Draft law on smoking control amending the law of 11 August 2006 on tobacco control and transposing Commission Delegated Directive 2022/2100/EU of 29 June 2022 amending Directive 2014/40/EU of the European Parliament and of the Council as regards the withdrawal of certain exemptions in respect of heated tobacco products;

The changes made by the draft law are shown in yellow

Consolidated version of the Law of 11 August 2006 on tobacco control, as amended

(...) Article 2.

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

1. ~~a)~~ 'tobacco products' means all products intended to be smoked, sniffed, sucked or chewed, as long as they are, at least partially, made from tobacco (Law of 13 June 2017), 'whether or not genetically modified, as well as products intended to be smoked even if they do not contain tobacco, with the sole exception of cigarettes and smoking products intended for medicinal use and that are presented as suppressing the desire to smoke or as reducing tobacco addiction.'
2. ~~b)~~ 'tobacco for oral use' means all products intended for oral use, including nasal use, with the exception of those intended to be smoked or chewed, consisting wholly or partly of tobacco, in the form of powder, fine particles or any combination of these forms - in particular those presented in portion sachets or porous sachets - or in a form resembling an edible foodstuff;
3. ~~c)~~ 'advertising' means any form of commercial communication that has the direct or indirect purpose or effect of promoting a tobacco product;
4. ~~d)~~ 'sponsorship' means any form of public or private contribution to an event, activity or individual with the aim or direct or indirect effect of promoting a tobacco product;
5. ~~e)~~ 'catering establishment' means any premises accessible to the public where meals are prepared or served for consumption on site or otherwise, even free of charge (Law of 18 July 2013)
6. ~~f)~~ 'drinking establishment' means any premises accessible to the public, the main or ancillary activity of which is to sell or offer, even free of charge, alcoholic or non-alcoholic beverages, intended to be consumed on site or taken away (Law of 13 June 2017)
7. ~~g)~~ 'smokeless tobacco product' means a tobacco product that does not use any combustion process, including chewing tobacco, nasal tobacco or tobacco for oral use;
8. ~~h)~~ 'novel tobacco product' means 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;
9. ~~i)~~ 'herbal product for smoking' means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process
10. ~~j)~~ 'tobacco products for smoking' means tobacco products other than a smokeless tobacco

product;

11. ~~k)~~ 'electronic cigarette' means a product or any component of such a product or device, including a cartridge, a tank and the device without a cartridge or tank, which can be used, by means of a mouthpiece, for the consumption of vapour or the inhalation of any substance whether or not it contains nicotine; electronic cigarettes may be disposable or refillable using a refill container and tank or a single-use cartridge;
12. ~~l)~~ 'refill container' means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;
13. ~~m)~~ 'ingredient' means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;
14. ~~n)~~ 'emissions' means substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;
15. ~~o)~~ 'maximum level' or 'maximum emission level' means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;
16. ~~p)~~ 'additive' means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging;
17. ~~q)~~ 'outside packaging' means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or a set of unit packets; transparent wrappers are not regarded as outside packaging;
18. ~~r)~~ 'unit packet' means the smallest individual packaging of a tobacco or related product that is placed on the market;
19. ~~s)~~ 'waterpipe tobacco' means 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;
20. ~~t)~~ 'characterising flavour' means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;
21. ~~u)~~ 'play area' means any space specially designed and equipped for collective use by children for play purposes;
22. ~~v)~~ 'smoking' means the act of inhaling the smoke produced by the combustion of a tobacco product or the vapour from an electronic cigarette or any other device of this nature;
23. 'tobacco' means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;
24. 'pipe tobacco' means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;
25. 'roll-your-own tobacco' means tobacco which can be used for making cigarettes by consumers or retail outlets;
26. 'chewing tobacco' means a smokeless tobacco product exclusively intended for the purpose of chewing;

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

28. 'tar' means raw, anhydrous, nicotine-free smoke condensate;

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

    - can be smoked as is and is not a cigar or cigarillo
    - is slipped into cigarette tubes by a simple, non-industrial process,
    - is wrapped in cigarette paper using a simple, non-industrial process;

30. 'cigar' or 'cigarillo' means a roll of tobacco that can be consumed via a combustion process and that is:

    - covered with an outer wrapper of tobacco;
    - with a threshed blend filler and with an outer wrapper of the normal colour of a cigar, of reconstituted tobacco, covering the product in full, including, where appropriate, the filter but not, in the case of tipped cigars, the tip, where the unit weight, not including filter or mouthpiece, is not less than 2.3 g and not more than 10 g, and the circumference over at least one third of the length is not less than 34 mm;

31. 'addictiveness' means 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;

32. 'toxicity' means 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;

33. 'health warning' means 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;

34. 'combined health warning' means a health warning consisting of a combination of a text warning and a corresponding photograph or illustration, as provided for in this Directive;

35. 'distance sale' means any form of distance sale, including cross-border sale, to consumers or by sellers from or to Luxembourg;

36. 'manufacturer' means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;

37. 'importer of tobacco' means the owner of, or a person having the right of disposal over, tobacco or related products that have been brought into the territory of the Union;

38. 'retail outlet' means any outlet where tobacco products are placed on the market including by a natural person;

39. 'nicotine' means nicotinic alkaloids and nicotine salts;

40. 'heating device' means any device or component thereof required for the consumption or use of a new tobacco product.

Article 3a.

(1) Manufacturers and importers of tobacco products are required to report, by brand and by type, to the Health Authorities, hereinafter 'the authorities', a list of all ingredients and their quantities used in the manufacture of tobacco products, in descending order of the weight of each ingredient included in the tobacco product, as well as tar, nicotine and carbon monoxide emission levels.

Manufacturers or importers shall also inform the authorities 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, the information required under this article shall be provided before the product is placed on the market.

(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 product shall provide the authorities with internal and external studies concerning the market and the preferences of consumer groups, including young people and current smokers, with regard to ingredients and emissions, as well as summaries of studies with a view to launching new products. Before the end of the first quarter of each year, they declare to the authorities their sales volume for the previous year, by brand and type, expressed in number of cigarettes/cigars/cigarillos or 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 authorities the in-depth studies they have carried out on this additive.

The purpose of the studies referred to in paragraph 1 is to examine, for each additive, whether it:

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

b) produces a characterising flavour;

c) facilitates the inhalation or absorption of nicotine; or

d) leads to the formation of substances with CMR properties - and in what quantities - and whether this has the effect of significantly or measurably increasing the CMR properties of any of the products

concerned.

(4a) Those studies shall take into account the intended use of the products concerned and examine in particular the emissions resulting 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.

(4b) Manufacturers or importers shall establish a report on the results of these studies. That report shall include an executive summary and a comprehensive overview compiling the available scientific literature on that additive and summarising internal data on the effects of the additive. The authorities may request from manufacturers and importers additional information concerning the additive concerned. This supplementary information shall form part of the report.

(4c)The authorities may evaluate the report provided for in paragraph 4b assessed by an independent scientific body, in particular as regards its completeness, methodology and conclusions.

A fee of EUR 5 000 is payable for each evaluation referred to in paragraph 1. This fee 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.

(4d) Small and medium-sized enterprises, as referred to in the Law of 9 August 2018, as amended, on an aid scheme for small and medium-sized enterprises, shall be exempted from the obligations pursuant to this Article, if a report on that additive 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 3b.

(1) The labelling of unit packets and any outside packaging and the tobacco product itself shall not include any element or feature that:

a) promotes a tobacco product or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions; labels shall not include any information about the nicotine, tar or carbon monoxide content of the tobacco product;

b) suggests that a particular tobacco product is less harmful than others or aims to reduce the effect of some harmful components of smoke or has vitalising, energetic, healing, rejuvenating, natural, organic properties or has other health or lifestyle benefits;

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

d) resembles a food or a cosmetic product;

e) suggests that a certain tobacco product has improved biodegradability or other environmental advantages.

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

(3) The vending machines for tobacco and tobacco products provided for in Article 9(3) must also bear the health warnings provided for in paragraphs 1 and 2 of this Article and in Article 4(1). Graphic representations on vending machines for tobacco and tobacco products other than health warnings are prohibited.

Article 4.

(1) Every unit packet and all outer packaging of cigarettes, rolling tobacco, waterpipe tobacco and products satisfying the definition of novel tobacco products carry a general warning, an information message and combined health warnings. Every unit packet and all outer packaging of a smoking tobacco product other than cigarettes, rolling tobacco, waterpipe tobacco and products satisfying the definition of novel tobacco products shall carry 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 packaging units and outer packaging referred to in paragraph 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 paragraph 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 authorities. A Grand-Ducal regulation shall specify the conditions for the approval and inspection of these laboratories.'

Article 4g.

(1) Manufacturers and importers of electronic cigarettes and refill containers are required to submit a notification to the authorities 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 regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect:

d) information on the nicotine doses and uptake when consumed under normal or reasonably foreseeable 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, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;

g) a declaration that the producer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions;

h) proof of payment of the fee mentioned in paragraph 4.

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

This fee 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 authorities 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 authorities annually:

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

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

c) the mode of sale of the products;

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

The authorities shall monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately 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 consider 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 authorities 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 authorities on any aspect relating to the safety and quality or any possible undesirable effects of electronic cigarettes or refill containers.

(8) Upon request by the Commission or the competent authorities of the other Member States, the authorities shall make all the information received in accordance with this Article available to the Commission and to the other Member States of the European Union.

Where the authorities 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 Commission and the competent authorities of the other Member States of the measures taken and communicate any useful information in its possession.

Article 4h.

(1) The nicotine-containing liquid may only be placed on the market in specific refill containers with a maximum volume of 10 ml, in disposable electronic cigarettes or in single-use cartridges. Cartridges or tanks must not exceed 2 ml.

(2) The nicotine-containing liquid must not contain more than 20 milligrams of nicotine per millilitre.

(3) The ~~nicotine-containing~~ liquid shall not contain any additives listed in Article 7(3)(c) to (g).

(4) Only ingredients of high purity are used in the manufacture of the nicotine-containing liquid. Substances other than the ingredients referred to in point (b) of the third paragraph of Article 4g shall only be present in the nicotine-containing liquid in trace levels, if such traces are technically unavoidable during manufacture.

(5) Except for nicotine, only ingredients that do not pose a risk to human health in heated or unheated form shall be used in the nicotine-containing liquid.

(6) Electronic cigarettes shall deliver the nicotine doses at consistent levels under normal conditions of use.

(7) Electronic cigarettes and refill containers are child- and tamper-proof, are protected against breakage and leakage and have a mechanism that ensures refilling without leakage. They shall be protected against breakage and leaks and are equipped with a device to ensure that they do not leak when filled.

(8) A Grand-Ducal regulation may define the technical standards relating to the refilling mechanism provided for in paragraph 7.

(...)

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 free offer 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 packaging, is prohibited.

(2a)The number of cigarettes per unit packet must comply with the 5-piece multiplier condition. The quantities of unit packets for rolling tobacco are laid down by a Grand-Ducal regulation.

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

a) containing a particular characterising flavour;

b) containing any technical device for modifying the odour 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 that, without combustion, have carcinogenic, mutagenic or reproductive toxicity properties;

h) containing flavours in one of their components such as filters, paper, packaging and capsules, or any technical device enabling the odour or taste of the tobacco products concerned or their burning intensity to be modified. Filters, paper and capsules must not contain tobacco or nicotine.

Tobacco products other than cigarettes, cigars, cigarillos, new tobacco products and roll-your-own tobacco are exempt from the bans referred to in points a) and h).

Article 8.

(1) Manufacturers and importers of novel tobacco products and heating devices submit a notification to the Directorate 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 authorities 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 novels

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, executive summaries thereof and market research on the preferences of various consumer groups, including young people and current smokers;

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

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

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

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

(...)

Article 10.

Infringements of the provisions of Articles 3, 3a(1), 3b, 4a(1), 4b(5), 4d, 4e, 4f, 4g(1), (6) and (7), Article 4h and of Articles 7, 8(1) and Article 9 of this Law, as well as infringements of the provisions of the Grand Ducal regulation to be issued pursuant to Articles 4 and 4e thereof, are punishable by a fine of between EUR 251 and EUR 50 000.
Infringements of the provisions of Article 4a paragraph 2 and Article 6 of this Law are 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 paragraph 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 Investigation are applicable to the penalties provided for in the first paragraph of this article.

Article 10a.

"(1)Without prejudice to Article 10 of the Criminal Code, infringements of the provisions of this law shall be investigated and detected by officials of the Customs and Excise Administration with a rank of brigadier principal or 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.

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(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) The officials of the Customs and Excise Administration referred to in this Article must have undergone special professional training on the investigation and detection of offences, on the provisions of this Law and on the implementing regulations. The programme and duration of the training, as well as the assessment procedures shall be laid down by a Grand-Ducal regulation.

Article 11.

In the event of infringements ~~offences~~ punishable in accordance with the provisions of Article 4a(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 officials of the Customs and Excise Administration authorised for this purpose by the Director of the Customs and Excise Administration.

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 a standard penalty notice:

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

2. if the offender declares that they are 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(2).

Payment of the fee 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.

If the fee is paid after this deadline, it shall be refunded in case of acquittal, and deducted from the fine.