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| The Kingdom of Belgium |
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| **FEDERAL PUBLIC SERVICE FOR PUBLIC HEALTH, THE SAFETY OF THE FOOD CHAIN AND THE ENVIRONMENT** |
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| **Royal Decree amending the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes** |
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| **PHILIPPE, King of the Belgians,** |
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| To all those present and to come, Greetings. |
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| Having regard to the Act of 24 January 1977 on the protection of consumer health with regard to foodstuffs and other products, in particular Article 6, § 1(a) thereof, as amended by the Act of 22 March 1989, Article 10(1), as replaced by the Act of 9 February 1994, and Article 10(3), as replaced by the Act of 10 April 2014, and Article 18, § 1, as replaced by the Act of 22 March 1989 and as amended by the Act of 22 December 2003; |
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| Having regard to the Royal Decree of 28 October 2016 on the manufacture and marketing of electronic cigarettes; |
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| Having regard to the opinion of the Finance Inspectorate issued on …; |
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| Having regard to opinion … of the Council of State, issued on XX, pursuant to Article 84, § 1(1)(2), of the Acts on the Council of State, consolidated on 12 January 1973; |
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| On the proposal of the Minister for the Economy, the Minister for Public Health and the Minister for Small and Medium-Sized Enterprises, |
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| I HAVE DECREED AND HEREBY DECREE: |
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| **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) a 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) a 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) a 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) the list 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.”. |
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| **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. |
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| **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 single-use cartridges.  The cartridges or reservoirs shall not exceed 2 millilitres. |
| § 2. Disposable electronic cigarettes are prohibited. |
| § 3. It is prohibited to place electronic cigarettes on the market which have attractive features that are not useful for operating the device. |
| § 4. The nicotine-containing liquid does not contain more than 20 milligrams of nicotine per millilitre. |
| § 5. 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.  The Minister shall establish a list of other prohibited additives and/or a list of authorised additives.  § 6. 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. |
| § 7. 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. |
| § 8. Electronic cigarettes deliver consistent doses of nicotine under normal use. |
| § 9. 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 8317:2003. The Minister shall define the technical standards for the refilling mechanism. |
| § 10. The Minister shall define the standards and methods of analysis to be used to verify the implementation of the provisions on composition and emissions in this Article. |
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| **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 packaging units with four similarly sized surfaces, the warning shall appear on two opposite surfaces, one of which is the main surface displaying the brand.  On cylindrical packaging units, the health warning shall appear only once and covers the entire circumference.  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;  4) any suggestion of a taste, smell, aroma, or the absence thereof. |
| § 13. 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. |
| § 14. Elements and devices prohibited under paragraphs 12 and 13 may include, inter alia, messages, symbols, names, trade marks, and figurative or other signs. |
| § 15. 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. |
| § 16. The Minister may lay down additional conditions as to the content and presentation of the information referred to in this Article. |
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| **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 permits.” |
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| **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, 4 and 8. |
| § 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.” |
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| **Article 7.** Article 7 of the same Decree is replaced by the following:  “Article 7 Sanctions  § 1. Electronic cigarettes, refill containers and nicotine-free refill containers which do not comply with the provisions of this Decree are to be regarded as harmful within the meaning of Article 18 of the Act of 24 January 1977 on the protection of consumer health with regard to foodstuffs 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 Act of 24 January 1977.  § 3. The manufacturer, importer, importer into Belgium and retailer may be held liable for non-compliance with the provisions of this Decree.” |
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| **Article 8.** This Decree shall enter into force on … |
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| **Article 9.** The Minister for the Economy, the Minister for Public Health and the Minister for Small and Medium-Sized Enterprises are responsible, insofar as each one is concerned, for the implementation of this Decree. |
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| Brussels, |
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| By the King: |
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| The Minister for the Economy, |
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| Pierre-Yves DERMAGNE |
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| The Minister for Public Health, |
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| Frank VANDENBROUCKE |
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| The Minister for Small and Medium-Sized Enterprises, |
| David CLARINVAL |