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

**7 NOVEMBER 2022. - Royal Decree amending the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes**

REPORT TO THE KING

Sire,

This draft Royal Decree amends the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes which partially transposes Directive 2014/40/EU.

The foreseen amendments mainly concern definitions, notification, composition and technical standards, labelling and distance selling. In addition, nicotine-free refill bottles will now also be regulated.

As regards the concept of “similar product”, Opinion 72.095/1/V of the Council of State is not followed. Indeed, in its opinion, the Council of State states that nicotine-free refill bottles cannot be regarded as similar products but must be considered as standard products.
However, whether or not nicotine is present in a product is not the only criterion to be taken into account in determining whether a product is considered a similar product or not.

This is what the Constitutional Court states in its judgement of 16/12/2021(1): “ The concept of ‘similar products’ in the definition of ‘tobacco products’ is intended to apply the ban on advertising in an evolutionary manner to products which, admittedly, may have different characteristics (e.g. in terms of components), but the use of which must be discouraged and with regard to which inducing consumption must be limited because they may result in health risks and social consequences similar to those of tobacco products.

By definition, “similar products” are products that do not contain tobacco but that resemble tobacco products. That similarity must relate to the manner in which the similar product is consumed or to the effect which is intended by means of it.”.

The Ghent Court of Appeal, in its judgement of 29 June 2022, also ruled as follows: “Per definitie zijn ‘soortgelijke producten’, zoals bedoeld en opgenomen in deze beide wetten, producten die geen tabak bevatten, maar die wel op tabaksproducten lijken. In dit kader lijkt een e-sigaret op een sigaret. Die gelijkenis heeft betrekking op de wijze waarop het soortgelijk product wordt gebruikt of op het effect dat met het soortgelijk product wordt beoogd. Uitgangspunt is de telkenmale bescherming van de volksgezondheid. Roken mag niet worden genormaliseerd.”

Electronic cigarettes, whether filled with liquids with or without nicotine, are similar to tobacco products in the way they are consumed (inhalation) and in their intended effect.

It should also be noted that, in its Opinion 65.468/3 of 20 March 2019 on the draft Royal Decree amending the Royal Decree of 5 February 2016 on the manufacture and marketing of tobacco products, the Council of State does not call into question the fact that herbal smoking products are similar products; this in spite of the fact that these products also do not contain nicotine. This clearly demonstrates that the presence of nicotine is not the only criterion to be taken into account when determining the similarity of the products.

In addition, the prohibition of sale to minors and the smoking ban apply to similar products. Not considering nicotine-free e-liquids as similar products would distort the implementation of the ban on the sale of tobacco products to minors, as minors could buy nicotine-free e-liquids (but not the e-cigarette itself).

The similarities between nicotine and non-nicotine products are so great that the WHO also notes that it is virtually impossible to distinguish the two. Moreover, in its decisions, the COP (Conference of the Parties) treats these products (ENDS and ENNDS) in the same way.(2)

As regards the concept of placing on the market, which is referred to in Article 2 of this Decree, it requires further explanation. This concept refers to the mere intention of making products available to consumers in Belgium 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 in an email to the FPS Public Health dated 14/08/2019. 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 placement 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 three national languages, as provided for in Article 4 of this Decree, is sufficient to consider that the product is placed on the Belgian market, regardless of where it is stored along the logistics chain.

Some amendments require further explanation.

As regards the definition of “importer in Belgium”, this is necessary in order for Belgium to fulfil the implementation obligations laid down in Directive 2014/40/EU and in particular Article 20.2 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 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.

The concept of “importer” is amended to correspond to the definition laid down in Directive 2014/40/EU.

With regard to notification, numerous amendments have been made. The new definitions make it possible to make the “importer in Belgium” also responsible for this procedure. In practice, the producer or importer in the EU may submit the notification data, even if neither of these undertakings has a registered office in Belgium. However, it is the importer in Belgium who is responsible for this and must therefore ensure that this has been done or do so themselves before marketing a product on the Belgian market. This means that any penalties for infringements can be attributed to an undertaking whose registered office is located in Belgium.
The notification file must also be supplemented with the labelling of the packaging units placed on the market and the leaflet referred to in Article 5(9). This will strengthen the tools available to the inspection service and allow the authorities to have a better overview of the quality of the information contained in the leaflet.
Any modifications of a product must be subject to the corresponding changes in its notification file submitted to the Service so the files correspond to the products placed on the market. All changes in a file are considered substantive modifications. The only exceptions are changes requested by the Service, changes in contact information and the addition of sales volume data from the preceding year.
The amendment to the Decree confirms that the Service publishes on its website a list of products whose notification file is complete (in a “positive list”) and that products that do not appear on that list cannot be placed on the market. They are to be considered harmful and subject to the penal sanctions laid down in this decree.
For a product to appear on the positive list, the notifier must enter the data as requested by the Service. This is important so data can be compared between different files. In cases of failure to follow these instructions and make requested corrections, the products will not appear on the positive list. The same applies in cases of failure to pay the fee.
Finally, changes are also made to the fees. Three different fees are introduced, according to the associated administrative burden.
A fee of EUR 200 applies to new product registrations.
Changes to existing product registrations incur a fee of EUR 100.
Each product registered is subject to an annual fee of EUR 50 to cover the costs of processing the data to be submitted each year. In addition, it is now stipulated that the notifier must provide these annual data before 1 March of the following year.
The invoice sent by the Service must be paid within 30 days.
In addition, it is stated that it is prohibited to market electronic cigarettes with attractive features that are not useful for operating the device. This means that electronic cigarettes cannot have any function other than the production of vapour to be inhaled. Videos of devices that use an LED lamp to change the vapour colour are available on the internet and social networks. Some try to make the shapes with the vapour, for instance. Electronic cigarettes must not be used for this purpose. This covers in particular the recommendations of the SHC in Opinion 9265 of October 2015 which states that “e-cigarettes (...) equipped with gadgets (...) (lights, smoke colouring, etc.) must be regulated, controlled and prohibited.”. An electronic cigarette is and remains a product that must not be presented in an attractive manner.
There is an opportunity for the Minister to establish a list of prohibited additives or establish a list of specifically authorised additives or even a combination of both lists. The Minister also has the opportunity to define the standards and methods of analysis to be used by manufacturers and importers to verify the implementation of the composition and emission provisions of Article 4. This will allow better comparability of the analysis results and therefore better control of the contents of liquids.
As regards labelling, Article 5 of the Royal Decree is amended to clarify that the leaflet and the list must at least be written in French, Dutch and German. This is to ensure that every Belgian consumer can understand the content of the leaflet and use the product correctly. It is also specified that the brand and sub-brand appearing on the packaging unit and outer packaging shall be identical to those entered in the notification system. This consistency is important in order to allow the control of products by the authorities.
The mention or suggestion of a taste, a smell, any aroma, can only be made in a single word and in a given font and size in order to make the product less attractive.

In addition, in accordance with § 10 of this Article 5, the flavour or flavours will be indicated in the mandatory list of ingredients. This list of ingredients can sometimes consist of several dozen additives, which makes the strict implementation of Article 5 § 10 sometimes very difficult given the small size of liquid containers. In this case, the manufacturer shall indicate at least: the aroma characterised neutrally (non-promotional) by mentioning the main flavour(s) that compose it, all ingredients above 0.1 % and all allergens regardless of their concentrations.

There is an opportunity for the Minister to lay down additional conditions regarding the content and presentation of mandatory labelling information. This implies, for example, the possibility of requesting specific requirements as to the content of the leaflet referred to in Article 5(9). The distance selling ban is confirmed and extended via the distance purchasing ban. This provision brings more consistency to this article. It is also specified that distance selling to third countries which authorise it is permitted provided that they comply with the specific provisions laid down by those third countries.

Finally, rules are laid down for nicotine-free refill containers. Indeed, apart from the CLP rules, no rules were laid down for these products, although they are numerous on the market and increasingly successful. The market has also adapted to the shortcomings of the legislation as consumers can now make their own blend after purchasing a nicotine-free e-liquid container and a nicotine “booster”. In terms of composition, the application of the provisions applicable to e-liquids with nicotine to all e-liquids will also make it possible to clearly prohibit all e-liquids containing CBD and thus to get out of the current uncertainty. Indeed, currently, nicotine-free e-liquids with CBD are considered as medicines when the CBD level is above 0.4 %, but this provision is practically not applied. It is necessary to frame these nicotine-free products because they also harmful to health.
The Superior Health Council of Belgium also recommended certain rules in its opinion of 2015. Indeed it indicates: “ The SHC recommends that the quality requirements for nicotine-containing electronic cigarettes should be identical to those for nicotine-free (except for nicotine). This view is also reiterated in its 2022 opinion: “ The SHC is of the opinion that the standards for nicotine containing e-liquids are applicable to nicotine free e-liquids and ingredients. Apart from nicotine, the ingredients in these e-liquids are identical. There is therefore no need to regulate them in any other way. As for the aspects of notification, distance selling, labelling, etc., the same regulatory principles should be applied or harmonised if it concerns nicotine. It is therefore necessary to adapt the current regulations by including nicotine-free refill containers (e-liquids).

Although not containing nicotine, nicotine-free e-liquids can pose health risks as stated in the article “Electronic cigarettes and health outcomes: systematic review of global evidence" (4): The main substances in e-cigarettes aerosol that raise health concern are metals (such as chromium, nickel, and lead), carbonyls (such as formaldehyde, acetaldehyde, acrolein and glyoxal), and particulate matter and some flavourings. Exposure to some metals may cause serious health effects, including diseases of the nervous, cardiovascular and respiratory systems. Carbonyl compounds are potentially hazardous to users. Formaldehyde is a human carcinogen, acetaldehyde is possibly carcinogenic to humans, acrolein is a strong irritant of the respiratory system and glyoxal shows mutagenicity.

In addition, this article states that the risks of electronic cigarettes are not only related to nicotine: “ E-cigarette-related risks increase with: higher nicotine concentrations in e-liquids; greater e-liquid volumes; “at home” e-liquid preparation; adulteration of e-liquids; inadequate labelling; lack of child-resistant packaging; longer durations of use; potential for multiple prescriptions; personal importation; flavourings and other factors increasing attractiveness to children and youth; and factors increasing the likelihood of use of e-cigarettes in youth and non-smokers, including advertising and promotion, lack of enforcement of regulations and high concentration nicotine salt products.”(5)

In addition to nicotine-containing liquids, there are also other chemical components. Vapour contains a number of chemical ingredients and impurities in quantities that can be harmful to health. These include propylene glycol, glycerol, aldehydes and metals. The concentrations of glycerol and propylene glycol vapour in nicotine-free electronic vapours are those of nicotine-containing electronic cigarettes. The main effects of these two substances influence damage to respiratory tissues and the effects of propylene glycol on lymphocytes (a type of white blood cells). Aldehydes are created in the formulation of liquids and metals are released from the vape. The use of electronic vapes can also lead to palpitations. It is therefore important to prevent young people from using electronic vaping products, even in the absence of nicotine. The results of a Dutch study also showed that the use of polyols when using e-cigarettes poses a high risk of respiratory damage for heavy vapers; for mild and moderate vapers, this risk cannot be ruled out either. Systemic effects cannot be excluded for heavy vapers. Exposure also occurs to the tobacco-specific nitrosamines NNK and NAT. For a heavy vaper, this leads to a risk of tumour formation in the respiratory tract.

In addition to the presence of carcinogens in e-liquids, the particles present in the vapour are also of concern. Particles can be the basis for the development of lung cancer and the SCHEER report indicates that e-cigarette vapour contains large amounts of particles.
It is also stated in the 2021ooison centre report that “In the context of chronic exposure, there is increasing scientific evidence that electronic cigarette users are exposed to a mixture of irritating, toxic and carcinogenic compounds. The long-term risks of e-cigarettes still need to be investigated, but many reports already mention exposure to formaldehyde, acrolein, vitamin E acetate, volatile organic compounds, heavy metals, ultrafine particles, etc. Similarly, flavouring agents added to e-cigarettes could be a source of lung disease. For example, diacetyl (2,3-butanedione) is a flavouring agent causing a lung disease called “popcorn worker's lung” if inhaled. The disease is characterised by obstructive pulmonary disease and obliterating bronchiolitis.”(6)

It is true that there is little literature demonstrating the health effects of nicotine-free e-liquids. However, on the basis of the precautionary principle, they should be legislated. Other Member States have already legislated these products; this is the case in the Netherlands(7), Hungary(8), Czech Republic(9), Finland(10), Latvia(11), Lithuania(12), Germany(13), Luxembourg and Denmark.

In addition, at the 7th Conference of the Parties to the WHO Framework Convention on Tobacco Control, a decision on electronic inhalers, whether or not containing nicotine, was taken inviting “Parties that have not yet banned their importation, sale and distribution of these products to consider banning or regulating such products”.(14)

As nicotine-free e-liquids are also considered similar products, there is no breach of the principle of equality and non-discrimination as the same categories of products are legislated in the same way.
It is therefore foreseen that the rules on notification, certain rules on composition and labelling and the provision on distance selling apply to these products. A specific health warning is also provided. The combination of these different provisions implies the prohibition of the marketing of nicotine-free liquids through a system allowing consumers to create their own individualised blend (such as a “juice bar” or “mixology” service). This was already the case for nicotine-containing liquids.

These different rules will make it possible to:

Know the market (see notification);

Have safer e-liquids (see composition);

Prevent children from easily open containers of e-liquid bottles (see composition);

Warn the consumer that the product is not recommended for non-smokers (see labelling);

Avoid that these products being attractive (especially to minors) (see. composition and labelling);

Avoid that these products are easily accessible (see distance selling). Article by article comments

Article 1. This article aims to add as well as amend certain definitions. The definition of “electronic cigarette” is clarified.

The definition of “nicotine-free refill container” is added.

The definition of importer is amended and the definition of importer in Belgium is added in order to allow the Belgian authorities to penalise the importer in Belgium in the event of a breach of the Decree.

The definitions of “cross-border distance selling”, “health warning”, “aroma” and “retailer” are added. These are definitions provided for in the Directive and which were missing from the Royal Decree.

Article 2.
This article aims to make many improvements to the electronic cigarette notification procedure:
- The final responsibility for the notification procedure lies with the importer in Belgium if the manufacturer or importer does not have a registered office in Belgium;

- The labelling of the packaging units must be submitted to the Service in the notification file;

- Information relating to a product whose notification file is in order is published on the Service’s website. Products that do not appear on this website cannot be placed on the market;

- The invoice sent by the Service for payment of the fee must be paid within 30 days;

- The payment system is amended: A fee of EUR 200 is due for the registration of new products, a fee of EUR 100 is due for a modification of an existing product registration and an annual fee of EUR 50 is due to cover the data processing costs to be provided each year. These must be supplied before 1 March of the following year.

Article 3. Article 4 is replaced in order to:

- prohibit attractive features that are not useful for the operation of the device;

- correct a transposition error (addition of 5° to § 4);

- allow the Minister to draw up a list of prohibited additives and/or a list of prohibited additives and/or a list of authorised additives in electronic cigarettes and refill containers;

— indicate that child safety devices must comply with ISO8317:2003.

Article 4. Article 5 of the Decree has been rewritten to distinguish the provisions applicable to the health warning from those applicable to the text of this warning.

Moreover, it clearly states that the leaflet and list must be available in at least the three national languages.

It was then added that the packaging units as well as any outer packaging must include the product-ID registered in the notification system.

In addition, it is stated that refill containers must have an expiry date that cannot be exceeded.

Finally, it was clarified that the brand and sub-brand on the packaging of the products must be the same as those introduced in the notification system.

Article 5. Article 6 of the Decree is amended in order to prohibit the distance selling of electronic cigarettes and refill bottles. A paragraph 2 shall be added in order to authorise distance selling to third countries which authorise it and in compliance with the specific provisions of these third countries.
Article 6. Article 6 is intended to create a new Article 6/1 in order to make provisions for nicotine-free refill containers.

This Article provides that the notification rules, certain rules on composition and labelling and the provision on distance selling shall apply to nicotine-free refill containers.

A specific health warning for these products is also provided for in paragraph 3 of this Article.

Article 7. Section 7 refers to the entry into force of the Decree.

Article 8. Article 8 deals with the implementation of the Royal Decree.

I have the honour to be,

Sire,

of Your Majesty

the most respectful and faithful servant,

The Minister for Public Health,

F. VANDENBROUCKE

(1) C.C., 16 December 2021, judgement 183/2021

(2) [https://apps.who.int/gb/fctc/PDF/cop6/FCTC\_COP6(9)-fr.pdf](https://apps.who.int/gb/fctc/PDF/cop6/FCTC_COP6%289%29-fr.pdf)

(3) WHO report on the global tobacco epidemic 2021: addressing new and emerging products. Geneva: World Health Organization; 2021 <https://www.who.int/teams/health-promotion/tobacco-control/global-tobacco-report-2021>

(4) Banks E, Yazidjoglou A, Brown S, Nguyen M, Martin M, Beckwith K, Daluwatta A, Campbell S, Joshy G. Electronic cigarettes and health outcomes: systematic review of global evidence. Report for the Australian Department of Health. National Centre for Epidemiology and Population Health, Canberra: April 2022.

(5) Idem

(6) Toxicovigilance, Hazardous mixtures poison control centre, Final report, March 2021.

(7) <https://wetten.overheid.nl/BWBR0004302/2018-11-17>

(8) 39/2013. (II. 14.) Korm. rendelet a dohssnytermékek eloállításáról, forgalomba hozatalssról és ellenorzésérol, a kombinsslt figyelmeztetésekrol, valamint az egészségvédelmi bírsssg alkalmazásának részletes szabsslyairól - Hatsslyos Jogszabsslyok Gyujteménye (jogtar.hu)

(9) <https://www.mzcr.cz/vyhlaska-c-37-2017-sb-o-elektronickych-cigaretach-nahradnich-naplnich-do-nich-a-bylinnych-vyrobcich-urcenych-ke-koureni/>

(10) 39/2013. (II. 14.) Korm. rendelet a dohssnytermékek eloállításáról, forgalomba hozatalssról és ellenorzésérol, a kombinsslt figyelmeztetésekrol, valamint az egészségvédelmi bírsssg alkalmazásának részletes szabsslyairól - Hatsslyos Jogszabsslyok Gyujteménye (jogtar.hu)

(11) Tabakas izstradajumu, augu smekesanas produktu, elektronisko smekesanas iericu un to akidrumu aprites likums (likumi.lv)

(12) I-1143 Lietuvos Respublikos tabako, tabako gaminiy ir su jais susijusiy gaminiy kontrols jstatymas (e-tar.lt)

(13) [https://www.bvl.bund.de/SharedDocs/Fachmeldungen/03\_ verbraucherprodukte/EN/2020/2020\_11\_16\_Fa\_Aenderung\_ Tabak\_engl.html](https://www.bvl.bund.de/SharedDocs/Fachmeldungen/03_%20verbraucherprodukte/EN/2020/2020_11_16_Fa_Aenderung_%20Tabak_engl.html)

(14) <https://fctc.who.int/fr/newsroom/news/item/18-11-2016-decisions-at-cop7-advance-implementationof-the-who-framework-convention-on-tobacco-control>

(15) MVT NL Staatsblad 2018, 8 v Overheid.nl > Officiële bekendmakingen (officielebekendmakingen.nl)

(16) De gezondheidsrisico's van e-sigaret gebruik, RIVM rapport 2014-0143, W.F. Visser et al. P. 30

(17) Swanton et al. 2022. Non-small-cell lung cancer promotion by air pollutants. DOI: <https://doi.org/10.21203/rs.3.rs-1770054/v1>

(18) SCHEER. Opinion on electronic cigarettes, 2021, p.30; https://www.irishmirror.ie/news/irish-news/health-news/warning-vapers-scientists-raise-alarm -27976287?utm\_source=twitter.com&utm\_ medium=social&utm\_campaign=sharebar

7 NOVEMBER 2022. - Royal Decree amending the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes

PHILIPPE, King of the Belgians,

To all those present and to come, Greetings.

Having regard to the Act of 24 January 1977 on the protection of consumer health with regard to foodstuffs and other products, Article 6, § 1(a), as amended by the Act of 22 March 1989, Article 10(1), as replaced by the Act of 22 March 1989, Article 10, paragraph 1, replaced by the Act of 9 February 1994;

Having regard to the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes;

Having regard to the communication to the European Commission, on 6 July 2021 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 Finance Inspectorate issued on 17 January 2022;
Having regard to the agreement of the State Secretary for the Budget, issued on 28 June 2022;
Having regard to opinion of the Council of State 72.095/1/V, issued on 16 September 2022, pursuant to Article 84, § 1(1)(2), of the Acts on the Council of State, consolidated on 12 January 1973;
On the proposal of the Minister for Public Health,
We hereby have decreed and decree:
Article 1. In Article 2 of the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes, the following amendments are made:
a) in point 1, the words “or not” are inserted between the words “of vapour containing” and the word “nicotine”;
b) the following point 2(1) is inserted, which reads:
“2(1) nicotine-free refill container: a container containing a liquid that does not contain nicotine, which may be used to refill an electronic cigarette;”;
c) the following point 10(1) is inserted, which reads:

“10(1) 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 its place of business is in that Member State;

b) in other cases: if its registered office, central administration or place of business, including a branch, agency or any other establishment, is located in that Member State;”;
d) point 13 is replaced by the following:

“13) importer: the owner or person having the right of disposal of electronic cigarettes, refill containers and nicotine-free refill containers brought into the territory of the European Union;”;
e) the following point 13(1) is inserted, which reads:

“13(1) importer into Belgium: the owner or person having the right of disposal of electronic cigarettes, refill containers and nicotine-free refill containers brought into the territory of Belgium;”;

f) Article 2 shall be supplemented by points 18, 19 and 20, which read:

“18) health warning: a warning about a product’s adverse effects on human health or about other unintended consequences of its consumption;
19) aroma: an additive that gives an odour and/or taste;
20) retailer: any point of sale in which electronic cigarettes, refill containers and nicotine-free refill containers are placed on the market, including by a natural person.”.
Article 2. Article 3 of the same Decree, amended by the Royal Decree of 17 May 2017, is replaced by the following:

“ Article 3. Notification
§ 1. The marketing of electronic cigarettes and refill containers is subject to notification to the Service. The manufacturer or importer or importer into Belgium, if the first two do not have a registered office in Belgium and have not notified the product, shall notify the Service of any electronic cigarette and refill container it intends to place on the market.
§ 2. This notification shall be submitted in electronic form six months before the scheduled marketing date.
§ 3. The notification shall contain, depending on whether it relates to an electronic cigarette or a refill container, the following information:
1) the name and contact details of the manufacturer, importer and importer into Belgium;
2) a list of all the ingredients contained in the product and the emissions resulting from the use of such product, by brand and type, with their quantities;
3) toxicological data relating to the ingredients and emissions of the product, including when heated, in particular with regard to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictiveness;
4) information on the dosage and inhalation of nicotine under normal or reasonably foreseeable consumption conditions;
5) a description of the product’s components, including, where applicable, the opening and refilling mechanism of the electronic cigarette or refill container;
6 a description of the production process, indicating in particular whether it involves mass production, and a declaration that the production process ensures compliance with the requirements of this Article;
7) a declaration that the manufacturer, importer and importer into Belgium assume full responsibility for the quality and safety of the product when it is placed on the market and under normal or reasonably foreseeable conditions of use;
8) the labelling of packaging units and any outer packaging and the contents of the leaflet as referred to in Article 5(9) of this Decree.
§ 4. Where the Service considers the information submitted to be incomplete, it shall be entitled to request that it be supplemented.
§ 5. Product information provided in accordance with paragraph 3 of this Article shall be made available on the Service’s website where the Service considers that it is complete and the invoice referred to in paragraph 7 of this Article has been paid. Products that do not appear on the list of validated products, published on the Service’s website, cannot be placed on the market.
When the information is introduced, information which constitutes trade secrets or is confidential in some other way must be marked. These claims must be justified upon request.
§ 6. The following information shall not be considered confidential or as constituting trade secrets:
1) ingredients used in quantities greater than 0.1 % of the liquid’s final formulation;
2) studies and data transmitted in accordance with this Article, in particular concerning the toxicity or addictiveness of the products. Where these studies are linked to specific trade marks, explicit and implicit references to the trade mark are deleted and the revised version is made available. Any notifying person must transmit to the Service the complete studies and data as well as the revised version.
§ 7. Any person who submits a notification to the Service pursuant to paragraphs 1 to 4 shall pay a fee of EUR 200 per product to the Budget Fund for raw materials and products.
This fee must be paid within 30 days of the invoice being sent.
This fee is due as soon as the data is entered into the notification system as defined by the Minister pursuant to Article 3, § 13 and is irrecoverable.
§ 8. The manufacturer, importer or importer into Belgium, if the first two do not have a registered office in Belgium and have not notified the product, shall, for each modification of a product resulting in a change in the data transmitted in accordance with paragraphs 1 to 4, submit the new relevant information. These changes are considered to be substantial changes 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 10 of this Article.
§ 9. Any person who submits a substantial modification to the Service pursuant to paragraph 8 shall pay a fee of EUR 100 per product to the Budget Fund for raw materials and products. This fee must be paid within 30 days of the invoice being sent.
This fee is due as soon as the data is modified in the notification system as defined by the Minister pursuant to Article 3, § 13 and is irrecoverable.
§ 10. The manufacturer or importer or importer into Belgium, if the first two do not have a registered office in Belgium and have not notified the product, shall submit to the Service each year, by not later than the first of March:
1) exhaustive data on the sales volumes of the previous year, by brand and type of product;
2) information on the preferences of different consumer groups, including young people, non-smokers and the main types of actual users;
3) the method of sale of the products;
4) summaries of any market studies carried out in respect of the above, including the translation thereof into English.
§ 11. Any person who submits annual data to the Service pursuant to paragraph 10 shall pay a fee of EUR 50 per product to the Budget Fund for raw materials and products.
This fee must be paid within 30 days of the invoice being sent.
This fee is due as soon as the data is entered into the notification system as defined by the Minister pursuant to Article 3, § 13 and is irrecoverable.
§ 12. The manufacturer or importer or importer into Belgium, if the first two do not have a head office in Belgium, shall set up and maintain a system for collecting information on all the suspected adverse effects of these products on human health.
If one of these economic operators considers, or has reason to believe, that electronic cigarettes or refill containers in its possession which are intended to be placed on the market or placed on the market are not safe, not of good quality or do not comply with this Decree, it shall immediately take the necessary corrective measures to ensure the compliance of the product concerned with this Decree, withdraw it or recall it, depending on the case. In such cases, the economic operator is also required to inform the Service immediately, specifying, in particular, the risks to human health and safety and any corrective measure taken, as well as the results of these corrective measures.
The Service may also request additional information from economic operators, for example on safety and quality aspects or any possible adverse effects of electronic cigarettes or refill containers.
§ 13. The model applicable to the transmission and making available of the information referred to in this Article and the method of transmission of the information required in this article may be specified by the Minister.
Article 3. Article 4 of the same Decree is replaced by the following:
“ Article 4. Composition and technical standards
§ 1. Nicotine-containing liquid shall only be placed on the market:
1) in specific refill containers with a maximum volume of 10 millilitres;
2) in disposable electronic cigarettes;
3) in single-use cartridges.
The cartridges or reservoirs shall not exceed 2 millilitres.
§ 2. It is prohibited to place electronic cigarettes on the market which have attractive features that are not useful for operating the device.
§ 3. The nicotine-containing liquid does not contain more than 20 milligrams of nicotine per millilitre.
§ 4. The nicotine-containing liquid does not contain the following additives:
1) vitamins or other additives which create the impression that the electronic cigarette has beneficial health effects or that the health risks it poses were 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 which, without needing combustion, have CMR properties;
5) additives that facilitate the inhalation or absorption of nicotine.
The Minister shall establish a list of other prohibited additives and/or a list of authorised additives.
§ 5. Only high purity ingredients are used in the manufacture of nicotine-containing liquid. Substances other than the ingredients referred to in Article 3, § 3(2) shall be present in the nicotine-containing liquid in the form of traces, if such traces are technically unavoidable during manufacture.
§ 6. Only ingredients that, whether heated or not, do not pose a risk to human health are used in nicotine-containing liquid, with the exception of nicotine.
§ 7. Electronic cigarettes deliver consistent doses of nicotine under normal use.
§ 8. Electronic cigarettes and refill containers are equipped with a child-resistant device and are tamper-proof; they are protected against breakage and leaks and are equipped with a device to ensure that they do not leak when filled. They comply with ISO 8317. The Minister shall define the technical standards for the refilling mechanism.
§ 9. The Minister shall define the standards and methods of analysis to be used to verify the implementation of the composition and emission provisions of this section.
Article 4. Article 5 of the same decree is replaced by the following:
“ Article 5. Labelling
§ 1. Each packaging unit of an electronic cigarette or refill container as well as any outer packaging shall bear the health warning provided for in this Article in Dutch, French and German. Each language shall be printed on a new line.
§ 2. The health warning shall occupy the entire surface of the packaging unit or of the outer packaging reserved for it. It shall not be commented on, paraphrased or referred to in any way whatsoever.
§ 3. The health warning on a packaging unit or any outer packaging shall be irremovably, indelibly printed and fully visible. It shall not be concealed or interrupted, in whole or in part, by tax stamps, price tags, security devices, wrappers, envelopes, boxes or any other item.
§ 4. The health warning shall remain intact when the packaging unit is opened.
§ 5. The health warning shall be framed with a black border with a width of 1 mm within the area reserved for this warning.
§ 6. The packaging units and any outer packaging for electronic cigarettes and refill containers shall include the following health warning:

“La nicotine contenue dans ce produit crée une forte dépendance. Son utilisation par les non-fumeurs n’est pas recommandée. [The nicotine contained in this product creates a strong addiction. Its use by non-smokers is not recommended.]
Dit product bevat de zeer verslavende stof nicotine. Het gebruik ervan wordt afgeraden voor niet-rokers.
Dieses Produkt enthält Nikotin : einen Stoff, der sehr stark abhängig macht. Es wird nicht für den Gebrauch durch Nichtraucher empfohlen.”.
§ 7. The health warning shall:
1) appear on the two largest surfaces of the packaging unit and any outer packaging.
On parallelepiped packaging units with four similarly sized surfaces, the warning shall appear on two opposing surfaces, one of which is the main display surface of the brand.

2) cover 35 % of the corresponding surface area of the packaging unit and any outer packaging;
3) be located at the bottom of the corresponding surface of the packaging unit and of any outer packaging and, on the parallelepiped packaging units and any outer packaging, is parallel to the side edge of the packaging unit or the outer packaging.

§ 8. The text of the health warning shall be:

1) parallel to the main text which appears on the surface reserved for this warning;
2) printed in bold black Helvetica on a white background with a character size such that the text occupies the largest possible portion of the surface intended for it without affecting its readability; and
3) in the centre of the surface reserved for it.
§ 9. The packaging units for electronic cigarettes and refill containers shall include a leaflet in at least Dutch, French and German which contains:
1) instructions for the use and storage of the product, including a note indicating that the use of the product is not recommended for young people and non-smokers;
2) contraindications;
3) warnings for specific risk groups;
4) possible side effects;
5) addictiveness and toxicity;
6) the contact details of the manufacturer or importer or importer into Belgium and of a natural or legal person within the European Union;
7) the number of the Anti-Poisons Centre.
§ 10. The packaging units as well as any outer packaging for electronic cigarettes and refill containers shall include a list in at least Dutch, French and German which contains:
1) all the ingredients, including flavours and allergens, contained in the product in descending order of weight;
2) an indication of the nicotine content of the product and the amount disseminated per dose;
3) the batch number preceded by the word “batch”;
4) a recommendation that the product be kept out of the reach of children in the form of text or a logo;
5) the product ID issued by the notification system defined by the Minister pursuant to Article 3, § 13.
§ 11. The refill containers have an expiry date. Refill containers whose expiry date has passed may no longer be placed on the market.
§ 12. Without prejudice to paragraph 10, the packaging units and any outer packaging for electronic cigarettes and refill containers shall not contain the following:
1) any suggestion that a given electronic cigarette or refill container is less harmful than others or is intended to reduce the effect of certain harmful components of smoke or has vitalising, energising, healing, rejuvenating, natural, biological or beneficial effects on health or lifestyle;
2) any resemblance to food or cosmetic products;
3) any suggestion that a given electronic cigarette or refill container is more easily biodegradable or has other environmental benefits.
§ 13. The suggestion of a taste, a smell, of any aroma can only be indicated via a single word in weighted, normal, regular Helvetica alphabetical typeface, black or white in a maximum of font 10.
§ 14. Packaging units 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.
§ 15. Elements and devices prohibited under paragraphs 13 and 14 may include, inter alia, messages, symbols, names, trade marks, and figurative or other signs.
§ 16. 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 3, § 13.
§ 17. The Minister may lay down additional conditions as to the content and presentation of the information referred to in this Article with the exception of paragraph 13.”
Article 5. Article 6 of the same Decree is replaced by the following:
“Article 6. Distance selling of electronic cigarettes
§ 1. Distance selling to consumers and distance purchasing by consumers of electronic cigarettes and refill containers are prohibited.
§ 2. By way of derogation from paragraph 1, cross-border distance selling is permitted if the legislation of the Member State of destination so allows.”
Article 6. In the same Decree, Article 6(1) is inserted, which reads:
“Article 6(1). Nicotine-free refill containers
§ 1. The notification provisions of Article 3 shall apply to nicotine-free refill containers.
§ 2. The provisions of Article 4 concerning the composition and the technical standards shall apply to nicotine-free refill containers, with the exception of paragraphs 1, 3 and 7.
§ 3. The provisions of Article 5, with the exception of paragraph 6, shall apply to nicotine-free refill containers.
The health warning for this type of product is as follows:
“ “Ce produit nuit à votre santé. Son utilisation par les non-fumeurs n’est pas recommandée. [This product harms your health. Its use by non-smokers is not recommended.]
Dit product schaadt uw gezondheid. Het gebruik ervan wordt afgeraden voor niet-rokers.
Dieses produkt schädigt Ire> Gesundheit. Es wird nicht für den Gebrauch durch Nichtraucher empfohlen”
§ 4. Article 6 on distance selling applies to nicotine-free refill containers.”
Article 7. This Decree shall enter into force six months after its publication in the Belgian Official Gazette (*Moniteur belge*), except for the retailer for which this Decree shall enter into force twelve months after its publication in the Belgian Official Gazette.
Article 8. The Minister for Public Health is responsible for the implementation of this Decree.
Issued in Brussels, on 7 November 2022.
PHILIPPE

By the King:

The Minister for Public Health,

F. VANDENBROUCKE

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