Government Decree No 120/2024 of 10 June 2024

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 lays down the following:

Section 1 Section 4 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)shall be replaced by the following:

‘Section 4 (1) The tobacco product shall not contain foreign substances.

(2) The tobacco product shall not contain

(a) vitamins or other additives giving the impression that the product has a beneficial physiological impact or is less harmful to health;

(b) caffeine, taurine or other additives and stimulant compounds that are associated with energy and vitality;

(c) additives that discolour the emissions;

(d) in the case of tobacco products for smoking, additives that facilitate inhalation or nicotine uptake;

(e) additives that, in an unburnt form, are carcinogenic, mutagenic or reprotoxic (hereinafter: have CMR properties).

(3) The tobacco product shall not contain any prohibited additives mentioned in Annex 4.

(4) It is prohibited to place on the market and to distribute tobacco products which do not comply with the requirements laid down in paragraphs (1)-(3).

(5) In addition to paragraphs (1)-(4), it is also prohibited to place on the market and to distribute cigarettes and roll-your-own tobacco that contain menthol and menthol derivative additives.

(6) The user, the registered trader, the importer or the authorised warehouse keeper (hereinafter together: notifier) must inform the National Centre for Public Health and Pharmacy (hereinafter: NNGYK) about the use of any new additive in the production of a tobacco product, and shall do so 6 months before the intended initial date of use, but no later than 30 days before the intended date of use. The notification shall contain the data set out in Annex 3. NNGYK shall keep an official register of the notified data and publish it on its website. There is no need to notify the use of natural parts of raw tobacco.

(7) The notification shall be accompanied by:

(a) an authorisation for use issued by an authority of a State which is party to the Agreement on the European Economic Area, if available, and

(b) a report issued by an accredited laboratory with the results of the test.

(8) Within 30 days of the notification, NNGYK shall examine whether the additive to be used belongs to the additives prohibited in the Decree, on the basis of the notification. If, in the course of the examination, NNGYK finds that the use of the additive (which is intended to be used) is not prohibited by law, it shall acknowledge the notification and inform the notifier accordingly. NNGYK shall inform the minister responsible for consumer protection about the notification. If no statement is made by NNGYK after a period of 30 days, the notified additive shall be deemed to be allowed for use.

(9) Studies on additives notified in accordance with paragraph (6) shall be submitted by the notifier to NNGYK within 2 years after they have started using them. Within 6 months of the submission of the documentation, the Ministry headed by the minister responsible for health shall examine whether the documentation gives any reason to include the additive in the list of prohibited additives pursuant to Annex 4. This examination shall be made on the basis of the documentation.

(10) If the Chief Medical Officer deems it necessary to include the additive in the list in Annex 4, they shall initiate the amendment of the legislation with the minister responsible for health, in order to extend the list.

(11) It shall be prohibited to use additives other than the notified additive and to use a tobacco additive under different conditions from the ones mentioned in the notification.

(12) Cigarettes released for free circulation must comply with the safety requirements of MSZ EN 16156:2011.

(13) In the case of cross-border distance sales, tobacco products shall be considered to be placed on the market in the Member State where the consumer is located.

(14) For the purposes of this Section, an additive which the manufacturer was authorised to use in the production of a tobacco product before 20 August 2016 on the basis of a legal authorisation or a specific authorisation, shall not be considered as a new additive and shall not be subject to the notification requirement set out in paragraph 6, provided that it is not included in the list of prohibited additives in Annex 4.’

Section 2 In Section 6(1)(a) of the 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 3 (1) In Section 15/A of the Decree,point (a) shall be replaced by the following:

(The unit packet)

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

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

(The unit packet)

‘(c) in the case of smoking tobacco, 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, with that in the case of water-pipe tobacco, a carton containing not more than 50 grams of water-pipe tobacco also constitutes a unit packet;’

Section 4 In Section 17 of the Decree,point (a) of paragraph (1) shall be replaced by the following:

(Compliance with this Decree)

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

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

Section 5 The following paragraph (6) shall be added to Section 18/A of the Decree:

‘(6) If the Chief Medical Officer deems it necessary on the basis of the report referred to in this Section, they shall initiate the amendment of the legislation with the minister responsible for health in order to prohibit the further use of the additives included in the priority list.’

Section 6 Section 18/C of the Decreeshall be replaced by the following:

‘Section 18/C (1) A herbal product for smoking may be placed on the market and distributed under the following conditions:

(a) it must not contain any additive referred to in Annex 4,

(b) it must not contain added 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, added taurine or other additives and stimulant compounds which are associated with energy and vitality,

(d) it must not contain additives facilitating inhalation, and

(e) additives with CMR properties.

(2) By way of derogation from paragraph (1), in respect of herbal products for smoking which are consumed by heating,

(a) the provision in paragraph 1(a) shall apply if the product may contain tea;

(b) the substances mentioned in points (b)-(d) of paragraph (1) may be used to the extent that they are essential components of the plant, the herb, the fruit or of the added flavouring substance.

(3) The producer, importer and distributor of 'herbal products for smoking' 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.

(4) The producer or importer of a herbal product for smoking shall also inform the bodies referred to in paragraph (3) 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.

(5) 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 the retail of tobacco products.' After examining the notifications regarding these herbal products for smoking, the Chief Medical Officer shall issue a certificate within 60 days of their submission, if the product does not need to be banned. If the Chief Medical Officer does not make a statement within 60 days, the notified product may be placed on the market and it may be distributed.

(6) NNGYK shall publish, on its website, all the information that has been received in accordance with paragraphs (3) and (4) about the ingredients that are used in the production of herbal products for smoking, and about their quantities or any changes to them. The publication of this data shall always respect the protection of the business secrets that the economic operator has marked.'

Section 7 (1) The following paragraph (1a) is added to Section 19/A of this Decree:

'(1a) By way of derogation from paragraph 1,in the case of nicotine-containing smoking substitutes, the notification according to Section 7/D(1) of Act XLII of 1999 shall be sent to the Chief Medical Officer by electronic means in accordance with the Act on general rules of electronic administration and trust services.'

(2) The following paragraph (2a) is added to Section 19/A of this Decree:

“(2a) By way of derogation from paragraph 2, in the case of nicotine-containing smoking substitutes, the content of the notification shall be subject to the requirements of Section 19/F(3) and (4)’

Section 8 In Section 19/B of the Decree,point (b) of paragraph (1) 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 or containers with a capacity not exceeding 2 ml, with all items in these subpoints being specially designed for this purpose.’

Section 9 (1) In Section 19/C of the Decree,paragraph (1) 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, for the purposes of this section: ‘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 are associated with energy and vitality;

(cd) additives that discolour the emissions;

(ce) additives facilitating inhalation, and

(cf) additives with CMR properties; and

(cg) ingredients with impurities in more than 0.1 %s;

(d) the nicotine-free liquid may only contain ingredients that are not harmful to human health – neither in reaction to heat or without that;

(f) the product is equipped with a child-proof seal, and

(g) the product 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 inserted:

'(6) The following health warning shall be shown on the two largest surfaces of unit packets and multipacks of nicotine-free refill containers, 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 10 The following heading 9/B is added to the Decree:

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

Section 19/F (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 shall submit a notification to the National Chief Medical Officer in electronic form, six months prior to the planned placing on the market, which shall contain the following data:

(a) the name and contact details of the producer, importer, distributor;

(b) a list of all the ingredients of the product, as well as the substances released, together with their quantities, by brand name and type;

(c) toxicological data on the ingredients of the product,

(d) a statement that the manufacturing process ensures compliance with the requirements of the legislation; and

(f) a declaration that the producer, importer or distributor 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 if there is any change to the product which affects the data referred to in paragraph (3).

Section 19/G (1) Nicotine-containing smoking substitutes may be placed on the market and distributed, if the product does not contain

(a) vitamins or other additives giving the impression that the product has a beneficial physiological impact or is less harmful to health;

(b) caffeine, taurine or other additives and stimulant compounds associated with energy levels and vitality;

(c) additives with CMR properties;

(d) 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 the following, in addition to those required in other legislation:

(a) all product ingredients listed in descending order by weight;

(b) the nicotine content per consumption unit of the product;

(c) the batch number; and

(d) the following warning in a clearly visible, legible and indelible manner: “The product should be kept out of reach of children.”

(4) The warning 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 letters 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) gives the impression that the product is less harmful than other products;

(c) gives the impression that the 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) gives the impression that some products are more biodegradable or have other environmental benefits.

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

(7) 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 element, packaging material, bag, box or other device when the product is placed on the market.

(8) The health warning referred to in paragraph (7) 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 letters 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.

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

(10) Following the examination of the notifications regarding nicotine-containing smoking substitutes, the National Chief Medical Officer shall issue a certificate within 60 days of the submission of these notifications, if the product does not need to be banned. If the National Chief Medical Officer does not make a statement within 60 days, the notified product is allowed to be placed on the market and may be distributed.’

Section 11 The following Section 21/Eshall be inserted in the Decree:

‘Section 21/E (1) Herbal products for smoking which were already on the market when Government Decree No 120/2024 of 10 June 2024 (hereinafter: Amending Decree 5) came into force 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,or herbal products for smoking which were earlier notified to the minister responsible for the agricultural policy,shall be notified to the National Chief Medical Officer in the manner and with the data content prescribed in Section 18/C of this Decree, as laid down in Amending Decree 5, until 31 December 2024. When fulfilling the notification obligation under this paragraph,this six-month time limit specified in Section 18/C(3) shall not be applicable.

(2) With the exception provided for in paragraph (3), products which fail to comply with the provisions of Amending Decree 5 but comply with the provisions of this Decree in effect prior to the entry into force of Amending Decree 5, as well as with the requirements of other applicable and governing legislation, may be handed over to retailers of tobacco products for placing on the market, for a maximum of 1 year from the date of the entry into force of this Decree.

(3) By way of derogation from paragraph (2), nicotine-containing smoking substitutes which do not comply with the provisions of Section 19/F(1) and (2) of this Decree, as laid down in Amending Decree 5, nor withthe provisions of Section 19/G(10), but comply with the provisions of this Decree in effect prior to the entry into force of Amending Decree 5, as well as with the requirements of other applicable and governing legislation, may be handed over to retailers of tobacco products for placing on the market, for a period not exceeding 3 months from the date of the entry into force of this Decree.

(4) Products which do not comply with the provisions of this Decree, as laid down in Amending Decree 5, but comply with the provisions of this Decree in effect prior to the entry into force of Amending Decree 5, as well as with the requirements of other applicable and governing legislation, and which were taken in stock by tobacco product retailers until the deadline set in paragraphs (2) and (3), may be placed on the market by tobacco product retailers for an unlimited period of time.'

Section 12 Annex 4 of the Decree shall be replaced by Annex 1 herein.

Section 13 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, as well as nicotine-containing smoking substitutes',

(b) in Section 4/A(1),the phrase 'its carcinogenic, mutagenic or reprotoxic properties (hereinafter: CMR properties)' is replaced by 'CMR properties',

(c) in Section 19/B(1)(i),the words 'child seal' are replaced by 'child-proof seal',

(d) 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 14 This decree shall enter into force on the fifteenth day following its publication.

Section 15 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 (sgd),

Prime Minister

Annex 1 to Government Decree No 120/2024 of 10 June 2024

“Annex 4 to Government Decree No 39/2013of 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	Krizein S

A	B
serial number	**Compound**
33	Coumarin-free tonka beans
34	Lactose
35	Maltose
36	Mannose
37	Methyl violet
38	Honey
39	Monoammonium phosphate
40	Sodium silicate
41	Solvent Red 1
42	Pectins
43	Polyethylene glycol (E 1251)
44	Riboflavin-5-phosphate
45	Sucrose octaacetate
46	Saccharine (E 954)
47	Sudan Blue 11
48	Tea
49	Theobromine
50	Cannabidiol (CBD)

”