COMMISSION IMPLEMENTING DECISION (EU) 2015/2183

of 24 November 2015

establishing a common format for the notification of electronic cigarettes and refill containers

(notified under document C(2015) 8087)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to 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 [1], and in particular Article 20(13) thereof,

Whereas:

(1) Directive 2014/40/EU provides that manufacturers and importers of electronic cigarettes and refill containers are to submit to the competent authorities of the Member States concerned a notification of any such products which they intend to place on the market or which are already placed on the market on 20 May 2016. The information should be submitted 6 months before the intended placing on the market of new or substantially modified products. The format for that notification should be laid down.

(2) The experience gained and the knowledge acquired with existing formats for the reporting of tobacco ingredients, where relevant, should be taken into account when developing the format.

(3) A common electronic notification format for submission of information on electronic cigarettes and refill containers should allow Member States and the Commission to process, compare, analyse and draw conclusions from the information received. The data will also provide a basis for assessing health impacts associated with these products.

(4) A common electronic entry gate for submission of data is essential to ensure uniform application of the notification obligations set out in Directive 2014/40/EU. In particular, a common entry gate facilitates and harmonises the submission of data from the manufacturer or importer to the Member States. Streamlining the submission process also reduces administrative burden for manufacturers, importers and national regulators and facilitates comparison of data. To facilitate multiple uploads, a repository might be established at the level of the common entry gate to allow for references to non-confidential documents.

The common entry gate should foresee tools for submission of information which are adequate both for companies which have comprehensive IT solutions in place (system to system submissions) and for companies which have no such solutions, in particular small and medium sized companies. Companies will be provided with a submitter identification number which should be used for all submissions by this company.

(5) Member States should be free to make the tools for submission of information laid down in this Decision available for submission of information required under Article 20(7) of Directive 2014/40/EU. The tools could also facilitate submission of other information on electronic cigarettes and refill containers pursuant to Article 20. Manufacturers and importers should be encouraged to keep data provided to Member States up-to-date. To facilitate comparison within the Union, Member States should encourage manufacturers and importers to submit updates during the first half of the subsequent calendar year. When sales data is reported under this format it should relate to the calendar year.

(6) When resubmitting data, including correcting errors in an earlier submission, the information should be provided through the common entry gate.

(7) In order to ensure the quality and comparability of data submitted, Member States should, where applicable, encourage manufacturers and importers to use agreed standards or testing methods. In the absence of agreed Union or international standards or testing methods, manufacturers and importers should clearly describe in their notifications the measurement methods used and should ensure that they are reproducible.

[1] OJ L 127, 29.4.2014, p. 1.

(8) In order to limit the administrative burden and ensure comparability between reported data, Member States should encourage manufacturers and importers to select compatible items when testing components of electronic cigarettes and refill containers placed on the market as separate items.

(9) Whilst the full responsibility for gathering, verifying, analysing as appropriate, storing and disseminating the data collected in accordance with this Decision lies with the Member States, they should have the possibility to store the data submitted to them at Commission facilities. The service offered by the Commission should provide Member States with technical tools to facilitate compliance with their obligations under Article 20 of Directive 2014/40/EU. The Commission will develop a standard service level agreement for this purpose. The Commission should keep an off-line copy of the data submitted through the common entry gate for the purpose of applying Directive 2014/40/EU.

(10) When submitting information on products with the same composition and design, manufacturers and importers should, to the extent possible, use the same product identification number, regardless of brand and subtype or whether they are placed on the market in one or more Member States.

(11) It is appropriate to lay down rules concerning the treatment of confidential data by the Commission in order to ensure the greatest possible transparency of product information for the general public, whilst ensuring that due account is taken of trade secrets. The legitimate expectation of consumers to have access to adequate information on the content of products they intend to consume should be weighed against manufacturers' interests of protecting recipes of their products. Having regard to those competing interests, data that could reveal ingredients used in small quantities in specific products should, in principle, be kept confidential.

(12) Personal data should be processed in accordance with the rules and safeguards laid down in Directive 95/46/EC of the European Parliament and of the Council [1] and of Regulation (EC) No 45/2001 of the European Parliament and of the Council [2].

(13) The measures provided for in this Decision are in accordance with the opinion of the Committee referred to in Article 25 of Directive 2014/40/EU,

HAS ADOPTED THIS DECISION:

Article 1

Subject matter

This Decision establishes a common format for the notification of information on electronic cigarettes and refill containers.

Article 2

Format for notification

1. Member States shall ensure that manufacturers and importers of electronic cigarettes and refill containers submit information referred to in Article 20(2) of Directive 2014/40/EU, including modifications and withdrawal from the market, in accordance with the format provided for in the Annex.

2. Member States shall ensure that manufacturers and importers of electronic cigarettes and refill containers submit the information referred to in paragraph 1 by means of a common entry gate for data submission.

[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[2] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

Article 3

Storage of data

Member States shall be entitled to use data storage services offered by the Commission to comply with their obligations under Article 20(2) of Directive 2014/40/EU provided they have signed a service level agreement with the Commission.

Article 4

Identification number of the data submitter

Before submitting information to Member States for the first time pursuant to this Decision, the manufacturer or importer shall apply for an identification number (Submitter ID) generated by the operator of the common entry gate. The manufacturer or importer shall, upon request, submit a document providing company identification and authentication of activities in accordance with the national legislation where the company is established. The Submitter ID shall be used for all subsequent submissions and in all subsequent correspondence.

Article 5

Identification number of the product

1. Based on the Submitter ID referred to in Article 4, the manufacturer or importer shall assign an E-Cigarette ID (EC-ID) for each product to be notified.

2. When submitting information on products with the same composition and design, manufacturers and importers shall, to the extent possible, use the same EC-ID, in particular where data are submitted by various members of a group of companies. This shall apply regardless of brand, subtype and the number of markets on which they are placed.

3. Where the manufacturer or importer is not able to ensure that the same EC-ID is used for products with the same composition and design, it shall at least provide, in so far as possible, the different EC-ID that were assigned to such products.

Article 6

Confidential data and disclosure of data

1. In their submission, manufacturers and importers shall mark all information which they consider to be a trade secret or otherwise confidential and shall, upon request, duly justify their claims.

2. In using the data transmitted for applying Directive 2014/40/EU and Regulation (EC) No 1049/2001 of the European Parliament and of the Council [1], the Commission shall, in principle, not consider the following information to be confidential or amount to a trade secret:

(a) ingredients used in quantities above 0,1 % of the final formulation of the liquid;

(b) studies and data submitted according to Article 20(2) of Directive 2014/40/EU, 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 accessible.

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Article 7

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 24 November 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

1. FIELD DESCRIPTIONS

All fields marked (M) in the common format are mandatory.

Filter dependent mandatory fields (F) become mandatory if a specific response is selected from a previous variable.

System generated fields (AUTO) are automatically generated by the software system.

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

2. SUBMITTER CHARACTERISTICS

The submitter is either the manufacturer or importer responsible for the submitted data.

Field #	Field	Description	Reporting	Submitter considers information confidential
	Submitter_ID	Submitter ID is the identification number attributed pursuant to Article 4	M	
	Submitter_Name	Official name of the submitter at Member State level, as linked to the VAT number	M	
	Submitter_SME	Indication whether the submitter, or its parent company if it exists, is an SME as defined in Commission Recommendation 2003/361/EC [1]	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_Company	Tick the box if the submitter has a parent company	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	

[1] Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).

2.1. **Manufacturer/Importer Parent company characteristics**

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

2.2. **Manufacturer/Importer affiliate company characteristics**

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 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 above) '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 e-liquid, but different design	M	

Field #	Field	Description	Reporting	Submitter considers information confidential
	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 product concerned	M	
	Product_Weight_E-liquid	Total weight of e-liquid in one product unit in mg.	F	
	Product_Volume_E-liquid	Total volume of e-liquid in one product unit in ml.	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 ([1])	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 ([2]) and as described in the 'Guidance on the Application of the CLP Criteria' ([3])	F	

([1]) For each manufacturer, the following information is to be provided: ID number if any, official name, address, country, business phone and functional business email.

([2]) 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 (OJ L 353, 31.12.2008, p. 1).

([3]) http://echa.europa.eu/documents/10162/13562/clp_en.pdf

3. PRODUCT INFORMATION SUBMISSION AND DESCRIPTION — 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 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	

Field #	Field	Description	Reporting	Submitter considers information confidential
	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	UPC-12 (Universal Product Code) of the product		
	Product_EAN_Number	EAN-13 or EAN-8 (European Article Number) of the product		
	Product_GTIN_Number	GTIN (Global Trade Identification Number) of the product		
	Product_SKU_Number	SKU (Stock Keeping Unit) number 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 ([1]). 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) number	M	
	Ingredient_CAS_Additional	Additional CAS numbers if applicable	F	

([1]) M and F in this section applies only for product types where applicable.

Field #	Field	Description	Reporting	Submitter considers information confidential
	Ingredient_FEMA_Number	FEMA (Flavour and Extract Manufacturers Association) 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 [1]		
	Ingredient_FL_Number	FL number (European Flavouring number as set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council [2]		
	Ingredient_EC_Number	European Community (EC) number [3], 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 mg 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 [4], if any.	M	
	Ingredient_CLP_Whether_ Classification	Indication whether the ingredient has been classified under Regulation (EC) No 1272/2008 of the European Parliament and of the Council [5] and is in the classification and labelling Inventory	M	
	Ingredient_CLP_Classification	Ingredient classification with to regard Regulation (EC) No 1272/2008	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	

Field #	Field	Description	Reporting	Submitter considers information confidential
	Ingredient_Tox_CMR	Existence of any studies relating to the carcinogenicity, mutagenicity or toxicity for reproduction of the ingredient.	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)	F/M	

(1) Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

(2) 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 (OJ L 354, 31.12.2008, p. 34).

(3) As created by the European Community Commission Decision 81/437/EEC, of 11 May 1981 laying down the criteria in accordance with which information relating to the inventory of chemical substances is supplied by the Member States to the Commission (OJ L 167, 24.6.1981, p. 31).

(4) 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 (OJ L 396, 30.12.2006, p. 1).

(5) 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 (OJ L 353, 31.12.2008, p. 1).

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	

Field #	Field	Description	Reporting	Submitter considers information confidential
	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 (Chemical Abstracts Service) number of emissions	F	
	Emission_IUPAC	IUPAC (International Union of Pure and Applied Chemistry) name of emissions, 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	

Field #	Field	Description	Reporting for e-cigarettes	Submitter considers information confidential	Reporting for refill container	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 ml (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 mg/ml	F		M	
	E-Cigarette_Battery_Type	Description of the battery type	F		N/A	
	E-Cigarette_Battery_Type_Capacity	Indication of the battery capacity in mAh	F		N/A	
	E-Cigarette_Volt/Watt_Adjustable	Indication whether the e-cigarette is voltage/wattage adjustable	M		N/A	
	E-Cigarette_Voltage	Nominal voltage of the e-cigarette if non-adjustable and recommended voltage if adjustable.	F		N/A	
	E-Cigarette_Voltage_Lower_Range	Lowest voltage obtainable	F		N/A	
	E-Cigarette_Voltage_Upper_Range	Highest voltage obtainable.	F		N/A	
	E-Cigarette_Wattage	Nominal wattage output if non-adjustable and recommended wattage if adjustable.	F		N/A	
	E-Cigarette_Wattage_Lower_Range	Lowest wattage obtainable	F		N/A	
	E-Cigarette_Wattage_Upper_Range	Highest wattage obtainable	F		N/A	
	E-Cigarette_Airflow_Adjustable	Indication whether the airflow of the e-cigarette is adjustable	M		N/A	
	E-Cigarette_Wick_Changeable	Indication whether the consumer may adjust/alter/replace the wick	M		N/A	

Field #	Field	Description	Reporting for e-cigarettes	Submitter considers information confidential	Reporting for refill container	Submitter considers information confidential
	E-Cigarette_Microprocessor	Indication whether the e-cigarette contains a microprocessor	M		N/A	
	E-Cigarette_Coil_Composition	Chemical composition of the wiring (coil) in the atomiser	M		N/A	
	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	