



EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Single Market Enforcement

Notification of Regulatory Barriers

Message 201

Communication from the Commission - TRIS/(2024) 0321

Directive (EU) 2015/1535

Notification: 2023/0405/LV

Forwarding of the response of the Member State notifying a draft (Latvia) to comments (5.2) of European Commission.

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1. MSG 201 IND 2023 0405 LV EN 03-10-2023 07-02-2024 LV ANSWER 03-10-2023

2. Latvia

3A. Ekonomikas ministrija

3B. Veselības ministrija

4. 2023/0405/LV - X00M - GOODS AND MISCELLANEOUS PRODUCTS

5.

6. The Responsible Authority (Ministry of Health) responds to the European Commission's comment as follows:

Regarding the EC's first comment on the amendment included in the draft law, according to which not only herbal smoking products that can be consumed via a combustion process, but also herbal smoking products that can be consumed via a heating process are covered by the definition of 'herbal smoking products', we point out that this amendment is included in the draft law to regulate heated herbal smoking products, as according to the information provided by the Latvian control authority: the Health Inspectorate, heated herbal smoking products have already entered the Latvian market, and none of them currently comply with the current definition of herbal smoking products in the Law On the Handling of Tobacco Products, Herbal Products for Smoking, Electronic Smoking Devices and Their Liquids ('the Tobacco Law'). As a result, restrictions laid down in the Tobacco Law (age limits, advertising restrictions, health warnings, etc.) cannot be applied to these products, and the Health Inspectorate cannot take the necessary control measures. The amendment included in the draft law does not stipulate that all herbal smoking products are to be classified only as heated in Latvia. The amendment included in the draft law only stipulates that according to the Latvian national law both products that can be consumed via a combustion process and products that can be consumed via a heating process can be classified as herbal smoking products. The amendment in the draft law aims to ensure that the same requirements and restrictions apply to products of plant origin with similar composition and definitions that only have different uses (combustion or heating). At the same time, we underline that, when assessing the amendments included in the draft law, the EC has not taken into account the definition of 'smoking' in the Tobacco Law (Section 1(26) of the Tobacco Law) that stipulates that the use of herbal smoking products (both via combustion and heating) should also be considered smoking. In the Tobacco Directive 2014/40/EU, no such separate definition of smoking is provided. At the same time, the EC has failed to take into account the amendment in Section 2(4) of the draft law that supplements Section 1(7) of the Tobacco Law with subparagraph (c), which defines an electronic heating device that is also intended for the use of herbal smoking products, thus providing that herbal smoking products can be also used in heating devices. At the same time, when discussing the clause of the draft law on heated herbal smoking products, no objections were raised by the industry regarding classification of the heated herbal smoking products as herbal smoking products in the Latvian law, accordingly, the same requirements would apply to them as those applied to herbal smoking products that can be consumed via a combustion process. We also underline that the amendment included in



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the draft law, i.e. to include both heated herbal smoking products and herbal smoking products that can be consumed via a combustion process in the definition of herbal smoking products will not cause any difficulties in classifying these products and taking the required control measures.

What concerns the second comment made by the EC, i.e. that MS should comply with the harmonised requirements laid down in the Tobacco Directive 2014/40/EU regarding the ingredients of electronic cigarettes, we point out that all requirements that apply to electronic cigarettes laid down in Article 20 of the Tobacco Directive 2014/40/EU, including with regard to ingredients, have already been transposed in the Latvian law, i.e. the Tobacco Law. We also draw your attention to the fact that the current requirements for ingredients of electronic cigarettes laid down in Article 20 of the Tobacco Directive 2014/40/EU are general and do not provide for a list of specific additives or ingredients. Article 20(3)(c) of the Tobacco Directive 2014/40/EU stipulates that nicotine-containing liquid does not contain the additives listed in Article 7(6), while Para (e) stipulates that except for nicotine, only ingredients that do not pose a risk to human health in heated or unheated form are used in the nicotine-containing liquid. Furthermore, currently at the EU level the Tobacco Directive 2014/40/EU does not prohibit the addition of flavourings (aromas) to liquids of electronic smoking devices. However, the Tobacco Directive 2014/40/EU gives Member States the right to adopt laws to allow or limit flavourings in electronic cigarettes (Recital 47 of Tobacco Directive 2014/40/EU). Please note that the draft law provides for a ban on placing on the market of liquids (both nicotine-containing and nicotine-free) of electronic smoking devices that contain flavourings, except flavourings that emulate the taste or aroma of tobacco. In addition, the draft law stipulates that the list of allowed flavourings emulating the taste or aroma of tobacco shall be included in an Annex listing the chemical names of specific substances. The list annexed to the draft law includes flavourings studied by the Dutch National Health Institute and used both in the Netherlands and other countries, such as Lithuania, for monitoring and controlling restrictions. The list drawn up by the Netherlands excluded all flavourings emulating the smell or taste of tobacco that produced a sweet taste and on which information was available in a publicly available database on the toxicity of their end ingredients. At the same time, as the Netherlands points out, although toxicity has been assessed for the substances included in that list, it cannot be claimed that those substances are completely safe if inhaled, since no advanced risk assessment of all of these substances has been made. These substances are, for example, used in food or cosmetics, but their impact on health has not been fully evaluated when inhaled. It should also be noted that there is currently a wide range of flavourings of electronic cigarette liquids available on the market, where flavourings used in the food chain or in cosmetics are mostly used, but no advanced risk assessment or risk assessment is made for most of these substances, when they are used in a heated form and inhaled. We point out that in the absence of a specific list of flavourings that emulate the taste or smell of tobacco annexed to the draft law, traders and manufacturers may be more prone not to comply with the agreed restriction as is confirmed by the experience of other countries that have restricted the addition of flavourings to liquids of electronic cigarettes. Accordingly, inclusion of such list in the Annex to the draft law will improve the monitoring of the provisions of the draft law, and the sellers of liquids for electronic smoking devices will also have uniform and clear requirements that will help to place only products that comply with the statutory requirements on the market.

European Commission

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