THE GOVERNMENT OF HUNGARY

GOVERNMENT

Decree

amending Government Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties

Acting under the authorisation granted by Section 8(5)(a), (g), (h), and (i) of Act XLII of 1999 on the protection of non-smokers and certain regulations on the consumption and distribution of tobacco products, and acting within the scope of its functions set out in Article 15(1) of the Fundamental Law, the Government establishes the following:

Section 1

In Section 6(1)(a) of Government Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties (hereinafter: Decree), the following point *(ai)* shall be added:

(The type of tobacco product shall be indicated on the unit packet as follows:)

'*(ai)* “heated tobacco product”.’

Section 2

(1) Section 15/A (a) of the Decree shall be replaced by the following:

(The unit packet)

‘(a) contains 20 cigarettes in the case of cigarettes,’

(2) Section 15/A (c) of the Decree shall be replaced by the following:

(*The unit packet*)

‘(c) in the case of smoking tobacco
(ca) is a rectangular or upright sachet containing smoking tobacco of minimum 30 g but not more than 50 grams, but in any event of a weight (grams) divisible by ten without any remainder,

(cb) in the case of water-pipe tobacco, is the unit packet referred to in point (ca) or a carton containing not more than 50 grams of water-pipe tobacco;’

Section 3

Section 17(1)(a) of the Decree shall be replaced by the following:

(Compliance with this Decree)

‘(a) with regard to the notification referred to in Section 4 and subheading 9/B – excluding the provisions on unit packets of products – shall be verified by the National Chief Medical Officer,’

(who will act within his competence in the event of a breach of this Decree.)

Section 4

In Section 18/A of the Decree, the following paragraph (6) shall be inserted:

‘(6) If the Chief Medical Officer deems it necessary on the basis of the report referred to in this Section, he shall prohibit the further use of the additives included in the priority list.’

Section 5

Section 18/C of the Decree shall be replaced by the following:

‘Section 18/C (1) A herbal product for smoking may be placed on the market and marketed under the following conditions:
(a) it must not contain any additive referred to in Annex 4,
(b) it must not contain vitamins or other additives which give the impression that the product has a beneficial physiological effect or is less harmful to health;
(c) it may not contain any caffeine, taurine or other additives and stimulant compounds associated with the notion of energy and vitality,
(d) it must not contain additives facilitating inhalation, or
(e) additives with CMR properties.’

(2) The producer, importer and distributor of herbal products for smoking, or the registered trader or the dealer holding an excise authorisation, shall make a notification if they wish to place herbal products for smoking on the market. The notification shall be submitted electronically to the Minister responsible for agricultural policy, the Minister for Health and the Chief Medical Officer, six months before the planned marketing. The notification shall be accompanied by a detailed description of the herbal product for smoking and information on all the ingredients and quantities used in the manufacture of the product, by brand name and subtype.

(3) The producer or importer of a herbal product for smoking shall also inform the bodies referred to in paragraph (2) if the composition of a product is modified in a way that affects the information provided in accordance with this Section. The producer or importer of a herbal product for smoking may be required to carry out further tests or provide additional information.

(4) When examining notifications on herbal products for smoking, the National Chief Medical Officer shall decide whether it is necessary to ban the product based on the data and information that have been provided, taking into account the provisions of the Act on reducing smoking prevalence among young people and retail of tobacco products.'

Section 6

(1) Section 19/B (1)(b) of the Decree shall be replaced by the following:

(Electronic cigarettes and refill containers may be placed on the market and distributed under the following conditions:)

'(b) nicotine-containing liquids or liquids containing nicotine in any form, used in electronic cigarettes or refill containers, may be placed on the market in the form of:
(ba) refill containers with a capacity not exceeding 10 ml,
(bb) disposable electronic cigarettes or single-use cartridges with a capacity not exceeding 2 ml, both specially designed for this purpose,'

(2) Section 19/B (5) of the Decree shall be replaced by the following:

'(5) The two largest surfaces of unit packets and multipacks of electronic cigarettes and refill containers, which are pre-filled with nicotine-containing refill liquid, shall bear the following health warning in a way that occupies at least 30 % of each surface: 'This product contains nicotine which is harmful to your health and leads to addiction.'

(3) In Section 19/B of the Decree, following paragraph (6a) shall be added:

'(6a) When examining notifications on electronic cigarettes and refill containers, the pharmaceutical administration shall act in the light of the Act on reducing smoking prevalence among young people and retail of tobacco products.'

Section 7

Section 19/C (1) of the Decree shall be replaced by the following:

'(1) Electronic devices imitating smoking and nicotine-free refill containers may be placed on the market and distributed under the following conditions:
(a) the liquid in them must not contain nicotine (hereinafter referred to as nicotine-free liquid);
(b) the nicotine-free liquid must not contain flavouring substances;
(c) the nicotine-free liquid must not contain
(ca) any additive specified in Annex 4;
(cb) vitamins or other additives giving the impression that the product has a beneficial physiological impact or is less harmful to health;
(cc) caffeine, taurine or other additives and stimulant compounds that give a feeling of improved energy and vitality;
(cd) additives that discolour the emissions;
(ce) additives facilitating inhalation, and

(cf) additives with CMR properties;
(d) the nicotine-free liquid must not contain ingredients with impurities in more than 0.1 %s;
(e) the liquid may only contain ingredients that are not harmful to human health – neither in reaction to heat or without that;
(f) it is equipped with a child-proof seal, and
(g) it is protected against breakage and leakage and is equipped with a mechanism to guarantee leak-proof refilling.'

(2) In Section 19/C of the Decree, the following paragraph (6) shall be added:

'(6) On the two largest surfaces of unit packets and multipacks of nicotine-free refill containers, the following health warning shall be indicated by occupying at least 30 % of each surface, in accordance with the requirements of Section 19/B(6): 'This product is a nicotine-free refill container. Use by children is prohibited.'

Section 8

The following subheading 9/B is added to the Decree:

'Section 9/B Rules on nicotine-containing smoking substitutes

Section 19/F (1)(1) Nicotine-containing smoking substitutes shall have a maximum nicotine content of 17 mg per consumption unit.

(2) The unit packet of a nicotine-containing smoking substitute shall contain a maximum of 20 products.

(3) Producers, importers and distributors of nicotine-containing smoking substitutes, or registered traders, or traders holding an excise authorisation shall, six months prior to the planned placing on the market, submit a notification to the National Chief Medical Officer in electronic form, with the provision of the following data:
(a) the name and contact details of the producer, importer, and trader with excise authorisation;
(b) a list of all the ingredients of the product, as well as the emissions generated with the use of the product and the substances released, as well as the quantities thereof, by brand name and type;
(c) toxicological data on the ingredients of the product, their impact on the health of consumers and users, taking into account their potential addictive effects;
(d) information on the product's valid nicotine dose and nicotine absorption when used for its intended purpose or under conditions which can reasonably be foreseen;
(e) a description of the manufacturing process, including whether the product has been manufactured in series production, and a statement that the manufacturing process ensures compliance with the requirements of the legislation; and
(f) a declaration that the producer, importer or trader holding an excise authorisation assumes full responsibility for the quality and safety of the product when placed on the market and used under normal or reasonably foreseeable conditions.

(4) A new notification shall be submitted in the event of any change to the product which affects the data referred to in paragraph (3).

Section 19/G(1) A nicotine-containing smoking substitute may be placed on the market and distributed if:
(a) the product does not contain
(aa) any additive referred to in Annex 4;
(ab) vitamins or other additives giving the impression that the product has a beneficial physiological impact or is less harmful to health;
(ac) caffeine, taurine or other additives and stimulant compounds associated with the feeling of improved energy levels and vitality;
(ad) additives facilitating nicotine uptake; and
(ae) additives with CMR properties;
(b) the product does not contain ingredients with impurities in more than 0.1 %.

(2) Unit packets of the product shall be accompanied by a leaflet containing:
(a) instructions of use and storage for the product and a warning that the use of the product is prohibited for under-age people;
(b) information on counter-indications;
(c) warnings pertinent to specific risk groups;
(d) information on possible adverse effects;
(e) information on addictive properties and toxicity; and
(f) the contact details of the producer, distributor or importer, as well as those of the contact person.

(3) Unit packets and multipacks of the product shall bear
(a) all product ingredients listed in descending order by weight;
(b) the nicotine content per dose of the product;
(c) the batch number; and
(d) each of the following warnings in a clearly visible, legible and indelible manner:
(da) ‘The product should be kept out of reach of children.’
(db) ‘The product may cause harm if swallowed.’

(4) The warnings referred to in paragraph (3) shall be printed in Helvetica bold in black on a white background. The inscription shall be in lower-case letters, except for the initials of the text, and where the use of capital lettering is required by a grammar rule.

(5) The labelling of unit packets and multipacks of the product and the product itself shall not contain any element or solution which:
(a) advertises the product in terms of its characteristics, health effects or the hazards and releases in a way that would create an erroneous impression, or encourages the consumption of the product in this way;
(b) suggests that a given product is less harmful than tobacco products, electronic cigarettes and electronic smoking substitutes;
(c) suggests that a product has vitalising, energising, healing, rejuvenating, natural, organic characteristics or other health or lifestyle benefits;
(d) refers to a flavour, odour, flavouring or other additive, or the absence thereof, in a way as to mislead the consumer;
(e) reminds one of a food or cosmetic product;
(f) suggests that some products are more biodegradable or have other environmental benefits.

(6) Unit packets and multipacks shall not suggest an economic advantage by using printed coupons that offer discounts or free distribution, or ‘buy one, get two’ promotions or other similar offers.

(7) The elements and solutions prohibited under paragraphs (5) and (6) include: texts, symbols, names, trademarks, figurative or other signs, and other indications similar to these.

(8) The following health warning shall be affixed to the two largest surfaces of unit packets and multipacks of the product, occupying at least 30 % of each surface: ‘This product contains nicotine which is harmful to your health and leads to addiction.’ The health warnings shall be printed in such a way as to be indelible on the unit packets and multipacks, including that they shall not be partially or completely hidden or obstructed by any seal, price tag, security device, packaging material, bag, box or other device when the product is placed on the market.

(9) The health warning referred to in paragraph (8) shall be printed in Helvetica bold in black on a white background. The inscription shall be in lower-case letters, except for the initials of the text, and where the use of capital lettering is required by a grammar rule. The health warning shall be placed centrally on the upper edge of the packet in the area reserved for printing.

(10) The unit packet of the product shall be equipped with a child-proof seal.

(11) The National Chief Medical Officer shall proceed in the examination of notifications regarding nicotine-containing smoking substitutes.

(12) The National Chief Medical Officer shall issue a certificate of compliance with the notification obligation if the notified product complies with Section 19/F and this section, within 60 days of receipt of the notification.’

Section 9

The following Sections 21/E and 21/F shall be inserted in the Decree:

‘Section 21/E (1) The notification of herbal products for smoking already on the market shall be submitted by the producer, importer and distributor or registered trader or by the trader holding an excise authorisation by 31 December 2023.

(2) In the case of nicotine-free refill containers, nicotine-free cartridges and nicotine-containing smoking substitutes, which were placed on the market between 1 September 2023 and 30 November 2023, the notification according to Section 7/D(1) of Act XLII of 1999 on the protection of non-smokers and certain regulations on the consumption and distribution of tobacco products shall be made by 29 March 2024.

Section 21/F At entities engaged in the retail sale of tobacco products, products which are on stock at the time of entry into force of Government Decree No …/2023 of [date] amending Decree No 39/2013 of 14 February 2013 on the production, placing on the market and control of tobacco products, on combined warnings, and the detailed provisions on the application of healthcare penalties (hereinafter: Amending Decree 5), may be placed on the market for an unlimited period if such products are:

(a) herbal products for smoking which are non-compliant with Section 18/C (1)-(3) as specified by Amending Decree 5;
(b) nicotine-free refill containers which are non-compliant with Section 19/C (1)-(4) and (6) as specified by Amending Decree 5;
(c) nicotine-containing smoking substitutes which are non-compliant with Section 19/F (1)-(4) and Section 19/G (1)-(10) as specified by Amending Decree 5; and
(d) heated tobacco products which lack the marking mentioned in Section 6 (1)(a)(ai) as specified by Amending Decree 5.'

Section 10

Annex 4 of the Decree shall be replaced by Annex 1 herein.

Section 11

In the Decree,
(a) in Section 1(1) the words 'refill liquids and electronic devices imitating smoking' shall be replaced by the words 'refill containers, electronic devices imitating smoking, nicotine-free refill containers and herbal products for smoking';
(b) in Section 19/D(1), the words 'producers of containers' shall be replaced by the words 'producers of containers, nicotine-free cartridges and nicotine-free refill containers'
.

Section 12

This decree shall enter into force on 23 October 2023.

Section 13

The draft of this decree has been notified in advance in accordance with Articles 5-7 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.

(Viktor Orbán)
Prime Minister

Annex 1 to Government Decree No…/2023 of [date]

"Annex 4 to Government Decree No 39/2013 of 14 February 2013

Prohibited additives

A	B
serial number	Compound
1	2-methyl-3-(para-isopropyl-phenyl)propionaldehyde
2	Agar-agar
3	Aluminium oxide
4	Ammonium acetate
5	Ammonium citrate
6	Ammonium formate
7	Ammonium bicarbonate
8	Ammonium hydrogen malate
9	Ammonium hydroxide
10	Ammonium carbamate
11	Ammonium chloride
12	Ammonium lactate
13	Ammonium malate
14	Ammonium succinate
15	Ammonium sulfamate
16	Ammonium tartrate
17	Anthraquinone Blue
18	Basic Blue 26
19	Succinic acid (E 363)
20	Dehydro-menthofurolactone
21	Di(2-ethylhexyl) adipate
22	Diammonium hydrogen phosphate
23	Diammonium carbonate
24	Diammonium malate
25	Diammonium succinate
26	Dibutyl phthalate
27	Phenol-formaldehyde-modified rosin
28	Galactose
29	Formic acid (E 236)
30	Carbamide (Urea) (E 927b)
31	Carmine Red
32	Caffeine
33	Krizein S
34	Coumarin-free tonka beans
35	Lactose
36	Maltose
37	Mannose
38	Methyl violet
49	Honey

40	Monoammonium phosphate
41	Sodium silicate
42	Solvent Red 1
43	Pectins
44	Polyethylene glycol (E 1251)
45	Riboflavin-5-phosphate
46	Sucrose octaacetate
46	Saccharine (E 954)
48	Sudan Blue 11
49	Taurine
50	Tea
51	Theobromine
52	Cannabidiol (CBD)

”