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If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet

Regulation No. 440

Adopted 5 July 2016

**Procedures for Providing and Processing Information on Tobacco Products, Tobacco Substitute Products, Herbal Products for Smoking, Electronic Cigarettes, and Their Refill Containers**

[*18 June 2024*]

*Issued pursuant to*

*Section 5, Paragraph two and Section 5.1, Paragraph one of the Law on the Handling of Tobacco Products, Tobacco Substitute Products, Herbal Products for Smoking, Electronic Smoking Devices and Their Liquids*

[*18 June 2024*]

**I. General Provisions**

1. This Regulation prescribes:

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

1.2. the amount of information to be provided on tobacco products, herbal products for smoking, electronic cigarettes, refill containers, and novel tobacco products which are planned to be placed on the market or for which the composition is being altered;

1.3. the procedures by which manufacturers and importers of tobacco products, herbal products for smoking, electronic cigarettes and refill containers, and novel tobacco products shall provide information to the Health Inspectorate;

1.4. the procedures by which the Health Inspectorate shall store, process, analyse and publish the information received from manufacturers and importers of tobacco products, herbal products for smoking, electronic cigarettes and their refill containers, and novel tobacco products;

1.5. the procedures by which manufacturers and importers shall provide information on tobacco substitute products to the Health Inspectorate and the amount of information to be provided.

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2. The manufacturer of the relevant product shall be responsible for timely and accurate provision of the information referred to in this Regulation if he or she conducts commercial activity within the European Union and the European Economic Area. If the manufacturer of the relevant product conducts commercial activity outside of the European Union and the European Economic Area and the importer of the relevant product conducts commercial activity within the European Union and the European Economic Area, the importer of the product concerned shall be responsible for provision of the required information. If the manufacturer and importer of the product concerned conducts commercial activity outside of the European Union and the European Economic Area, the manufacturer and importer shall be responsible for the provision of the information referred to in this Regulation.

**II. Information to be Provided on Tobacco Products**

3. Manufacturers and importers of tobacco products shall provide information on each brand and type of a tobacco product to the Health Inspectorate in conformity with Annexes 2 and 4 to this Regulation (regarding Sub-paragraph 3.1.3), including:

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 shall be provided on the ingredients indicated in the list:

3.1.1. a statement setting out the reasons for the inclusion of such 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, Authorisation 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 under Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling 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 on the ingredients in burnt or unburnt form, referring in particular to their effects on the health of consumers and taking into account any 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 such emissions which are not tar, nicotine and carbon monoxide emissions, and their levels if such information is available, and also the methods used for the measurement of such emissions.

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

4.1. the studies available to them on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions;

4.2. executive summaries of any market surveys carried out when launching new product.

5. Manufacturers and importers of tobacco products shall each year report to the Health Inspectorate on the sales volumes in the previous year per brand and type of the tobacco product (in sticks or kilograms).

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

7. The information referred to in Paragraphs 3 and 4 of this Regulation shall be submitted prior to placing on the market of a novel tobacco product and also prior to placing on the market of such tobacco product the composition of which has been modified.

8. When providing the information referred to in Paragraphs 3 and 4 of this Regulation, manufacturers and importers shall indicate which information is considered a trade secret or otherwise confidential information by them, and shall appropriately justify their statements upon request of the Health Inspectorate.

9. The Health Inspectorate has the right to request that manufacturers or importers carry out studies in order to assess the effects of the ingredients contained in tobacco products on health, taking into account their addictiveness and toxicity.

9.1 Prior to placing cigarettes on the market, manufacturers and importers shall submit to the Health Inspectorate testing reports issued by accredited laboratories and an assessment certifying that the cigarettes conform to reduced ignition propensity requirements.

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**III. Enhanced Reporting Obligation on Cigarettes and Roll-your-own Tobacco**

10. Manufacturers and importers of cigarettes and roll-your-own tobacco shall carry out comparative studies on each additive for cigarettes and roll-your-own tobacco the composition of which includes the additives referred to in Annex 1 to this Regulation. The following shall be examined in these studies:

10.1. whether the additive contributes to the toxicity or addictiveness of the products concerned, and whether this has the effect of increasing the toxicity or addictiveness of the products concerned to a significant or measurable degree;

10.2. whether the additive results in a characterising flavour;

10.3. whether the additive facilitates inhalation or nicotine uptake;

10.4. whether the additive leads to the formation of substances that have carcinogenic, mutagenic or toxic for reproduction properties, and whether, upon reaching a specific quantity, this has the effect of increasing the carcinogenic, mutagenic or toxic for reproduction properties to a significant or measurable degree.

11. The studies referred to in Paragraph 10 of this Regulation shall take into account the intended use of the products 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 in Annex 1 to this Regulation in their cigarettes and roll-your-own tobacco may carry out a joint study if that additive is used in the composition of the comparable product.

13. Manufacturers or importers shall prepare a report on the results of the comparative studies carried out. The report shall include an executive summary and a comparative overview compiling the available scientific literature on that additive and summarising internal data on the effects of the additive.

14. Manufacturers or importers shall submit the report referred to in Paragraph 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 Annex 1 to this Regulation. The Health Inspectorate may also request the manufacturers or importers to include supplementary information on the additive concerned in the report.

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

16. When submitting the report referred to in Paragraph 13 of this Regulation to the Health Inspectorate, manufacturers and importers shall indicate which information included in the report is considered a trade secret.

17. Small and medium-sized enterprises shall be exempted from the obligation specified in this Regulation to carry out comparative studies and to prepare a report on the results of such studies if another manufacturer or importer has already prepared a report on the relevant additive.

**IV. Information to be Provided on Electronic Cigarettes and Refill Containers**

18. Manufacturers and importers of electronic cigarettes and refill containers shall submit a notification to the Health Inspectorate on the 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 an electronic cigarette or refill container, and also any time when the composition of the electronic cigarette or refill container is significantly modified. Depending on whether the product is an electronic cigarette or refill container, the notification shall include information in conformity with Annexes 3 and 4 to this Regulation (regarding Sub-paragraph 18.3), including:

18.1. the manufacturer, the responsible legal or natural person within the European Union, and the importer into the European Union, as well as contact details;

18.2. a list of all ingredients contained in and emissions resulting from the use of the product, by brand and type, including quantities thereof;

18.3. toxicological data on the product’s ingredients and emissions (including when heated), including effects of ingredients and emissions on the health of consumers when inhaled and taking into account their addictive effect;

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

18.5. a description of the components of the product, including the opening and refill mechanism of the electronic cigarette or refill container;

18.6. a description of the production process, including information on series production, and a declaration that the production process of the relevant product ensures conformity with the requirements of laws and regulations;

18.7. a declaration that the manufacturer 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;

18.8. a certification and testing report issued by an accredited laboratory:

18.8.1. on the quantitative and qualitative content of specified emissions in mass units;

18.8.2. on the nicotine doses delivered by an electronic cigarette at consistent levels under normal conditions of use.

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19. If the Health Inspectorate establishes that the information provided in accordance with Paragraph 18 of this Regulation is incomplete, it has the right to request that the manufacturer or importer of the relevant product supplements the provided information.

20. Each year manufacturers and importers of electronic cigarettes and refill containers shall submit the following to the Health Inspectorate for the previous year:

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

20.2. information on the preferences of various consumer groups, including young people, non-smokers, in relation to the electronic cigarettes and refill containers and indicating also the main types of product users;

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

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

21. When submitting the information requested in this Regulation, manufacturers and importers of electronic cigarettes and refill containers shall indicate which information is considered a trade secret or otherwise confidential information by them, and shall appropriately justify their statements upon request.

**IV.1 Information to be Provided on Tobacco Substitute Products**

[*18 June 2024*]

21.1 Manufacturers and importers of tobacco substitute products shall submit a notification to the Health Inspectorate on the tobacco substitute products which are planned to be placed on the market. The notification shall be submitted six months prior to the intended placement on the market in Latvia and also each time the composition of the tobacco substitute product is significantly modified. The notification shall include information in accordance with Annexes 3 and 4 to this Regulation (on Sub-paragraph 21.13), including:

21.11. the manufacturer, the responsible legal or natural person within the European Union, and the importer into the European Union, as well as contact details;

21.12. a list of all ingredients and quantities of the respective product by brand and type in milligrams;

21.13. toxicological data on the ingredients of the product, including information on the effects of the ingredients on the health of consumers, taking into account their potential addictive effect;

21.14. information on the nicotine doses and uptake when consumed under normal or foreseeable conditions of use;

21.15. a description of the production process, including information on series production, and a declaration that the production process of the relevant product ensures its conformity with laws and regulations;

21.16. a declaration that the manufacturer 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.

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21.2 If the Health Inspectorate establishes that the information provided in accordance with Paragraph 21.1 of this Regulation is incomplete, it has the right to request that the manufacturer or importer of the relevant product supplements the provided information.

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21.3 Manufacturers or importers of tobacco substitute products shall submit the following information on the previous year to the Health Inspectorate each year by no later than 1 July:

21.31. information on the sales volume of each brand and type of tobacco substitute product;

21.32. available information on the preferences for different tobacco substitute products among various consumer groups, including young people and non-smokers, also indicating the main types of product users;

21.33. information on the modes of sale of the tobacco substitute products;

21.34. executive summaries of any market surveys carried out in respect of the information referred to in Sub-paragraphs 21.11, 21.32, and 21.33 of this Regulation, including an English translation thereof.

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21.4 When submitting the information requested in this Regulation, manufacturers and importers of tobacco substitute products shall indicate which information is considered a trade secret or otherwise confidential information by them, and shall appropriately justify their statements upon request.

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**V. Information to be Provided on Herbal Products for Smoking**

22. Prior to placing on the market of a new herbal product for smoking, manufacturers and importers shall submit a list of any ingredients to the Health Inspectorate which are used in manufacture of the relevant herbal product for smoking, indicating their quantity by brand and type of the herbal product for smoking.

22.1 Herbal ingredients shall be indicated by the Latin name of the plant, the name of the plant part used, and the preparation method (finely chopped crude plant, extract, essential oil, powder). Information on herbal products for smoking shall be provided in accordance with Annex 2 to this Regulation.

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23. If the composition of the herbal product for smoking is modified in a way that affects the information referred to in Paragraph 22 of this Regulation, manufacturers and importers of the herbal product for smoking shall inform the Health Inspectorate thereof. Information shall be provided before the herbal product for smoking the composition of which has been modified is placed on the market.

24. When submitting the information referred to in Paragraphs 22 and 23 of this Regulation to the Health Inspectorate, manufacturers and importers of herbal products for smoking shall indicate which information is considered a trade secret.

24.1 The Health Inspectorate shall have the right to require that manufacturers or importers of herbal products for smoking carry out additional tests or submit additional information on the herbal product for smoking regarding which a notification is submitted.

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**VI. Information to be Provided on Novel Tobacco Products**

25. Manufacturers and importers shall submit a relevant notification to the Health Inspectorate six months prior to the intended placing on the market of a novel tobacco product in conformity with Annex 2 to this Regulation. 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 ingredients and emissions of the novel tobacco product in accordance with Paragraph 3 of this Regulation;

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

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

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

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

27. The Health Inspectorate has the right to require that manufacturers or importers of novel tobacco products carry out additional tests or submit additional information on the novel tobacco product regarding which a notification is submitted.

**VII. Procedures by which Manufacturers and Importers of Tobacco Products (Including Novel Tobacco Products), Tobacco Substitute Products, Herbal Products for Smoking, Electronic Cigarettes, and Refill Containers shall Provide Information and the Amount of Information to be Provided**

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28. The information referred to in this Regulation on tobacco products, herbal products for smoking, and also novel tobacco products shall be provided to the Health Inspectorate by manufacturers and importers in the form laid down in Annex 2 to this Regulation, using the Common Entry Gate EU-CEG intended for the provision of data (hereinafter – the portal).

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29. The information referred to in this Regulation on electronic cigarettes and refill containers, including on changes and removal from the market, shall be provided to the Health Inspectorate by manufacturers and importers of electronic cigarettes and refill containers in the form laid down in Annex 3 to this Regulation, using the portal.

30. Prior to the primary submission of information to the portal, a manufacturer or importer shall request an identification number of the submitter generated by the operator of the portal. The manufacturer or importer shall, upon request, upload a document to the portal containing the identification data of the merchant and a certification on the field of operation in accordance with the legal acts of such country in which commercial activity is conducted. The same identification number of the submitter shall be used for further provision of information and in further correspondence.

31. The manufacturer or importer shall assign an identification number of the product to each product reported. On the basis of the identification number of the submitter referred to in Paragraph 30 of this Regulation, the identification number of the product for tobacco products shall be created using the letter combination “TP-ID”, but for electronic cigarettes, refill containers, and tobacco substitute products – “EC-ID”.

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32. When submitting information on products with the same composition and design, manufacturers and importers shall, as much as possible, use the same identification number of the product, particularly in cases when data is submitted by different participants of a group of companies. This condition shall be applied regardless of the brand type and sub-type, and also regardless of the number of countries in which the products have been placed on the market. If the manufacturer or importer cannot ensure that the same identification numbers of products are used for products with the same composition and design, at least the different identification numbers of products assigned to the products shall be indicated as much as possible.

32.1 When submitting the information referred to in Paragraph 32 of this Regulation and adding a new presentation to the identification number of a previously notified product, the submitter shall inform the Health Inspectorate in writing:

32.11. on presentation parameters, attaching the certification form laid down in Annex 5 to this Regulation which applies to electronic cigarettes and refill containers;

32.12. on the product structure, submitting a drawing that specifies the product model, brand (brand name and sub-brand name), dimensions (indicated in millimetres), names of the depicted parts, date, and the details of the preparer or approver (company name, responsible employee’s given name, surname, and signature);

32.13. if necessary for the comparison of products notified in multiple presentations, the Health Inspectorate shall have the right to request to submit photographic documentation in which the respective products are shown in a single image alongside a ruler or caliper from at least two perspectives (front view and side view).

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**VIII. Procedures for Processing, Storing and Publishing Information**

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

33.1. information is available to the European Commission and other Member States of the European Union and of the European Economic Area;

33.2. confidentiality is ensured when processing a trade secret and other confidential information.

34. The Health Inspectorate shall publish the information which has been submitted by manufacturers and importers in accordance with Sub-paragraphs 3.1, 3.3, 3.4 and Paragraphs 10, 18, and 22 of this Regulation on its website. The information which has been indicated as a trade secret by manufacturers and importers shall not be published.

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

35.1. the additives included in the composition of tobacco products which are not flavourings, and their quantity;

35.2. the ingredients included in the composition of tobacco products which are not additives and the quantity of which exceeds 0.5 % of the total weight of a tobacco product unit, and their quantity;

35.3. the flavourings included in the composition of cigarettes and roll-your-own tobacco the quantity of which exceeds 0.1 % of the total weight of a tobacco product unit, and their quantity;

35.4. the flavourings included in the composition of pipe tobacco, cigars, cigarillos, smokeless tobacco products and any other tobacco products the quantity of which exceeds 0.5 % of the total weight of a tobacco product unit, and their quantity;

35.5. studies and data submitted in accordance with Sub-paragraphs 3.1.3, 3.2, and 3.4, and also Paragraph 9 of this Regulation, particularly on toxicity and addictiveness. If such studies are related to specific brands, direct and indirect references to the brand shall be removed and the edited version shall be submitted;

35.6. the ingredients used in quantities exceeding 0.1 % of the total weight of a unit of the herbal product for smoking, and their quantity.

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36. Within the meaning of this Regulation, the following information submitted on electronic cigarettes and refill containers, and also tobacco substitute products shall not considered to be confidential information or a trade secret:

36.1. the ingredients used in quantities exceeding 0.1 % of the total weight of the product without packaging material;

36.2. studies and data submitted in accordance with Paragraphs 18 and 21.1 of this Regulation, particularly on toxicity and addictiveness. If such studies are related to specific brands, direct and indirect references to brands shall be removed and the edited version shall be made available.

[*18 June 2024*]

**IX. Closing Provisions**

37. The information referred to in Paragraphs 3 and 4 of this Regulation on the tobacco products which have been placed on the market until 20 May 2016 shall be submitted until 20 November 2016.

38. The information referred to in Paragraph 18 of this Regulation on electronic cigarettes and refill containers which have been placed on the market until 20 May 2016 shall be submitted until 20 November 2016.

39. The obligation referred to in Paragraphs 13 and 14 of this Regulation to prepare and submit a report on the additives referred to in Annex 1 to this Regulation shall be applicable from 1 January 2017.

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

41. Tobacco substitute products that have been notified to the Health Inspectorate from 1 August 2024 to 1 September 2024 may be placed on the market from 1 January 2025.

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**Informative Reference to the European Union Directive**

This Regulation contains legal norms arising 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 Māris Kučinskis

Minister for Health Anda Čakša

**Annex 1**

Cabinet Regulation No. 440

5 July 2016

[*18 June 2024*]

**Priority List of Additives Used in Cigarettes and Roll-your-own tobacco Subject to Enhanced Reporting Obligations**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Additive | Chemical formula (if available) | Number of the chemical substance in the register of chemical substances (CAS number(s)) applicable to the substance (not exhaustive) |
| 1. | Carob bean |  | 9000-40-2,  84961-45-5 |
| 2. | Cocoa |  | 84649-99-0,  84649-99-3,  95009-22-6,  8002-31-1 |
| 3. | Diacetyl | C4H6O2 | 431-03-8 |
| 4. | Fenugreek |  | 68990-15-8,  977018-53-3,  84625-40-1 |
| 5. | Fig |  | 90028-74-3 |
| 6. | Geraniol | C10H18O | 106-24-1,  8000-46-2 |
| 7. | Glycerol | C3H8O3 | 56-81-5 |
| 8. | Guaiacol | C6H4(OH)(OCH3) | 90-05-1 |
| 9. | Guar gum |  | 9000-30-0 |
| 10. | Liquorice root |  | 68916-91-6 |
| 11. | Maltol | C6H6O3 | 118-71-8 |
| 12. | Menthol | C10H20O | 2216-51-5,  15356-60-2,  89-78-1,  1490-04-6,  8006-90-4,  68606-97-3,  84696-51-5,  8008-79-5 |
| 13. | Propylene glycol | C3H8O2 | 57-55-6 |
| 14. | Sorbitol | C6H14O6 | 50-70-4 |
| 15. | Titanium dioxide | TiO2 | 13463-67-7,  1317-70-0 |

**Annex 2**

Cabinet Regulation No. 440

5 July 2016

[*18 June 2024*]

**Electronic Form for Submission of Information on Tobacco Products**

**1. Field description**

1.1. All fields marked “M” in the electronic form for submission of information on tobacco products (hereinafter – the common format) are mandatory.

1.2. Fields marked “F” in the common format become mandatory if a specific response is selected from a previous variable.

1.3. Fields “AUTO” are automatically generated by the software system.

1.4. For fields in which the response is to be selected from a list, corresponding reference tables will be provided in the common format which will be maintained and published on the website of the European Commission.

**2. Characteristics of the manufacturer or importer responsible for the submitted data (hereinafter – the submitter)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Submitter\_ID | Submitter ID number (hereinafter – the submitter ID) assigned in accordance with Paragraph 30 of Cabinet Regulation No. 440 of 5 July 2016, Procedures for Providing and Processing Information on Tobacco Products, Tobacco Substitute Products, Herbal Products for Smoking, Electronic Cigarettes, and Their Refill Containers (hereinafter – the Regulation) | M |  |
|  | Submitter\_Name | Official name of the submitter at Member State level, as linked to the value added tax (hereinafter – VAT) number | M |  |
|  | Submitter\_SME | Indication whether the submitter or its parent undertaking (if any) is a small or medium-sized enterprise | M |  |
|  | Submitter\_VAT | VAT number of the submitter | M |  |
|  | Submitter\_Type | Indication whether the submitter is a manufacturer or importer | M |  |
|  | Submitter\_Address | Address of the submitter | M |  |
|  | Submitter\_Country | Country in which the submitter has its seat/domicile | M |  |
|  | Submitter\_Phone | Business phone of the submitter | M |  |
|  | Submitter\_Email | Functional business email address of the submitter | M |  |
|  | Submitter\_Has\_Parent\_Undertaking | Tick the box if the submitter has a parent undertaking | M |  |
|  | Submitter\_Has\_Affiliate\_Company | Tick the box if the submitter has an affiliate company | M |  |
|  | Submitter\_Appoints\_Enterer | Tick the box if the submitter has appointed a third party to submit data on its behalf (‘enterer’) | M |  |

**2.1. Characteristics of the parent undertaking of the submitter**

For the parent undertaking, the following information must be provided: submitter ID (if any), official name, address, country, business phone, and functional business email address.

**2.2. Affiliate company characteristics of the submitter**

For each affiliate, the following information must be provided: Submitter ID number (if any), official name, address, country, business phone and functional business email address.

**2.3. Enterer reporting on behalf of the submitter**

For the enterer, the following information must be provided: Submitter ID number (if any), official name, address, country, business phone and functional business email address.

**3. Product information submission and description**

**Part A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Submission\_Type | Type of submission for the product | M |  |
|  | Submission\_Start\_Date | Submission date will be filled in automatically when the user submits the information about the product | AUTO |  |
|  | Product\_ID\_(TP-ID) | the identification number of the product (TP-ID) used in the system in the following format: ‘submitter ID-year-product number’ (NNNNN-NN-NNNNN), where:  ‘submitter ID’ is the ID number of the submitter (see Paragraph 2);  ‘year’ is the year within which data on the product were submitted for the first time (2 digits);  ‘product number’ is the number attributed by the submitter to the product when submitting data for the first time | M |  |
|  | Product\_ID\_Other\_Exist | Indication whether the submitter is aware of another product(s) with the same design and composition that is marketed in the EU using a different TP-ID | M |  |
|  | Product\_ID\_Other | List TP-ID of the product(s) with same design and composition. If TP-ID of the product(s) is not known to the submitter, full brand and subtype name(s) as well as Member State(s) where product(s) is placed on the market shall at least be provided | F |  |
|  | Product\_Same\_Composition\_Exist | Indication whether the submitter is aware of another product(s) with the same proportion of ingredients in the tobacco blend composition | M |  |
|  | Product\_Same\_Composition\_Other | List TP-ID of the product(s) with the same proportion of ingredients in the tobacco blend composition. If TP-ID of the product(s) is not known to the submitter, full brand and subtype name(s) as well as Member State(s) where product(s) is placed on the market shall at least be provided | F |  |
|  | Product\_Type | Type of the respective tobacco product in accordance with Part 1 of Annex 6 to this Regulation | M |  |
|  | Product\_Length | Average length of the product unit in millimetres | F |  |
|  | Product\_Diameter | Average diameter (measured at the point with maximal diameter) of the product unit in millimetres | F |  |
|  | Product\_Weight | Weight of one product unit, including the moisture, in milligrams (one unit for loose tobacco is 1 gram) | M |  |
|  | Product\_Tobacco\_Weight | Total weight of the tobacco in one product unit in milligrams | M |  |
|  | Product\_Manufacturer\_Identification | If the submitter is not the manufacturer, the official company name(s) of the manufacturer(s) of the product, including its contact details shall be indicated (for each manufacturer, the following information must be provided: submitter ID number, if any, official name, address, country, business phone, and functional business e-mail address) | F |  |
|  | Product\_Filter | Existence of a filter in the product | F |  |
|  | Product\_Filter\_Length | Length of the product filter in millimetres | F |  |
|  | Product\_Production\_Site\_Address | For each manufacturer, address(es) of the site(s) where production is completed | M |  |
|  | Product\_Technical\_File | Technical document setting out a general description of the additives used and their properties | F | |
|  | Product\_Market\_Research\_File | Studies on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, available to submitter as well as executive summaries of any market surveys carried out when launching new products. To be updated in case new data become available | M |  |

**Part B**

Where products are presented for sale in different formats or where the same product is presented for sale in different Member States, the following variables must be completed for each format and each Member State:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Product\_Brand\_Name | Brand name under which the product is marketed in the Member State to which information is being submitted. | M |  |
|  | Product\_Brand\_Subtype\_Name | Product ‘subtype name’ (if any) as marketed in the Member State to which the product information is being submitted | M |  |
|  | Product\_Launch\_Date | Date on which the submitter plans to launch/launched the product on the market | M |  |
|  | Product\_Withdrawal\_Indication | Indication that the submitter plans to withdraw/withdrew the product from the market | M |  |
|  | Product\_Withdrawal\_Date | Date on which the submitter plans to withdraw/withdrew the product from the market | F |  |
|  | Product\_Submitter\_Number | ID number used internally by the submitter | M  At least one of those numbers must be used consistently for all submissions made by a single submitter |  |
|  | Product\_UPC\_Number | Universal Product Code (UPC-12) of the product |  |
|  | Product\_EAN\_Number | European Article Number (EAN-13 or EAN-8) of the product |  |
|  | Product\_GTIN\_Number | Global Trade Identification Number (GTIN) of the product |  |
|  | Product\_SKU\_Number | Stock Keeping Unit (SKU) number(s) of the product |  |
|  | Product\_National\_Market | Member State to which the product information below is being provided | M |  |
|  | Product\_Package\_Type | Type of product package | M |  |
|  | Product\_Package\_Units | Number of individual product units in the unit packet | M |  |
|  | Product\_Package\_Net\_Weight | Net weight of one unit packet in grams | F |  |
|  | Product\_Sales\_Volume | Information on annual sales volume of the product per Member State to be reported annually in product units or in kilograms loose tobacco | M |  |
|  | Product\_Other\_Market\_Data | Supplementary market data available to the submitter on the market and, in relation to cigarettes, a file containing a testing report along with an assessment demonstrating that the cigarettes have been tested and conform to reduced ignition propensity requirements in accordance with the standards specified in Section 4, Paragraph 2.1 of the Law on the Handling of Tobacco Products, Tobacco Substitute Products, Herbal Products for Smoking, Electronic Smoking Devices and Their Liquids.  To be updated in case new data become available | F |  |
|  | File containing an image of the unit packet of product presentation | Image of the unit packet. The image must be clear enough to display details and enable the identification of unique product presentations |  |  |

**4. Description of ingredients: tobacco1**

For each of the tobacco ingredients used in the product, the following variables must be completed for each combination of leaf cure method, leaf type and part type.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Tobacco\_Part\_Type | Type of tobacco plant part (see definition of tobacco under the Law on the Handling of Tobacco Products, Tobacco Substitute Products, Herbal Products for Smoking, Electronic Smoking Devices and Their Liquids) | M |  |
|  | Tobacco\_Part\_Type\_Other | Name of the tobacco part type if ‘other’ | F |  |
|  | Tobacco\_Part\_Description\_File | General description of the manufactured part type in the recipe. The description must provide detailed information on the quantitative and qualitative composition of the manufactured tobacco | F |  |
|  | Tobacco\_Part\_Manufactured\_Supplier | For each supplier, the official company name(s) including its contact details. For each supplier, the following information must be provided: Submitter ID (if any), official name, address, country, business phone and functional business email address | F |  |
|  | Tobacco\_Leaf\_Type | Type of tobacco leaf used | M |  |
|  | Tobacco\_Leaf\_Type\_Other | Name or description of the tobacco leaf type if ‘other’ or ‘unspecified’ | F |  |
|  | Tobacco\_Leaf\_Cure\_Method | Method used to cure the tobacco leaf | M |  |
|  | Tobacco\_Leaf\_Cure\_Method\_Other | Name or description of the cure method used if ‘other’ | F |  |
|  | Tobacco\_Quantity | Weight per product unit in milligrams | M |  |

**5. Description of ingredients: additives and other substances/elements**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Ingredient\_Category | Category of product component (e.g. filters, papers etc.) | M |  |
|  | Ingredient\_Category\_Other | The category of product component if ‘other’ | F |  |
|  | Ingredient\_Name | Chemical name of the ingredient | M |  |
|  | Ingredient\_CAS | CAS (Chemical Abstracts Service) (hereinafter – CAS) number | M |  |
|  | Ingredient\_Additional\_CAS | Additional CAS numbers if applicable | F |  |
|  | Ingredient\_FEMA\_Number | Flavour and Extract Manufacturers Association (hereinafter – FEMA) number (if any) | F  If a CAS number does not exist, at least one of those four numbers must be indicated. If more than one number is indicated, those numbers must be indicated in the following order of importance FEMA>Additive>FL>EC |  |
|  | Ingredient\_Additive\_Number | If the ingredient is a food additive, its food additive ‘E number’ set out in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives |  |
|  | Ingredient\_FL\_Number | European Flavouring (FL) number, if any, as set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC |  |
|  | Ingredient\_EC\_Number | European Community (EC) number, if any |  |
|  | Ingredient\_Quantity\_Fluctuate | Indication whether the ingredient quantity fluctuates across production batches | M |  |
|  | Ingredient\_Recipe\_Quantity | Standard weight of the ingredient included in one product unit in milligrams according to recipe | M |  |
|  | Ingredient\_Recipe\_Range\_Min\_Level | Indication of the lowest weight (milligrams) of the ingredient in one product unit according to recipe, if the declared quantity fluctuates in order to adjust for the natural variations of the tobacco leaf | F |  |
|  | Ingredient\_Recipe\_Range\_Max\_Level | Indication of the highest weight (milligrams) of the ingredient in one product unit according to recipe, if the declared quantity fluctuates in order to adjust for the natural variations of the tobacco leaf | F |  |
|  | Ingredient\_Measured\_Mean\_Quantity | Weight of the ingredient in mg that was actually added per product unit during the reporting period (calculated in the form of the statistical mean of the quantities of that ingredient added to each produced standardised batch) | F |  |
|  | Ingredient\_Measured\_SD | Statistically derived standard deviation of the mean quantity of ingredient added per product unit within each standardised batch | F |  |
|  | Ingredient\_Measured\_Number | Number of measurements considered | F |  |
|  | Ingredient\_Function | Function(s) of the ingredient | M |  |
|  | Ingredient\_Function\_Other | Function of the ingredient if ‘other’ | F |  |
|  | Ingredient\_Priority\_Additive | Indication whether the ingredient is part of the list of additives included in Annex 1 to the Regulation | M |  |
|  | Ingredient\_Priority\_Additive\_Files | Copies of the report(s) which 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 | F |  |
|  | Ingredient\_Unburnt\_Status | Indication whether the ingredient in unburnt form is characterised by any known type of toxicity or has carcinogenic, mutagenic or toxic for reproduction properties | M |  |
|  | Ingredient\_REACH\_Registration | Ingredient registration number pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation 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, if any | M |  |
|  | Ingredient\_CLP\_Whether\_Classification | Indication whether the substance has been classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, and is included in the classification and labelling inventory | M |  |
|  | Ingredient\_CLP\_Classification | Ingredient classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, and is included in the classification and labelling inventory | F |  |
|  | Ingredient\_Tox\_Data | Availability of toxicological data, concerning a substance, either in isolation or as part of a mixture. In each case, specify whether the toxicological data relate to the substance in burnt or unburnt form | M |  |
|  | Ingredient\_Tox\_Emission | Existence of studies that indicate the chemistry and/or toxicity of emissions | F/M |  |
|  | Ingredient\_Tox\_CMR | Existence of any study relating to the carcinogenicity, mutagenicity or toxicity for reproduction of the ingredient (hereinafter – CMR) | F/M |  |
|  | Ingredient\_Tox\_CardioPulmonary | Existence of *in vitro* and *in vivo* assays to evaluate the toxicological effects of the ingredient on the heart, blood vessels or respiratory tract | F/M |  |
|  | Ingredient\_Tox\_Addictive | Existence of an analysis of the possible addictive properties of the ingredient | F/M |  |
|  | Ingredient\_Tox\_Other | Existence of any other toxicological data not stated above | F/M |  |
|  | Ingredient\_Tox/Addictive\_File | Upload available studies indicated in the previous six fields (Ingredient Tox Data, Emission, CMR, CardioPulmonary, Addictive, Other) in accordance with the format specified in Annex 4 to this Regulation | F/M |  |

**6. Tar, nicotine and carbon monoxide emissions and other emissions**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Emission\_Tar | Tar yield according to the standard LVS ISO 4387 “Cigarettes – Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine” with the accuracy of measurements determined in accordance with the standard LVS ISO 8243 “Cigarettes – Sampling” | F |  |
|  | Emission\_Nicotine | Nicotine yield according to the standard LVS ISO 10315 “Cigarettes – Determination of nicotine in smoke condensates – Gas-chromatographic method” with the accuracy of measurements determined in accordance with the standard LVS ISO 8243 “Cigarettes – Sampling” | F |  |
|  | Emission\_CO | Carbon monoxide yield according to the standard LVS ISO 8454+A1 “Cigarettes – Determination of carbon monoxide in the vapour phase of cigarette smoke – NDIR method” with the accuracy of measurements determined in accordance with the standard LVS ISO 8243 “Cigarettes – Sampling” | F |  |
|  | Emission\_TNCO\_Lab | Identification of the laboratory/laboratories used to measure emissions of tar, nicotine and carbon monoxide | F |  |
|  | Emission\_Other\_Available | Indication as to whether other emissions have been measured (for each ‘other emission’ measured, all ‘Emission\_Other’ fields in this section must be completed) | M |  |
|  | Emission\_Other\_Methods\_File | Description of the measurement methods used to assess the other emission | F |  |
|  | Emission\_Other\_Name | Chemical name of the other emission produced during the testing of the product | F |  |
|  | Emission\_Other\_CAS | CAS number of the other emission | F |  |
|  | Emission\_Other\_IUPAC | International Union of Pure and Applied Chemistry (IUPAC) name of the other emission, should a CAS number not exist | F |  |
|  | Emission\_Other\_Quantity | Quantity of the other emission produced during the process of using the product, based on the measurement method used | F |  |
|  | Emission\_Other\_Units | Unit in which the other emission is measured | F |  |

**7. Cigarette specific (M and F in this section apply only to cigarettes)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Cigarette\_Characterising\_Flavour | Classification of the cigarettes having a characterising flavour as referred to in Paragraph 4 of the Transitional Provisions of the Law on the Handling of Tobacco Products, Tobacco Substitute Products, Herbal Products for Smoking, Electronic Smoking Devices and Their Liquids | M |  |
|  | Cigarette\_Filter\_Ventilation | Total ventilation of the filter (0–100 %) | M |  |
|  | Cigarette\_Filter\_Drop\_Pressure\_Closed | Drop of pressure with closed vents (mmH2O) | M |  |
|  | Cigarette\_Filter\_Drop\_Pressure\_Open | Drop of pressure with open vents (mmH2O) | M |  |

**8. Smokeless (chewing tobacco, nasal tobacco, and tobacco for oral use) specific (M and F in this section apply only to smokeless products)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Smokeless\_pH | pH of the product | M |  |
|  | Smokeless\_Nicotine\_Content | Total nicotine content of the product per product unit | M |  |

**9. Roll-your-own and pipe tobacco specific (M and F in this section apply only to roll-your-own and pipe tobacco)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field | Field | Description | Reporting | Submitter considers information confidential |
|  | Roll-your-own/pipe\_Total\_Nicotine\_Content | Total nicotine content of the loose product per product unit | M |  |

**10. Specific information on novel tobacco product**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field | Field | Description | Reporting | Submitter considers information confidential |
|  | Novel\_Detailed\_Description\_File | A PDF file describing the available scientific studies on the toxicity, addictiveness, and attractiveness of the novel tobacco product, particularly concerning its ingredients and emissions | M |  |
|  | Novel\_User Instruction File | A PDF file describing the available scientific studies, their executive summaries, and market surveys on the preferences among various consumer groups, including young people and current smokers | M |  |
|  | Novel\_Risk/Benefit\_File | A PDF file describing other available and relevant information, including a risk/benefit analysis of the product, its expected impact on tobacco cessation, its expected impact on tobacco use initiation, and the expected consumer perception | M |  |
|  | Novel\_Study | Other available studies/information that are specified in Part VI of this Regulation and have not been submitted in the previously mentioned data fields | M |  |

1Does not apply to herbal products for smoking.

**Annex 3**

Cabinet Regulation No. 440

5 July 2016

[*18 June 2024*]

**Electronic Form for Submission of Information on Electronic Cigarettes, Refill Containers, and Tobacco Substitute Products**

**1. Field description**

1.1. All fields marked “M” in the electronic form for submission of information on electronic cigarettes, refill containers, and tobacco substitute products are to be filled in mandatory.

1.2. Filter dependent mandatory fields “F” become mandatory if a specific response is selected from a previous variable.

1.3. Fields “AUTO” are automatically generated by the software system.

1.4. For fields in which the response is to be selected from a list, corresponding reference tables will be provided, maintained and published on a European Commission website.

**2. Characteristics of the manufacturer or importer responsible for the submitted data (hereinafter – the submitter)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Submitter\_ID | Submitter ID number (hereinafter – the submitter ID) attributed in accordance with Paragraph 30 of Cabinet Regulation No. 440 of 5 July 2016, Procedures for Providing and Processing Information on Tobacco Products, Tobacco Substitute Products, Herbal Products for Smoking, Electronic Cigarettes, and Their Refill Containers (hereinafter – the Regulation) | M |  |
|  | Submitter\_Name | Official name of the submitter at Member State level, as linked to the value added tax (hereinafter – VAT) number | M |  |
|  | Submitter\_SME | Indication whether the submitter or its parent undertaking (if any) is a small or medium-sized enterprise | M |  |
|  | Submitter\_VAT | VAT number of the submitter | M |  |
|  | Submitter\_Type | Indication whether the submitter is a manufacturer or importer | M |  |
|  | Submitter\_Address | Address of the submitter | M |  |
|  | Submitter\_Country | Country in which the submitter has its seat/domicile | M |  |
|  | Submitter\_Phone | Business phone of the submitter | M |  |
|  | Submitter\_Email | Functional business email address of the submitter | M |  |
|  | Submitter\_Has\_Parent\_Undertaking | Tick the box if the submitter has a parent undertaking | M |  |
|  | Submitter\_Has\_Affiliate\_Company | Tick the box if the submitter has an affiliate company | M |  |
|  | Submitter\_Appoints Enterer | Tick the box if the submitter has appointed a third party to submit its data on its behalf (‘enterer’) | M |  |

**2.1. Characteristics of the parent undertaking of the submitter**

For the parent undertaking, the following information must be provided: submitter ID (if any), official name, address, country, business phone, and functional business email address.

**2.2. Affiliate company characteristics of the submitter**

For each affiliate, the following information must be provided: Submitter ID number (if any), official name, address, country, business phone and functional business email address.

**2.3. Enterer reporting on behalf of the submitter**

For the enterer, the following information must be provided: Submitter ID number (if any), official name, address, country, business phone and functional business email address.

**3. Product information provision and description**

**Part A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Submission\_Type | Type of submission for the product | M |  |
|  | Submission\_Start\_Date | Submission date will be filled in automatically by the system when the user submits the information about the product | AUTO |  |
|  | Product\_ID (EC-ID) | EC-ID is the identification number of the product used in the system in the format ‘submitter ID-year-product number’ (NNNNN-NN-NNNNN), where:  ‘submitter ID’ is the ID number of the submitter (see Paragraph 2);  ‘year’ is the year within which data on the product were submitted for the first time (2 digits);  ‘product number’ is the number attributed by the submitter to the product when submitting data for the first time | M |  |
|  | Product\_ID\_Other\_Exist | Indication whether the submitter is aware of other product(s) with the same design and composition that is marketed in the EU using a different EC-ID | M |  |
|  | Product\_ID\_Other | List EC-ID of the product(s) with same design and composition. If EC-ID of the product(s) is not known to the submitter, full brand and subtype name(s) as well as Member State(s) where product(s) is placed on the market shall at least be provided | F |  |
|  | Product\_Same\_Composition\_Exist | Indication whether the submitter is aware of other product(s) with the same composition of liquid containing nicotine (hereinafter – e-liquid), but different design | M |  |
|  | Product\_Same\_Composition\_Other | List EC-ID of the product(s) with the same composition of e-liquid but different design. If EC-ID of the product(s) is not known to the submitter, brand and subtype name(s) as well as Member State(s) where product(s) is placed on the market shall at least be provided | F |  |
|  | Product\_Type | Type of the respective product in accordance with Part 2 of Annex 6 to this Regulation | M |  |
|  | Product\_Weight\_E-liquid | Total weight of e-liquid in one product unit in milligrams  Weight of the tobacco substitute product (chemical mixture) in the product unit in milligrams | F |  |
|  | Product\_Volume\_E-liquid | Total volume of e-liquid in one product unit in millilitres | F |  |
|  | Product\_Manufacturer\_Identification | If the submitter is not the manufacturer, the official company name(s) of the manufacturer(s) of the product including its contact details (for each manufacturer, the following information is to be provided: ID number if any, official name, address, country, business phone and functional business email) | F |  |
|  | Product\_Production\_Site\_Address | For each manufacturer, address(es) of the site(s) where production is completed | M |  |
|  | Product\_CLP\_Classification | Overall product classification (including labelling elements) as a mixture of substances based on Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 and as described in the ‘Guidance on the Application of the Classification, Labelling and Packaging Criteria’ | F |  |

**Part B**

Where the products are presented for sale in different formats or where the same product is presented for sale in different Member States, the following information must be provided for each format and each Member State:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Product\_Brand\_Name | Brand name under which the product is marketed in the Member State to which information is being submitted | M |  |
|  | Product\_Brand\_Subtype\_Name | Product ‘subtype name’ (if any) as marketed in the Member State to which the product information is being submitted | M |  |
|  | Product\_Launch\_Date | The date on which the submitter plans to launch/launched the product on the market | M |  |
|  | Product\_Withdrawal\_Indication | Indication that the submitter plans to withdraw/withdrew the product from the market | M |  |
|  | Product\_Withdrawal\_Date | Date on which the submitter plans to withdraw/withdrew the product from the market | F |  |
|  | Product\_Submitter\_Number | ID number used internally by the submitter | M  At least one of those numbers must be used consistently for all submissions made by a single submitter |  |
|  | Product\_UPC\_Number | Universal Product Code (UPC-12) of the product |  |
|  | Product\_EAN\_Number | European Article Number (EAN-13 or EAN-8) of the product |  |
|  | Product\_GTIN\_Number | Global Trade Identification Number (GTIN) of the product |  |
|  | Product\_SKU\_Number | Stock Keeping Unit (SKU) number(s) of the product |  |
|  | Product\_National\_Market | Member State to which the product information is being provided | M |  |
|  | Product\_Package\_Units | Number of individual units in the unit packet | M |  |

**4. Description of ingredients contained in the product**

For each ingredient used in the product, variables in the following section shall be completed (M and F in this section applies only for product types where applicable). In the case of products containing more than one item with ingredients, the following variables must be completed for each of these items.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Ingredient\_Name | Chemical name of the ingredient | M |  |
|  | Ingredient\_CAS | CAS (Chemical Abstracts Service) (hereinafter – CAS) number | M |  |
|  | Ingredient\_Additional\_CAS | Additional CAS numbers if applicable | F |  |
|  | Ingredient\_FEMA\_Number | Flavour and Extract Manufacturers Association (hereinafter – FEMA) number if any | F  If a CAS does not exist, at least one of those four numbers must be indicated. If more than one number is indicated, those numbers must be indicated in the following order of importance FEMA>Additive> FL>EC |  |
|  | Ingredient\_Additive\_Number | If the ingredient is a food additive, its food additive ‘E number’ set out in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives |  |
|  | Ingredient\_FL\_Number | European Flavouring (FL) number, if any, as set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC |  |
|  | Ingredient\_EC\_Number | European Community (EC) number, if any |  |
|  | Ingredient\_Function | Function(s) of the ingredient | M |  |
|  | Ingredient\_Function\_Other | Function of the ingredient if ‘other’ | F |  |
|  | Ingredient\_Recipe\_Quantity | Weight of the ingredient included in one product unit in milligrams according to recipe | M |  |
|  | Ingredient\_Non\_Vaporised\_Status | Indication whether the ingredient in non-vaporised form is characterised by a known type of toxicity or has carcinogenic, mutagenic or toxic for reproduction properties | M |  |
|  | Ingredient\_REACH\_Registration | Registration number pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation 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, if any | M |  |
|  | Ingredient\_CLP\_Whether\_Classification | Indication whether the substance has been classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation No 1907/2006 and is in the classification and labelling inventory | M |  |
|  | Ingredient\_CLP\_Classification | Ingredient classification with regard to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 | F |  |
|  | Ingredient\_Tox\_Data | Availability of toxicological data, concerning a substance, either in isolation or as part of a mixture. In each case, specify whether the toxicological data relate to the substance in heated or unheated form | M |  |
|  | Ingredient\_Tox\_Emission | Existence of studies that inform about the chemistry and/or toxicity of emissions | F/M |  |
|  | Ingredient\_Tox\_CMR | Existence of any study relating to the carcinogenicity, mutagenicity or toxicity for reproduction of the ingredient (hereinafter – CMR) | F/M |  |
|  | Ingredient\_Tox\_CardioPulmonary | Existence of *in vitro* and *in vivo* assays to evaluate the toxicological effects of the ingredient on the heart, blood vessels or respiratory tract | F/M |  |
|  | Ingredient\_Tox\_Addictive | Existence of an analysis of the possible addictive properties of the ingredient | F/M |  |
|  | Ingredient\_Tox\_Other | Existence of any other toxicological data not stated above | F/M |  |
|  | Ingredient\_Tox/Addictive\_File | Upload available studies indicated in the previous six fields (Ingredient Tox Data, Emission, CMR, CardioPulmonary, Addictive, Other) in accordance with the format specified in Annex 4 to this Regulation | F/M |  |

**5. Emissions**

Where multiple emissions have been measured, variables in the following sections are requested for each individual emission. In the case of products containing more than one item or more than one combination of an e-cigarette or refill container, the following variables must be completed for each of these items or combinations.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting | Submitter considers information confidential |
|  | Emission\_Test\_Product\_EC-ID | If the product requires an additional product(s) for use, the EC-ID of the additional product(s) used to carry out the tests must be provided. If EC\_ID of the additional product(s) is not known to the submitter, brand and subtype name(s) as well as Member State(s) where product is placed on the market shall at least be provided | F |  |
|  | Emission\_Product\_Combination | If the product contains more than one item or more than one combination of an e-cigarette or refill container, specification of the item or combination used to measure the emission | F |  |
|  | Emission\_Methods\_File | Description of the measurement methods used to assess the emissions, including reference to the relevant approved standard, when available | M |  |
|  | Emission\_Name | Name of the emission produced during the testing of the product | M |  |
|  | Emission\_CAS | CAS number of emissions | F |  |
|  | Emission\_IUPAC | International Union of Pure and Applied Chemistry (hereinafter – IUPAC) name of emissions shall be provided, should a CAS number not exist | F |  |
|  | Emission\_Quantity | Quantity of emissions produced during the process of using the product based on the measurement method used | M |  |
|  | Emission\_Units | Unit in which the emission is measured | F |  |

**6. Product design**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting for e-cigarettes | Submitter considers information confidential | Reporting for refill containers and tobacco substitute products | Submitter considers information confidential |
|  | E-Cigarette\_Description | Description of the product to facilitate unique product identification, including a description of all items and the individual parts (components/e-liquid) | M |  | M |  |
|  | E-Cigarette\_Liquid\_Volume/Capacity | Volume/capacity in millilitres (for devices, indicate tank size, for cartridges/cartomisers or for refill container actual volume when placed on the market) | M |  | M |  |
|  | E-cigarette\_Nicotine\_Concentration | Nicotine concentration in milligrams/millilitres | F |  | M |  |
|  | E-Cigarette\_Battery\_Type | Description of the battery type | F |  | Not applicable |  |
|  | E-Cigarette\_Battery\_Type\_Capacity | Indication of the battery capacity in mAh | F |  | Not applicable |  |
|  | E-Cigarette\_Volt/Watt\_Adjustable | Indication whether the e-cigarette is voltage/wattage adjustable | M |  | Not applicable |  |
|  | E-Cigarette\_Voltage | Nominal voltage of the e-cigarette if non-adjustable. Recommended voltage of the e-cigarette if adjustable | F |  | Not applicable |  |
|  | E-Cigarette\_Voltage\_Lower\_Range | Lowest voltage obtainable | F |  | Not applicable |  |
|  | E-Cigarette\_Voltage\_Upper\_Range | Highest voltage obtainable | F |  | Not applicable |  |
|  | E-Cigarette\_Wattage | Nominal wattage output if non-adjustable. Recommended wattage output if adjustable | F |  | Not applicable |  |
|  | E-Cigarette\_Wattage\_Lower\_Range | Lowest wattage obtainable | F |  | Not applicable |  |
|  | E-Cigarette\_Wattage\_Upper\_Range | Highest wattage obtainable | F |  | Not applicable |  |
|  | E-cigarette\_Airflow\_Adjustable | Indication whether the airflow of the e-cigarette is adjustable | M |  | Not applicable |  |
|  | E-Cigarette\_Wick\_Changeable | Indication whether the consumer may adjust/alter/replace the wick | M |  | Not applicable |  |
|  | E-Cigarette\_Microprocessor | Indication whether the e-cigarette contains a microprocessor | M |  | Not applicable |  |
|  | E-Cigarette\_Coil\_Composition | Chemical composition of the wiring (coil) in the atomiser | M |  | Not applicable |  |
|  | E-Cigarette\_Nicotine\_Dose/Uptake\_File | Description of the measurement methods used to assess consistent dosing and nicotine uptake, including reference to the relevant approved standard, when available. Description of the outcomes of the assessment | M |  | M |  |
|  | E-Cigarette\_Production\_File | Description of the final production process, including series production | M |  | M |  |
|  | E-Cigarette\_Production\_Conformity | Declaration that the production process ensures conformity (including but not limited to information on series production) | M |  | M |  |
|  | E-Cigarette\_Quality\_Safety | Declaration that the manufacturer 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 | M |  | M |  |
|  | E\_Cigarette\_Opening/Refill\_File | Description of the opening and refill mechanism, where applicable | F |  | M |  |
|  | File of the packaging and information leaflet, user instructions | Consumer information provided on the packaging and in the information leaflet (PDF or scanned file) | M |  | M |  |

**7. Sales data on the previous calendar year**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Field # | Field | Description | Reporting for e-cigarettes | Submitter considers information confidential | Reporting for refill containers and tobacco substitute products | Submitter considers information confidential |
|  | Product Presentation\_Sales Volume | Information on the sales volume of the product in the Member State per year shall be reported in product units | M |  | M |  |
|  | Product\_Presentation\_Sales\_Year | Calendar year for which the annual sales volume is reported | M |  | M |  |

**Annex 4**

Cabinet Regulation No. 440

5 July 2016

[*18 June 2024*]

**Minimally Required Information on the Toxicological Data of the Ingredient**

**Toxicological data on [name of the submitted ingredient]**

1. Name of the ingredient (IUPAC).

2. CAS/EC number of the ingredient.

3. Toxic properties of the ingredient (in its unburned/unheated form).

4. Changes in the toxic properties of the ingredient during heating (considering the expected temperature-induced changes during the product use).

5. Toxic properties of the ingredient in its burned form (if the product is burned during its use).

6. Addictiveness of the ingredient.

7. Interaction of the ingredient with nicotine.

8. Interaction of the ingredient with other product ingredients in its unheated/unburned form.

9. Interaction of the ingredient with other product ingredients during heating/burning.

10. Effects of the ingredient on the health of consumers (including cumulative effects on the body), taking into account the method of the product use/ingredient uptake (e.g., inhalation, oral consumption).1 The toxicokinetic properties of the substance (i.e., absorption, metabolism, distribution, and elimination) and the following exposure types should be analysed:

1) acute exposure (acute toxicity, irritation, and corrosive effects);

2) sensitisation;

3) repeated exposure toxicity;

It should be specified whether the toxicological data are based on human data, animal data, or in vitro tests, along with the sources/references for this data. If the health effects are unknown, this should be specified.

11. The effects of emissions of the ingredient on the health of consumers, including its addictive effect. It should be specified whether the toxicological data are based on human data, animal data, or in vitro tests, along with the sources/references for this data. If the health effects are unknown, this should be specified.

Date of preparation and version of the prepared toxicological data summary/report, the given name, surname, position, and signature of the preparer

Note.

All provided toxicological data must be scientifically justified, and the sources/references for the provided data shall be cited in accordance with the APA format. If no data are available on any of the aforementioned paragraphs, this shall be properly and adequately justified.

**Annex 5**

Cabinet Regulation No. 440

5 July 2016

[*18 June 2024*]

**CERTIFICATION of Presentation Parameters**

|  |  |  |
| --- | --- | --- |
| Brand information    Technical parameters to be submitted | Brand name / sub-brand name for the initially notified presentation and ID number | Brand name / sub-brand name for the additionally notified presentation and ID number |
|  |  |
| Model\* |  |  |
| Battery capacity, mAh (rechargeable/non-rechargeable, built-in/external)\* |  |  |
| Power (W)\* |  |  |
| Resistance (Ω)\* |  |  |
| Material of the heating element wire (coil, spiral) |  |  |
| E-liquid capacity, ml (refillable/non-refillable) |  |  |
| Nicotine content, mg/ml or % |  |  |
| Total number of puffs |  |  |
| Packaging material(s) (list) |  |  |
| Weight (finished product without liquid) (g) |  |  |
| Weight (finished product with liquid) (g)\*\* |  |  |
| External dimensions of the product (L x W x H), mm |  |  |

Notes.

\*For refill containers and cartridges, indicate “not applicable”.

\*\* For devices without refillable liquid, indicate “not applicable”.

Manufacturer’s name \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Certification preparation date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ version \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Given name, surname, position of the preparer \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Annex 6**

Cabinet Regulation No. 440

5 July 2016

[*18 June 2024*]

**Product Types and Description**

1. Types of products to be submitted under the section of tobacco products:

1.1. cigar (a tobacco product intended for smoking);

1.2. cigarette (a tobacco product intended for smoking);

1.3. cigarillo (a tobacco product intended for smoking);

1.4. herbal product for smoking (a product based on plants, herbs, or fruit which contains no tobacco (including nicotine) and which can be consumed via a combustion or heating process);

1.5. novel tobacco product (including heated tobacco);

1.6. other (a product placed on the market before 19 May 2014 but not included in other categories);

1.7. pipe tobacco (a tobacco product intended for smoking);

1.8. roll-your-own tobacco (a tobacco product intended for smoking);

1.9. water pipe tobacco (a tobacco product intended for smoking).

2. Types of products to be submitted under the section of electronic cigarettes:

2.1. disposable electronic cigarette;

2.2. rechargeable electronic cigarette without refillable liquid;

2.3. rechargeable electronic cigarette with a single type of refillable liquid;

2.4. refillable electronic cigarette without refillable liquid;

2.5. refillable electronic cigarette with a single type of refillable liquid;

2.6. separate electronic cigarette component that may contain liquid;

2.7. kit – a package containing more than one electronic cigarette and/or more than one refill container/cartridge (with a single type of refillable liquid);

2.8. other (does not fit into any of the other categories, including tobacco substitute products);

2.9. refill container/cartridge filled with liquid.