

Published: 2024-03-19

Numac: 2024002313

FEDERAL PUBLIC SERVICE FOR PUBLIC HEALTH, SAFETY OF THE FOOD CHAIN
AND THE ENVIRONMENT

**3 MARCH 2024. - Royal Decree on the manufacture and placing on the
market of tobacco products and herbal smoking products**

REPORT TO THE KING

Sire,

Pursuant to Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products, the existing Royal Decree of 5 February 2016 on the manufacture and placing on the market of tobacco products and herbal smoking products, which already partially transposed Directive 2014/40/EU, had to be amended.

Given that a number of additional changes were made at the same time, which had an impact on its legibility and structure, it was decided to annul the existing Decree of 5 February 2016 and replace it with a new Decree. Many existing provisions are included in this new Decree. Thus, the content of the report to the King of the Royal Decree of 26 April 2019 amending the Royal Decree of 5 February 2016 on the manufacture and marketing of tobacco products is still current and applies to this Royal Decree.

The content of this former report to the King is reproduced below:

“ As regards the definition of Belgian importer, this is necessary in order for Belgium to comply with the implementation obligations laid down in Directive 2014/40/EU and in particular Article 5 thereof. This requires being able to implement coercive measures (fines, seizures,...) with a responsible company in case of non-compliance with the legislation. The definition of importer as laid down in Directive 2014/40/EU does not allow the inspection service responsible for monitoring to act against importers in the European Union. It is therefore necessary to define the Belgian importer who will be responsible for the import into Belgian territory, so that the Belgian authorities can then turn against that Belgian importer in the event of an infringement.

In addition, not all Member States have a monitoring service to handle any requests for sanctions from the Belgian authorities.

As regards the rules on ingredients, by analogy with the prohibition laid down in paragraph 4 of Article 5, a prohibition on placing on the market is laid down for technical elements which are not initial components of tobacco products, allowing changes in the intensity of combustion, the colour of emissions, the smell or taste of tobacco products, in order to prevent manufacturers from placing on the market products which reduce the impact of the prohibition on tobacco products

containing characterising flavours. (1)

As regards the thickness of the cigarette pack, clarification is needed so that the thickness is not less than 20 mm. This requirement is clear from the interpretation defended in the European Commission's 'non-paper' of 01/09/2017. Belgium is therefore merely clarifying an already existing rule. (2)

As regards the presentation of products, the Minister has the option to draw up a list of prohibited tobacco product brands and to lay down an authorisation procedure for tobacco product brands not yet placed on the market. This option is pursuant to Article 13 of Directive 2014/40/EU and merely specifies the practical arrangements for the implementation of that Article. A similar provision has been applied in France since January 2017 following the entry into force of the Order of 19 May 2016 enacting Directive 2014/40/EU concerning the manufacture, presentation and sale of tobacco and related products. Thanks to this change, brands such as 'cheap tobacco', 'vogue', 'corset' etc. may be prohibited. (3)

As regards the presentation and content of unit packets, it is clarified that each tobacco product and each plant-based smoking product must be packaged. This clearly prohibits the sale of individual cigarettes and requires that each cigar be packaged in order to be sold. In addition, this also clarifies the fact that tobacco and, in particular, shisha tobacco, cannot be sold in bulk, as is often the case in shisha bars.

(4)

With regard to new tobacco products, the definition of 'device' has been added to anticipate the placing on the market of new tobacco products to be consumed using apparatus. In addition, Article 14, which legislates new tobacco products, has been amended with a detailed procedure in the event of the introduction of a new tobacco product on the market. This article also sets out the provisions of the Royal Decree which apply to such products (Articles 4, 5, 6, 11, 12, § 3 and 13). Finally, the Minister shall decide which of the provisions of Articles 7, 8, 9 and 10 apply, namely the labelling provisions. The Minister will therefore decide whether a new notified tobacco product will be associated, in terms of labelling, with cigarettes, rolling tobacco and waterpipe tobacco, with other smoking products or with smokeless tobacco products.'

Certain provisions or amendments are new and require further explanation.

There is a significant change in definitions. A definition of the word "product" has been added to include tobacco products and herbal smoking products.

This simplifies the reading of the Decree, as many provisions apply to both categories.

Similarly, the definition of a device falling within the scope of the Decree is expanded to include devices for all products. Until now, only devices for new tobacco products have been covered by this definition. Therefore, all devices with which a tobacco product (e.g. a water pipe) or a herbal smoking product (e.g. a vaporiser) can be consumed are subject to the corresponding provisions (including notification, labelling rules, the distance selling ban)

A definition of heated tobacco product (the definition in Delegated Directive

2022/2100) is also added. According to this delegated directive, this new category of new products must comply with stricter labelling and composition requirements. Heated products not containing tobacco but other plant substances will also be subject to the provisions applicable to herbal smoking products.

Article 4 on the notification has been completed. First, the notification of all products, namely (new) tobacco products and herbal smoking products, is included in this Article. The product notification must now also include the name and contact details of the manufacturer, importer and, where applicable, of the importer in Belgium. Furthermore, additional information is required for new tobacco products.

The Decree also provides for mandatory notification of devices to be placed on the Belgian market, except for pipes and waterpipes. For devices, various data must be communicated to the department, including a description of components, directions for use, a fact sheet, etc.

As regards the notification of devices, it should be clarified that in the EUCEG system this is only possible for devices intended for new tobacco products. The notification obligation therefore currently only applies to these devices. However, with the extension of the definition, as soon as the system allows and subject to timely communication by the Department, we will apply this obligation to the devices of all other products.

An importer whose registered office is located in another Member State may also submit the notification.

There are also other changes to the notification procedure:

Notification for tobacco products will no longer be required annually.

- It is legally specified that the Department may request to complete the information submitted. Additional testing may also be required for new tobacco products.

- The new Decree explicitly states that the products will only be placed in the positive list on the FPS website if the information submitted is complete and the royalty has been paid to the Reporting Service. Products and devices not included in the list of validated products and devices shall not be placed on the market.

The Decree sets new royalty prices for the notification procedure:

- EUR 200 for tobacco products and herbal smoking products;

- EUR 4 000 for new tobacco products and devices.

Substantial changes require an update of the file and the payment of an additional royalty of EUR 100 per product or device.

Each year, additional data must be entered in the file, including studies, sales volume figures, etc. An additional royalty of EUR 50 per product or device is required for this purpose.

Finally, it is legally specified that royalties are due as soon as data are entered into the system and are payable to the Budgetary Funds within 30 days of sending the invoice. Fees are not recoverable in any way.

The former Article 5 on composition becomes Article 6 and is reinforced. Thus, compositional requirements become stricter for new heated tobacco products and

herbal smoking products. For example, they may not have filters, paper and capsules that contain tobacco and/or nicotine.

As regards the ban on the placing on the market of technical elements which could alter or improve the smell, taste, intensity of combustion, smoke production, colour of emissions and/or consumption of products, we would like to give some examples of products concerned: instant pellets inserted in filters that change the taste of tobacco, flavoured leaves for rolling tobacco, etc.

Labelling requirements are also strengthened. Thus, Article 7 provides that health warnings of new products may no longer be affixed by means of adhesives.

The provisions of the former Article 9 of the Royal Decree are deleted so that the rules on the labelling of tobacco products for smoking are the same for all these products. The article is supplemented by the provisions on combined health warnings for smoking tobacco products. Cigars and cigarillos that were previously exempt from certain labelling requirements will now be labelled like other tobacco products for smoking (cigarettes, rolling tobacco and waterpipe tobacco). They will therefore have the combined health warning and the information message.

The provisions on new tobacco products transpose Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions for heated tobacco products.

The prohibition on the offer of products is added to the prohibition on distance selling and buying of Article 14. This prohibition is interpreted by analogy with the prohibition on the offer of alcohol and tobacco products to minors. Products and devices simply cannot be made available to Belgian consumers online. This means that websites/platforms must be secure in order to ensure that Belgian consumers simply cannot buy these products and devices.

In the Royal Decree of 5 February 2016, it was stated that the provisions of Article 14 applied to devices (new tobacco products). Therefore, a new tobacco product device had to carry the health warning for smoking or smoke-free tobacco products (according to the Minister's decision). Since a device does not contain tobacco in itself, a specific warning is provided on its packaging. By analogy, this warning is also provided for all other devices for the consumption of tobacco products or herbal smoking products. The aim is to warn consumers that the consumption of products using these devices is harmful to health. These products are very similar to conventional products and have a similar effect, so a warning is necessary.

The issue of liability for infringements is linked to the concept of 'placing on the market'. This concept refers to the mere intention of making products available to consumers in the Union and not to the actual making available of the products to consumers (i.e. when they are available for sale). This has been confirmed by the European Commission by email to the Inspection Service on 14.8.2019. This position was confirmed again by the Commission at the meeting on 15.10.2019.

The Commission states in its meeting report:

“ One Member States raised a discussion point on the concept of 'placing on the market', primarily in relation to inspections and enforcement activities. SANTE

recalled that several provisions of the TPD referred to the intended destination market. In addition, the TPD contains provisions with obligations and requirements that already apply at the manufacturing or distribution stage, and as such, prior to the placing on the market (e.g. TNCO levels, traceability). Finally, it should be considered that, in principle, the actual destination market must be defined at the time of packaging, given its regulatory relevance with regard to TPD requirements (i.e. type of combined health warnings, traceability markings, and fiscal markings/security features).’

The presence on products of health warnings in the 3 national languages is a factor (sufficient) to consider that the product is placed on the Belgian market, regardless of where it is stored along the logistics chain.

Article by article comments

Article 1. Article 1 indicates that the Decree transposes Directive 2014/40/EU and Delegated Directive (EU) 2022/2100.

Article 2. Article 2 concerns definitions.

Article 3. Article 3 deals with the level of cigarette emissions.

Article 4. Article 4 deals with the notification of products.

Article 5. Article 5 deals with enhanced reporting requirements for cigarettes and rolling tobacco.

Article 6. Article 6 deals with the composition of products and provides for various prohibitions.

Article 7. Article 7 sets out the general provisions applicable to health warnings.

Article 8. Article 8 deals with general warnings and the information message for smoking tobacco products.

Article 9. Article 9 deals with combined health warnings on smoking tobacco products.

Article 10. Article 10 deals with the labelling of smokeless tobacco products.

Article 11. Article 11 deals with the labelling of new tobacco products.

Article 12. Article 12 deals with the labelling of herbal smoking products.

Article 13. Article 13 deals with the labelling of devices.

Article 14. Article 14 deals with the presentation of products.

Article 15. Article 15 deals with the presentation and content of unit packets.

Article 16. Article 16 concerns the prohibition on distance offering, buying and selling.

Article 17. Article 17 concerns sanctions.

Article 18. Article 18 states that the Royal Decree of 5 February 2016 is repealed.

Article 19. Article 19 deals with transitional measures.

Article 20. Article 20 deals with the entry into force of the Decree.

Article 21. Article 21 deals with jurisdiction.

I have the honour to be,

Sire,

Your Majesty’s

most respectful and faithful servant,

The Minister for Public Health,

F. VANDENBROUCKE

Notes

1 See Article 5 § 5, point 1 and 2, of this Decree

2 See Article 8, § 3, point 1, of this Decree

3 See Article 14, point 4, of this Decree.

4 See Article 15, § 4, of this Decree.

3 MARCH 2024. - Royal Decree on the manufacture and placing on the market of tobacco products and herbal smoking products

PHILIPPE, King of the Belgians,

To all those present and to come, Greetings.

Having regard to the Law of 24 January 1977 on the protection of consumer health with regard to food commodities and other products, Article 2(1), Article 6, § 1(a), as amended by the Law of 22 March 1989, Article 10(1), as replaced by the Law of 9 February 1994, and Article 10(3), as replaced by the Law of 10 April 2014, and Article 18, § 1, as replaced by the Law of 22 March 1989 and as amended by the Law of 22 December 2003;

Having regard to the Royal Decree of 5 February 2016 on the manufacture and marketing of tobacco products and herbal smoking products;

Having regard to the communication to the European Commission, dated 25 April 2023, pursuant to Article 5(1) 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;

Having regard to the opinion of the Inspector of Finance, issued on 10 October 2023;

Having regard to the approval of the Secretary of State for the Budget, issued on 20 November 2023;

Having regard to the request for opinion to the Council of State within 30 days, pursuant to Article 84(1), subparagraph 1(2) of the law on the Council of State, consolidated on 12 January 1973;

Whereas the request for an opinion was placed on 6 February 2024 in the registry of the Legislation Section of the Council of State under number 75.566/3;

Having regard to the decision of the Legislation Section of 9 February 2024 not to give an opinion within the period requested, pursuant to Article 84(5), of the Laws on the Council of State, consolidated on 12 January 1973;

Having regard to the interfederal strategy 2022-2028 for a tobacco-free generation of 14 December 2022;

On the proposal of the Minister for Public Health,

WE HAVE DECREED AND HEREBY DECREE:

CHAPTER 1. - General provisions

Article 1. This Decree partially transposes:

(1) Directive 2014/40/EU of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the

manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

(2) Commission Delegated Directive (EU) 2022/2100 of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products.

CHAPTER 2. - Definitions

Article 2. For the application of this Decree, the following mean:

(1) tobacco: leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

(2) tobacco product: a product that can be consumed and consists, even partly, of tobacco, whether genetically modified or not;

(3) smokeless tobacco product: tobacco product which does not involve any combustion processes, including chewing, snuff and oral tobacco;

(4) tobacco product for smoking: a tobacco product that is not a smokeless tobacco product;

(5) pipe tobacco: tobacco intended exclusively for use in a pipe by means of a combustion process;

(6) rolling tobacco: tobacco which can be used for making cigarettes by consumers or retailers;

(7) chewing tobacco: a smokeless tobacco product intended exclusively for chewing;

(8) snuff: a smokeless tobacco product that can be consumed nasally;

(9) tobacco for oral use: all tobacco products for oral use, with the exception of those intended to be inhaled or chewed, consisting wholly or partially of tobacco, in the form of powder, fine particles or any combination thereof, in particular those in sachet portions or porous bags;

(10) cigarette: a roll of tobacco that can be consumed via a combustion process and which is further defined in Article 5 of the Law of 3 April 1997 regarding the tax regime applicable to manufactured tobacco;

(11) cigar: a roll of tobacco that can be consumed via a combustion process and which is further defined in Article 4 of the Law of 3 April 1997 regarding the tax regime applicable to manufactured tobacco;

(12) cigarillo: a type of small cigar, which is further defined in Article 7 of the Royal Decree of 27 January 2009 on the exemption from import duties and excise duties granted for international passenger traffic;

(13) waterpipe tobacco: a tobacco product that can be consumed by means of a waterpipe. In accordance with this Decree, waterpipe tobacco shall be deemed to be smoking tobacco. If a product can be used both via waterpipes and as rolling tobacco, it shall be deemed to be rolling tobacco;

(14) new tobacco product: a tobacco product that:

(a) does not fall into any of the following categories: cigarette, rolling tobacco, pipe tobacco, waterpipe tobacco, cigar, cigarillo, chewing tobacco, snuff or oral tobacco; and

(b) is placed on the market after 19 May 2014;

- (15) heated tobacco product: a new tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by users, which, based on its characteristics, is a smokeless tobacco product or a smoking tobacco product;
- (16) herbal product for smoking: a product based on plants, aromatic plants or fruits, not containing tobacco and which can be consumed by means of a combustion or heating process;
- (17) device: any device necessary for the consumption and/or use of a product;
- (18) product: tobacco product and herbal product for smoking;
- (19) ingredient: tobacco, an additive, as well as any other substance or element in a product, including paper, filter, ink, capsules and glues;
- (20) nicotine: nicotinic alkaloids;
- (21) tar: anhydrous and nicotine-free raw smoke condensate;
- (22) emissions: substances released when a product is used for the intended purpose, such as substances contained in smoke or those released when using a smokeless tobacco product;
- (23) maximum level or maximum emission level: the maximum content or emission, including equal to zero, of a substance present in a tobacco product, measured in milligrams;
- (24) additive: a substance other than tobacco, which is added to a product, its unit packaging or any outer packaging;
- (25) aroma: an additive that gives an odour and/or taste;
- (26) characteristic aroma: a clearly identifiable smell or taste other than that of tobacco, originating from an additive or combination of additives, including fruit, spices, aromatic plants, alcohol, confectionery, menthol or vanilla (non-exhaustive list), which is identifiable before or during consumption of the product;
- (27) CMR: carcinogenic, mutagenic and reprotoxic;
- (28) addictiveness: the pharmacological potential of a substance to create dependence, a state that alters an individual's ability to control his behaviour, most often by inducing a reward effect or a decrease in withdrawal symptoms, or both;
- (29) toxicity: the extent to which a substance may produce harmful effects on the human organism, including effects occurring over time, usually due to repeated or continuous consumption or exposure;
- (30) outer packaging: any packaging in which the products are placed on the market, including a unit packet or a set of unit packets; additional transparent wrappers are not regarded as outer packaging;
- (31) unit packet: the smallest individual packaging of a product placed on the market;
- (32) pouch: a unit packet of rolling tobacco, presented either as a rectangular pocket with a flap covering the opening or as a flat bottom pocket;
- (33) health warning: a warning about adverse effects on human health of a product or other unintended consequences of its consumption, including warning messages, combined health warnings, general warnings and information messages;
- (34) combined health warning: a health warning combining a warning message and

a corresponding photo or illustration;

(35) distance selling: any sale concluded under an organised distance selling system, without the simultaneous physical presence of the seller and the buyer, by the exclusive use of one or more distance communication techniques, up to and including the time when the sale is concluded;

(36) cross-border distance selling: distance selling to consumers where the consumer, at the time of ordering the product from the retailer, is located in a Member State other than the Member State or third country in which that retailer is established; a retailer shall be deemed to be established in a Member State:

a) for natural persons: if his place of business is in that Member State;

b) in other cases: if his registered office, central administration or place of business, including a branch, agency or any other establishment, is located in that Member State;

(37) consumer: a natural person acting for purposes which do not fall within the scope of his commercial or professional activities;

(38) manufacturer: any natural or legal person who manufactures a product or has a product designed or manufactured, and who markets this product under their own name or brand;

(39) import of products: the introduction into the territory of the European Union of products which, at the time of their introduction, are not placed under a customs suspensive procedure or arrangement, as well as the removal of products from a customs suspensive procedure or arrangement;

(40) importer: the owner or a person having the right to dispose of products introduced from the European Union;

(41) importer in Belgium: the owner or person entitled to dispose of the products brought into the territory of Belgium;

(42) placing on the market: making products, irrespective of their place of manufacture, available to Union consumers, for consideration or otherwise, including by distance selling; in the case of cross-border distance selling, the product shall be deemed to be placed on the market in the Member State in which the consumer is located;

(43) retailer: any point of sale at which products are placed on the market, including by a natural person;

(44) Service: the General Directorate of Animals, Plants and Food of the Federal Public Service Public Health, Food Chain Safety and Environment;

(45) Minister: the Minister for Public Health.

CHAPTER 3. - The emission level

Article 3. § 1. The maximum emission levels of cigarettes placed on the market or manufactured are:

(1) 10 mg of tar per cigarette;

(2) 1 mg of nicotine per cigarette;

(3) 10 mg of carbon monoxide per cigarette.

§ 2. The emissions of tar, nicotine and carbon monoxide from cigarettes are measured on the basis of standard ISO 4387 for tar, ISO 10315 for nicotine and

ISO 8454 for carbon monoxide.

The accuracy of tar, nicotine and carbon monoxide measurements is determined in accordance with standard ISO 8243.

§ 3. The measurements referred to in paragraph 2 shall be verified by laboratories approved and monitored by the Service. These laboratories do not belong to the tobacco industry and are not controlled, directly or indirectly, by the latter.

The Service shall communicate to the European Commission a list of approved laboratories, specifying the criteria used for the approval and the means of surveillance used, and shall update that list in the event of any modification.

CHAPTER 4. - Notification

Article 4. § 1. The placing on the market of products and devices, with the exception of pipes and waterpipes, is subject to notification to the Service. The manufacturer or importer or importer in Belgium, if the first two do not have a registered office in Belgium and have not notified the product, shall submit a notification to the Service for each product and device it intends to place on the market.

This notification shall be submitted in electronic form six months before the scheduled marketing date.

§ 2. Before transmitting information to the Member States in accordance with this Article for the first time, the manufacturer or importer in Belgium shall request an identification number (Supplier ID) generated by the operator of the common point of entry. Upon request, the manufacturer or importer or importer in Belgium shall submit a document in which the undertaking is identified and its activities are authenticated in accordance with Belgian legislation. The supplier identification number shall be used for all subsequent transmissions and in any subsequent correspondence.

§ 3. On the basis of the Supplier ID referred to in paragraph 2, the manufacturer, importer or importer in Belgium shall assign an identification number to each product or device (product ID).

When transmitting information on products of the same composition and presentation, manufacturers and importers shall use as far as possible the same product ID, in particular when data are transmitted by different members of an industrial clustering. This provision applies regardless of the brand, subtype and number of markets in which these products are placed.

When the manufacturer or importer or importer in Belgium is unable to guarantee the use of the same product ID for products having the same composition and presentation, he shall supply, as far as possible, the different ID products which have been assigned to these products.

§ 4. The product notification shall contain at least the following data by brand and type:

- (1) a list of all the ingredients, together with their quantities, used in the manufacture of these products, in descending order of the weight of each ingredient;
- (2) the emission levels referred to in Article 3(1);

- (3) when such data are available, information on other emissions and their levels;
- (4) labelling;
- (5) the name and contact details of the manufacturer, importer and, if applicable, importer in Belgium.

§ 5. The notification of devices shall contain at least the following information, by brand and type:

- (1) a description of the parts;
- (2) the directions for use;
- (3) a data sheet;
- (4) an image of the device and the packaging;
- (5) information on the type of product that may be consumed;
- (6) the name and contact details of the manufacturer, importer and, if applicable, importer in Belgium.

§ 6. The notification of new tobacco products shall contain, in addition to the data referred to in paragraph 4 of this Article, at least the following data by brand and type:

- (1) a detailed description of the new tobacco product;
- (2) the directions for use;
- (3) the image of the product;
- (4) available scientific studies on toxicity, addictiveness and attractiveness of the new tobacco product, in particular as regards its ingredients and emissions;
- (5) the studies available, their summary report and market analyses concerning the preferences of different consumer groups, including young people and current smokers;
- (6) other available and relevant information, including a risk/benefit analysis of the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption as well as predicted consumer perception.

The manufacturer or importer or importer in Belgium, if the first two do not have a registered office in Belgium, of new tobacco products, shall submit to the Service any new or up-to-date information on the studies, research and other information referred to in paragraphs 4, (1) to (5) and 6, (1) to (6).

§ 7. The notification shall be submitted in electronic form via the common electronic entry point for data transmission.

§ 8. The list referred to in paragraph 4(1) shall be accompanied by a declaration setting out the reasons for the presence of the various ingredients in the products concerned. That list shall also indicate the status of the ingredients, by specifying in particular whether they have been registered in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as well as the restrictions applicable to these substances, establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 and Council Directive 76/769/EEC and Directives 91/155/EEC,

93/67/EEC, 93/105/EC and 2000/21/EC and their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) No 1907/2006.

§ 9. The list referred to in paragraph 4(1) shall also be accompanied by toxicological data relevant to these ingredients, with and without combustion, as the case may be, relating in particular to their effects on the health of consumers and taking into account, inter alia, any addictiveness which they give rise to. In addition, for cigarettes and rolling tobacco, a technical document setting out a general description of the additives used and their properties shall be submitted by the manufacturer or importer or importer in Belgium, if the first two do not have a registered office in Belgium.

§ 10. Where the Service considers the information submitted to be incomplete, it shall be entitled to request that it be supplemented.

For new tobacco products, it may also require further testing.

§ 11. The information provided in accordance with paragraphs 4, 5 and 6 of this Article shall be made available on the Service's website when the Service considers that it is complete and the invoice referred to in this Article has been paid. Products and devices, with the exception of pipes and waterpipes, which do not appear on the list of validated products and devices published on the Service's website, cannot be placed on the market.

When introducing the information, information that constitutes trade secrets or information that is otherwise confidential must be indicated. These claims must be justified upon request.

§ 12. Any person who submits a notification of a product, with the exception of a new tobacco product, to the Service, is required to pay the fee of EUR 200, per product.

§ 13. Any person who submits a notification of a device or a new tobacco product to the Service is required to pay the fee of EUR 4,000 per device or new tobacco product.

§ 14. The manufacturer, importer or importer in Belgium, if the first two do not have a registered office in Belgium and have not notified the product or device, shall, for each modification of a product or device causing a change to the data transmitted pursuant to paragraphs 4, 5, 6 and 8 submit the corresponding new information. These changes are considered to be substantial amendments with the exception of changes requested by the Service, changes in contact information and the introduction of sales volume data for the previous year as defined in paragraph 16 of this Article.

§ 15. Any person who submits a substantial change to the Service pursuant to paragraph 14, shall be required to pay the fee of EUR 100 per product or device.

§ 16. The manufacturer or importer or importer in Belgium, if the first two do not have a registered office in Belgium and have not notified the product or the device, shall submit to the Service each year, by not later than 1st March:

- (1) exhaustive data on sales volumes of the previous year, by brand and type of product or device, in Belgium, expressed in number of devices/cigarettes/cigars/cigarillos or in kilograms;
- (2) internal and external studies concerning the market and preferences of different consumer groups, including young people and current smokers, in terms of ingredients and emissions;
- (3) the summaries of any market research they conduct when launching new products/devices.

§ 17. Any person submitting the annual data to the Service pursuant to paragraph 16 shall be required to pay a fee of EUR 50 per product or per device.

§ 18. The model applicable to the transmission and making available of the information referred to and the method of transmission of the information required in this Article are specified by the Minister.

§ 19. Each fee mentioned in this Article must be paid to the budget fund for raw materials and products within 30 days of sending the invoice.

This fee is due as soon as the data are entered into the notification system defined by the Minister pursuant to paragraph 18 and is irrecoverable.

Article 5. § 1. The placing on the market of cigarettes and rolling tobacco is subject, in accordance with Article 6(1) of Directive 2014/40/EU, to enhanced reporting requirements which apply to certain additives contained in a priority list of cigarettes and rolling tobacco.

§ 2. The manufacturer or importer or importer in Belgium if the first two do not have a registered office in Belgium, cigarettes or rolling tobacco containing an additive included in the priority list provided for in paragraph 1 of this Article shall carry out in-depth studies to examine, for each additive, whether it:

- (1) contributes to the toxicity or addictiveness of the products concerned, and whether this has the effect of increasing the toxicity or addictiveness of any of the products concerned to a significant or measurable degree;
- (2) produces a characteristic aroma;
- (3) facilitates inhalation or nicotine uptake;
- (4) leads to the formation of substances that have CMR properties, the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measurable degree.

§ 3. These studies shall take into account the intended use of products concerned and shall examine in particular the emissions resulting from the combustion process involving the additive concerned. The studies shall also examine the interaction of this additive with other ingredients contained in the products concerned. The manufacturer or importer or importer in Belgium if the first two do not have a registered office in Belgium, which uses an identical additive in its tobacco products, may carry out a joint study if the additive is used in products of comparable composition.

§ 4. The manufacturer or importer or importer in Belgium if the first two do not have a registered office in Belgium shall draw up a report on the results of these studies. That report shall include an executive summary and a comprehensive

overview compiling the available scientific literature on this additive and summarising internal data on the effects of the additive.

The manufacturer or importer or importer in Belgium if the first two do not have a registered office in Belgium shall submit these reports to the Service no later than 18 months after the additive concerned has been included in the priority list under paragraph 1. The Service may also ask the manufacturer or importer or importer in Belgium if the latter two do not have a registered office in Belgium, for additional information concerning the additive concerned. This supplementary information shall form part of the report.

§ 5. SMEs as defined in Commission Recommendation 2003/361/EC are exempt from the obligations of this Article if a report on the additive concerned has been drawn up by another manufacturer or another importer.

§ 6. The composition of the priority list of additives subject to an enhanced declaration as defined in this Article shall be determined by the Minister. The Minister may require further clarification regarding the studies to be provided in accordance with this Article.

CHAPTER 5. - Composition

Article 6. § 1. It is prohibited to place on the market tobacco products containing a characteristic aroma.

Tobacco products other than cigarettes, rolling tobacco and heated tobacco products are exempted from this prohibition.

§ 2. The placing on the market of tobacco products for oral use as defined in Article 2(9) shall be prohibited.

§ 3. It is prohibited to place on the market tobacco products containing the following additives:

- (1) vitamins or other additives creating the impression that a product has beneficial effects on health or that its health risks have been reduced;
- (2) caffeine or taurine or other additives and stimulants associated with energy and/or vitality;
- (3) additives that give colouring properties to emissions;
- (4) additives that facilitate the absorption of nicotine;
- (5) additives that facilitate inhalation;
- (6) additives which, without combustion, have CMR properties.

Chewing tobacco and snuff are exempt from the prohibition referred to in paragraph 3(5).

The Minister may establish a list of prohibited additives and/or a list of authorised additives.

§ 4. It is prohibited to place on the market herbal smoking products containing the following additives:

- (1) vitamins or other additives creating the impression that a product has beneficial effects on health or that its health risks have been reduced with the exception of cannabis sativa;
- (2) caffeine or taurine or other additives and stimulants associated with energy and/or vitality;

- (3) additives that give colouring properties to emissions;
- (4) additives which, without combustion, have CMR properties.
- (5) nicotine.

The Minister may establish a list of prohibited additives and/or a list of authorised additives.

§ 5. It is prohibited to place on the market:

- (1) products containing aromas in any of their components such as filters, paper, packaging and capsules or products containing any technical feature enabling the odour or taste of the products concerned or their intensity of combustion to be modified;
- (2) filters, paper and capsules containing tobacco and/or nicotine;
- (3) technical elements enabling to modify or improve the odour, taste, intensity of combustion, production of smoke, colour of emissions and/or consumption of products;
- (4) technical elements including additives mentioned in paragraph 3 of this Article. Herbal smoking products and tobacco products other than cigarettes, rolling tobacco and heated tobacco products shall be exempted from the prohibition referred to in paragraph 5(1).

§ 6. It shall be prohibited to place on the market products containing additives in quantities which increase, during consumption, in a significant or measurable manner on the basis of scientific data, their toxic effects or their addictiveness or their CMR properties. The Minister may request an opinion from the Superior Health Council in order to identify these products.

§ 7. The Service may collect proportionate fees from manufacturers, importers and, where applicable, importers in Belgium of products to assess whether a tobacco product contains a characteristic aroma, whether the products contain prohibited additives or aromas and whether a product contains additives in quantities that significantly increase its toxic effects, its addictiveness or its CMR properties.

CHAPTER 6. - Labelling and packaging

General provisions on health warnings

Article 7. § 1. Each unit packet of a product and every outer packaging shall bear the health warnings provided for in this Chapter in Dutch, French and German. Each language shall be printed on a new line.

§ 2. Health warnings shall cover the entire surface of the unit packet or the outer packaging reserved for them. They are not commented, paraphrased and cannot be referenced in any way.

§ 3. Health warnings on a unit packet or any outer packaging shall be printed non-removably, indelibly and fully visible. They shall not be concealed or interrupted, in whole or in part, by tax stamps, price tags, security devices, over-packaging, envelopes, boxes or any other item.

§ 4. On unit packets of devices and products other than cigarettes and rolling tobacco in pouches and new tobacco products, health warnings may be affixed by means of adhesives, provided that the latter are non-removable.

§ 5. Health warnings shall remain intact when the unit packet is opened, except for

packages with a foldable top cover for which health warnings may be interrupted by the opening of the package, but only in a way that ensures the graphical integrity and visibility of the text, photos and warning information.

§ 6. Health warnings shall not in any way conceal or interrupt tax stamps, price labels, markings for identification and traceability or safety features on unit packets.

§ 7. The dimensions of the health warnings provided for in Articles 8, 9, 10 and 11 shall be calculated according to the area concerned when the package is closed.

§ 8. The health warnings shall be framed with a black border of 1 mm width within the surface reserved for these warnings.

§ 9. The text of the health warnings is parallel to the main text on the surface reserved for these warnings.

§ 10. The brand and sub-brand appearing on the packaging unit and outer packaging shall be identical to those entered in the notification system as defined by the Minister pursuant to Article 4, § 18.

General warnings and information message on tobacco products for smoking
Article 8. § 1. Each unit packet and any outer packaging of tobacco products for smoking shall bear the following general warning:

“Smoking Kills - Stop Now

Roken is dodelijk - Stop nu

Rauchen ist tödlich - hören Sie jetzt auf”.

§ 2. Each unit packet and any outer packaging of tobacco products for smoking shall bear the following information message:

“Tobacco smoke contains more than 70 carcinogenic substances

Tabaksrook bevat meer dan 70 stoffen die kanker veroorzaken

Tabakrauch enthält über 70 Stoffe, die erwiesenermaßen krebserregend sind”.

§ 3. The general warning and the information message shall be printed as follows:

(1) for cigarette packets, waterpipe tobacco packets and rolling tobacco in parallelepiped packets, the general warning shall appear on the bottom part of one of the lateral surfaces of the unit packets, and the information message shall appear on the bottom part of the other lateral surface. These health warnings have a width greater than or equal to 20 mm. This provision implies that the thickness of the cigarette pack may not be less than 20 mm;

(2) for packets in the form of a folding box with a tilting lid, and whose lateral surface is therefore split into two when the packet is opened, the general warning and the information message appear in their entirety on the largest parts of these two separate surfaces. The general warning also appears on the inner part of the upper surface, visible when the packet is open. The lateral surfaces of this type of packet shall be 16 mm or higher;

(3) in the case of rolling tobacco marketed in pouches, the general warning and the information message appear on the surfaces that guarantee complete visibility of these health warnings. The Minister determines the exact location of the general warning and information message on rolling tobacco in pouches, taking into account the different forms of pouches;

(4) in the case of rolling tobacco and waterpipe tobacco in cylindrical packets, the general warning shall appear on the outer surface of the lid and the information message on its inner surface. Both the general warning and the information message must cover 50 % of the surfaces on which they are printed.

§ 4. The general warning and the information message referred to in paragraphs 1 and 2 shall be in the centre of the surface reserved for them and, on parallelepiped packets and any outer packaging, parallel to the side edge of the unit packet or outer packaging.

§ 5. The text of the general warning and information message referred to in paragraphs 1 and 2 shall be printed in black Helvetica bold on a white background with a font size such that the text occupies the largest possible portion of the surface intended for it without affecting its readability.

Combined health warnings on tobacco products for smoking

Article 9. § 1. Each unit packet and any outer packaging of tobacco products for smoking shall bear combined health warnings.

§ 2. Combined health warnings:

(1) cover 65 % of both the outer front and back surface of the unit packet and any outer packaging.

On cylindrical packets:

- both combined health warnings, shall be equidistant from each other, each covering 65 % of their respective half of the curved surface;

- the combined health warnings shall occupy the full width of both surfaces to which they are applied;

(2) comply with the following dimensions, in the case of unit packets of cigarettes:

a) height: At least 44 mm;

b) width: At least 52 mm;

(3) consist of the same warning message and the same corresponding colour photograph on both sides of the unit packet and any outer packaging;

(4) shall appear against the upper edge of a unit packet and any outer packaging, and shall be oriented in the same way as any other information appearing on that surface of the packaging.

§ 3. The Minister may lay down technical specifications concerning the composition, layout, presentation and form of the combined health warnings, taking into account the different forms of packets. The Minister may also lay down the rules for the serial use of combined health warnings and annual rotations thereof.

Labelling of smokeless tobacco products

Article 10. § 1. Each unit packet of smokeless tobacco products and any outer packaging shall bear the following health warning:

“This tobacco product harms your health and is addictive

Dit tabaksproduct schaadt uw gezondheid en is verslavend

Dieses Tabakerzeugnis schädigt Ihre Gesundheit und macht süchtig”.

§ 2. The health warning referred to in paragraph 1 shall comply with the requirements of Article 8(4). The text of the health warnings is in accordance with

the requirements of Article 8, § 5 and is parallel to the main text on the surface reserved for these warnings.

Furthermore:

(1) it shall appear on the two largest surfaces of the unit packet and any outer packaging.

(2) it shall cover 35 % of the corresponding surface area of the unit packet and any outer packaging;

Labelling of new tobacco products

Article 11. The Service evaluates the characteristics of new tobacco products.

Depending on these characteristics, new tobacco products are labelled in accordance with the provisions on smoking tobacco products referred to in Articles 7, 8 and 9 or in accordance with the provisions smokeless tobacco products referred to in Articles 7 and 10.

Labelling of herbal smoking products

Article 12. § 1. Each unit packet of herbal smoking products and any outer packaging shall bear the following health warning:

" Smoking this product harms your health

Het roken van dit product schaadt uw gezondheid

Das Rauchen dieses Produkts schädigt Ihre Gesundheit".

§ 2. The health warning referred to in paragraph 1 shall comply with the requirements of Articles 7 and 8(4). The text of the health warning complies with the requirements of Article 8(5) and is parallel to the main text on the surface reserved for this warning.

In addition, the health warning:

(1) appears on the two largest surfaces of the unit packet and any outer packaging.

(2) covers 35 % of the corresponding surface area of the unit packet and any outer packaging;

Labelling of devices

Article 13. § 1. Each unit packet of a device and every outer packaging shall bear the following health warning:

“ Consumption of a tobacco product or herbal product for smoking with this device is detrimental to your health.

Het gebruik van een product op basis van tabak of van een voor roken bestemd kruidenproduct via dit apparaat schaadt uw gezondheid.

Der Konsum von Tabakwaren und pflanzlichen Raucherzeugnissen mittels dieses Apparats schädigt Ihre Gesundheit.”

§ 2. The health warning referred to in paragraph 1 shall comply with the requirements of Articles 7 and 8(4). The text of the health warnings complies with the requirements of Article 8(5) and is parallel to the main text on the surface reserved for this warning.

In addition, the health warning:

(1) appears on the two largest surfaces of the unit packet and any outer packaging.

(2) covers 35 % of the corresponding surface area of the unit packet and any outer packaging;

Presentation of the product

Article 14. § 1. The labelling of unit packets, any external packaging and the product itself may not include any element or device which:

- (1) contributes to the promotion of a product or encourages its consumption by giving an erroneous impression as to the characteristics, health effects, risks or emissions of the product. The labels do not include information on the nicotine, tar or carbon monoxide content of the tobacco product;
- (2) suggests that a product is less harmful than others or is intended to reduce the effect of certain harmful components of smoke or has revitalising, energising, curative, rejuvenating, natural, biological or beneficial effects on health or lifestyle;
- (3) refers to taste, smell, any aroma or other additives or the absence thereof;
- (4) resembles a food or cosmetic product;
- (5) suggests that a product is more easily biodegradable or has other environmental benefits.

§ 2. Unit packets and any outer packaging shall not suggest any economic benefits by means of printed vouchers, discount offers, free distribution, “two for the price of one” promotions or other similar offers. Any mention of the price, excluding the price mentioned on the tax sign, is prohibited.

§ 3. Elements and devices prohibited under paragraphs 1 and 2 may include, in particular, messages, symbols, names, trade marks, and figurative or other signs.

§ 4. Pursuant to the provisions of this Article, the Minister may draw up a list of prohibited brands of tobacco products, even if these tobacco products are already on the market. A transition period of one year for ceasing the marketing of prohibited brands shall be granted. The Minister sets out the procedure to be followed to include a tobacco product on the list of prohibited brands. The Minister may establish an authorisation procedure for trademarks of tobacco products not yet placed on the market.

§ 5. The provisions of this Article shall apply to technical elements, such as filters and paper, which enable to consume products.

Presentation and content of unit packets of products and devices

Article 15. § 1. The unit packets of cigarettes have a parallelepiped shape. Unit packets of rolling tobacco shall have a parallelepiped or cylindrical shape, or the shape of a pouch.

§ 2. A cigarette unit packet contains at least 20 cigarettes, a maximum of 50 cigarettes and a multiple of five cigarettes.

A unit packet of rolling tobacco and waterpipe tobacco shall contain a minimum of 30 grams and a maximum of 1000 grams of rolling tobacco.

Unit packets shall contain a quantity of rolling tobacco measured in multiple grams of:

- ten when the quantity of tobacco is between 30 and 100 grams;
- hundred when the quantity of tobacco is between 101 and 1000 grams.

§ 3. A cigarette unit packet may consist of cardboard or flexible material and has no opening capable of being closed or resealed after the first opening, with the

exception of the top hinged cover and the tilting lid of a folding box. For packets with a hinged top cover and a tilting lid opening, the lid shall be articulated only on the back of the unit packet.

§ 4. Each product and device placed on the market must be packed or must have outer packaging.

§ 5. Each unit packet of a product shall include a leaflet with information on the risks associated with the consumption of the product as well as information on breaking nicotine addiction. The Minister defines the content of the information contained in the leaflet.

CHAPTER 7. - Distance offer, selling and purchasing

Article 16. § 1. The offer, distance selling to the consumer and distance purchasing by the consumer of products and device are prohibited.

§ 2. By way of derogation from paragraph 1, cross-border distance selling is permitted if the legislation of the destination Member State so permits.

CHAPTER 8. - Final provisions

Section 1. - Sanctions

Article 17. § 1. Products, technical elements and devices which do not comply with the provisions of this Decree are to be regarded as harmful within the meaning of Article 18 of the Law of 24 January 1977 on the protection of consumer health with regard to food commodities and other products.

§ 2. Infringements of the provisions of this Decree shall be investigated, recorded, pursued and punished in accordance with the provisions of the above-mentioned Law of 24 January 1977.

Section 2. - Repeal

Article 18. The Royal Decree of 5 February 2016 on the manufacture and placing on the market of tobacco products and herbal smoking products is repealed on 31 December 2024.

Section 3. - Transitional measures

Article 19. Tobacco products and herbal smoking products manufactured or placed on the market in accordance with the Royal Decree of 5 February 2016 on the manufacture and placing on the market of tobacco products and herbal smoking products may be placed on the market until 31 December 2024.

Section 4. - Entry into force

Article 20. This Decree enters into force on 1 January 2025, except Articles 2, 6 and 11 as regards heated tobacco products, which enter into force on the day of publication in the Belgian Official Gazette.

Section 5. - Implementing article

Article 21. The Minister for Public Health shall be responsible for the implementation of this Decree.

Done in Brussels, on 3 March 2024.

PHILIPPE

By the King:

The Minister for Public Health,

F. VANDENBROUCKE

[beginning](#)

Published: 2024-03-19
Numac: 2024002313