Unofficial Translation
12 July 2016, No. 132 (5704)

LATVIAN [coat of arms] HERALD

OFFICIAL PUBLICATION OF THE REPUBLIC OF LATVIA OP 2016/132.1

Cabinet Regulation No. 440

Riga, 5 July 2016 (Protocol Decision No. 33 17.§)

Procedure for the Submission and Processing of Information on Tobacco Products, Herbal Products for Smoking, Electronic Cigarettes and Associated Refill Containers

Issued pursuant to the second part of Section 5 of the Law on Trade in Tobacco Products, Herbal Smoking Products, Electronic Smoking Devices and Associated Liquids

I. General issue

This Regulation sets out:

1.1 the scope of information to be submitted on tobacco products, electronic cigarettes, refill containers and herbal products for smoking placed on the market;

1.2 the scope of information to be submitted on tobacco products, herbal products for smoking, electronic cigarettes, refill containers and novel tobacco products that are planned to be placed on the market or whose composition is modified;

1.3 procedures for the submission of information on tobacco products, herbal products for smoking, electronic cigarettes and refill containers and novel tobacco products by manufacturer or importers to the Health Inspectorate;

1.4 procedures for the storage, processing, analysis and publication by the Health Inspectorate of information on tobacco products, herbal products for smoking, electronic cigarettes and associated refill containers and novel tobacco products received from manufacturers or importers.

2. The manufacturer of the product concerned shall be responsible for the timely and accurate submission of the information referred to this Regulation, if the manufacturer engages in commercial activity in the European Union and the European Economic Area. If the manufacturer of the product concerned engages in commercial activity outside of the European Union and the European Economic Area and the importer of the product concerned engages in commercial activity in the European Union and the European Economic Area, the importer of the product concerned shall be responsible for submitting the information requested. If the manufacturer and importer of the product concerned engage in commercial activity outside of the European Union and the European Economic Area, the manufacturer and importer of the product concerned shall be responsible for submitting the information referred to in this Regulation.

II. Information to be submitted on tobacco products

3. Manufacturers and importers of tobacco products shall submit to the Health Inspectorate the following information by brand and type of tobacco product:

3.1 a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco product, in descending order of the weight of each ingredient included in the tobacco product. In addition, the following information is to be submitted with respect to the ingredients referred to in the list:

3.1.1 a statement setting out the reasons for the inclusion of the ingredients in the tobacco product;

3.1.2 the status of the ingredients, including whether they have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the registration, evaluation, authorization and restriction of chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as well as their classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006;

3.1.3 toxicological data regarding the ingredients in burnt or unburned form referring in particular to their effects on the health of consumers and taking into account all their addictive effects;

3.2 for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties;

3.3 emission levels for tar, nicotine and carbon monoxide;

3.4 information on emissions that are not tar, nicotine or carbon monoxide emissions and their levels, if such information is available, and also the methods used to measure these emissions.

4. In addition to the information referred to in point 3 of this Regulation, manufacturers and importers of tobacco products shall submit to the Health Inspectorate:

4.1 available studies about market research and choices in various consumer groups, including young people and regular smokers, relating to ingredients and emissions;

4.2 summaries of any market research carried out prior to the launching of new tobacco products.

5. Manufacturers and importers of tobacco products shall inform the Health Inspectorate, annually, of their sales volumes in the previous year per brand and type of tobacco product (in sticks or kilograms).

6. Manufacturers or importers shall also inform the Health Inspectorate whenever the composition of a tobacco product is modified in a way that can affect the information referred to points 3 and 4 of this Regulation.

7. The information referred in points 3 and 4 of this Regulation shall be submitted prior to the placing on the market of the new tobacco product and prior to the placing on the market of a tobacco product whose composition is modified.

8. In submitting the information referred in points 3 and 4 of this Regulation, manufacturers and importers shall indicate which information they consider to be a trade secret or otherwise confidential information, and shall, upon request of the Health Inspectorate, duly justify their claims.

9. The Health Inspectorate shall be entitled to request that manufacturers or importers carry out studies to assess the effect of tobacco product ingredients on health, taking into account their toxicity and addictiveness.

III. Enhanced reporting requirements for cigarettes and roll-your-own tobacco

10. Manufacturers and importers of cigarettes and roll-your-own tobacco for cigarettes and roll-your-own tobacco containing the additives referred to in Appendix 1 of this Regulation shall carry out comparative studies on each additive. The studies shall examine:

10.1 whether the additive contribues to the toxicity or addictiveness of the products concerned, and whether as a result the toxicity or addictiveness of the products concerned is increased to a significant or measurable degree;

10.2 whether the additive results in a characterizing flavor;

10.3 whether the additive facilitates nicotine inhalation or uptake;

10.4 whether the additive leads to the formation of substances that have carcinogenic, mutagenic or reprotoxic properties and that, reaching a set quantity, increase the carcinogenic, mutagenic or reprotoxic properties of the product concerned to a significant or measurable degree.

11. The studies referred to point 10 of this Regulation shall take into account the intended use of the product concerned and examine the emissions resulting from the combustion process involving the additive concerned, and also examine the interaction of that additive with other ingredients contained in the product concerned.

12. Manufacturers or importers using the same additive referred to Appendix 1 of this Regulation in their cigarettes or roll-your-own tobacco may carry out a joint study when using that additive in the composition of a comparable product.

13. Manufacturers or importers shall prepare a report on the results of the comparative studies carried out. That report shall include a summary and a comparative overview compiling the available scientific literature on the additive concerned and summarizing the study data on the effects of the additive.

14. Manufacturers or importers shall submit the report referred to point 13 of this Regulation to the European Commission and a copy thereof to the Health Inspectorate at the latest 18 months after the additive concerned has been included in the list included in Appendix 1 of this Regulation. The Health Inspectorate may also request that manufacturers or importers include supplementary information regarding the additive concerned in the report.

15. The Health Inspectorate may require the report referred to in point 13 of this Regulation to be peer reviewed by a scientific body, in particular as regards its comprehensiveness, methodology and conclusions. The manufacturers and importers shall pay the scientific body concerned for the peer review.

16. In submitting the report referred to in point 13 of this Regulation to the Health Inspectorate, manufacturers and importers shall specify which information contained in the report is to be considered to be a trade secret.

17. Small and medium-sized enterprises shall be exempted from the obligations to carry out comparative studies and prepare a report with the results of these studies, if a report on the additive concerned has already been prepared by another manufacturer or importer.

IV. Information to be submitted on electronic cigarettes and refill containers

18. Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the Health Inspectorate of electronic cigarettes and refill containers planned to be placed on the market. The notification shall be submitted six months prior to the intended placing on the market of the electronic cigarettes and refill containers, and also every time the composition of the electronic cigarettes and refill containers is substantially modified. The notification shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

18.1 the manufacturer, responsible legal or natural person with the European Union and importer into the European Union, and also contact information;

18.2 a list of ingredients and emissions, including quantities thereof, of the product concerned, by brand and type;

18.3 toxicological data regarding the product's ingredients and emissions, also when heated, including the effects of the ingredients and emissions on the health of consumers when inhaled and taking into account any addictive effect;

18.4 information on the nicotine doses and uptake when consumed under normal or foreseeable conditions;

18.5 a description of the product components, including the opening and refill mechanisms of the electronic cigarette or refill containers;

18.6 a description of the production process, including whether it involves series production, and a declaration that the production process of the product concerned ensures conformity with legislative requirements;

18.7 a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product placed on the market when used under normal or reasonably foreseeable conditions.

19. If the Health Inspectorate considers that the information submitted in accordance with point 18 of this Regulation is incomplete, it shall be entitled to request that the manufacturer or importer of the product concerned submit additional information.

20. Manufacturers and importers of electronic cigarettes and refill containers shall submit, annually, to the Health Inspectorate for the previous year:

20.1 information on sales volumes, by brand and type of the electronic cigarette and refill container;

20.2 information on which electronic cigarettes and refill containers are preferred by various consumer groups, including young people and non-smokers, showing also the main types of product users;

20.3 information on the mode of sale of electronic cigarettes and refill containers;

20.4 summaries of market surveys carried out in respect of the information referred to in sub-points 20.1, 20.2 and 20.3 of this Regulation, including an English translation thereof.

21. In submitting the information requested by this Regulation, manufacturers and importers of electronic cigarettes and refill containers shall indicate which information they consider to be a trade secret or otherwise confidential information, and shall, upon request, duly justify their claims.

V. Information to be submitted on herbal products for smoking

22. Prior to the placing on the market a new herbal product for smoking, manufacturers and importers shall submit to Health Inspectorate a list of all ingredients that are used in the manufacture of the herbal product for smoking concerned, and quantities thereof, by each brand and type of the herbal product for smoking.

23. Manufacturers and importers of an herbal product for smoking shall inform the Health Inspectorate when the composition of the herbal product for smoking is modified in a way that affects the information referred to in point 22 of this Regulation. The information shall be submitted prior to the placing on the market of the herbal product for smoking whose composition is modified.

24. In submitting to the Health Inspectorate the information referred in points 22 and 23 of this Regulation, manufacturers and importers of herbal products for smoking shall indicate which information they consider to be a trade secret.

VI. Information to be submitted on novel tobacco products

25. Manufacturers and importers shall submit an appropriate notification to the Health Inspectorate six months prior to the intended placing on the market of a novel tobacco product. The notification shall include:

25.1 a detailed description of the novel tobacco product;

25.2 instructions for use of the novel tobacco product;

25.3 information on the ingredients and emissions of the novel tobacco product in accordance with point 3 of this Regulation;

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

25.5 available studies, summaries thereof and market research on the choices made by various consumer groups, including young people and regular smokers;

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

26. Manufacturers and importers of novel tobacco products shall submit to the Health Inspectorate any new or updated information on the studies or market research and other information referred to in sub-points 25.4, 25.5 and 25.6 of this Regulation.

27. The Health Inspectorate shall be entitled to require manufacturers or importers of a novel tobacco product to carry out additional tests or submit additional information on the novel tobacco product about which notification is submitted.

VII. Procedures for the submission of information by manufacturers and importers of tobacco products (including novel tobacco products), herbal products for smoking, electronic cigarettes and refill containers

28. Manufacturers and importers shall submit to the Health Inspectorate the information on tobacco products, herbal products for smoking and also novel tobacco products referred to in this Regulation in accordance with the form provided for in Appendix 2 of this Regulation by means of the common electronic entry portal for data submission (hereinafter – portal).

29. Manufacturers and importers of electronic cigarettes and refill containers shall submit to the Health Inspectorate the information on electronic cigarettes and refill containers, including on modifications and removal from the market, referred to in this Regulation in accordance with the form provided for in Appendix 3 of this Regulation by means of the portal.

30. Prior to submitting information into the portal for the first time, the manufacturer or importer shall apply for a submitter identification number generated by the operator of the portal. The manufacturer or importer shall, upon request, upload to the portal a document providing the economic operator's identification and authentication of activities in accordance with the national legislation where commercial activity takes place. The same submitter identification number shall be used for subsequent submissions of information and in subsequent correspondence.

31. The manufacturer or importer shall assign a product identification number for each product that is reported. Based on the submitter identification number referred in point 30 of this Regulation, the product identification number for tobacco products shall be formed using the letter combination "TP-ID" and for electronic cigarettes and refill containers using the letter combination "EC-ID".

32. When submitting information on products with the same composition and design, manufacturers and importers shall, to the extent possible, use the same product identification number, in particular where data are submitted by various members of a group of companies. This condition shall apply regardless of brand, subtype and the number of countries in which they are placed on the market. Where the manufacturer or importer is not able to ensure that the same product identification numbers are used for products with the same composition and design, it shall at least provide, in so far as possible, the different product identification numbers that were assigned to such products.

VIII. Procedures for the processing, storage and publication of data

33. In accordance with this Regulation the Health Inspectorate shall store the information submitted via the portal by manufacturers and importers in the national data repository of the European Commission, ensuring that:

33.1 the information is available to the European Commission and other member states of the European Union and the European Economic Area;

33.2 confidentiality is respected when processing trade secrets and other confidential information.

34. The Health Inspectorate shall publish on its website information submitted by manufacturers and importers in accordance with sub-points 3.1, 3.3 and 3.4 and points 10, 18 and 22 of this Regulation. Information indicated by manufacturers and importers as trade secrets shall not be published.

35. Within the meaning of this Regulation, the following information submitted on tobacco products is not considered to be confidential information or a trade secret:

35.1 additives, other than flavorings, included in the composition of tobacco products, and the quantities thereof;

35.2 ingredients, other than additives, included in the composition of tobacco products in quantities above 0.5% of the total tobacco product unit weight, and the quantities thereof;

35.3 flavorings included in the composition of cigarettes and roll-your-own tobacco in quantities above 0.1% of the total tobacco product unit weight, and the quantities thereof;

35.4 flavorings included in the composition of pipe tobacco, cigars, cigarillos, smokeless tobacco products and all other tobacco products in quantities above 0.5% of the total tobacco product unit weight, and the quantities thereof;

35.5 studies and data submitted according to sub-points 3.1.3, 3.2 and 3.4 and point 9 of this Regulation, in particular on toxicity and addictiveness. Where those studies are linked to specific brands, the explicit and implicit references to the brand shall be removed and the redacted version shall be submitted.

36. Within the meaning of this Regulation the following information submitted on electronic cigarettes and refill containers is not considered to be confidential information or a trade secret:

36.1 ingredients used in quantities above 0.1% of the end composition of the liquid;

36.2 studies and data submitted according to point 18 of this Regulation, in particular on toxicity and addictiveness. Where those studies are linked to specific brands, the explicit and implicit references to the brand shall be removed and the redacted version shall be submitted.

IX. Concluding issues

37. For tobacco products placed on the market by 20 May 2016, the information referred to in points 3 and 4 of this Regulation shall be submitted by 20 November 2016.

38. For electronic cigarettes and refill containers placed on the market by 20 May 2016, the information referred to in point 18 of this Regulation shall be submitted by 20 November 2016.

39. The obligations referred to in points 13 and 14 to prepare and submit a report on the additives referred to in Appendix 1 of this Regulation shall be applied until 1 January 2017.

40. Manufacturers and importers of tobacco products shall submit the information referred to in point 5 of this Regulation for the first time in 2016 on sales volumes for 2015.

Informational reference to the European Union directive

This Regulation incorporates provisions of law from Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

Prime Minister *Maris Kucinskis*

Minister of Health *Anda Caksa*