when the testing of the samples is carried out by different laboratories (i.e. testing to determine the content of elements, aflatoxins, PAHs, and active substances is carried out separately for each group of substances in a different laboratory).

Where testing for several of groups of the above analyses is carried out in a single laboratory, the quantity of the sample taken to that laboratory shall be at least 100 g or 100 ml, in accordance with the minimum sample size requirement of the laboratory carrying out the testing of the sample (the aggregate sample size thus need not be the sum of the aggregate sample sizes given in points 2.1-2.4). At the same time, however, compliance must be ensured with the requirements for the minimum number and size of subsamples specified in the relevant table under any of points 2.1.1, 2.2.1, 2.3.1, and 2.4.1.

3. Acceptance of a lot

3.1. Acceptance of a lot for demonstration of conformance to the maximum concentration of active substances in a psychomodulatory substance

Acceptance: If the laboratory sample conforms to the maximum concentration of active substances set out in Annex 1 to this Decree, after correction for recovery and taking into account the measurement uncertainty with respect to the assessed maximum concentration (note: in this case, the measurement uncertainty is taken into account only by adding it to the measured value).

3.2. Acceptance of a lot for demonstration of conformance to the microbiological requirements for psychomodulatory substances

Acceptance: If the laboratory sample conforms to the permissible values of the microbiological indicators set out in Annex 3 to this Decree. Measurement uncertainty is not taken into account.

3.3. Acceptance of a lot for demonstration of conformance to the chemical requirements for psychomodulatory substances

Acceptance: If the laboratory sample conforms to the permissible values of the chemical indicators set out in Annex 3 to this Decree, after correction for recovery and taking into account the measurement uncertainty with respect to the assessed maximum concentration (note: in this case, the measurement uncertainty is taken into account only by adding it to the measured value).

3.4. Acceptance of a lot for demonstration of conformance to the declared quantity of active substances

Acceptance: If the laboratory sample conforms to the declared quantity of the active substance on the packaging of the psychomodulatory substance, after correction for recovery and taking into account the measurement uncertainty to the detriment of the assessed maximum quantity of the active substance.

3.5. Acceptance of a lot for demonstration of conformance to the declared quantity of the psychomodulatory substance in a unit packet

Acceptance: If the laboratory sample conforms to the declared quantity of the psychomodulatory substance in the unit packet and does not exceed the maximum quantity of the psychomodulatory substance in the unit packet set out in Annex 1 to this Decree.