Draft Law No 8333 amending the amended Law of 11 August 2006 on tobacco control and transposing Commission 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

Consolidated text of the amended Law of 11 August 2006 on tobacco control

(Extracts)

Article 1. The purpose of this Law is, in the interests of public health, to implement tobacco control measures.

Article 2. For the purposes of this Law, the following definitions shall apply:

~~a)~~ **1.** 'tobacco products' means all products intended to be smoked, sniffed, sucked or chewed, provided that they are, even partially, made of tobacco, whether genetically modified or not, and products intended to be smoked even if they do not contain tobacco, except cigarettes and smoking products which are intended for medicinal use and which are presented as suppressing the desire to smoke or reduce tobacco addiction.

~~b)~~ **2.** 'tobacco for oral use': all products intended for oral use, except those intended for smoking or chewing, made wholly or partly of tobacco, in the form of powder, fine particles or any combination thereof — in particular those presented in portioned sachets or porous sachets — or in a form resembling an edible foodstuff;

~~c)~~ **3.** 'advertising': any form of commercial communication which has the direct or indirect purpose or effect of promoting a tobacco product;

~~d)~~ **4.** 'sponsorship': any form of public or private contribution to an event, activity or individual with the direct or indirect purpose or effect of promoting a tobacco product;

~~e)~~ **5.** 'catering establishment': any premises accessible to the public where meals are prepared or served, whether or not for consumption on site, whether free of charge or against payment,

~~f)~~ **6.** 'drinking establishment': any premises accessible to the public, the principal or ancillary activity of which is to sell or offer alcoholic or non-alcoholic beverages, whether or not free of charge, for consumption on-site or for take-away;

~~g)~~ **7.** 'smokeless tobacco product': a tobacco product that does not use any combustion process, including chewing tobacco, nasal tobacco or tobacco for oral use;

~~h)~~ **8.** 'novel tobacco product': a tobacco product that does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use;

~~i)~~ **9.** 'herbal product for smoking': a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process;

~~j)~~ **10.** 'tobacco products for smoking': tobacco products other than smokeless tobacco products;

~~k)~~ **11.** 'electronic cigarette': a product or any component of this product or device, such as a cartridge, container or a device without a cartridge or container, which can be used, by means of a mouthpiece, for vapour consumption or inhalation of any substance whether or not containing nicotine; electronic cigarettes may be disposable or refillable using a refill container and tank or a single-use cartridge;

~~l)~~ **12.** 'refill container': a receptacle with a liquid whether or not containing nicotine, which can be used to refill an electronic cigarette;

~~m)~~ **13.** 'ingredient': tobacco, an additive and any other substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;

~~n)~~ **14.** 'emissions': substances released when a tobacco product or related product is used for the intended purposes, such as substances contained in smoke or substances released by the use of a smokeless tobacco product;

~~o)~~ **15.** 'maximum level' or 'maximum emission level': the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;

~~p)~~ **16.** 'additive': a substance other than tobacco which is added to a tobacco product **or a sachet of nicotine**, to its unit packet or any outer packaging;

~~q)~~ **17.** 'outer packaging': any packaging in which tobacco products or related products are placed on the market, comprising a unit packet or a set of unit packets; additional transparent wrappers are not regarded as outer packaging;

~~r)~~ **18.** 'unit packet': the smallest individual packet of a tobacco product or related product that is placed on the market;

~~s)~~ **19.** 'waterpipe tobacco': a tobacco product that can be consumed via a waterpipe. For the purpose of this Directive, waterpipe tobacco is deemed to be a tobacco product for smoking. If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco;

~~t)~~ **20.** 'characterising flavour': a clearly identifiable smell or flavour other than that of tobacco, derived from an additive or combination of additives, including one of fruit, spices, herbs, alcohol, sweets, menthol or vanilla, which is identifiable before or during the consumption of the tobacco product;

~~u)~~ **21.** 'play area': any space specially designed and equipped for collective use in play by children;

~~v)~~ **22.** 'smoking': the inhaling of smoke from the combustion of a tobacco product or vapour from an electronic cigarette or any other such device.

23. 'tobacco': leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

24. 'pipe tobacco': tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;

25. 'roll-your-own tobacco': tobacco which can be used for making cigarettes by consumers or retail outlets;

26. 'chewing tobacco': a smokeless tobacco product exclusively intended for the purpose of chewing;

27. 'nasal tobacco': a smokeless tobacco product that can be consumed via the nose;

28. 'tar': the raw anhydrous nicotine-free condensate of smoke;

29. 'cigarette': a roll of tobacco that can be consumed via a combustion process and that:

a) can be smoked as is and is not a cigar or cigarillo;

b) is slipped into cigarette tubes using a simple, non-industrial process;

c) is wrapped in cigarette paper using a simple, non-industrial process;

30. 'cigar': a roll of tobacco that can be consumed by means of a combustion process and that:

a) is covered with an outer wrapper made of tobacco;

b) is filled with a threshed blend and fitted with an outer wrapper made of tobacco, of the normal colour of a cigar, covering the product in full, including the filter if applicable, but not the tip in the case of tipped cigars, when their unit weight, without the filter or tip, is equal to or greater than 2.3 g but not more than 10 g, and their circumference is equal to or greater than 34 mm over at least one third of their length;

31. 'cigarillos': a type of small cigar with a maximum weight of 3 g per piece;

32. 'addictiveness': the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both;

33. 'toxicity': the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure;

34. 'health warning': a warning concerning the adverse effects on human health of a product or other undesired consequences of its consumption, including text warnings, combined health warnings, general warnings and information messages;

35. 'combined health warning': a health warning consisting of a combination of a text warning and a corresponding photograph or illustration;

36. 'distance selling': any sale concluded under an organised distance selling scheme, without the simultaneous physical presence of the seller and the buyer, through the exclusive use of one or more means of remote communication, up to and including the moment when the sale is concluded;

37. 'manufacturer': any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or brand;

38. 'importer of tobacco products or related products': the owner or a person entitled to have tobacco products or related products brought into the territory of the European Union;

39. 'retailer': any point of sale where tobacco products are placed on the market, including by a natural person;

40. 'nicotine': nicotinic alkaloids and nicotine salts;

41. 'heating device': any device or component thereof which is necessary for the consumption or use of a novel tobacco product;

42. 'novel nicotine product': any product which does not contain tobacco and made of, even partially, nicotine, intended for human consumption, with the exception of devices to stop smoking sold in pharmacies, nicotine sachets or electronic cigarettes;

43. 'nicotine sachet': a tobacco-free oral product made wholly or partly of synthetic or natural nicotine, mixed with vegetable fibres or an equivalent substrate, and presented in the form of powder, fibres, particles or paste or a combination of these forms portioned in sachets, in porous sachets or in an equivalent form, without being intended for smoking, and which may also be marketed as a nicotine pouch;

44. 'heated tobacco product': a novel tobacco product that is heated to produce an emission containing nicotine and other chemicals, which is then inhaled by the users, and which, according to its characteristics, is a smokeless tobacco product or a tobacco product for smoking.

Article 3. (1) Advertising of tobacco, its products, ingredients, electronic cigarettes and refill containers, **or nicotine sachets,** and any free distribution of a tobacco product or an electronic cigarette or refill container **or nicotine sachets** is not authorised.

This prohibition includes the use of the brand logo or the name of the tobacco brand or of the tobacco products or electronic cigarette products or refill container**, or nicotine sachet,** and the use of any other representation or indication which may refer to them on everyday objects other than those directly related to the use of tobacco or electronic cigarettes **or of nicotine sachets**.

This provision shall not apply to categories of objects presented on the market before 9 April 1989 under names, brands or logos identical to those of tobacco or tobacco products.

(2) The following shall not be regarded as advertising within the meaning of the preceding paragraph:

— signs or signals affixed for the purpose of indicating them on the buildings of establishments in which the products covered by this Law are manufactured or stored, as long as they do not contain any indication other than the name of the manufacturer or distributor, the name of the brand produced or distributed or a graphic or photographic representation of the brand or its packaging or logo;

— the mere indication, on a vehicle normally used for the sale of tobacco, or of its products or of electronic cigarettes and refill containers, the name of the product, its composition, name and address of the manufacturer and, where applicable, the distributor, and the graphic or photographic representation of the product, its packaging and the brand logo.

(3) The provisions of paragraph 1 shall not apply to:

— publications and online communication services published by professional organisations of producers, manufacturers and distributors of tobacco products, electronic cigarettes and refill containers for their members, nor to specialised professional publications or online communication services published professionally which are only accessible to producers, manufacturers and distributors of tobacco products and electronic cigarettes and refill containers.

— printed and edited publications and online communication services made available to the public by persons established in a country outside the European Union, where those publications and online communication services are not primarily aimed at the Community market.

(4) The provisions of paragraph 1 shall not apply to advertising within tobacco outlets. In shops which also offer for sale products not covered by this Law, this derogation applies only to areas reserved for the sale of tobacco products**, nicotine sachets,** as well as e-cigarettes and refill containers, and in shops with no subdivision into sales areas, in close proximity to the stalls displaying tobacco products**, nicotine sachets**, electronic cigarettes or refill containers.

The advertising authorised under the preceding subparagraph may be made only by means of posters and billboards. It may not specifically target an audience of minors, nor make use of health-oriented arguments, nor include text, a name or a figurative sign suggesting that a particular product is less harmful than another, nor contain a representation of a person known to the general public.

(5) Any sponsorship of tobacco or tobacco products or electronic cigarettes or refill containers **or nicotine sachets** is prohibited.

Article 3*a*. (1) Manufacturers and importers of tobacco products are required to report, by brand and type, to the Health Directorate; hereinafter referred to as 'the Directorate', a list of all ingredients and quantities thereof used in the manufacture of tobacco products, in descending order of the weight of each ingredient included in the tobacco product, as well as the levels of tar, nicotine and carbon monoxide emissions.

Manufacturers and importers of nicotine sachets, electronic cigarettes or novel nicotine products are required to send, by brand and type, to the Directorate a list of all the ingredients and quantities thereof used in the manufacture of the products.

Manufacturers or importers shall also inform the Directorate if the composition of a product is modified in such a way as to affect the information communicated under this Article.

For a novel or modified tobacco product, **and for a novel nicotine product,** the information required pursuant to this Article shall be provided prior to the placing on the market of that product.

(2) The list referred to in paragraph 1 is accompanied by a declaration which includes information on the status of the ingredients with regard to Regulation (EC) No 1907/2006 of 18 December 2006 and Regulation (EC) No 1272/2008 of 16 December 2008, toxicological data, effects on consumer health, the addictiveness of the ingredients, the reason for the use of the ingredients, and a general description of the additives used and their properties.

(3) Manufacturers and importers of tobacco products**, and manufacturers and importers of nicotine sachets,** shall communicate to the Directorate the internal and external market studies and the preferences of consumer groups, including young people and current smokers, regarding ingredients and emissions, as well as summaries of studies for the launch of new products. They shall report annually, before the end of the first quarter, to the Directorate the volume of their sales for the past year, by brand and type, expressed in number of cigarettes/cigars/cigarillos**, number of nicotine sachets** or in kilograms.

(4) By no later than eighteen months after the inclusion of an additive on the priority list drawn up in accordance with the implementing decision provided for in Article 6 of Directive 2014/40/EU of 3 April 2014, manufacturers and importers shall submit to the Directorate the in-depth studies they have carried out on this additive.

The studies referred to in subparagraph 1 aim to examine for each additive whether it:

a) contributes to the toxicity or addictiveness of the products in question and if this results in a significant or measurable increase in toxicity or addictiveness of one of the products concerned;

b) has a characterising flavour;

c) facilitates the inhalation or absorption of nicotine; or

d) leads to the formation of substances that have CMR properties — and in what amounts — and if so whether this has the effect of significantly or measurably increasing the CMR properties of one of the products concerned.

(4*a*) These studies shall take into account the intended use of the products concerned and shall examine in particular: emissions from the combustion process involving the additive concerned. The studies shall also examine the interaction of that additive with other ingredients contained in the products concerned. Manufacturers or importers using the same additive in their tobacco products may carry out a joint study when using that additive in a comparable product composition.

(4*b*) Manufacturers or importers shall establish a report on the results of these studies. This report shall include a summary and detailed presentation of scientific publications available for this additive and summarise the internal data relating to it. The Directorate may request additional information from manufacturers and importers regarding the additive concerned. This supplementary information shall form part of the report.

(4*c*) Small and medium-sized enterprises, as referred to in the amended Law of 9 August 2018 concerning an aid scheme for small and medium-sized enterprises, shall be exempt from obligations pursuant to paragraphs 4 to 4*b* of this Article where a report on the additive concerned is prepared by another manufacturer or importer.

(5) Manufacturers and importers are required to indicate which of the information they provide in accordance with paragraph 1 they consider to be covered by commercial confidentiality.

(6) For substances other than tar, nicotine and carbon monoxide emitted by cigarettes and for substances emitted by tobacco products other than cigarettes, manufacturers and importers shall indicate the methods used to measure emissions.

Article 3*b*. (1) The labelling of unit packets, any outer packaging and the tobacco product **or nicotine sachet** shall not include any element or device which:

a) contributes to the promotion of a tobacco **or nicotine** product or incentivises its consumption by giving an erroneous impression as to the characteristics, effects on health, risks or emissions of that product; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

b) suggests that a tobacco product, **nicotine sachet or novel nicotine product** is less harmful than others or aims to reduce the effect of certain harmful components of smoke, or has vitalising, energising, curative, rejuvenating, natural, organic or beneficial effects on health or lifestyle;

c) refers to taste, smell, any flavours or other additives or the absence thereof;

d) resembles a food or a cosmetic product;

e) suggests that a given tobacco product**, nicotine sachet or novel nicotine product** is more readily biodegradable or has other environmental benefits.

(2) The unit packets and any outer packaging shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.

(3) Automatic devices for distributing tobacco and tobacco products, as provided for in Article 9(3), shall also bear the health warnings provided for in Article 4(1). Graphic representations on vending machines for tobacco and tobacco products other than health warnings are prohibited.

Article 4. (1) Each unit packet and any outer packaging of cigarettes, roll-your-own tobacco ~~and~~ **,** waterpipe tobacco**, nicotine sachets and novel tobacco products** must have a general warning, an information message and combined health warnings. Each unit packet and any outer packaging of a tobacco product for smoking other than cigarettes, roll-your-own tobacco ~~and~~ **,** waterpipe tobacco**, nicotine sachets and novel tobacco products** must have a general warning and a specific warning message.

The content of the general warning, the information messages, the specific warning message and the combined health warnings, the languages used, the printing and presentation methods and the surface area of the various packet units and outer packaging referred to in subparagraph 1 covered by the warnings and messages are laid down by a Grand-Ducal Regulation.

(2) The maximum levels of tar, nicotine and carbon monoxide emissions are laid down by a Grand-Ducal Regulation, which also lays down the methods for measuring such emissions.
The emissions measurements referred to in subparagraph 1 are verified by the National Health Laboratory or by any laboratory approved by the Minister for Health. These laboratories, which do not belong to the tobacco industry and are not controlled either directly or indirectly by it, are controlled by the Directorate. A Grand-Ducal Regulation shall specify the conditions for the approval and inspection of these laboratories.

(...)

Article 4*g*. (1) Manufacturers and importers of electronic cigarettes and refill containers are required to submit a notification to the Directorate regarding any such product they intend to place on the market.

(2) The notification referred to in paragraph 1 shall be submitted in electronic form six months before the planned date of placing on the market. A new notification must be submitted for any substantial modification to the product.

(3) The notification referred to in paragraph 1 shall contain the following information, depending on whether it concerns an electronic cigarette or a refill container:

a) the name and contact details of the manufacturer, a responsible legal or natural person within the Union, and, if applicable, the importer into the Union;

b) 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;

c) 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;

d) information on the dosage and inhalation of nicotine under normal or reasonably foreseeable consumption conditions;

e) a description of the product's components, including, where applicable, the opening and refilling mechanism of the electronic cigarette or refill container;

f) 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;

g) a declaration that the manufacturer and importer 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;

h) proof of payment of the fine provided for in paragraph 4.

(4) A fine of EUR 5 000 is due for each notification referred to in paragraph 1.

This fine is payable via payment or transfer to a bank account held by the Registration and Domains Administration, together with an indication of the applicant's identity and the purpose of the payment or transfer.

5) Where the Directorate consider the information submitted to be incomplete, they shall be entitled to request that it be supplemented.

(6) Manufacturers and importers of electronic cigarettes and refill containers shall submit to the Directorate annually:

a) comprehensive data on sales volumes, by brand and type of product;

b) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users;

c) the method of sale of the products;

d) summaries of any market surveys carried out in respect of the above, including an English translation thereof.

The Directorate shall monitor market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately to traditional tobacco consumption among young people and non-smokers.

(7) Manufacturers and importers of electronic cigarettes and refill containers shall set up and maintain a system for collecting information on any suspected adverse effects of these products on human health.

If an economic operator considers or has reason to believe that electronic cigarettes or refill containers in their possession which are intended to be placed on the market or are placed on the market are unsafe, not of good quality or do not comply with this Law, that economic operator shall immediately take the necessary corrective measures to make the product concerned compliant, withdraw it or recall it, as appropriate.

In such cases, the economic operator is obliged to inform the Directorate immediately, specifying in particular the risks to human health and safety, any corrective measures taken and the results of these corrective measures.

Additional information may be requested from economic operators by the Directorate on any aspect relating to the safety and quality or any possible undesirable effects of electronic cigarettes or refill containers.

8) At the request of the Commission or of the competent authorities of the other Member States, the Directorate make all information received in accordance with this Article available to the Commission and to the other Member States of the European Union.
(9) Where the Directorate find or have reasonable grounds to believe that an electronic cigarette or refill container, although compliant with this Article, could present a serious risk to human health, they shall take the appropriate provisional measures. It shall immediately inform the European Commission and the competent authorities of the other Member States of the measures taken and provide all relevant information at its disposal.

(...)

Article 5. The Government shall set up or subsidise structured consultation and information activities, with the following tasks:

— to raise public awareness of the health risks associated with tobacco consumption and exposure to tobacco smoke, as well as the benefits of quitting smoking and of smoke-free lifestyles;

— to raise public awareness of the health risks associated with the consumption of nicotine sachets;

— to provide the public with information on the ingredients of the various tobacco products **or nicotine sachets** placed on the market, indicating the levels of harmful substances;

— to offer consultations to the public, in particular to people who want to quit smoking.

Health information related to smoking and health education shall be provided at all levels of school education.

Article 6. (1) Smoking is prohibited:

1. inside and around hospitals;

2. in communal parts of institutions for elderly people used for accommodation, including lifts and corridors;

3. in waiting rooms at the doctor, dentist and other health professionals as well as in medical analysis laboratories;

4. in pharmacies;

5. inside and around schools of all types of education; 6. in premises intended to accommodate or accommodate minors under the age of sixteen; 7. in all indoor sports or leisure establishments;

8. in cinemas, entertainment halls and theatres well as in the halls and corridors of buildings in which they are located;

9. in museums, art galleries, libraries and reading rooms, open to the public;

10. in the halls and rooms of State buildings, municipalities and public institutions;

11. in any collective means of transport of persons, even when stationary or parked;

12. in playgrounds, as well as in all sports venues with minors below the age of 16, engaged in sporting activity there;

13. a) in catering establishments,

b) in pastry and bakery sections in catering establishments and pastry and bakery tea rooms;

14. in discotheques within the meaning of the rules on the nomenclature and classification of classified establishments;

15. in shopping malls, shopping centres and showrooms open to the public;

16. in the sales areas of all food shops;

17. in drinking establishments;

18. in premises for communal use in accommodation establishments, including lifts and corridors.

19. in any vehicle in the presence of a child under the age of twelve.

(2) The prohibition referred to in paragraph 1(1) does not apply to smoking rooms specifically set up for that purpose by the operator of a hospital and in open air smoking areas.

With the exception of smoking rooms that can be set up inside closed psychiatric wards, only one smoking room may be permitted per hospital. This smoking room must be located away from the services and arranged in such a way that tobacco smoke does not reach staff or the public. Access to smoking rooms is strictly restricted to hospitalised patients who request it.

Only one open-air smoking area may be permitted per hospital. This smoking area must be separated from any access area of the hospital. It must be clearly marked as a space reserved for smokers.

(3) For the places referred to in paragraph 1(13)(a), (17) and (18), a smoking area may be installed in a separate room in which the prohibition referred to in this Article does not apply.

The smoking area must be fitted with a smoke extraction or air cleaning system.

The smoking area must be designed and constructed in such a way as to minimise the inconvenience caused by the smoke to non-smokers and cannot be a transit zone.

The technical characteristics of the smoke extraction or air purification system and the conditions referred to in the above subparagraph shall be laid down by Grand-Ducal Regulation.

The area of the smoking room may not exceed 30 per cent of the total area of the room as defined in points (e) and (f) of Article 2 respectively of the premises referred to in paragraph 1(18).

The smoking room must be clearly identified as a room reserved for smokers. One or more signals recalling the ban on smoking in areas reserved for non-smokers must be installed so that anyone present can be aware of it.

The operator of the premises is required to take measures to prevent minors from having access to the smoking room. No service may be provided in the smoking room. Only beverages may be taken into the smoking room.

The operation of the smoking room is subject to prior authorisation by the Minister, who shall grant it on the basis of a report by the Health Directorate only if the requirements laid down in this Article are met.

The Health Directorate ensures that the above requirements are met.

(4) A sign warning of the risks of passive smoking must be placed visibly at the entrance to the smoking rooms and smoking zones referred to in paragraphs 2 and 3.

(5) It is forbidden to consume nicotine sachets:

1. within the establishments referred to in paragraph 1(5). ;

2. in the rooms referred to in paragraph 1(6). ;

3. in sports venues referred to in paragraph 1(12).

Article 7. (1) The placing on the market, sale, distribution or offering free of charge, possession with a view to sale, and importation for commercial purposes of tobacco for oral use are prohibited.

(2) The placing on the market, sale, distribution or offering free of charge of packets of fewer than twenty **and more than fifty** cigarettes, as well as containers of fewer than thirty **and more than one thousand grams** of rolling tobacco, regardless of their packet, is prohibited.

(2*a*) The number of cigarettes per unit packet must comply with the 5-piece multiplier condition.

The quantities of unit packets for roll-your-own tobacco must comply with the following conditions:

a) each unit packet weighing between 30 g and 50 g must constitute a multiple of 5 g;

b) each unit packet weighing between 50 g and 100 g must constitute a multiple of 10 g;

c) each unit packet weighing between 100 g and 500 g must constitute a multiple of 25 g;

d) each unit packet weighing between 500 g and 1 000 g must constitute a multiple of 50 g;

(3) It is prohibited to market, sell, distribute or offer free of charge tobacco products:

a) containing a particular characterising flavour;

b) containing any technical device for altering the smell or taste of tobacco products, or their burning intensity;

c) containing vitamins or other additives suggesting that a tobacco product has health benefits or that its health risks have been reduced;

d) containing caffeine, taurine or other additives and stimulants associated with energy and vitality;

e) containing additives that give colouring properties to smoke emissions;

f) containing additives that facilitate the inhalation or absorption of nicotine;

g) containing additives which, without combustion, have carcinogenic, mutagenic or toxic properties for human reproduction;

h) containing flavours in any of their components, such as filters, paper, packets and capsules, or any technical device for altering the smell or taste of the tobacco products concerned or their burning intensity. Filters, paper and capsules must not contain tobacco or nicotine.

Tobacco products other than cigarettes**, heated tobacco products** and roll-your-own tobacco are exempted from the prohibitions in points (a) and (h).

(4) It is prohibited to market, sell, distribute or offer free of charge nicotine sachets containing either:

a) more than 0.048 mg nicotine per sachet;

b) additives that facilitate the absorption of nicotine;

c) caffeine, taurine, CBD or other additives and stimulants associated with energy or relaxation.

Nicotine sachets must be fitted with a child safety device and must be tamper-proof.

Manufacturers of nicotine sachets are required to comply with the hygiene rules laid down in Article 4 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs for food business operators.

Article 8. (1) Manufacturers and importers of novel tobacco products shall submit a notification to management six months before the planned date of placing such products on the market. This notification shall be submitted by electronic means. It shall be accompanied by a detailed description of the novel tobacco product in question and its instructions for use. **The Directorate shall make available to the European Commission the information received pursuant to this Article.**

(2) The notification referred to in paragraph 1 must contain the following information:

a) the list of all ingredients, together with their quantities, used in the manufacture of the novel tobacco product, and emissions and levels thereof, in accordance with Article 4;

b) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, in particular as regards its ingredients and emissions;

c) available studies, summaries thereof and market research on the preferences of various consumer groups, including young people and current smokers;

d) other relevant information available, including a risk/benefit analysis of the product, its expected effects on the cessation of tobacco consumption, its expected effects on initiation of tobacco consumption; and

e) proof of payment of the fine provided for in paragraph 4.

(3) Manufacturers and importers of novel tobacco products shall submit to the Directorate any new or updated information on the studies, research and other information referred to in paragraph 2(b) to (d). The Directorate may require manufacturers or importers of novel tobacco products to carry out additional tests or to submit additional information.

(4) A fine of EUR 5 000 is due for each notification referred to in paragraph 1. This fine is payable via payment or transfer to a bank account held by the Registration and Domains Administration, together with an indication of the applicant's identity and the purpose of the payment or transfer.

(5) The placing on the market of novel tobacco products is subject to prior authorisation to be issued by the Minister on the advice of the Directorate.

Article 9. (1) Placing on the market, selling, holding with a view to selling and importation for commercial purposes of sweets and toys intended for children made with the clear intention of giving the product or its packaging the appearance of a type of tobacco product**, nicotine sachet** or an electronic cigarette or refill are prohibited.

(2) It shall be prohibited to sell or offer free of charge tobacco and tobacco products, **nicotine sachets,** as well as electronic cigarettes and refill containers for minors under the age of 18. **In case of doubt about whether its customers are at least 18 years of age, the seller must require the presentation of an identity document for verification purposes.**

(3) Any operator of automatic distribution equipment supplying tobacco and tobacco products, electronic cigarettes and refill containers, **or nicotine sachets,** is required to take measures to prevent access of minors under 18 years to such apparatus.

(4) Any operator of a tobacco outlet or a store offering tobacco products for sale, as well as electronic cigarettes and refill containers, must ensure that these products are kept in such a way that customers cannot access them without the assistance of an employee.

(5) The distance selling of tobacco products, **nicotine sachets,** and electronic cigarettes and refill containers, including where the purchaser is located abroad, is prohibited.

The acquisition or introduction from another Member State of the Union or the importation from third countries of tobacco products, as well as electronic cigarettes and refill containers sold remotely shall also be prohibited.

Transactions between traders and professionals shall not be covered by the prohibitions in this paragraph.

Article 10. Infringements of the provisions of Articles 3, 3*a***(1) and (2)**, 3*b*, 4*a*(1), 4*c*(5), 4*d*, 4*e*, 4*f*, 4*g*(1), (6) and (7), of Article 4*h* and of Articles 7, 8(1) and of Article 9 of this Law, as well as infringements of the provisions of the Grand-Ducal Regulation to be issued by virtue of Articles 4 and 4*e* thereof, are punishable by a fine of between EUR 251 and 50 000.

Infringements of the provisions of **Article 4*a*(2) and of** Article 6 of this Law shall be punishable by a fine of between EUR 25 and 250.

An operator of one of the establishments referred to in paragraph 1 under 13(a), 17 and 18 of Article 6, or someone acting on their behalf, who deliberately fails to ensure compliance by the establishment with the prohibition set out in the aforementioned Article, shall be punished by a fine of EUR 251 to 1 000. The same penalty applies to any operator or person acting on behalf of an operator who installs in an establishment a smoking room clearly identified as a room reserved for smokers, but which does not meet the requirements defined in paragraph 3 of the aforementioned Article.

In the event of a repeat offence within two years of a final conviction, the fines provided for in the first subparagraph of this Article may be increased to twice the maximum.

The provisions of Book 1 of the Criminal Code and of Articles 130-1 to 132-1 of the Code of Criminal Procedure are applicable to the penalties provided for in the first subparagraph of this Article.

Article 10*a*. (1) Without prejudice to Article 10 of the Criminal Code, infringements of the provisions of this Law shall be investigated and recorded by officials of the Customs and Excise Administration, hereinafter referred to as 'ADA', from the rank of senior sergeant and higher. The aforementioned officials may carry out checks on compliance with the provisions of this Law.

(2) In the performance of their duties under this Article, the customs and excise officials referred to shall have the status of judicial police officers. They shall report any infringements in written statements that shall serve as evidence in the absence of proof to the contrary. Their competence covers the entire territory of the Grand Duchy of Luxembourg.

(3) Before taking up their duties, they shall take the following oath before the Luxembourg district court, sitting in civil matters: " I swear to perform my duties with integrity, accuracy and impartiality.'

(4) ADA officials referred to in this Article must have undergone specific professional training on the investigation and detection of infringements, and on the provisions of this Law and its implementing regulations.

Specific professional training is organised by the ADA as part of the continuous training of public officials, as required by the ADA.

The specific professional training programme, which is theoretical and cannot last more than 10 hours, shall cover the investigation and detection of infringements under this Law and its implementing regulations. The content of the training programme is specified by a Grand-Ducal Regulation. That regulation also lays down detailed rules for the knowledge check organised by the ADA within three months of the end of the period in which the courses are held.

The checks are marked separately by two markers. A candidate passes the exam if he or she has obtained at least half of the maximum marks in each of the tests, provided that the total number of marks obtained is at least three fifths of the total maximum marks that can be obtained.

In case of failure, the candidate may take part in the next knowledge check organised by the ADA. The candidate is free to participate again in the training.

(5) Doctors of the Health Directorate, who have the status of judicial police officers within the meaning of Article 8 of the amended Law of 21 November 1980 on the organisation of the Health Directorate, are responsible for investigating and detecting infringements of Article 3*a*(1) and (2), 3*b*, 7 and 9 of this Law.'

Article 11. In the of case ~~of breaches~~ of **infringements** in accordance with the provisions of **Article 4*a*(2) and** Article 6, fines may be issued by officials of the Grand-Ducal Police authorised for this purpose by the Director-General of the Grand-Ducal Police and by the officials of the Customs and Excise Administration authorised for this purpose by the Director of the Customs and Excise Administration.

In the case of offences punishable in accordance with the provisions of Article 6(1)(12), fines may be issued by municipal staff who satisfy the conditions of Article 15-1*a* of the Criminal Code.

The fine is subject to the condition either that the offender agrees to pay the amount due immediately to the pre-qualified officials, or, where the fine cannot be collected at the place where the offence was committed, to pay it within the time limit set by the summons. In the latter case, payment may be made at the Grand-Ducal police office, the customs and excise office or by transfer to the postal or bank account indicated in the same summons.

The fine shall be replaced by regular minutes:

1) if the offender has not paid within the specified time limit;

2) if the offender declares that he or she is unwilling or unable to pay the fine(s);

3) if the offender was a minor at the time of the offence.

The fine amount and the methods of payment shall be laid down by a Grand-Ducal Regulation, which shall also lay down the procedures for applying this Article.

Any reminder costs are an integral part of the fine.

The amount to be collected by means of a fine may not exceed the maximum fine provided for in Article 10, subparagraph 2.

Payment of the fine within 30 days of the moment the infringement is found, plus any costs provided for in the fifth subparagraph of this paragraph, halts all legal proceedings.

Where the fine has been paid after this period, it shall be reimbursed in the event of acquittal, and shall be deducted from the fine imposed and from any legal costs in the event of conviction.

(...)