#### ACT

#### of ..... 2024

### amending Act No 167/1998 on addictive substances and amending certain other acts, as amended, and other related acts

Parliament has adopted the following Act of the Czech Republic:

## PART ONE Amendment to the Act on Addictive Substances

#### Article I

Act No 167/1998, on addictive substances and on amendments to certain other acts, as amended by Act No 354/1999, Act No 117/2000, Act No 132/2000, Act No 57/2001, Act No 185/2001, Act No 407/2001, Act No 320/2002, Act No 223/2003, Act No 362/2004, Act No 228/2005, Act No 74/2006, Act No 124/2008, Act No 41/2009, Act No 141/2009, Act No 281/2009, Act No 291/2009, Act No 106/2011, Act No 341/2011, Act No 375/2011, Act No 18/2012, Act No 167/2012, Act No 50/2013, Act No 273/2013, Act No 135/2016, Act No 243/2016, Act No 298/2016, Act No 65/2017, Act No 183/2017, Act No 366/2021 and Act No 417/2021, is amended as follows:

1. In Section 1(1), at the end of subparagraph (b), the word 'and' is replaced by a comma.

2. In Section 1, the full stop at the end of paragraph (1) is replaced by the word 'and' and a subparagraph (d) is added, which reads as follows:

'(d) handling of psychomodulating substances and scheduled psychoactive substances.'.

3. In Section 2, subparagraphs (l) to (s) are added at the end of paragraph 1 which, including footnote 2h, read as follows:

- '(l) 'psychomodulating substances' mean new psychoactive substances<sup>2h</sup>) and other substances with psychoactive effect that do not pose a serious risk to public health or a risk of severe social impacts on individuals and society, and are listed in the Government Regulation on the Schedule of psychomodulating substances and products thereof;
- (m) 'production of psychomodulating substances' means cleaning, sorting, processing, packaging and other treatment of psychomodulating substances in order to making them available on the market;
- (n) 'placing psychomodulating substances on the market' means any provision of psychomodulating substances to the final consumer;

- (o) 'distribution of psychomodulating substances' means their purchase for further resale and sale; placing psychomodulating substances on the market is not considered to be a distribution;
- (p) 'unit packet of a psychomodulating substance' means a single packet of a psychomodulant that is placed on the market;

(q) 'import of psychomodulating substances' means their physical transfer into the Czech Republic;

- (r) 'export of psychomodulating substances' means their physical transfer outside the Czech Republic;
- (s) 'scheduled psychoactive substances' mean new psychoactive substances for which, in the light of existing scientific knowledge, severe health and social risks cannot be ruled out and are listed in the Government Regulation on Scheduled psychoactive substances and products thereof.
- <sup>2h</sup>) Article 1(4) of Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as amended.'.

4. In Section 8a, the words ', psychomodulating substances or included psychoactive substances' are added at the end of paragraph 2.

5. In Part One, a new Chapter VII is inserted after Chapter VI which, including the headings and footnotes 10m, 10p to 10zc, reads as follows:

#### **'CHAPTER VII**

# PSYCHOMODULATING SUBSTANCES AND SCHEDULED PSYCHOACTIVE SUBSTANCES

# Part 1 Psychomodulating substances

# Section 33a Handling of psychomodulating substances

(1) The handling of psychomodulating substances means:

- a) research of psychomodulating substances;
- b) production, import and distribution of psychomodulating substances;
- c) the purchase and marketing of psychomodulating substances in order to place them on the market, as well as the acquisition and marketing of other rights in rem and obligations attached to them, with the exception of marketing by means of distance communication;
- d) the purchase of psychomodulating substances in order to place them on the market, as well as the acquisition of other rights in rem and obligations attached to them for that purpose, and their marketing by means of distance communication;
- e) storage and transport of psychomodulating substances for others, with the exception of storage and transport for the purpose of delivering to consumers a psychomodulating substance purchased by means of distance communication pursuant to the Act on the on the protection of health from the harmful effects of addictive substances;

f) growing plants or fungi from which psychomodulating substances can be obtained.

(2) The cultivation and handling of plants of technical hemp and technical hemp pursuant to Section 5(5), or the handling of hemp extract and tincture containing no more than 1 % of substances from the tetrahydrocannabinol group, for industrial, food, cosmetic, technical or horticultural purposes shall not be considered as handling psychomodulatory substances.

(3) Furthermore, as a handling of psychomodulating substances shall not be considered to be:

- a) the possession of psychomodulating substances by natural persons for personal use;
- b) the handling of small quantities of psychomodulating substances by a natural persons;
- c) handling of psychomodulating substances by an accredited laboratory for the purpose of issuing a certificate pursuant to Section 33f(3);
- d) the handling of psychomodulating substances within the activities of state authorities within their competence, activities of local self-government units within their delegated competence and activities in ensuring local public order matters within their independent competence and activities of the Army of the Czech Republic, the Police of the Czech Republic, the General Inspectorate of Security Forces, the Prison Service of the Czech Republic and the Customs Administration of the Czech Republic in the performance of their tasks.

(4) The handling of psychomodulants referred to in paragraph 1(a), (b), (c), (d) and (f) shall also include the storage and transport of psychomodulants related to those activities.

(5) The handling of psychomodulation substances other than those referred to in paragraphs 1 and 4 is prohibited.

## Section 33b A permit to handle psychomodulating substances

The handling of psychomodulating substances requires a permit, unless otherwise provided for in this Act.

#### Section 33c Issuance of permits to handle psychomodulating substances

(1) Permits to handle psychomodulation substances are issued by the Ministry of Health. The permit for handling only authorises the activities referred to therein. The permit referred to in the first sentence shall be issued for an indefinite period.

(2) The permit to handle psychomodulation substances is non-transferable.

(3) The permit to handle psychomodulation substances may only be granted to a legal person or an entrepreneurial natural person.

(4) Applications for permits to handle of psychomodulating substances shall be submitted on a form issued by the Ministry of Health, the specimen of which is laid down in implementing legislation. The application shall include

- a) name, registered office, identification number, if assigned, and legal form, in the case of a legal person;
- b) name(s) and surname(s), date of birth, registered office and identification number, if assigned, in the case of a sole trader;

c) a list and description of the activities pursuant to Section 33a(1) for which the applicant is applying;

- d) the address of the establishment(s) where the psychomodulating substances will be handled;
- e) name and address of website, the title of the application or other electronic interface identifier and a description of the age verification system<sup>10m</sup>) and of securing its operation in the case of handling pursuant to Section 33a(1)(d).

(5) The application referred to in paragraph 4 shall be accompanied by:

- a) a business licence;
- b) the consent of the owner of the property to carry out the activities specified in the application, if the applicant is not the owner of the property;
- c) a research project with justification, a list of research questions, a description of the methodology, the analytical strategy and the research implementation team, in the case of an application for a handling permit pursuant to Section 33a(1)(a);
- d) proof of payment of the fee for psychomodulating substances pursuant to the Administrative Fees Act, with the exception of an application for a permit to handle psychomodulating substances pursuant to Section 33a(1)(a);
- f) proof of integrity pursuant to Section 8a; Section 8a(4) shall apply mutatis mutandis.

(6) The Ministry of Health shall publish a list of persons handling psychomodulation substances, including the data referred to in paragraph 4, on its website.

(7) The document referred to in paragraph 5(a) shall not be required in the case of an application for a permit to handle psychomodulation substances pursuant to Section 33a(1)(a) if the applicant is a university<sup>10p</sup>), public research institution<sup>10q</sup>) or health service provider<sup>10r</sup>).

(8) A legal person or a entrepreneurial natural person dealing with psychomodulation substances shall notify the Ministry of Health without undue delay of any changes and additions concerning the particulars referred to in paragraph 4 and the documents referred to in paragraph 5.

(9) A permit to handle psychomodulatory substances pursuant to Section 33a(1)(d) may only be issued to a person who holds a valid authorisation for the handling of psychomodulatory substances pursuant to Section 33a(1)(c).

(10) In the case that the applicant does not attach to the application the document referred to in paragraph 5(d), the procedure for the application for authorisation to handle psychomodulation substances shall not be initiated and the Ministry of Health shall postpone the matter by a resolution. The resolution shall be recorded in the file. The resolution cannot be appealed. The applicant shall be informed of the resolution by appropriate means.

#### Section 33d

## Cancellation and revocation of permits for the handling of psychomodulating substances

(1) If a legal person or an entrepreneurial natural person ceases to carry out an activity for which a permit to handle psychomodulating substances has been issued, they shall notify the Ministry of Health thereof without undue delay. The notification referred to in the first sentence shall be made on a form issued by the Ministry of Health, the specimen of which shall be laid down in the implementing legislation.

(2) The Ministry of Health decides to revoke the authorisation for the handling of psychomodulating substances

- a) in the cases pursuant to paragraph (1); or
- b) at the request of a corporate entity or entrepreneurial natural person who has been granted a permit to handle psychomodulating substances; the request to cancel the permit to handle psychomodulating substances shall be made on a form issued by the Ministry of Health, the specimen of which shall be laid down in implementing legislation.

(3) The Ministry of Health shall decide to withdraw the authorisation for the handling of psychomodulatory substances;

- a) if a legal person or an entrepreneurial natural person has been finally convicted of a criminal offence the substance of which is related to the handling of psychomodulating substances or classified psychoactive substances;
- b) if the maintenance fee is not paid according to the Administrative Fees Act.

(4) Furthermore, the Ministry of Health may decide to withdraw the permit to handle psychomodulatory substances;

- a) if it finds that the corporate entity or entrepreneurial natural person has provided false or incomplete information in the application;
- b) if a corporate entity or entrepreneurial natural person, when the handling of psychomodulating substances, breaches an obligation laid down in this Act and has been finally fined for this infraction;
- c) if a corporate entity or entrepreneurial natural person breaches the Act on the protection of health against the harmful effects of addictive substances10s) when handling psychomodulating substances and has been finally fined.

(5) A person whose permit for the handling of psychomodulatory substances has been withdrawn in accordance with paragraphs 3 or 4 may be granted a new permit to handle psychomodulatory substances not earlier than two years after the date on which the decision to withdraw the authorisation for the handling of psychomodulatory substances became final. This shall apply mutatis mutandis to a legal person whose statutory body is a person who has been the statutory body of the holder of a handling permit at the time when the validity of the handling permit was withdrawn.

(6) If the Ministry of Health decides to withdraw the permit to handle psychomodulatory substances or by its decision revokes the permit to handle psychomodulatory substances, it shall specify in the decision a time limit for the ceasing the operations and the manner in which the psychomodulatory substances are to be handled.

## Section 33e Labelling of psychomodulating substances

(1) The manufacturer or distributor of psychomodulation substances shall ensure that the following particulars appear on the unit packet and the outside packaging of psychomodulation substances, in accordance with the implementing legislation:

- a) the text 'Psychomodulating substance';
- b) the name of the psychomodulating substance;
- c) the subtype and form of the psychomodulating substance;
- d) the name of the active substances;
- e) the net quantity of psychomodulating substance in the unit packet;
- f) the net quantity of active substances in the unit packet;
- g) the name(s) and surname, or the name or business name and address of the registered office of the manufacturer(s);
- h) the country of origin;
- i) the date of manufacture;
- j) batch identification;
- k) the best-before date;
- l) information for consumers on effects and risks;
- m) information on the recommended dosage;
- n) a safety warning regarding the dangers of use of the product by minors;
- o) a health warning;
- p) information on the presence of substances that may cause allergies or intolerance in certain persons.

(2) The manner in which the particulars referred to in paragraph 1 are to be stated and defined in detail shall be laid down in implementing legislation.

(3) A batch means a quantity of identical types of unit packages of psychomodulating substances manufactured under the same conditions, from the same raw material and at the same time.

(4) Consumer information notice, safety warning on the danger of use of the product by minors and health warning shall mean the textual and graphic information provided for in the implementing legislation.

(5) The information on the packaging shall not encourage the risky use of the psychomodulation substance.

(6) Psychomodulation substances may not be placed on the market without the labelling referred to in paragraph 1.

(7) The person who places psychomodulatory substances on the market by means of distance communication shall, when offering psychomodulating substances to the consumer by means of distance communication, provide the data referred to in subparagraphs (a) to (h) and (l) to (p) of paragraph 1 before the completion of the purchase and include them in the material supporting distance sales or make them available by other appropriate means; where other means are used, the mandatory information on psychomodulation substances shall be provided to the consumer free of charge and all mandatory particulars shall be made available to the consumer at the time of delivery.

#### Section 33f

## Production, distribution and marketing of psychomodulatory substances

(1) The manufacturer of psychomodulation substances shall comply with the requirements of good manufacturing practice at all stages of production. The requirements for good manufacturing practice are laid down in an implementing legislation.

(2) The manufacturer or distributor of psychomodulation substances shall verify, before making it available for placing on the market, that the batch of psychomodulation substances placed on the market complies with the requirements concerning the maximum concentration of active substances in psychomodulation substances and the maximum permissible chemical and microbiological contamination.

(3) The certificate of verification of compliance with the obligations referred to in paragraph 2 shall be issued by an accredited laboratory. Without this certificate, the batch cannot be placed on the market.

(4) For the purposes of this Act, an accredited laboratory means a laboratory that is accredited by an accreditation body under the Czech technical standard governing the requirements for the competence of testing and calibration laboratories10t) to carry out such tests under the Act governing conformity assessment10u). The scope of accreditation of a laboratory shall include the laboratory analytical, test or diagnostic methods used by the laboratory to demonstrate compliance with the requirements referred to in paragraph 2.

(5) The manufacturer, distributor or person who places psychomodulative substances on the market are obliged to:

- a) use only packaging and packaging materials that protect the product against deterioration, prevent substitution or alteration of the contents without opening or changing the packaging;
- b) in the case of psychomodulating substances intended for oral use, use only packaging which complies with the requirements for articles and materials intended to come into contact with food<sup>10v</sup>);
- c) place on the market or make available for placing on the market psychomodulating substances solely in unit packets;
- d) immediately exclude from further placing on the market or making available for placing on the market psychomodulating substances
  - 1. packed in packaging which does not conform to the requirements for articles and materials intended to come into contact with food or in packaging which does not protect psychomodulating substances from deterioration<sup>10w</sup>)<sup>, 10x</sup>;
  - 2. inadequately or incorrectly labelled; or
  - 3. which are smelling, if the odour is not a characteristic of the product, or are damaged, deformed, contaminated or obviously chemically or microbiologically disturbed.

(6) It shall be prohibited to place or make available for placing on the market psychomodulating substances which:

a) are misleadingly labelled or offered in a deceptive manner;

- b) resemble confectionery, chocolate or chocolate sweets<sup>10</sup>), biscuits or long-life pastries<sup>10z</sup>), or other foodstuffs;
- c) resemble a toy or a product intended for children;
- d) are of unknown origin;
- e) contain tobacco, nicotine, nicotine salts, narcotics and psychotropic substances or other psychomodulating substances;
- f) contain caffeine, taurine or other stimulant ingredients;
- g) exceed the maximum permitted amount of psychomodulating substance or the maximum permitted amount of active substance in a unit packet or exceed the maximum permitted concentrations of active substances; or
- h) may cause damage to health due to contamination.

(7) Furthermore it is prohibited to:

- a) provide free or other benefits in the form of goods or services in connection with the sale of psychomodulating substances;
- b) provide free or other benefits in the form of psychomodulating agents in connection with the sale of goods or services.

(8) Implementing legislation shall lay down technical requirements for the composition, appearance, quality and characteristics of psychomodulation substances, including the maximum permitted amount of active substances in unit packets, maximum permitted concentrations of active substance, prohibited elements and features in the placing on the market of psychomodulation substances and requirements for maximum permissible chemical and microbiological contamination.

## Section 33g Import and export of psychomodulating substances

(1) The import of psychomodulation substances shall be permitted only to a person who has been granted a handling permit pursuant to Section 33a(1)(b).

(2) The export of psychomodulation substances outside the territory of the Czech Republic shall be prohibited, with the exception of exports by a natural person in small quantities for personal use.

(3) In case the State from which the import is to take place requires the importer to have an import permit issued by the Czech Republic, the Ministry of Health shall issue confirmation to the importer that an import authorisation is not required for the import of the psychomodulatory substance into the Czech Republic.

(4) Section 23 shall apply mutatis mutandis to transit operations involving psychomodulation substances.

#### Section 33h

# Records of handling of psychomodulating substances and annual reporting

(1) A person handling psychomodulation substances pursuant to Section 33a(1) shall keep a record of handling of psychomodulatory substances.

(2) The person referred to in paragraph 1 shall, by the end of February, submit to the Ministry of Health a report on the production, cultivation, distribution, purchase, sale, import of psychomodulatory substances and the status and movement of their stocks for the previous calendar year.

(3) The details and content of the records, the manner in which it is to be kept and verified and the model form for the notification referred to in paragraph 2 shall be laid down in implementing legislation.

## Part 2 Listing of psychoactive substances

## Section 33i Listing of new psychoactive substances

(1) The Ministry of Health, in cooperation with the State Health Institute and the Office of the Government of the Czech Republic ('the Office'), on the basis of its own findings or on the basis of cooperation within the framework of the European Union's Early Warning System on new psychoactive substances, shall propose to the Government the inclusion of a new psychoactive substance in the list of scheduled psychoactive substances or on the list of addictive substances.

(2) The proposal referred to in paragraph 1 shall include a rapid evaluation of the new psychoactive substance to which Section 33k(2) shall apply mutatis mutandis.

#### Section 33j Handling of scheduled psychoactive substances

(1) The handling of scheduled psychoactive substances means:

- a) research of scheduled psychoactive substances;
- b) The production, export, import and distribution of scheduled psychoactive substances, the purchase of scheduled psychoactive substances for purposes of placing them on the market and placing them on the market, as well as the acquisition and marketing of other rights in rem and related obligations for that purpose and their marketing.

(2) As a handling of scheduled psychoactive substances shall not be considered to be:

- a) the possession of scheduled psychoactive substances by natural persons in small quantities for personal use;
- b) the handling of scheduled psychoactive substances within the framework of the activities of state bodies within their remit, the activities of local self-governing units within their delegated remit and activities in ensuring local public order matters in their own right, and the activities of the Army of the Czech Republic, the Police of the Czech Republic, the General Inspectorate of Security Forces, the Prison Service of the Czech Republic and the Customs Administration of the Czech Republic in the performance of their tasks.

(3) The handling of scheduled psychoactive substances, with the exception of handling referred to in paragraph 1(a), is prohibited.

(4) A legal person or sole trader who intends to handle scheduled psychoactive substances for research purposes shall apply to the Ministry of Health for a permit to handle the scheduled psychoactive substances. The provisions of Section 33a(4), Section 33c, Section 33d(1) and (2), Section 33d(3)(a) and Section 33d(4) to (6) shall apply mutatis mutandis to handle scheduled psychoactive substances.

(5) The provisions of Section 33h shall apply mutatis mutandis to the recording of handling of scheduled psychoactive substances.

#### Section 33k

## Assessment of scheduled psychoactive substances, psychomodulating substances and addictive substances

(1) Where a substance has been included in the list of scheduled psychoactive substances, the Ministry of Health, in cooperation with the National Health Institute and the Office, shall carry out a risk assessment of the added psychoactive substance and after its termination, but no later than 2 years after the inclusion of the substance on the list of scheduled psychoactive substances, propose to the Government the inclusion of that substance in the list of psychomodulation substances or in the list of addictive substances, or propose that the substance remains on or be removed from the list of scheduled psychoactive substances.

(2) When carrying out the assessment referred to in paragraph 1, the Ministry of Health shall, in cooperation with the National Institute for Health and the Office, examine in particular:

- a) pharmacological and toxicological properties of the substance;
- b) the extent and nature of the substance's psychoactivity;
- c) the potential of the substance to cause addiction;
- d) the potential of the substance to cause health or social problems;
- e) information on the supply, production, import, export and market of the substance for human consumption or other purposes, in particular whether the substance is a foodstuff pursuant to Regulation No 178/200210za) of the European Parliament and of the Council) or a medicinal product under the Pharmaceuticals Act<sup>2e</sup>);
- f) information on the occurrence of use and occurrence of intoxications, death and other health and social consequences of the use of the substance;

g) evaluation and recommendations of international organisations and bodies of the European Union<sup>10zb</sup>).

(3) On the basis of new findings, the Ministry of Health, in cooperation with the State Institute of Health and the Office, shall reassess the risk assessment of a classified psychoactive substance or a substance that has been included in the list of psychomodulatory substances or in the list of addictive substances, even repeatedly.

(4) After each assessment under paragraph 3, the Ministry of Health, in cooperation with the State Institute of Health and the Office, shall propose to the Government to place the substance on the list of scheduled psychoactive substances or on the list of psychomodulatory

substances or on the list of addictive substances and, at the same time, to remove the substance from the list on which it was previously placed, except where the result of the evaluation under paragraph 3 is a conclusion that the substance should not be placed on a list other than the list on which it is placed.

(5) If a substance included in the list of classified psychoactive substances, the list of psychomodulatory substances or the list of addictive substances is included in the list of new authorised foods of the Union pursuant to the Regulation of the European Parliament and of the Council on novel foods10zc), the Ministry of Health, in cooperation with the State Institute of Health and the Authority, shall propose to the Government the removal of the substance from the list of classified psychoactive substances, the list of psychomodulatory substances or the list of addictive substances.

(6) The list of scheduled psychoactive substances and the list of psychomodulation substances are laid down in implementing legislation.

Titles VII to IX become Titles VIII to X.

<sup>&</sup>lt;sup>10m</sup>) Section 3 of Act No 250/2017 on electronic identification.

<sup>&</sup>lt;sup>10</sup><sup>p</sup>) Act No 111/1998 on higher education institutions and amending and supplementing other acts (the Higher Education Act), as amended.

<sup>&</sup>lt;sup>10q</sup>) Act No 341/2005 on public research institutions, as amended.

<sup>&</sup>lt;sup>10</sup>r) Act No 372/2011 on health services and the conditions for the provision thereof (Health Services Act), as amended.

<sup>&</sup>lt;sup>10s</sup>) Act No 65/2017 on the protection of health against the harmful effects of addictive substances, as amended.

<sup>&</sup>lt;sup>10t</sup>) ČSN EN ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories.

<sup>&</sup>lt;sup>10u</sup>) Act No 22/1997 on technical product requirements and on changes and amendments to certain acts, as amended.

<sup>&</sup>lt;sup>10v</sup>) Ministry of Health Decree No 38/2001 on hygiene requirements for products intended to come into contact with food and meals, as amended.

<sup>&</sup>lt;sup>10w</sup>) 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.

<sup>&</sup>lt;sup>10x</sup>) Section 26(5) of Act No 258/2000 on public health protection and amending certain related acts, as amended.

<sup>&</sup>lt;sup>10y</sup>) Decree No 76/2003 laying down requirements for natural sweeteners, honey, confectionery, cocoa powder and mixtures of cocoa with sugar, chocolate and chocolate candies, as amended.

<sup>&</sup>lt;sup>10z</sup>) Decree No 18/2020 on requirements for milled cereal products, pasta, bakery products and cakes and doughs.

<sup>&</sup>lt;sup>10za</sup>) Regulation (EU) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

<sup>&</sup>lt;sup>10zb</sup>) Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of a drug and repealing Council Decision 2005/387/JHA. Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006 as regards information exchange on, early warning and risk assessment of new psychoactive substances.

<sup>&</sup>lt;sup>10zc</sup>) Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.'.

6. At the end of subparagraph (a) of Section 34(1), the following point (5) is added:

'5. the State Agricultural and Food Inspectorate ('Food Inspectorate') in cases concerning psychomodulating substances and classified psychoactive substances;'.

7. In Section 34, new paragraphs (8) and (9) are inserted after paragraph (7), which, including footnote 10zd, read as follows:

'(8) In carrying out inspection activities in cases concerning psychomodulating substances and scheduled psychoactive substances, the Food Inspection Authority shall proceed in accordance with paragraph (2), the Inspection Code and the Act on the State Agricultural and Food Inspectorate. When a breach of obligations relating to psychomodulating substances and scheduled psychoactive substances is detected, the inspection shall proceed in accordance with the Act on the State Agricultural and Food Inspectorate.

(9) For the collection, preparation and testing of samples of psychomodulation substances in order to establish their compliance and compliance with the conditions of their manufacture, distribution and placing on the market, the provisions shall apply, with the exception of the right of the inspected person to have a second expert opinion, food and Tobacco Products Act<sup>10zd</sup>) acoordingly.

The existing paragraph (8) is renumbered as paragraph (10).

8. In Section 36(1), the following words are added at the end of subparagraph (a) ', contrary to Section 33b, handles psychomodulation substances without a permit to handle psychomodulation substances or, contrary to Section 33j, handles classified psychoactive substances without permit to handle the scheduled psychoactive substances'.

9. In Section 36(1)(d), the words 'or in an application for a handling permit pursuant to Section 33c(4) or Section 33j(4)' are inserted after the text 'Section 8(6)'.

10. InSection 36(1), at the end of subparagraph (f), the words ", in contravention of Section 33c(8), fails to notify the Ministry of Health of an amendment to the information contained in an application for a permit to handle psychomodulatory substances or, in contravention of Section 33j(4), fails to notify the Ministry of Health of an amendment to the information contained in an application for a permit to handle scheduled psychoactive substances" are added.

<sup>&</sup>lt;sup>10zd</sup>) Section 16(7) and (8) of Act No 110/1997 on foodstuffs and tobacco products and amending certain related acts, as amended.'.

11. In Section 36(1), the following words are added at the end of subparagraph (h): 'failure to notify the end of the handling of psychomodulation substances, contrary to Section 33d(1), or, contrary to Section 33j(4), notify the ceasing of handling the scheduled psychoactive substances'.

12. At the end subparagraph (i) of Section 36(2), the word 'or' is deleted.

13. At the end of paragraph (2) of Section 36, the full stop is replaced by a comma and the following subparagraphs (k) to (u) are added:

'(k) handles a psychomodulating substance contrary to Section 33a(5);

(l) fails to ensure the labelling of psychomodulating substances pursuant to Section 33e;

(m) fails to comply with the requirement of good manufacturing practice, contrary to Section 33f(1);

- (n) contrary to Section 33f(2), provides a batch of psychomodulating substance for placing on the market that does not meet the maximum concentration requirements for active substances or chemical or microbiological requirements;
- (o) places or provides for placing on the market a batch of a psychomodulating substance without a certificate pursuant to Section 33f(3);
- (p) fails to comply with any of the requirements pursuant to Section 33f(5) or breaches any of the prohibitions pursuant to Section 33f(6)(a) to (g) or Section 33f(7);
- (q) contrary to Section 33f(6)(h), places or provides for placement on the market a psychomodulating substance that may cause harm to health because of contamination;
- (r) breaches the export ban pursuant to Section 33g(2);
- (s) contrary to Section 33g, imports a psychomodulating substance;
- (t) fails to comply with the obligation to report or keep records pursuant to Section 33h; or
- (u) contrary to Section 33j(3), handles a scheduled psychoactive substance.'

14. In Section 37 the paragraph (2) reads as follows:

(2) An offence under Section 36(2) shall be punishable by a fine not exceeding:

- a) 500,000 CZK for the offence referred to in subparagraphs (a) to (q), (s) or (t),
- b) 1,000,000 CZK in the case of an offence pursuant to Section 36(2)(r) or (u).'.

15. In Section 39(2), at the end of subparagraph b), the word 'or' shall be deleted.

16. In Section 39(2), subparagraph (c) reads as follows:

'(c) allows the unauthorised ingestion of addictive, psychomodulating or scheduled psychoactive substances by a person under the age of 18 years, unless the offence is more severely punishable;'.

17. In Section 39, the following subparagraphs (d) and (e) are added at the end of paragraph 2:

- '(d) handles the psychomodulating substance in quantities greater than small; or
- (e) handles a small amount of a scheduled psychoactive substance without permission.'.

18. In Section 39(6), the number '15,000' is replaced by the number '50,000'.

19. In Section 40, the paragraph (1) reads as follows:

'(1) Offences pursuant to Section 36(1) and (2), with the exception of a) Section 36(1)(l) and (q), committed in a healthcare establishment, including a pharmacy;

b) Section 36(1)(m), (o), (p), (r), (x) and (y); and
c) Section 36(2)(a), (b), (i), (k) to (q) and (u);

are dealt with by the Ministry of Health.'.

20. In Section 40 the following new paragraph (7) is inserted after paragraph (6):

'(7) Offences pursuant to Section 36(1)(a) committed in connection with the handling of psychomodulating substances or scheduled psychoactive substances and pursuant to Section 36(2)(k) to (q) and (u) are dealt with by the Food Inspection Authority.'.

Paragraphs (7) to (9) are renumbered as paragraphs (8) to (10).

21. At the end of Section 43a(1), the full stop is replaced by a comma and the following subparagraph (d) is added:

'(d) provides information pursuant to Section 33c(4) and (5) to the Food Inspection Authority.'.

22. In Section 43a, the full stop at the end of paragraph 3 is replaced by a comma and a subparagraph (c) is added which, including footnote 10z, reads as follows:

'(c) enforce fines and collect fees related to psychomodulating substances<sup>10ze</sup>).

23. In Section 43a the following paragraph (5) is added:

(5) The Food Inspection Authority carries out inspection activity in the field of psychomodulating and scheduled psychoactive substances in accordance with this Act.'.

<sup>&</sup>lt;sup>10ze</sup>) Item 100(d) to (i) including the note of Act No 634/2004 on administrative fees, as amended.'.

24. In Section 44c, after paragraph (2), following new paragraph (3) is inserted:

(3) The Government shall establish by regulation

- a) the list of psychomodulating substances pursuant to Section 33k(6); and
- b) the list of scheduled psychoactive substances pursuant to Section 33k(6).'.

Paragraphs (3) to (5) are renumbered as paragraphs (4) to (6).

25. In Section 44c(6), the words 'and Section 24f(3)' are replaced by ', Section 24f(3), Section 33c(4), Section 33d(1), Section 33d(2)(b) and 33h(3)'.

26. In Section 44c, the following paragraph (7) is added:

'(7) The Ministry of Health, in cooperation with the Office, shall issue a decree implementing Section 33e(2) and (4) and Section 33f(1) and (8).'.

## Article II Transitional provisions

- 1. The Government may decide, in justified cases, within one year from the date of entry into force of this Act, to include a new psychoactive substance in the list of psychomodulation substances. In the case of the procedure under the first sentence, Section 33i(2) of Act No. 167/1998, as amended from the date of entry into force of this Act, shall apply mutatis mutandis and Section 33i(1) of Act No. 167/1998, as amended from the date of entry into force of this Act, shall apply mutatis mutandis and Section 33i(1) of Act No. 167/1998, as amended from the date of entry into force of this Act, shall not apply.
- 2. Persons handling psychomodulation substances shall adapt their activities to the conditions laid down in Act No 167/1998, in the version in force from the date of entry into force of this Act, within 90 days of the date of entry into force of this Act.

#### PART TWO Amendment to the Advertising Regulation Act

#### Article III

Act No 40/1995 on the regulation of advertising and amending and amending Act No 468/1991 on the operation of radio and television broadcasting, as amended, as amended by Act No 258/2000, Act No 231/2001, Act No 256/2001, Act No 138/2002, Act No 320/2002, Act No 132/2003, Act No 217/2004, Act No 326/2004, Act No 480/2004, Act No 384/2005, Act No 444/2005, Act No 25/2006, Act No 109/2007, Act No 160/2007, Act No 36/2008, Act No 296/2008, Act No 281/2009, Act No 132/2010, Act No 28/2011, Act No 245/2011, Act No 375/2011, Act No 275/2012, Act No 279/2013, Act No 303/2013, Act No 202/2015, Act No 180/2016, Act No 188/2016, Act No 26/2017, Act No 66/2017, Act No 183/2017, Act No 299/2017, Act No 238/2020, Act No 90/2021, Act No 174/2021, Act No 242/2022, Act No 314/2022, Act No 376/2022 and Act No 349/2023 is amended as follows:

1. A new Section 3b is inserted after Section 3a, which, including the heading of footnote 11, reads as follows:

### 'Section 3b **Psychomodulating substances**

(1) Advertising which has as its object or direct or indirect effect the promotion of psychomodulatory substances<sup>11</sup>) disseminated through information society services10a) or in the periodical press<sup>2</sup>), non-periodical publications<sup>3</sup>), on leaflets, posters or other printed matter or in any other manner shall be prohibited.

(2) Any form of sponsorship of actions, activities or individuals the object or effect of which is to promote psychomodulation substances shall be prohibited.

(3) As an advertising of psychomodulation substances shall also be considered:

- a) any form of commercial message the purpose or direct or indirect effect of which is to promote a psychomodulating substance;
- b) distribution of a psychomodulating substance free of charge, the purpose or direct or indirect effect of which is to promote the psychomodulating substance, or distribution free of charge that has such a direct or indirect effect in relation to sponsorship pursuant to paragraph (2).

(4) The prohibition of advertising referred to in paragraph 1 shall not apply to advertising of psychomodulation substances indoors in a shop specialised in the sale of psychomodulation substances.

2. In Section 7(g), the words 'and for advertising for psychomodulatory substances,' are inserted after 'including sponsorship,'.

3. In Section 8(1), the word 'or' is deleted at the end of subparagraph (n).

4. At the end of Section 8(1) the full stop is replaced by the word', or', and the following subparagraph (p) is added:

'p) contrary to Section 3b(1), spreads advertising for psychomodulating substances.'.

5. In Section 8(2), at the end of subparagraph (d), the word 'or' is deleted.

6. In Section 8, at the end of paragraph (2), the full stop is replaced by the word ', or', and a subparagraph (m) is added, which reads as follows:

<sup>&</sup>lt;sup>11</sup>) Act No 167/1998, as amended.'

'f) commissions advertising for psychomodulating substances that is contrary to Section 3b(1).'.

7. In Section 8(3), the word 'or' is deleted at the end of subparagraph (f).

8. In Section 8, at the end of paragraph (3) the full stop is replaced by the word', or', and the following subparagraph (h) is added:

'h) processes advertising for psychomodulating substances that is contrary to Section 3b(1).'.

9. In Section 8(5), subparagraph (c) reads as follows:

'(c) up to CZK 2,000,000 for an offence pursuant to paragraph (1)(b), (c), (d), (e), (f), (g), (h), (i), (k), (l), (n), (o) or (p), pursuant to paragraph (2)(a), (b), (c), (e) or (f) or paragraph (3)(a), (b), (c), (d), (e), (g) or (h).'.

10. In Section 8a(1), the word 'or' is deleted at the end of subparagraph (q).

11. In Section 8a, the full stop at the end of paragraph 1 is replaced by the word 'or' and the following subparagraph (s) is added:

's) contrary to Section 3b(1), spreads advertising for psychomodulating substances.'.

12. In Section 8a(2), the word 'or' is deleted at the end of subparagraph (k).

13. In Section 8a, at the end of paragraph (2), the full stop is replaced by the word ', or', and a subparagraph (m) is added, which reads as follows:

'(m) commissions advertising psychomodulating substances contrary to Section 3b(1).'.

14. In Section 8a(3), the word 'or' is deleted at the end of subparagraph (j).

15. In Section 8a, the full stop at the end of paragraph 3 is replaced by 'or' and a subparagraph (l) is added, which reads as follows:

(l) creates advertising for psychomodulating substances that is contrary to Section 3b(1).'.

16. In Section 8a(4)(d), the words 'Section 3 or Section 3a' are replaced by 'Section 3, 3a or 3b'.

17. In Section 8a(5)(b), the words 'or (r)' are replaced by ', (r) or (s)'.

18. In Section 8a(6)(b), the words 'or (l)' are replaced by ', (l) or (m)'.

19. In Section 8a(7)(b), the words 'or (k)' are replaced by ', (k) or (l)'.

# PART THREE Amendment of the Food and Tobacco Products Act

#### Article IV

Act No 110/1997 on foodstuffs and tobacco products and amending and supplementing certain related acts, as amended by Act No 119/2000, Act No 306/2000, Act No 146/2002, Act No 131/2003, Act No 274/2003, Act No 94/2004, Act No 316/2004, Act No 558/2004, Act No 392/2005, Act No 444/2005, Act No 229/2006, Act No 296/2007, Act No 120/2008, Act No 227/2009, Act No 281/2009, Act No 375/2011, Act No 279/2013, Act No 139/2014, Act No 180/2016, Act No 26/2017, Act No 183/2017, Act No 302/2016, Act No 277/2019, Act No 174/2021 and Act No 167/2023, is amended as follows:

1. In the final part of the provision the Section 3(1)(i), the words 'these data shall be notified to the competent public health protection authority, which shall immediately transmit them to the other supervisory authorities referred to in Section 16' is replaced by the words 'these data shall be notified to the regional public health centre in the course of the operation of the catering service referred to in Section 16(1)(a), which shall immediately transmit them to the State Veterinary Administration and, when providing catering services other than those referred to in Section 16(1)(a), Section 16(2)(a) and Section 16(3)(a), the State Agricultural and Food Inspectorate shall be notified to the State Veterinary Inspectorate, which shall immediately transmit them to the State Veterinary Administration,'.

2. In Section 3(1)(q), in point (1), the text '(f)' is replaced by '(h)'.

3. At the end of subparagraph (f) of Section 10(1), the word 'and' is replaced by a comma.

4. In Section 10, at the end of paragraph (1), the full stop is replaced by the word 'and', and the following subpargagraph (h) is added, which, including footnote 48a reads as follows:

'h) containing psychomodulating substances or scheduled psychoactive substances pursuant to the Addictive Substances Act<sup>48a</sup>).

<sup>48a</sup>) Act No 167/1998, on addictive substances, as amended.'.

5. In Section 12j, the following paragraph (6) is added:

(6) Herbal products intended for smoking must not contain psychomodulating substances or scheduled psychoactive substances.'.

6. In Section 16(1)(a), the words 'if this check is not carried out pursuant to paragraph 2(a) or paragraph 3(a),' is replaced by 'in the context of the provision of health services<sup>52</sup>), social services<sup>52a</sup>) and childcare services in a children's group<sup>52b</sup>), in relation to catering in school catering establishments<sup>52c</sup>) or university catering, in the Prison Service of the Czech Republic<sup>52d</sup>), in pre-trial detention centres<sup>52e</sup>), in prisons<sup>52f</sup>), in institutions for the enforcement of security dementia<sup>52g</sup>) and within schools in nature, children's recovery and other similar actions for children<sup>52h</sup>),'.

Footnotes 52 to 52h read as follows:

<sup>52a</sup>) Section 3(a) of Act No 108/2006, on social services.

- <sup>52d</sup>) Act No 555/1992, on the Prison Service and Judiciary Guards of the Czech Republic, as amended.
- <sup>52e</sup>) Act No 293/1993 on the execution of pre-trial detention, as amended.
- <sup>52f</sup>) Act No 169/1999 on the enforcement of custodial sentences and amending certain related acts, as amended.
- <sup>52g</sup>) Act No 129/2008 on the performance of security detention and amending certain related acts, as amended;
- <sup>52h</sup>) Sections 8, 11a and 12 of Act No 258/2000, as amended.'.

7. At the end of Section 16(1)(b), the word 'and' is replaced by a comma.

8. The full stop at the end of paragraph (1) of Section 16 is replaced by the word 'and' and a subparagraph (d) is added, which reads as follows:

'(d) for the packaging of food of animal origin that takes place in establishments approved for such activities in accordance with Section 22 of the Veterinary Act, unless such checks are carried out in accordance with paragraph (2)(c) or (3)(c).'.

9. In Section 16(5)(d), the words 'pursuant to paragraph 2(a)' are replaced by the words 'pursuant to paragraph 1(a), paragraph 2(a)'.

<sup>&</sup>lt;sup>v52</sup>) Section 2(2) of Act No 372/2011, on health services and the conditions for their provision (Health Services Act), as amended by Act No 65/2017.

<sup>&</sup>lt;sup>52b</sup>) Section 2 of Act No 247/2014, as amended.

<sup>&</sup>lt;sup>52c</sup>) Sections 119 and 119a of Act No 561/2004, as amended.

#### PART FOUR Amendments to the Public Health Protection Act

#### Article V

Act No 258/2000 on the protection of public health and amending certain related acts, as amended by Act No 254/2001, Act No 274/2001, Act No 13/2002, Act No 76/2002, Act No 86/2002, Act No 120/2002, Act No 320/2002, Act No 274/2003, Act No 356/2003, Act No 362/2003, Act No 167/2004, Act No 326/2004, Act No 562/2004, Act No 125/2005, Act No 253/2005, Act No 381/2005, Act No 392/2005, Act No 444/2005, Act No 59/2006, Act No 74/2006, Act No 186/2006, Act No 189/2006, Act No 222/2006, Act No 264/2006, Act No 342/2006, Act No 110/2007, Act No 296/2007, Act No 378/2007, Act No 124/2008, Act No 130/2008, Act No 274/2008, Act No 227/2009, Act No 281/2009, Act No 301/2009, Act No 151/2011, Act No 298/2011, Act No 375/2011, Act No 466/2011, Act No 115/2012, Act No 333/2012, Act No 223/2013, Act No 64/2014, Act No 247/2014, Act No 250/2014, Act No 252/2014, Act No 82/2015, Act No 267/2015, Act No 243/2016, Act No 250/2016, Act No 298/2016, Act No 183/2017, Act No 193/2017, Act No 202/2017, Act No 225/2017, Act No 277/2019, Act No 205/2020, Act No 238/2020, Act No 403/2020, Act No 544/2020, Act No 36/2021, Act No 94/2021, Act No 261/2021, Act No 284/2021, Act No 363/2021, Act No 314/2022, Act No 384/2022, Act No 152/2023, Act No 167/2023, Act No 281/2023 and Act No 412/2023, is amended as follows:

1. In Section 26 the following paragraph, 8 is added, which, including footnote 109, reads as follows:

(8) At all stages of production, processing and distribution of food, food business operators may use only materials and articles intended to come into contact with food that comply with the requirements laid down in special legislation.<sup>109</sup>).

2. In Section 92a, after paragraph (14), the following new paragraph (15) is inserted:

'(15) A food business operator referred to in Section 26(8) shall be guilty of an offence

by:

a) failing to comply with an obligation imposed pursuant to Section 26(8);

b) failing to comply with an obligation imposed by a decision issued on the basis of directly applicable EU legislation governing the performance of official inspection;<sup>86</sup>).'.

Paragraph (15) is renumbered paragraph (16).

3. In Section 92a(16)(a), the words 'or paragraph 14' are replaced by ', paragraph 14 or 15'.

<sup>&</sup>lt;sup>109</sup>) For example, 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, Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Decree No 38/2001 on health requirements for food contact products, as amended.".

#### PART FIVE Amendment of the Radio and Television Broadcasting Act

#### Article VI

Act No 231/2001 on radio and television broadcasting and amending other acts, as amended by Act No 309/2002, Act No 274/2003, Act No 341/2004, Act No 501/2004, Act No 626/2004, Act No 82/2005, Act No 127/2005, Act No 348/2005, Act No 235/2006, Act No 160/2007, Act No 296/2007, Act No 304/2007, Act No 124/2008, Act No 384/2008, Act No 41/2009, Act No 196/2009, Act No 227/2009, Act No 132/2010, Act No 153/2010, Act No 302/2011, Act No 420/2011, Act No 458/2011, Act No 142/2012, Act No 275/2012, Act No 406/2012, Act No 496/2012, Act No 181/2014, Act No 250/2014, Act No 79/2015, Act No 139/2016, Act No 180/2016, Act No 14/2017, Act No 183/2017, Act No 202/2023 and Act No 253/2023 is amended as follows:

1. In Section 48(1), the words 'or psychomodulation substances' are added at the end of subparagraph (g).

2. In Section 53, the words 'or psychomodulatory substances' are added at the end of paragraph 2.

3. In Section 53a(4), the word 'or' is deleted at the end of subparagraph (a).

4. In Section 53a(4), the full stop at the end of subparagraph (b) is replaced by the word 'or' and the following subparagraph (c) is added:

'(c) psychomodulating substances or product placement of a person whose principal activity is producing or sale of psychomodulating substances.'.

#### PART SIX

#### Amendment to the Act on the Czech Agricultural and Food Inspection Authority

#### Article VII

Act No 146/2002 on the State Agricultural and Food Inspectorate and amending certain related acts, as amended by Act No 94/2004, Act No 316/2004, Act No 321/2004, Act No 444/2005, Act No 120/2008, Act No 281/2009, Act No 291/2009, Act No 407/2012, Act No 308/2013, Act No 138/2014, Act No 250/2014, Act No 180/2016, Act No 243/2016, Act No 26/2017, Act No 65/2017, Act No 183/2017, Act No 302/2017, Act No 238/2020, Act No 174/2021, Act No 261/2021, Act No 244/2022, Act No 247/2022 and Act No 167/2023 is amended as follows:

1. In footnote 3a, the words '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, Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food' are deleted.

2. In Section 3(2)(k), the words 'and psychomodulatory substances' are inserted after the words 'advertising of food'.

3. In Section 3(2), the subparagraph (p) is deleted.

The exeisting subparagraph (q) becomes subparagraph (p).

4. In Section 3(2), subparagraphs (q) and (r) are added, and which, including footnotes 3b and 3c, read as follows:

- '(q) checks compliance with obligations under the Act on the Protection of Health against the Harmful Effects of Addictive Substances<sup>3b</sup>);
- (r) checks compliance with the obligations laid down for psychomodulating substances and classified psychoactive substances under the Addictive Substances Act<sup>3c</sup>).
- <sup>3b</sup>) Act No 65/2017 on the protection of health against the harmful effects of addictive substances, as amended.
- <sup>3c</sup>) Act No 167/1998 on addictive substances and on amendments to certain other acts, as amended.'.

5. In Section 3(3)(b), point 4 reads as follows:

'4. samples of substances it is responsible for checking under the Addictive Substances Act and samples taken from sites, objects or equipment used in the handling of psychomodulating substances in laboratories which meet the conditions for the operation of laboratories laid down in the technical standard governing the general requirements for the competence of testing and calibration laboratories<sup>33</sup>);'.

6. In Section 3, the paragraph (5) reads as follows:

'(5) For the control samples taken, the inspected person shall be reimbursed at the level of the price at which the inspected person sells or purchased an agricultural product, foodstuff, tobacco products or psychomodulating substance, provided that he applies for reimbursement within 6 months of becoming aware of the fact that the agricultural product, foodstuff, tobacco products or psychomodulating substance complied with the requirements laid down in special legislation,3) directly applicable European Union legislation3a) or international treaties.7) Compensation shall be granted to the inspected person within a maximum of 30 days from the date of application.'.

7. In Section 3, the paragraph (7) reads as follows:

(7) If the analysis of the sample reveals that agricultural products, foodstuffs, tobacco products or psychomodulatory substances or places or equipment used in the production or placing on the market of foodstuffs or in the handling of psychomodulatory substances do not comply with the requirements laid down in special legislation<sup>3</sup>), directly applicable provisions of the European Union<sup>3a</sup>) or international treaties<sup>7</sup>), the inspection authority shall decide that the inspected person shall pay the costs of the analysis. If the analysis pursuant to the first sentence, with the exception of psychomodulating substances, has been carried out by the Inspection, the inspected person shall bear the costs of the analysis pursuant to implementing legislation. The reimbursement of the costs of the analysis shall be a revenue of the State budget and shall be collected by the inspectorate that imposed it.'.

8. In ' 3c, the following paragraph (6) is added:

'(6) The Inspection shall also include another website in the list of websites without the prior decision referred to in paragraph (1), if it is apparent that its content is identical or almost identical to the website already registered.'.

9. Section 3d reads as follows:

'Section 3d

An internet access service provider in the Czech Republic must

- a) prevent access to websites included in the list of websites within 15 days of the date of publication of the website in the list of websites;
- b) terminate the blocking of access to the website within 7 days of the deletion of the website from the list of websites.'.

10. In Section 5(1)(a), point (1) reads as follows:

'1. production or marketing of agricultural products or foodstuffs,<sup>29</sup>) or the manufacture, distribution or placing on the market of tobacco products or psychomodulating substances, where such agricultural products, foodstuffs, tobacco products or psychomodulating substances do not comply with the requirements laid down in specific legislation<sup>3</sup>), directly applicable European Union legislation3a) or an international treaty;<sup>7</sup>)'.

11. In Section 5(1)(a)(2), the words 'by specific legislation<sup>3</sup>)<sup>6</sup>)<sup>9</sup>)<sup>17</sup>)" shall be replaced by "specific legislation<sup>3</sup>)<sup>9</sup>)" and the words "or not accompanied by a written declaration in accordance with a specific legal provision<sup>17</sup>) or directly applicable European Union legislation<sup>3a</sup>)' are deleted.

Footnote 17 is deleted.

12. In Section 5(1)(a), in points (3) and (4), the words 'or psychomodulation substances' are inserted after 'tobacco products'.

13. In Section 5(1)(b), the following point 4 is added, which reads as follows:

'4. psychomodulating substances or classified psychoactive substances that do not meet the requirements of the Addictive Substances Act or are handled contrary the Addictive Substances Act;'.

14. In Section 5(1)(d), in point (2), the words ', psychomodulation substances' are inserted after the words 'tobacco products'.

15. In Section 5(1)(e), the word 'or' is deleted at the end of point 2.

16. In Section 5(1), the word 'or' is added at the end of subparagraph (e) and the following point 4 is added:

'4. entrance to the premises where psychomodulating substances are handled, or the handling of psychomodulating substances by persons coming into direct contact with psychomodulating substances, where there is a suspicion that there has been non-compliance with the requirement of Good Manufacturing Practice (GMP) under the Addictive Substances Act on the personal hygiene of persons handling psychomodulating substances within the undertaking for which they work;'.

17. In Section 5(1)(g), in point (1), the words 'or packaging and packaging materials coming into contact with foodstuffs' are deleted.

18. In Section 5(1)(g), the following point 4 is added:

'4. upon detection of psychomodulating substances which do not comply with the requirements of the Addictive Substances Act;'.

19. In Section 5(1), the subparagraph (l) reads as follows:

- (l) orders
  - 1. the withdrawal of agricultural products or foodstuffs from the market or of tobacco products or psychomodulation substances from distribution or from the market where such agricultural products, foodstuffs, tobacco products or psychomodulation substances do not comply with the requirements laid down in specific legislation<sup>3</sup>), directly applicable European Union legislation<sup>3a</sup>) or an international treaty<sup>7</sup>), or
  - 2. taking back from consumers of agricultural products, foodstuffs, tobacco products or psychomodulation agents, where such agricultural products,

foodstuffs, tobacco products or psychomodulation substances do not comply with the requirements laid down in a separate legal provision<sup>3</sup>), directly applicable European Union legislation<sup>3a</sup>) or an international treaty<sup>7</sup>) and inform the consumer effectively and accurately of the reason for taking back.'.

20. In Section 5(6), the words 'or persons handling psychomodulating substances' are inserted after 'food businesses'.

21. In Section 5(7), the words 'food or tobacco products' are replaced by 'foodstuffs, tobacco products or psychomodulatory substances'.

22. In Section5a, paragraph (1) reads as follows:

'(1) The inspector shall grant consent to the resumption of production of agricultural products, foodstuffs, tobacco products or psychomodulating substances, the marketing of agricultural products or foodstuffs, or the marketing or distribution of tobacco products or psychomodulating substances, or the use of packaging, labels, devices, equipment or premises prohibited under Section 5(1)(a) if the defective condition has been rectified; consent must be given without delay and no later than within 15 days from the date on which the inspected person has demonstrated that the defective condition has been rectified.'.

23. In the introductory part of Section 5a(2), after the words 'pursuant to Section 5(1) (e)(3),' the words 'or the entry or handling of psychomodulants by persons suspended pursuant to Section 5(1)(e)(4)' is inserted.'.

24. In Section 5a(2)(a), the words 'or that a person whose entry or handling of psychomodulatory substances has been suspended meets the requirements for personal hygiene as part of good manufacturing practice under the Addictive Substances Act' is inserted after the word 'legislation'.

25. In Section 5b(6), the words ', psychomodulation substances, scheduled psychoactive substances' are inserted after the words'tobacco products'.

26. In Section 11(1)(e), the words 'or end of the containment' are inserted after 'preventive measures' and the words 'or deleted from the list of websites' are inserted after the words 'list of websites'.

## PART SEVEN Amendment to the Criminal Code

#### Article VIII

Act No 40/2009, the Criminal Code, as amended by Act No 306/2009, Act No 181/2011, Act No 330/2011, Act No 357/2011, Act No 375/2011, Act No 420/2011, Act No 193/2012, Act No 360/2012, Act No 390/2012, Act No 399/2012, Act No 494/2012, Act No 105/2013, Act No 241/2013, the ruling of the Constitutional Court, published under No 259/2013, Act No 141/2014, Act No 86/2015, Act No 165/2015, Act No 377/2015, Act No 47/2016, Act No 150/2016, Act No 163/2016, Act No 188/2016, Act No 321/2016, Act No 323/2016, Act No 455/2016, Act No 55/2017, Act No 58/2017, Act No 204/2017, Act No 287/2018, Act No 315/2019, Act No 114/2020, Act No 165/2020, Act No 333/2020, Act No 336/2021, the ruling of the Constitutional Court, published under No 206/2021, Act No 417/2021, Act No 130/2022, Act No 240/2022, Act No 422/2022, Act No 429/2022 and Act No 173/2023, is amended as follows:

1. In Section 130, the existing text becomes paragraph (1) and the following paragraph (2) is added:

(2) For the purposes of this Act, psychomodulating substances and scheduled psychoactive substances are also considered to be addictive substances.'.

# 2. Section 204, including heading, reads as follows:

#### 'Section 204

# Administering alcohol, psychomodulating substances or scheduled psychoactive substances to a child

(1) Any person who sells, administers or makes available to a child alcohol, psychomodulation substance or included psychoactive substance shall be punished by imprisonment for up to one year.

(2) The offender shall be punished by a term of imprisonment of between six months and five years if he commits the act referred to in paragraph 1 against a child under the age of 15.'.

3. A new Section 251a is inserted after Section 251, which, including the heading, reads as follows:

#### 'Section 251a Unauthorised handling of psychomodulating substances

(1) A person who handles psychomodulation substances to a greater extent shall be punished by imprisonment for up to two years, a fine or an operating ban.

(2) The offender shall be punished by a term of imprisonment of between six months and five years, a fine or an operating ban:

- a) if they cause significant damage as a result of the act referred to in paragraph 1;
- b) if they cause significant harm to health as a result of the act referred to in paragraph 1;
- or
- c) if they gain substantial profit for themselves or for another person by such an act.

(3) A sentence of imprisonment for 2 to 8 years will be imposed on the offender:

- a) if they cause large scale damage as a result of the act referred to in paragraph 1;
- b) if they cause serious harm to health or death to at least two people as a result of the act referred to in paragraph 1; or
- c) if they gain great profit for themselves or for another person by such an act.'.

4. A new Section 286a is inserted after Section 286, which, including the heading, reads as follows:

#### 'Section 286a

## Illicit production and other handling of scheduled psychoactive substances

(1) Any person who, in quantities greater than small, unlawfully products, imports, exports, arranges, arranges, arranges, sells or otherwise procures or possesses for others a classified psychoactive substance shall be punished by a term of imprisonment for up to two years, a fine or an operating ban.

(2) The offender shall be punished by a term of imprisonment of between six months and five years, a fine or an operating ban:

- a) if they cause significant damage as a result of the act referred to in paragraph 1;
- b) if they cause significant harm to health as a result of the act referred to in paragraph 1; or
- c) if they gain substantial profit for themselves or for another person by such an act.

(3) A sentence of imprisonment for 2 to 8 years will be imposed on the offender:

- a) if they cause large scale damage as a result of the act referred to in paragraph 1;
- b) if they cause serious harm to health or death to at least two people as a result of the act referred to in paragraph 1; or
- c) if they gain great profit for themselves or for another person by such an act.'.

5. In Section 287(1), the words 'or psychomodulatory substances' are inserted after the words 'other than alcohol'.

## PART EIGHT Amendment to the Administrative Fees Act

# Article IX

In the annex to Act No 634/2004 on administrative fees, as amended by Act No 217/2005, Act No 228/2005, Act No 361/2005, Act No 444/2005, Act No 545/2005, Act

No 553/2005, Act No 48/2006, Act No 56/2006, Act No 57/2006, Act No 81/2006, Act No 109/2006, Act No 112/2006, Act No 130/2006, Act No 136/2006, Act No 138/2006, Act No 161/2006, Act No 179/2006, Act No 186/2006, Act No 215/2006, Act No 226/2006, Act No 227/2006, Act No 235/2006, Act No 312/2006, Act No 575/2006, Act No 106/2007, Act No 261/2007, Act No 269/2007, Act No 374/2007, Act No 379/2007, Act No 38/2008, Act No 130/2008, Act No 140/2008, Act No 182/2008, Act No 189/2008, Act No 230/2008, Act No 239/2008, Act No 254/2008, Act No 296/2008, Act No 297/2008, Act No 301/2008, Act No 309/2008, Act No 312/2008, Act No 382/2008, Act No 9/2009, Act No 141/2009, Act No 197/2009, Act No 206/2009, Act No 227/2009, Act No 281/2009, Act No 291/2009, Act No 301/2009, Act No 346/2009, Act No 420/2009, Act No 132/2010, Act No 148/2010, Act No 153/2010, Act No 160/2010, Act No 343/2010, Act No 427/2010, Act No 30/2011, Act No 105/2011, Act No 133/2011, Act No 134/2011, Act No 152/2011, Act No 188/2011, Act No 245/2011, Act No 249/2011, Act No 255/2011, Act No 262/2011, Act No 300/2011, Act No 308/2011, Act No 329/2011, Act No 344/2011, Act No 349/2011, Act No 350/2011, Act No 357/2011, Act No 375/2011, Act No 428/2011, Act No 458/2011, Act No 472/2011, Act No 19/2012, Act No 37/2012, Act No 53/2012, Act No 119/2012, Act No 169/2012, Act No 172/2012, Act No 202/2012, Act No 221/2012, Act No 225/2012, Act No 274/2012, Act No 350/2012, Act No 359/2012, Act No 399/2012, Act No 407/2012, Act No 428/2012, Act No 496/2012, Act No 502/2012, Act No 503/2012, Act No 50/2013, Act No 69/2013, Act No 102/2013, Act No 170/2013, Act No 185/2013, Act No 186/2013, Act No 232/2013, Act No 239/2013, Act No 241/2013, Act No 257/2013, Act No 273/2013, Act No 279/2013, Act No 281/2013, Act No 306/2013, Act No 313/2013, Statutory Measure of the Senate No 344/2013, Act No 101/2014, Act No 127/2014, Act No 187/2014, Act No 249/2014, Act No 257/2014, Act No 259/2014, Act No 264/2014, Act No 268/2014, Act No 331/2014, Act No 81/2015, Act No 103/2015, Act No 204/2015, Act No 206/2015, Act No 224/2015, Act No 268/2015, Act No 314/2015, Act No 318/2015, Act No 113/2016, Act No 126/2016, Act No 137/2016, Act No 148/2016, Act No 188/2016, Act No 229/2016, Act No 243/2016, Act No 258/2016, Act No 264/2016, Act No 298/2016, Act No 319/2016, Act No 324/2016, Act No 369/2016, Act No 63/2017, Act No 170/2017, Act No 194/2017, Act No 195/2017, Act No 199/2017, Act No 202/2017, Act No 204/2017, Act No 206/2017, Act No 222/2017, Act No 225/2017, Act No 251/2017, Act No 261/2017, Act No 289/2017, Act No 295/2017, Act No 299/2017, Act No 302/2017, Act No 304/2017, Act No 371/2017, Act No 90/2018, Act No 171/2018, Act No 193/2018, Act No 286/2018, Act No 307/2018, Act No 135/2019, Act No 176/2019, Act No 209/2019, Act No 255/2019, Act No 277/2019, Act No 279/2019, Act No 364/2019, Act No 368/2019, Act No 369/2019, Act No 115/2020, Act No 117/2020, Act No 119/2020, Act No 334/2020, Act No 336/2020, Act No 337/2020, Act No 501/2020, Act No 524/2020, Act No 543/2020, Act No 13/2021, Act No 14/2021, Act No 90/2021, Act No 261/2021, Act No 270/2021, Act No 274/2021, Act No 284/2021, Act No 300/2021, Act No 362/2021, Act No 366/2021, Act No 371/2021, Act No 374/2021, Act No 426/2021, Act No 91/2022, Act No 96/2022, Act No 217/2022, Act No 225/2022, Act No 246/2022, Act No 314/2022, Act No 372/2022, Act No 376/2022, Act No 431/2022, Act No 432/2022, Act No 458/2022, Act No 88/2023, Act No 149/2023, Act No 173/2023, Act No 185/2023, Act No 271/2023, Act No 277/2023, Act No 349/2023, Act No 414/2023, Act No 469/2023 and Act No 1/2024, item 100 reads as follows:

'Item 100

a) Issuance of permit for handling narcotic substances, psychotropic substances or preparations <sup>59</sup>	CZK	5000
b) Issuance of a permit for the export or import of narcotic substances, psychotropic substances		
or preparations <sup>59</sup> )	CZK	1000

(C) Issuance of a permit for the export or import of poppy seeds	CZK	500
d) Commencement of proceedings for issuing a permit for the handling of psychomodulating substances pursuant to Section 33a(1)(b) of the Addictive Substances Act	CZK	200000
e) Commencement of proceedings for issuing a permit for the handling of psychomodulating substances pursuant to Section 33a(1)(b) of the Addictive Substances Act in the case of production of psychomodulating substances in an establishment, for each establishment where, according to the application, production of psychomodulating substances is to take place		200000
f) Commencement of proceedings for issuing a permit for handling pursuant to Section 33a(1)(c) of the Addictive Substances Act, for each establishment where psychomodulating substances are sold		20000
g) Commencement of proceedings for issuing a permit for the handling of psychomodulating substances pursuant to Section 33a(1)(d) of the Addictive Substances Act, for each website or application		200000
h) Commencement of proceedings for issuing a permit for the handling of psychomodulating substances pursuant to Section 33a(1)(e) of the Addictive Substances Act		20000
(I) Commencement of proceedings for issuing a permit for the handling of psychomodulating substances pursuant to Section 33a(1)(f) of the Addictive Substances Act, for each establishment where plants or fungi are cultivated from which psychomodulating substances can be obtained	1	200,000

Note

For the items in subparagraphs (d) to (i), an annual renewal fee shall be levied in the same amount as the fee for the initiation of an authorisation procedure, payable on 31 January of the fee period of one calendar year.'.

#### PART NINE

#### Amendment to the Act on on-demand audiovisual media services

#### Article X

Act No 132/2010, on on-demand audiovisual media services and amending certain acts (the On-demand Audiovisual Media Services Act), as amended by Act No 302/2011, Act No 142/2012, Act No 180/2016, Act No 183/2017, Act No 238/2020, Act No 261/2021 and Act No 242/2022, is amended as follows:

1. In Section 8, the full stop at the end of paragraph (2) is replaced by a comma and the following subparagraph (f) is added:

'f) audiovisual commercial communications relating to psychomodulating substances.'.

2. In Section 9, the words 'or psychomodulatory substances' are added at the end of paragraph 2.

3. In Section 10(4), at the end of subparagraph (a) the word 'or' is deleted.

4. In Section 10, the full stop at the end of paragraph 4 is replaced by 'or' and the following subparagraph (c) is added:

'(c) psychomodulating substances or product placement of a person whose principal activity is producing or sale of psychomodulating substances.'.

# PART TEN

# Amendment to the Act on the protection of health against the harmful effects of addictive substances

#### Article XI

Act No 65/2017 on the protection of health against the harmful effects of addictive substances, as amended by Act No 183/2017, ruling of the Constitutional Court, promulgated under No 81/2018, Act No 220/2021, Act No 59/2023, Act No 173/2023 and Act No 349/2023, is amended as follows:

1. In Section 2(a), the words ', psychomodulating substances, scheduled psychoactive substances' are inserted after the words 'narcotics and psychotropic substances'.

2. In Section 2, the full stop at the end of subparagraph (q) is replaced by a comma and the following subparagraphs (r) and (s) are added:

- '(r) 'goods associated with psychomodulating substances' mean devices intended for use or use of psychomodulating substances and other goods and products associated with the use or use of psychomodulating substances;
- (s) 'nicotine-containing product' means a nicotine-containing product or its compounds that is not a medicinal product under the Medicines Act.'.

3. In the title of Title II, the words 'TOBACCO FREE NICOTINE BAGS' are replaced by the words ', TOBACCO FREE NICOTINE BAGS AND NICOTINE-CONTAINING PRODUCTS.'.

4. In the title of Section 3, the words 'and tobacco-free nicotine pouches' shall be replaced by 'Tobacco-free nicotine pouches and nicotine-containing products".

5. In Section 3(1), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

6. In the introductory part of Section 3(2), the words 'and tobacco-free nicotine pouches' are replaced by ',tobacco-free nicotine pouches and nicotine-containing products'.

7. In Section 3(3), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

8. In the first sentence of Section 3(4), after the word 'administer', the words ', as well as gratuitously transfer or convey as a form of consideration,' shall be inserted and in the second sentence the words 'smoking aids' shall be replaced by 'or administer, as well as gratuitously transfer or convey as a form of consideration, smoking aids and aids for the application or use of electronic cigarettes, nicotine pouches without tobacco and nicotine-containing products'.

9. In Section 3(4), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

10. In the heading of Section 5, the words **'and tobacco-free nicotine pouches'** shall be replaced by **' tobacco-free nicotine pouches and nicotine-containing products**".

11. In Section 5(1), the words 'or tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

12. In Section 5(2), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

13. In Section 5(3), the words 'or tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches or nicotine-containing products'.

14. In the heading above the title of Section 6, the words 'and tobacco-free nicotine pouches' shall be replaced by ' tobacco-free nicotine pouches and nicotine-containing products".

15. In Section 6(1), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

16. In Section 6(2), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

17. In Section 6(3), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

18. In the introductory part of Section 6(4), the words 'and tobacco-free nicotine pouches' are replaced by', tobacco-free nicotine pouches and nicotine-containing products'.

19. In Section 6(4)(b), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

20. In Section 6(7), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

21. In Section 7(1), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

22. In Section 7(2), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

23. In Section 7(3), the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

24. In Part One, the following Chapter IV is inserted after Chapter III, including the headings and footnotes 6a to 6e:

# CHAPTER IV RESTRICTIONS ON THE AVAILABILITY OF PSYCHOMODULATING SUBSTANCES

#### Section 16a

# Prohibition of sale of psychomodulating substances

(1) The following is prohibited.

- a) Selling psychomodulating substances and goods related to psychomodulating substances outside a shop specialised in the sale of psychomodulating substances;
- b) Entering a shop specialising in the sale of psychomodulatory substances and goods related to psychomodulatory substances for persons under 18 years of age;
- c) Selling or administering psychomodulating substances to a person under the age of 18 years;
- d) Selling psychomodulating substances via a vending machine.

(2) In addition, it shall be prohibited to sell psychomodulation substances

- a) in a food processing  $plant^{6a}$ ;
- b) in healthcare establishments and in premises associated with their operation;
- c) in schools and school facilities;
- d) in establishments for the social and legal protection of children, in establishments carrying on trades having as their object care of children under three years of age, premises where childcare services are provided for groups of children, or in

establishments where extracurricular education and training is provided and that are not included in the register of schools and school facilities;

e) at events intended for persons under the age of 18;

f) in the transit area of airports.

## Section 16b Certain conditions of sale of psychomodulating substances

(1) If a seller offers more than one type of psychomodulant, they must be appropriately separated from each other.

(2) At the point of sale of psychomodulatory substances, the seller must provide consumers with a clearly visible information message prohibiting the sale of those goods to persons under the age of 18. The text of the prohibition of sale must be written in black letters on a white background with a font size of at least 2 cm. The text of the sales ban reads as follows: 'The sale of psychomodulants to persons under the age of 18 is prohibited.'.

(3) Pursuant to Section 16a(1)(b), when entering a shop, the seller shall display a clearly visible information notice on the entry ban to persons under the age of 18. The text of the entry ban must be taken in black letters on a white background of at least 2 cm. The text of the entry ban reads as follows: 'Entry for persons under 18 years of age is prohibited.'.

(4) The person selling psychomodulating substances and the person transferring the psychomodulatory substances when sold by means of distance communication shall be older than 18 years of age.

#### Section 16c

## Sale of psychomodulating substances by means of distance communication

(1) In the case of the sale of psychomodulatory substances by means of distance communication, psychomodulation substances may only be sold through a means of distance communication which is specialised exclusively in the sale of psychomodulation substances and goods related to psychomodulation substances.

(2) Only a legal or professional natural person authorised to do so under the Addictive Substances Act may sell psychomodulatory substances by means of distance communication6b) and who is also authorised to run and who operates a shop in which they sell psychomodulatory substances pursuant to the Addictive Substances Act.<sup>6c</sup>).

(3) Psychomodulating substances may be sold by means of distance communication, provided that their sale to persons under the age of 18 is excluded; for this purpose, the seller of these products by means of distance communication must use a qualified system in accordance with the Electronic Identification Act.<sup>6d</sup>). The seller is obliged to ensure that, at the time of the sale of the goods, it is verified that the consumer is not under the age of 18. In order to comply with the obligation under the second sentence, the qualified manager shall make available to the seller of psychomodulation substances, by means of distance communication, data on the age of the purchaser;<sup>6e</sup>).

(4) The seller of psychomodulation substances by means of distance communication is obliged to ensure that the goods are delivered to the purchaser's own hands. Where a seller of psychomodulation substances, by means of distance communication, sends goods to the purchaser through a sole trader or a legal person who arranges for the delivery of the psychomodulation substance purchased by means of distance communication, they shall deliver the goods through a person who will arrange for the goods to be handed over to the purchaser's own hands.

(5) For the purposes of this Act, handing over the goods into the buyer's own hands means the handing over of the goods to the buyer at which

- a) the goods cannot be handed over to a person other than the buyer, with the exception of an accepting person who is over the age of 18 years and has an order identification number for the goods;
- b) the physical presence of the buyer or the accepting person pursuant to (a), the purchaser or the accepting person pursuant to (a) establishes his or her identity and subsequently confirms receipt of the goods in writing at the time of receipt;
- c) it is prohibited handing over the goods without the presence of a natural person acting on behalf of the person responsible for the delivery of the psychomodulating substance, in particular by means of automated parcel lockers.

(6) The seller of psychomodulation substances by means of distance communication shall keep a record of the delivery of the goods containing the following information:

- a) the place, date and exact time the goods were delivered;
- b) the name of the buyer or accepting person pursuant to paragraph (5)(a) and the number of their personal ID;
- c) the handwritten signature of the buyer or the accepting person pursuant to paragraph (5)(a), confirming receipt of the goods;
- d) the name of the natural person who verified the identity of the buyer or accepting person pursuant to paragraph (5)(a) and handed over the goods to him or her, as well as their signature confirming this fact.

(7) Where goods are handed over by the person responsible for the delivery of the psychomodulation substance in accordance with the second sentence of paragraph 4, the handing over of the goods in accordance with paragraph 6 shall be recorded by the person responsible for the delivery of the psychomodulation substance, who shall forward the recorded data to the seller immediately upon delivery of the goods.

(8) Only the following may be used to prove the identity of the purchaser or the transferee referred to in subparagraphs (a) and (b) of paragraph 5:

- a) a valid identity card or passport in the case of citizen of the Czech Republic;
- b) a valid identity card, passport or residence document, in the case of a citizen of another Member State of the European Union, or a citizen of the Schengen Area;
- c) a valid personal document that allows residence in the Czech Republic or a passport, in the case of a third-country national.

(9) If a seller of psychomodulants offers more than one type of psychomodulant by means of distance communication, they must be appropriately separated from each other.

(10) The seller of psychomodulation substances by means of distance communication shall inform consumers of the prohibition of selling to persons under the age of 18 years in a

clearly visible manner in a manner proportionate to the possibilities of the means of distance communication prior to the sale of those products.

(11) The seller of psychomodulatory substances by means of distance communication is obliged to indicate his name, registered office address and personal identification number at the point of sale of these products.

(12) A seller of psychomodulation substances by means of distance communication shall not use or pass on personal data of the consumer obtained in the context of that sale for purposes other than the purchase in question.

(13) The cross-border sale of psychomodulation substances by means of distance communication is prohibited.

- <sup>6b</sup>) Section 33b of Act No 167/1998 on addictive substances and amending certain other acts.
- <sup>6c</sup>) Section 33a(1)(c) of Act No 167/1998
- <sup>6d</sup>) Section 2 and 3 of Act No 250/2017 on electronic identification, as amended.
- <sup>6e</sup>) Section 22(3) of Act No 250/2017'.

The existing Chapters IV to X shall be referred to as Chapters V to XI.

25. In Section 17(1), the words 'and prohibit' are replaced by a comma and the words ', the use of psychomodulation substances or scheduled psychoactive substances' are inserted after the words 'electronic cigarettes'.

26. In Section 17(2)(a), the words ', use of psychomodulating substances or scheduled psychoactive substances' are inserted after the words 'alcoholic beverages'.

27. In Section 17(2)(b), the words ', use of psychomodulating substances or scheduled psychoactive substances' are inserted after the words 'alcoholic beverages'.

28. In Section 25, the words 'and tobacco-free nicotine pouches' are replaced by ', tobacco-free nicotine pouches and nicotine-containing products'.

29. In Section 30(3), the words 'and Section 16' are replaced by the words ', Section 16 and Section 16a(2)(a), (b) and (d).'.

30. In Section 30, the paragraph (5) reads as follows:

(5) The State Agricultural and Food Inspectorate monitors compliance with the obligations laid down in Section 3(1) and (3) in respect of tobacco products, tobacco-free nicotine pouches and nicotine-containing products, Section 4(1) as regards food products,

<sup>&</sup>lt;sup>6a</sup>) Article 3(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended.

Section 5(1) and (2), Section 6(1) to (5) and Section 7 in respect of tobacco products, tobaccofree nicotine pouches and nicotine containing products, Section 11(1), (2)(e) and (g), Section 11(4), Section 13(1), Section 15(1) to (3) and Sections 16a to 16c; when checking compliance with the obligations laid down in Section 3(3), Section 6(1), Section 7(2) and (3), Section 15(1), Section 16a(1)(b) and (c) and Section 16c(3) to (5), the State Agricultural and Food Inspection Authority is authorised to carry out test purchases through persons under the age of 18.'.

31. In Section 30(6), the words 'and Section 11(3)' are replaced by the words ', Section 11(3) and Section 16a(2)(c) and (d)'.

32. In Section 30(8), the words 'and Section 13(1)' is replaced by the words ', Section 13(1), Section 16a and Section 16b'.

33. In Section 31(2), the words ', psychomodulation substances' are inserted after the words 'intended for smoking'.

34. In Section 31(3), the words ', nicotine-containing products' are inserted after 'tobacco-free nicotine pouches'.

35. In Section 33(5), the words ', nicotine-containing products' are inserted after 'tobacco-free nicotine pouches'.

36. In Section 35(1)(a), the words 'or Section 11' are replaced by the words', Section 11', the words 'or Section 16a(1)(a) and (d) or Section 16a(2)' are inserted after the words 'or 4' and the words ', nicotine-containing product, psychomodulation substance' are inserted after the words 'tobacco-free nicotine pouches'.

37. In Section 35(1)(b), the words 'or Section 16a(1)(c)' are inserted after the words 'Section 3(4)', the words 'or tobacco-free nicotine pouches' are replaced by the words ', tobacco-free nicotine pouches, a nicotine-containing product or psychomodulation substance' and the words 'or, contrary to Section 16a(1)(b), allow such a person to enter a shop specialised in the sale of psychomodulation substances' is inserted after the words 'to a person under the age of 18 years'.

38. In Section 35(1)(h), the words 'or use a psychomodulatory substance' are inserted after 'an electronic cigarette' and the words 'and 2' are inserted after the words 'Section 17(1)'.

39. In Section 35(2)(e), ', nicotine-containing product' is inserted after 'nicotine pouch without tobacco content'.

40. In Section 35(2)(g), ', psychomodulation substances' is inserted after 'to smoke'.

41. In Section 36(1)(a), 'or Section 3(3)' is replaced by ', Section 3(3), Section 16a(1) (a) or (d), or Section 16a(2)(a), (b), (c), (d) or (f)' and 'or nicotine pouch without tobacco content' is replaced by ', nicotine pouch without tobacco content, nicotine-containing product or psychomodulation substance'.

42. In Section 36(1)(b), the words 'or Section 16a(2)(e)' are inserted after the words 'Section 3(2)(d)' and 'or tobacco-free nicotine pouch' is replaced by ', nicotine pouch without tobacco content, nicotine-containing product or psychomodulation substance'.

43. In Section 36(1)(c), the words 'or Section 16a(1)(c)' are inserted after the words 'Section 3(4)' and 'or tobacco-free nicotine pouches' is replaced by ', tobacco-free nicotine pouches, nicotine containing nicotine or psychomodulation substance'.

44. In Section 36(1)(f), the words 'or tobacco-free nicotine pouch' are replaced by the words ', a tobacco-free nicotine pouch or nicotine-containing product' and the words 'or fail to comply with the obligation under Section 16b(1)' are added at the end of the text.

45. In Section 36(1)(g), the words 'or Section 13(1)' are replaced by ', Section 13(1) or Section 16b(2)'.

46. In Section 36(1)(h), the words 'or Section 13(2)' are replaced by the words ', Section 13(2) or Section 16b(4)' and the words ', nicotine containing products, psychomodulating substances' are inserted after the words 'tobacco-free nicotine pouches'.

47. In Section 36(1)(i), the words ', nicotine-containing products, psychomodulating substances' are inserted after the words 'tobacco-free nicotine pouches' and the words 'Section 7 or 15' is replaced by the words '7, 15 or 16c,'.

48. In Section 36(1), the word 'or' is deleted at the end of subparagraph (s).

49. In Section 36, at the end of paragaraph (1), the full stop is replaced by a comma and the following subparagraphs (u) and (v) are added:

- 'u) contrary to Section 16a(1)(b), allow a person under the age of 18 years to enter a shop specialised in the sale of psychomodulating substances and goods related to psychomodulating substances to; or
- v) fails to comply with the obligation under Section 16b(3).'.

50. In Section 36(10)(d), the words '(j) or (p)' are replaced by '(j), (p), (u) or (v)'.

51. A new Section 36a is inserted after Section 36, which, including the heading, reads as follows:

#### 'Section 36a

#### Offences related to the handover of psychomodulating substances

(1) Entrepreneurial natural person or a legal person undertaking the delivery of a psychomodulatory substance purchased by means of distance communication commits an offence by:

a) handing over a psychomodulating substance contrary to Section 16c(4) and (5);

b) handing over a psychomodulating substance to a person under the age of 18 contrary to Section 16c(4) and (5);

c) failing to record the handover of the goods or failing to transmit the recorded information to the seller pursuant to Section 16c(7).

(2) A fine of up to CZK 800,000 may be imposed for the offences referred to in paragraph 1.'.

52. In Section 37, the words ', psychomodulation substance' are inserted after the words 'inteded for smoking'.

53. In Section 39(1), the first sentence is replaced by the sentence 'Forfeited or confiscated tobacco products, herbal smoking products and psychomodulation substances shall be destroyed.'.

54. In Section 40(1)(d), the words 'pursuant to Section 35(1)(a), (d) and (m) and Section 36(1)(a), (e) to (g), (i), (j) and (o)' are replaced by the words 'pursuant to Section 35(1)(a), (d) and (m), Section 36(1)(a), (e) to (j), (o), (u) and (v), Section 36(8) and Section 36a'.

#### Article XII Transitional provisions

- 1. Persons handling psychomodulatory substances are obliged to adapt their activities to the conditions set out in Act No. 65/2017, as in force from the date of entry into force of this Act, within 90 days from the date of entry into force of this Act.
- 2. A seller or other operator of a shop selling nicotine-containing products is obliged tt adapt its activities to the conditions laid down in Act No 65/2017, as in force from the date of entry into force of this Act, within 30 days of the date of entry into force of this Act.

## PART ELEVEN Amendment to the Act on video-sharing platform services

## Article XIII

In Section 7, at the end of paragraph (3) of Act No 242/2022 on video-sharing platform services and amending certain related acts (the Video-sharing Platform Services Act), the words 'or psychomodulating substances' are added.

#### PART TWELVE TECHNICAL REGULATION

#### Article XIV

This Act 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.

#### PART THIRTEEN EFFECTIVE DATE

#### Article XV

This Act shall come into effect on the first day of the second calendar month following its promulgation.