## ACT

of

## amending the Act on protection of health against the consequences of consumption of tobacco and tobacco products<sup>1)</sup>

**Article 1.** The Act of 9 November 1995 on protection of health against the consequences of consumption of tobacco and tobacco products (Journal of Laws of 2024, item 1162), shall be amended as follows:

- 1) in Article 2:
  - a) points 17 and 18 shall read as follows:
    - '17) smoking of electronic cigarettes consumption of either nicotine-containing vapour or nicotine-free vapour emitted by an electronic cigarette;
    - 18) refill container a receptacle that contains a nicotine-containing liquid, which can be used for refilling an electronic cigarette, or a receptacle that contains a nicotine-free liquid that is intended to be used in electronic cigarettes;',
  - b) points 20 and 21 shall read as follows:
    - '20) electronic cigarette a product that can be used for consumption of nicotine-containing vapour or nicotine-free vapour via a mouthpiece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank; electronic cigarettes can be disposable or refillable by means of a refill container or a tank, or rechargeable with single-use cartridges;
    - 21) related product an electronic cigarette, a refill container, a herbal product for smoking, and a nicotine pouch;',
  - c) points 23 to 25 shall read as follows:
    - '23) promotion of tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories:

This Act was notified to the European Commission on..., under No..., pursuant to § 4 of the regulation of the Council of Ministers of 23 December 2002 concerning the manner in which the national notification system of standards and legal acts functions (Journal of Laws, item 2039, and of 2004, item 597) which implements the provisions of 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 (codification) (OJ EU L 241 of 17.9.2015, p. 1).

- a) distributing to the public of tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories,
- b) organising tastings of tobacco products, nicotine pouches, electronic cigarettes or refill containers,
- c) organising bonus offer sales of tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories, or competitions based on their purchase, as well as other forms of public encouragement to purchase or use them, regardless of the form of reaching the target group,
- d) offering tobacco products or nicotine pouches to consumers at a reduced price compared to the price printed on the unit packet;
- 24) retail outlet an outlet where tobacco products, nicotine pouches, electronic cigarettes, or refill containers are placed on the market, also by a natural person;
- 25) advertising of tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories:
  - a) disseminating messages, brand images of tobacco products, nicotine pouches, electronic cigarettes, refill containers, tobacco accessories, or symbols associated with them,
  - b) disseminating the names or graphic symbols of entities producing tobacco products, nicotine pouches, electronic cigarettes, refill containers, or tobacco accessories, not different from the names and graphic symbols of tobacco products, nicotine pouches, electronic cigarettes, refill containers, tobacco accessories, or symbols associated with them;
  - designed for the promotion of brands of tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories, excluding information used for commercial purposes in relations between entities involved in the manufacture of, distribution of and trade in tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories;',
- d) point 28 shall read as follows:

- '28) sponsorship providing financial or in-kind support to the activities of natural persons, legal persons, or organisational units without legal personality, related to the display of names of tobacco products, nicotine pouches, electronic cigarettes, refill containers, or tobacco accessories, of entities manufacturing such products, and of their graphic symbols;
- e) point 44a shall be added after point 44 reading as follows:
  - '44a) nicotine pouch all products for oral use, except those intended for inhalation, not containing tobacco but containing nicotine, whether or not mixed with other ingredients, which are presented in pouch portions or available in pouches;';
- 2) the words 'and Article 11h(1) and (2)' in Article 3a(4) and (5) shall be replaced by ', Article 11h(1) and (2) and Article 11ha(1) and (2)';
- 3) Article 6 shall read as follows:
  - 'Article 6. 1. It shall be prohibited to make tobacco products, nicotine pouches, electronic cigarettes or refill containers available to persons under 18 years of age. A retail outlet shall display in a visible and legible manner the following information: "Selling tobacco products, nicotine pouches, electronic cigarettes or refill containers to persons under 18 years of age is prohibited (Art. 6(1) of the Act of 9 November 1995 on protection of health against the consequences of consumption of tobacco and tobacco products)."
  - 2. In case of doubt as to the age of majority of a person intending to purchase tobacco products, nicotine pouches, electronic cigarettes or refill containers, the seller may request presentation of a document confirming their age.
  - 3. It shall be prohibited to place on the market tobacco products, nicotine pouches, electronic cigarettes, or refill containers on the premises of entities performing medical activities within the meaning of the regulations concerning medical activities, of organizational units of the education system referred to in the regulations concerning the education system, and of sports and leisure venues.
  - 4. It shall be prohibited to place on the market tobacco products, nicotine pouches, electronic cigarettes or refill containers and parts thereof with the use of vending machines.

- 5. It shall be prohibited to sell cigarettes in packets containing less than twenty pieces and in bulk without packaging.
- 6. It shall be prohibited to place on the market tobacco products, nicotine pouches, electronic cigarettes or refill containers and parts thereof with the use of a self-service system, with the exception of duty-free shops.
  - 7. Only the following may be placed on the market in the Republic of Poland:
  - 1) tobacco and related products meeting the requirements laid down in the Act and in delegated acts;
  - 2) tobacco and related products for which the obligations related to reporting and provision of information laid down in the Act have been fulfilled. (\*);
- 4) Article 7f shall read as follows:

'Article 7f. Distance selling, including cross-border distance selling, of the following items shall be prohibited:

- 1) tobacco products;
- 2) electronic cigarettes and refill containers and parts thereof;
- 3) nicotine pouches.';
- 5) in Article 8:
  - a) in paragraph 1, the introduction to enumeration shall read as follows:
    - 'It shall be prohibited to advertise tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories, or to promote tobacco products, nicotine pouches, electronic cigarettes, refill containers or tobacco accessories, or to advertise or promote products imitating the said products, or symbols related to the use of tobacco, tobacco products, nicotine pouches, electronic cigarettes or refill containers, and in particular:',
  - b) paragraph 3 shall read as follows:
    - '3. It shall be prohibited to display in a retail outlet items imitating the packaging of tobacco products and items imitating the packaging of nicotine pouches, electronic cigarettes or refill containers.';
- 6) in Article 8a(4)(1), after the words '(OJ L 353, 31.12.2008, p. 1, as amended)', the words ', hereinafter referred to as "Regulation No 1272/2008" shall be added;
- 7) in Article 11c:
  - a) in paragraph 1:

- point 1 shall read as follows:
  - (1) Nicotine-containing and nicotine-free liquids shall only be placed in dedicated refill containers, the capacity of which shall not exceed 10 ml, and in the case of disposable electronic cigarettes or disposable cartridges, the capacity of disposable cartridges or tanks shall not exceed 2 ml;',
- points 3–5 shall read as follows:
  - '3) nicotine-containing liquid and nicotine-free liquid shall not contain the additives listed in Article 7c(3);
  - 4) only ingredients of high purity shall be used in the manufacture of nicotine-containing and nicotine-free liquids, and substances other than the ingredients referred to in Article 11b(5)(2) may be present in the nicotine-containing and nicotine-free liquids in trace levels, if such traces are technically unavoidable during manufacture;
  - 5) except for nicotine, in nicotine-containing liquids and in nicotine-free liquids only ingredients shall be used that do not pose a risk to human health in heated or unheated form;',
- b) paragraph 2 shall read as follows:
  - '2. Technical standards for the refill mechanism of electronic cigarettes that can be used for the consumption of nicotine-containing vapour, and for the refill mechanism of refill containers with nicotine-containing liquid are set out in Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes (OJ L 101, 16.4.2016, p. 15). That Decision shall apply mutatis mutandis to the definition of technical standards for the refill mechanism of electronic cigarettes that may be used for the consumption of nicotine-free vapour, and for the refill mechanism of refill containers with nicotine-free liquid.',
- c) paragraph 7 shall read as follows:
  - '7. The packaging referred to in paragraph 6, in the case of electronic cigarettes that can be used for the consumption of nicotine-containing vapour, and of refill containers with nicotine-containing liquid, shall carry the following health warning:

'The product contains nicotine, which quickly causes addiction.'.',

d) paragraph 7a shall be added after paragraph 7, reading as follows:

'7a. The packaging referred to in paragraph 6, in the case of electronic cigarettes that can be used only for the consumption of nicotine-free vapour, and of refill containers with nicotine-free liquid, shall carry the following health warning: 'Product harmful to health.'.';

## 8) in Article 11f:

- a) paragraph 1 shall read as follows:
  - '1. Where the President of the Bureau finds, or has reasonable grounds to believe, that certain electronic cigarettes that can be used for consuming nicotine-containing vapour, or refill containers with nicotine-containing liquid, or a given type of electronic cigarettes that can be used for consuming nicotine-containing vapour, or of refill containers with nicotine-containing liquid may pose a serious risk to human health, the President shall, by decision, suspend their manufacture or placing on the market or order their withdrawal from the market for the time necessary for an assessment by the European Commission.',
- b) paragraph 3(2) shall read as follows:
  - '2) issue a decision to completely halt the manufacture or placing on the market or to order withdrawal from the market of certain electronic cigarettes that may be used for the consumption of nicotine-containing vapour, or of refill containers with nicotine-containing liquid, or of a type of electronic cigarettes that may be used for the consumption of nicotine-containing vapour, or of refill containers with nicotine-containing liquid, if the European Commission considers that the action taken was justified.',
- c) paragraph 5 shall read as follows:
  - '5. The delegated acts shall lay down a prohibition to place on the market certain electronic cigarettes that may be used for the consumption of nicotine-containing vapour, or refill containers with nicotine-containing liquid, or a type of electronic cigarettes that may be used for the consumption of nicotine-containing vapour, or refill containers with nicotine-containing liquid.',
- 9) the following Articles 11ha to 11hc shall be inserted after Article 11h:

'Article 11ha. 1. The manufacturer or importer of nicotine pouches shall submit to the President of the Bureau a list of all ingredients, including their quantities, used in the manufacture of these products, broken down by brand and type.

- 2. The manufacturer or importer of nicotine pouches shall inform the President of the Bureau when the composition of a product is modified in a way that affects the information provided pursuant to paragraph 1.
- 3. The information referred to in paragraphs 1 and 2 shall be submitted to the President of the Bureau at least 6 months before the date of placing new or modified nicotine pouches on the market.
- 4. The information referred to in paragraphs 1 and 2 shall be published in the Public Information Bulletin on the website of the office serving the President of the Bureau, with the rules of trade secret protection taken into account.
- 5. The manufacturer or importer of nicotine pouches, when submitting information in accordance with paragraphs 1 to 3, shall indicate the information it considers to be trade secrets.
- 6. The manufacturer or importer shall pay to the bank account specified by the President of the Bureau, within 14 days from the date of receipt of a request for payment, an annual fee for receiving, storing, processing, analysing, and publishing information on nicotine pouches submitted pursuant to paragraphs 1 and 2, in the amount of the average monthly remuneration in the enterprise sector, excluding profit-related bonuses for the previous year, as announced by the President of the Statistics Poland. The fee constitutes state budget revenue.
- 7. The format for the submission and making available of information on nicotine pouches is laid down in Commission Implementing Decision (EU) 2015/2186.

Article 11hb. 1. Nicotine pouches shall meet the following requirements:

- 1) The nicotine content of a nicotine pouch shall not exceed 20 mg/g;
- 2) A nicotine pouch shall not contain the additives listed in Article 7c(3);
- 3) No ingredients increasing nicotine addictiveness shall be used in the nicotine pouches manufacturing process.
- 2. The unit packet and any outside packaging of nicotine pouches shall carry the following health warning:

<sup>&#</sup>x27;This product damages your health and is addictive.'.

- 3. The health warning referred to in paragraph 2 shall be:
- 1) printed in black Helvetica bold type on a white background;
- 2) at the centre of the surface reserved for them, and on cuboid unit packets and any outside packaging, they shall be parallel to the lateral edge of the unit packet or of the outside packaging.
- 4. The text of the health warning referred to in paragraph 2 shall be parallel to the main text on the surface reserved for this warning.
  - 5. The health warning referred to in paragraph 2 shall:
  - 1) appear on the two largest surfaces of the unit packet and any outside packaging;
  - 2) cover 30 % of the surfaces of the unit packet and any outside packaging.
- 6. Unit packets and any outside packaging of nicotine pouches shall not include the elements or features referred to in Article 8(4)–(6), with the exception of Article 8(4)(1) as regards information on nicotine content and Article 8(4)(3) as regards information on flavourings.

Article 11hc. 1. The provisions of the Act concerning nicotine pouches shall not apply to nicotine pouches for which a marketing authorisation must be obtained on the basis of the provisions of the Pharmaceutical Law or which are subject to the requirements laid down in the regulations concerning medical devices.

- 2. Regulation No 1907/2006 and Regulation No 1272/2008 shall apply to nicotine pouches,';
- 10) in Article 11i(1), the words 'and Article 10(8)' shall be replaced by ', Article 10(8) and Article 11ha(6)';
- 11) Article 11j shall be added after Article 11i and shall read as follows:
  - 'Article 11j. The Trade Inspection, acting pursuant to the Act of 15 December 2000 on Trade Inspection (Journal of Laws of 2024, items 312 and 1222), shall check entrepreneurs' compliance with the provisions of the Act to the extent not reserved for other authorities.
- 12) in Article 12, points 3 and 4 shall read as follows:
  - '3) displays in a retail outlet items imitating the packaging of tobacco products, nicotine pouches, electronic cigarettes or refill containers contrary to the provisions of Article 8(3),

- 4) places on the unit packet or any outside packaging of tobacco products or nicotine pouches any elements or features which suggests economic advantages, as referred to in Article 8(5),';
- 13) in Article 12c, the following points 13 and 14 shall be added after point 12:
  - '13) makes available for the first time for resale or makes available for the first time for placing on the market nicotine pouches without complying with the obligation to provide the list of ingredients referred to in Article 11ha(1), with regard to their type or brand,
  - 14) manufactures or imports with a view to placing on the market nicotine pouches which do not comply with the requirements laid down in Article 11hb(1) to (6),
- 14) Article 13(1)(1) is given the following wording:
  - '1) places tobacco products, nicotine pouches, electronic cigarettes or refill containers on the market or does not display information about the prohibition of their sale contrary to the provisions of Article 6(1), (3) to (6),
- 15) Article 15 shall read as follows:
  - 'Article 15. 1. If an offence referred to in Article 12(5) to (8), Articles 12a to 12c, or Article 13(1)(1) is committed, the court may order the forfeiture of tobacco products or nicotine pouches that are the subject of the offence, even if they are not the property of the perpetrator.
  - 2. If the offence referred to in Article 12(3) is committed, the court may order the forfeiture of items imitating the packaging of tobacco products, nicotine pouches, electronic cigarettes or refill containers which are the subject of the offence, even if they are not the property of the perpetrator.
  - 3. The court may order the forfeiture of tobacco products, nicotine pouches, items imitating the packaging of tobacco products, nicotine pouches, electronic cigarettes or refill containers not owned by the perpetrator if their owner or another authorised person, without exercising the care required in the circumstances, anticipated or could have anticipated that they could be used or intended to be used for committing a criminal offence.
- 16) in Article 15a(1)(7), the full stop shall be replaced by a semicolon and point 8 shall be added and read as follows:

'8) fails to submit or fails to submit in time the list of ingredients referred to in Article 11ha(2).

**Article 2.** In the case of electronic cigarettes that may be used solely for the consumption of nicotine-free vapour, and of refill containers with nicotine-free liquid placed on the market before the date of entry into force of this Act, the notifications and designations referred to in Article 11b(1) of the Act amended with Article 1 shall be made within 6 months from the date of entry into force of this Act.

Article 3. Electronic cigarettes which may be used only for the consumption of nicotine-free vapour and refill containers with nicotine-free liquid which do not meet the requirements referred to in Article 11c of the Act amended with Article 1, in the wording laid down by this Act, may remain on the market for no longer than 6 months from the date of entry into force of this Act.

Article 4. The content of the information referred to in Article 6(1) of the Act amended with Article 1, displayed in a retail outlet before the date of entry into force of this Act, shall be adapted to the content of the information referred to in Article 6(1) of the Act amended with Article 1, in the wording laid down by this Act, within 6 months of the date of entry into force of this Act.

**Article 5.** Nicotine pouches may remain on the market in vending machines or in a self-service system for no longer than 6 months from the date of entry into force of this Act.

**Article 6.** The manufacturer or importer of nicotine pouches placed on the market before the date of entry into force of this Act shall submit to the President of the Bureau for Chemical Substances the list referred to in Article 11ha(1) of the Act amended with Article 1, in the wording laid down by this Act, within 6 months of the date of entry into force of this Act.

**Article 7.** Nicotine pouches which do not meet the requirements laid down in Article 11hb of the Act amended with Article 1, in the wording laid down by this Act, may remain on the market for no longer than 6 months from the date of entry into force of this Act.

**Article 8.** The Act enters into force 14 days after the day of announcement.