TPD_data_dictionary_electronic_cigarettes

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1. Field description

1.1 Data Type

Data Type	Description	Example or Regular expression
Text (1000)	Alphanumeric values limited to 1000 characters	E.g. 'Abcd' or '123455588845'
Text (500)	Alphanumeric values limited to 500 characters	E.g. 'Abcd' or '123455588845'
Text (300)	Alphanumeric values limited to 300 characters	E.g. 'Abcd' or '123455588845'
Text (100)	Alphanumeric values limited to 100 characters	E.g. 'Abcd' or '123455588845'
Text (40)	Alphanumeric values limited to 40 characters	E.g. 'Abcd' or '123455588845'
Decimal	Number values, decimal allowed	E.g. '1' or '2.2' or '3.33'
Integer	Rounded number values, no decimal numbers	E.g. '1' or '22' or '333'
File	Files as provided in pdf form	E.g. 'XXXXX.pdf'
Date	Text corresponding to the following format: DD/MM/YYYY	E.g. '22/03/2012'
List	Must be only one of the values present in the 'Values' column	
Boolean	Boolean value	0 (false/disabled)1 (true/enabled)
Component	A bloc defined in the data dictionary	4. Product
	Numeric characters	[[0-9][\+] [\(\)\.]]*
Phone	Plus sign, left parenthesis, right parenthesis, full stop	
	Maximum 20 characters	
Email	Maximum 80 characters	^['_a-z0-9-]+(\.['_a-z0-9-]+)*@[a-z0-9-]+(\.[a-z0-9-]+)*\.(([a-z]{2,3}))\$
Submitter ID	Numeric identifier provided to the submitter of the data by the Administrative center	E.g. '02565'
	Maximum 5 digit identifier	
E-cigarette Identifier (EC-ID)	Numeric identifier in the form of Submitter number- year after 2000- product number: NNNNN-NN-NNNNN	E.g. '02565-15-00230'
CAS Identifier	A numeric code that can contain up to 10 digits divided by hyphens into three parts	E.g. '58-08-2'
	Maximum 10 characters	
FEMA Identifier	4 digit Numeric with the following format NNNN	E.g. '1234'
Food Additive	5 digit Alpha-numeric	E.g. 'E1402' or 'E160'
Identifier	Maximum 5 characters	

FL Identifier	An alpha-numeric code consisting of the letters 'FL' followed by 5 digits, with a point after the first 2 digits Maximum 10 characters	E.g. 'FL 16.012' or 'FL 14.152'
EC Identifier	Usually a 7 digit numeric code including hyphens in the form NNN-NNN-N maximum 9 characters	E.g. '200-003-9'

1.2 Priority Type

There are multiple types of mandatory/optional fields in the current system as noted in the table below.

Туре	Explanation
Automatically filled by the system (A)	The variable is automatically generated by the software system for each submission.
Mandatory (M)	The variable must be completed to successfully submit the report.
Optional (O)	The variable is for supplementary fields which could be required by individual Member
	States.

2. Submission

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
	Submitter_Details	The submitter information.	Component	Simple	M	See 3.1
	Product	The product description.	Component	Simple	М	<u>See 4.</u>

3. Submitter

3.1 Submitter details

Item#	Field	Description	Data Type	Cardinality	Priority	Values
1	Submitter_ID	Submitter ID is the identification number attributed pursuant to Article 4.	Submitter ID	Simple	М	
2	Submitter_SME	Indication whether the submitter, or its parent company if it exists, is an SME as defined in Commission Recommendation 2003/361/EC1.	Boolean	Simple	М	
3	Submitter_Has_VAT	Indication whether the submitter has a VAT number. If no, the "Submitter_VAT" field is not applicable.	Boolean	Simple	М	
4	Submitter_VAT	VAT number of the submitter.	Text (40)	Simple	M if the value of field 3 is "yes" otherwise N/A	
5	Submitter_Type	Indication whether the submitter is a manufacturer or importer.	List	Simple	M	See 10.1
	Submitter_Company_Details	The company details of the submitter.	Component	Simple	М	See 9.1
6	Submitter_Has_Parent_Company	Tick the box if the submitter has a parent company.	Boolean	Simple	М	
	Submitter_Parent_Details	The details of the parent company.	Component	Simple	M if the value of field 6 is "yes"	See 3.2
7	Submitter_Has_Affiliate_Company	Tick the box if the submitter has an affiliate company (any type of relationship with another company(-ies) linked to the product at question, no legal ownership	Boolean	Simple	М	

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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).

		structure necessarily required).				
	Submitter_Affiliate_Details	The details of the affiliate company.	Component	Multiple	M if the value of field 7 is "yes"	See 3.3
8	Submitter_Appoints_Enterer	Tick the box if the submitter has appointed a third party to submit its data on its behalf ('enterer').	Boolean	Simple	М	
	Submitter_Enterer_Details	The details of the third party reporting on behalf of the submitter.	Component	Simple	M if the value of field 8 is "yes"	See 3.4

3.2 Parent details

Item #	Field	Description	Data Type	Cardinality	Priority	Values
9	Submitter_Parent_Has_ID	Indication whether the submitter parent has a submitter ID. If not, the "Submitter_Parent_ID" field is not applicable.	Boolean	Simple	М	
10	Submitter_Parent_ID	Submitter ID of the parent company, if any. This is the identification number attributed pursuant to Article 4.	Submitter ID	Simple	M if the value of field 9 is "yes" otherwise N/A	
	Parent_Company_Details	The company details of the parent submitter.	Component	Simple	М	<u>See 9.1</u>

3.3 Affiliate details

Item #	Field	Comments	Data Type	Cardinality	Priority	Values

11	Submitter_Affiliate_Has_ID	Indication whether the submitter affiliate has a submitter ID. If not, the "Submitter_Affiliate_ID" field is not applicable.		Simple	М	
12	Submitter_Affiliate_ID	Submitter ID of the affiliate company, if any. This is the identification number attributed pursuant to Article 4.		Simple	M if the value of field 11 is "yes" otherwise N/A	
	Affiliate_Company_Details	The company details of the affiliate submitter.	Component	Simple	М	See 9.1

3.4 Enterer reporting on behalf of the submitter

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
13	Enterer_Has_ID	Indication whether the enterer reporting on behalf of the submitter has a submitter ID. If not, the "Enterer_ID" field is not applicable.	Boolean	Simple	M	
14	Enterer_ID	Submitter ID of the enterer reporting on behalf of the submitter, if any. This is the identification number attributed pursuant to Article 4.	Submitter ID	Simple	M if the value of field 13 is "yes" otherwise N/A	
	Enterer_Company_Details	The company details of the enterer reporting on behalf of the Submitter.	Component	Simple	М	<u>See 9.1</u>

3.5 Manufacturer

Only applicable in cases when the submitter is not the actual manufacturer of the final product at question.

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
15	Manufacturer_Has_ID	Indication whether the manufacturer has a submitter ID. If not, the "Manufacturer_ID" field is not applicable.	Boolean	Simple	M	
16	Manufacturer_ID	Submitter ID of the manufacturer, if any, if the submitter is not the manufacturer. This is the identification number attributed pursuant to Article 4.	Submitter ID	Simple	M if the value of field 15 is "yes" otherwise N/A	
	Manufacturer_Company_Details	The company details of the manufacturer, if the submitter is not the manufacturer.	Component	Simple	М	See 9.1
	Product_Production_Site_Address	For the manufacturer, address(es) of the site(s) where production is completed.	Component	Multiple	M	<u>See 9.2</u>

4. Product

Item#	Field	Comments	Data Type	Cardinality	Priority	Values
	Product_Information_Part_A	The common product description.	Component	Simple	М	See 4.1
	Product_Information_Part_B	Description of the format(s) and respective Member State(s) in which the product is presented for sale.	Component	Multiple	M	See 4.2
	Ingredients	The ingredients defined in the product.	Component	Multiple	M if the product type value is 1 or 2 or 4 or 7	<u>See 5.</u>
	Emissions	The emissions of the product.	Component	Multiple	M if the product type value is 1 or 2 or 3 or 4 or 5 or 6 or 7	<u>See 6.</u>
	Product_Design	The design of the product.	Component	Simple	М	<u>See 7.</u>

4.1 Product information submission and description – Part A

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
17	Submission_Type	Type of submission for the product.	List	Simple	М	<u>See 10.2</u>
18	Submission_General_Comment	General comments to accompany the submission. When modifying/correcting an existing notification, please indicate here which information is being changed.	Text (1000)	Simple	0	

19	Submission_Start_Date	Submission date will be filled in automatically by the system when the user submits the information about the product.	Date	Simple	A	Automatically completed by the EU- CEG system
20	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	EC-ID	Simple	M	
		'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				
21	Product_Previous_ID (EC-ID)	In the case of substantial modification to an already notified product (entailing a new EC-ID), indication of the previous EC-ID of the product.	EC-ID	Simple	M if the submission type value is 2	
22	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.	Boolean	Simple	M	
23	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.	EC-ID or Text (300)	Multiple	M if the value field 22 is "yes"	
24	Product_Same_Composition_Exist	Indication whether the submitter is aware of other product(s) with the same composition of e-liquid, but different design.	Boolean	Simple	М	
25	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	EC-ID or Text (300)	Multiple	M if the value of field 24 is	

		product(s) is placed on the market shall at least be provided.			"yes"	
26	Product_Type	Type of product concerned.	List	Simple	М	See 10.3
27	Product_Weight_E-liquid	Total weight of e-liquid in one product unit in mg.	Decimal	Simple	M if the product type value is 1 or 2 or 4 or 7	
28	Product_Volume_E-liquid	Total volume of e-liquid in one product unit in ml.	Decimal	Simple	M if the product type value is 1 or 2 or 4 or 7	
	Product_Manufacturer_Identification	If the submitter is not the manufacturer of the product at question, the official company name(s) of the manufacturer(s) of the product including its contact details.	Component	Multiple	M if the value of the submitter type is 1	See 3.5
29	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 .	Text (300)	Simple	M if the product type value is 1 or 2 or 4 or 7	
30	Product_Market_Research_File	Information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users.	File	Multiple	0	

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)

31	Product_Studies_Summaries_File	Executive summaries of any market studies carried out	File	Multiple	0	
		in respect of the above fields (Sales Volume, Mode of				
		Sales, Market Research), including an English				
		translation thereof				

4.2 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.

Item#	Field	Comments	Data Type	Cardinality	Priority	Values
32	Product_National_Market	Member State in which the product (presentation) is marketed and to which the product information is being provided.	List	Simple	M	See 10.10
33	Product_National_Comment	General comments to accompany national market notification.	Text (1000)	Simple	0	
34	Product_Brand_Name	Brand name under which the product is marketed in the Member State to which information is being submitted.	Text (100)	Simple	M	
35	Product_Brand_Subtype_Name_Exist	Indicates if the product "subtype name" exists. Subtype name provides further product identification beyond a product's brand name.	Boolean	Simple	M	
36	Product_Brand_Subtype_Name	Product "subtype name" (if any) as marketed in the Member State to which the product information is being submitted.	Text (100)	Simple	M if the value of field 35 is "yes"	
37	E-cigarette_Launch_Date	The date on which the submitter intends to launch/launched the product (in its specific presentation) on the market.	Date	Simple	М	

38	E-cigarette_Withdrawal_Indication	Indication that the submitter intends to withdraw/withdrew the product (in its specific presentation) from the market.	Boolean	Simple	M	
39	E-cigarette_Withdrawal_Date	Date on which the submitter intends to withdraw/withdrew the product (in its specific presentation) from the market.	Date	Simple	M if the value field 38 is "yes"	
40	Product_Submitter_Number	ID number used internally by the submitter. (other than those listed below).	Text (40)	Simple	M if the fields 41, 42, 43 and 44 are empty	At least one of those numbers must be used consistently to identify unique product presentations for all submissions made by a
41	Product_UPC_Number	UPC-12 (Universal Product Code) of the product.	Text (40)	Simple	M if the fields 40, 42, 43 and 44 are empty	single Submitter.
42	Product_EAN_Number	EAN-13 or EAN-8, (European Article Number) of the product.	Text (40)	Simple	M if the fields 40, 41, 43 and 44 are empty	
43	Product_GTIN_Number	GTIN (Global Trade Identification Number) of the product.	Text (40)	Simple	M if the fields 40, 42, 43 and 44 are empty	
44	Product_SKU_Number	SKU (Stock Keeping Unit) number(s) of the product.	Text (40)	Simple	M if the fields 40, 41, 42 and 43 are empty	
45	Product_Package_Units	Number of individual units in the unit packet.	Integer	Simple	M	

46	Product_Unit_Packet_Picture_File	The picture of the unit packet. The picture should be	File	Multiple	0	
		clear enough to view details and to assist in the identification of unique products.				
		identification of unique products.				
	Annual_Sales_Submission	The submission of the annual sales volume and other information for the national market in question.	Component	Multiple	0	<u>See 8.</u>

5. Ingredients contained in the product

5.1 Ingredient

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
47	Ingredient_Name	The chemical name of the ingredient.	Text (300)	Simple	M if the product type value is 1 or 2 or 4 or 7	
48	Ingredient_Identification_Refill_ContainerCartridge	Identification of the refill container/cartridge.	Text (300)	Simple	M if the product type value is 6 otherwise N/A	
49	Ingredient_CAS_Exist	Indication that a CAS number exists for the ingredient.	Boolean	Simple	M if the product type value is 1 or 2 or 4 or 7	
50	Ingredient_CAS	The CAS number.	CAS Identifier	Simple	M if the product type value is 1 or 2 or 4 or 7 and the value of the field 49 is "yes"	
51	Ingredient_CAS_Additional	Additional CAS numbers if applicable.	CAS Identifier	Multiple	0	Maximum 10 additional CAS numbers.
52	Ingredient_FEMA_Number	FEMA (Flavour and Extract Manufacturers Association) number, if any.	FEMA Identifier	Simple	M if the product type value is 1 or 2 or 4 or 7 and the	If a CAS number does not exist, at least one of those four numbers must be indicated. If more than one number

53	Ingredient_Additive_Number	If the ingredient is a food additive, its food additive "E	Food Additive	Simple	fields 50, 53, 54, 55 and 56 are empty	is indicated, those numbers must be indicated in the following order of importance FEMA > Additive > FL > EC >
		number" set out in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁴ .	Identifier		product type value is 1 or 2 or 4 or 7 and the fields 50, 52, 54, 55 and 56 are empty	Other.
54	Ingredient_FL_Number	The FL number, if any (European Flavouring number as set out in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁵).	FL Identifier	Simple	M if the product type value is 1 or 2 or 4 or 7 and the fields 50, 52, 53, 55 and 56 are empty	
55	Ingredient_EC_Number	The European Community (EC) number, if any.	EC identifier	Simple	M if the product type value is 1 or 2 or 4 or 7 and the fields 50, 52, 53, 54 and 56 are empty	

⁴ 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).

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).

56	Ingredient_Other_Number	ID number used internally by the submitter. (in absence of any of the above listed number types).	Text (40)	Simple	M if the product type value is 1 or 2 or 4 or 7 and the fields 50, 52, 53, 54 and 55 are empty	
57	Ingredient_Function	Function(s) of the ingredient.	List	Multiple	0	See 10.7
58	Ingredient_Function_Other	Function of the ingredient if "other".	Text (100)	Simple	O if the value of field 57 is "other" otherwise N/A	
59	Ingredient_Recipe_Quantity	Weight of the ingredient included in one product unit in mg according to recipe.	Decimal	Simple	M if the product type value is 1 or 2 or 4 or 7	
60	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.	List	Simple	M if the product type value is 1 or 2 or 4 or 7	See 10.8
61	Ingredient_REACH_Registration	Indication whether the REACH registration number might be not available for substances.	List	Simple	0	not yet registeredexempted/out of scope

62	Ingredient_REACH_Registration_Number	Registration number pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁶ , if any.	Text (40)	Simple	M if the product type value is 1 or 2 or 4 or 7 and the items 61 is empty	
63	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 ⁷ and is in the classification and labelling Inventory.	Boolean	Simple	M if the product type value is 1 or 2 or 4 or 7	
64	Ingredient_CLP_Acute_Tox_Oral	The ingredient classification with regards to acute oral toxicity based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	-1 -2 -3 -4
65	Ingredient_CLP_Acute_Tox_Dermal	The ingredient classification with regards to acute dermal toxicity based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of	-1 -2 -3 -4

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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).

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).

					field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	
66	Ingredient_CLP_Acute_Tox_Inhalation	The ingredient classification with regards to acute inhalation toxicity based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	-1 -2 -3 -4
67	Ingredient_CLP_Skin_Corrosive/Irritant	The ingredient classification as a skin corrosive/irritant based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	- 1A - 1B - 1C - 2
68	Ingredient_CLP_Eye_Damage/Irritation	The ingredient classification as responsible for eye damage/irritation based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67,	-1 -2

						•
					68, 69, 70, 71, 72, 73, 74, 76	
69	Ingredient_CLP_Respiratory_Sensitisation	The ingredient classification with regards to respiratory sensitisation based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	-1
70	Ingredient_CLP_Skin_Sensitisation	The ingredient classification with regards to skin sensitisation based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	-1 -1A -1B
71	Ingredient_CLP_Mutagen/Genotox	The ingredient classification with regards mutagenicity/genotoxicity based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73,	- 1A - 1B - 2

					74, 76	
72	Ingredient_CLP_Carcinogenity	The ingredient classification with regards to its carcinogenity based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	- 1A - 1B - 2
73	Ingredient_CLP_Reproductive_Tox	The ingredient classification with regards to its reproductive toxicity based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes" : 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	– 1B_lact
74	Ingredient_CLP_STOT	The ingredient classification with regards to its specific target organ toxicity based on Regulation (EC) No 1272/2008 (for the most relevant exposure type/organ combination).	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	-1 -2 -3

75	Ingredient_CLP_STOT_Description	Reference to relevant exposure type(s) and to the specific organ(s) affected based on the above classification.	Text (500)	Simple	M if value of field 63 is "yes"	
76	Ingredient_CLP_Aspiration_Tox	The ingredient Classification with regards to aspiration toxicity based on Regulation (EC) No 1272/2008.	List	Simple	At least one the following must be populated if value of field 63 is "yes": 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 76	-1
	Ingredient_Toxicity	The toxicity details of the ingredient.	Component	Simple	M if the product type value is 1 or 2 or 4 or 7	<u>See 5.2</u>

5.2 Ingredient Toxicity details

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
77	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.	List	Dropdown	M if the product type value is 1 or 2 or 4 or 7	<u>See 10.9</u>
78	Ingredient_Tox_Emission	Existence of studies that indicate the chemistry and/or toxicity of emissions.	Boolean	Simple	M if the product type value is 1 or 2 or 4 or 7	

79	Ingredient_Tox_CMR	Existence of any study relating to the carcinogenicity, mutagenicity or toxicity for reproduction of the ingredient.	Boolean	Simple	M if the product type value is 1 or 2 or 4 or 7
80	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.	Boolean	Simple	M if the product type value is 1 or 2 or 4 or 7
81	Ingredient_Tox_Addictive	Existence of an analysis of the possible addictive properties of the ingredient	Boolean	Simple	M if the product type value is 1 or 2 or 4 or 7
82	Ingredient_Tox_Other	Existence of any other toxicological data not stated above.	Boolean	Simple	M if the product type value is 1 or 2 or 4 or 7
83	Ingredient_Tox_Emission_File	The upload available studies indicated in the ingredient tox emission field. (Guidance: studies should refer in particular to effects on the health of consumers and take into account, inter alia, any addictive effects.)	File	Multiple	M if the value of field 78 is "yes"
84	Ingredient_Tox_CMR_File	The upload available studies indicated in the ingredient tox cmr field. (Guidance: studies should refer in particular to effects on the health of consumers and take into account, inter alia, any addictive effects.)	File	Multiple	M if the value of field 79 is "yes"
85	Ingredient_Tox_CardioPulmonary_File	The upload available studies indicated in the ingredient tox cardiopulmonary field.	File	Multiple	M if the value of field 80 is

		(Guidance: studies should refer in particular to effects on the health of consumers and take into account, inter alia, any addictive effects.)			"yes"	
86	Ingredient_Tox_Addictive_File	The upload available studies indicated in the ingredient tox addictive field. (Guidance: studies should refer in particular to effects on the health of consumers and take into account, inter alia, any addictive effects.)	File	Multiple	M if the value of field 81 is "yes"	
87	Ingredient_Tox_Other_File	The upload available studies indicated in the ingredient tox other field. (Guidance: studies should refer in particular to effects on the health of consumers and take into account, inter alia, any addictive effects.)	File	Multiple	M if the value of field 82 is "yes"	

6. 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.

Item #	Field	Comments	Data Type	Cardinality	Priority	Values
88	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.	EC-ID or Text (300)	Multiple	0	
89	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.	Text (500)	Simple	0	
90	Emission_Methods_File	Description of the measurement methods used to assess the emissions, including reference to the relevant approved standard, when available.	File	Simple	M	
91	Emission_Name	Name of the emission produced during the testing of the product.	List	Simple	М	See 10.4
92	Emission_Name_Other	Name of other emission produced during the testing of the product.	Text (100)	Simple	M if the value of field 91 is "other"	
93	Emission_CAS	CAS (Chemical Abstracts Service) number of emissions.	CAS Identifier	Simple	M if the value of fields 94 is empty	
94	Emission_IUPAC	IUPAC (International Union of Pure and Applied Chemistry) name of emissions, should a CAS number not exist.	Text (100)	Simple	M if the value of fields 93 is empty	
95	Emission_Quantity	Quantity of emissions produced during the process of using the product, based on the measurement method used.	Numeric	Simple	М	

96	Emission_Units	Unit in which the emission is measured.	Text (40)	Simple	М	

7. Product design

Item#	Field	Description	Data Type	Cardinality	Priority	Values
97	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).	Text (1000)	Simple	М	
98	E-Cigarette_Identification_E- Cigarette_Device	Identification of the refill container/cartridge.	Text (300)	Simple	M if the product type value is 6 otherwise N/A	
99	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).	Decimal	Simple	M if the product type value is 1 or 2 or 3 or 4 or 5 or 7	See 10.3
100	E-Cigarette_Nicotine_Concentration	Nicotine concentration in mg/ml.	Decimal	Simple	M if the product type value is 1 or 2 or 4 or 7	See 10.3
101	E-Cigarette_Battery_Type	Description of the battery type.	Text (300)	Simple	0	
102	E-Cigarette_Battery_Type_Capacity	Indication of the battery capacity in mAh.	Decimal	Simple	0	
103	E-Cigarette_Volt/Watt_Adjustable	Indication whether the e-cigarette is voltage/wattage adjustable.	List	Simple	M if the product type value is 1 or 2 or 3 or 4 or 5	See 10.5
104	E-Cigarette_Voltage	Nominal voltage of the e-cigarette if non-adjustable and recommended voltage if adjustable.	Decimal	Simple	M if the volt/watt adjustable value is 1 or 2	 Yes, voltage and wattage adjustable Yes, only voltage adjustable

105	E-Cigarette_Voltage_Lower_Range	The lower voltage obtainable.	Decimal	Simple	M if the volt/watt adjustable value is 1 or 2	- Yes, voltage and wattage adjustable - Yes, only voltage adjustable
106	E-Cigarette_Voltage_Upper_Range	The upper voltage obtainable.	Decimal	Simple	M if the volt/watt adjustable value is 1 or 2	Yes, voltage and wattage adjustableYes, only voltage adjustable
107	E-Cigarette_Wattage	The nominal wattage output if non-adjustable and recommended wattage if adjustable.	Decimal	Simple	M if the volt/watt adjustable value is 1 or 3	- Yes, voltage and wattage adjustable - Yes, only wattage adjustable
108	E-Cigarette_Wattage_Lower_Range	The lower wattage obtainable.	Decimal	Simple	M if the volt/watt adjustable value is 1 or 3	Yes, voltage and wattage adjustableYes, only wattage adjustable
109	E-Cigarette_Wattage_Upper_Range	The upper wattage obtainable.	Decimal	Simple	M if the volt/watt adjustable value is 1 or 3	Yes, voltage and wattage adjustableYes, only wattage adjustable
110	E-Cigarette_Airflow_Adjustable	Indication whether the airflow of the e-cigarette is adjustable.	Boolean	Simple	M if the product type value is 1 or 2 or 3 or 4 or 5	
111	E-Cigarette_Wick_Changeable	Indication whether the consumer may adjust/alter/replace the wick.	Boolean	Simple	M if the product type value is 1 or 2 or 3	

					or 4 or 5
112	E-Cigarette_Microprocessor	Indication whether the e-cigarette contains a microprocessor.	Boolean	Simple	M if the product type value is 1 or 2 or 3 or 4 or 5
113	E-Cigarette_Coil_Composition	Chemical composition of the wiring (coil) in the atomiser.	Text (300)	Simple	M if the product type value is 1 or 2 or 3 or 4 or 5
114	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.	File	Simple	M if the product type value is 1 or 2 or 3 or 4 or 5 or 6 or 7
115	E-Cigarette_Production_File	Description of the final production process, including series production.	File	Simple	M
116	E-Cigarette_Production_Conformity	Declaration that the production process ensures conformity (including but not limited to information on series production).	Boolean	Simple	M
117	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.	Boolean	Simple	M
118	E-Cigarette_Opening/Refill_File	Description of the opening and refill mechanism, where applicable.	File	Simple	M if the product type value is 4 or 5 or 7
119	E-Cigarette_Child_Tamper_Proof	Declaration that the product is child resistant and tamper proof protected against breakage and leakage and has a mechanism that ensures refilling without	Boolean	Simple	0

		leakage (where applicable).				
120	E-Cigarette_High_Purity	Declaration that only ingredients of high purity are used in the manufacture of the liquid.	Boolean	Simple	0	
121	E-Cigarette_Non_Risk	Declaration that the product (with an exception for its nicotine content) does not pose reasonably foreseeable risk to human health under normal conditions of use.	Boolean	Simple	0	
122	E-Cigarette_Consistent_Dosing	Declaration of nicotine dosing at consistent levels during product use and across batches under normal or reasonably foreseeable conditions.	Boolean	Simple	0	
123	E-Cigarette_Consistent_Dosing_Methods	Description of how consistent dosing is ensured, including reference to the relevant approved standard, when available.	File	Simple	0	
124	E-Cigarette_Leaflet_File	Upload of scanned file of the leaflet of information for consumers.	File	Simple	0	
125	E-Cigarette_Coil_Resistance	Indication of the coil resistance in ohm.	Decimal	Simple	0	

8. Submission of annual product data

Item#	Field	Description	Data Type	Cardinality	Priority	Values
126	Product_Sales_Volume	Information on annual sales volume of the product per Member State to be reported annually in product units.	Numeric	Simple	0	
127	Product_Mode_of_Sales	Description of mode of sale of the product.	File	Simple	0	
128	Product_Sales_Volume_Year	Calendar year of the annual sales volume of the product per Member State.	Numeric	Simple	0	

9. Company and production site details

9.1 Company data

Item #	Field	Description	Data Type	Cardinality	Priority	Values
129	Company_Name	Official name of the company at the Member State level, as linked to the VAT number.	Text (100)	Simple	M	
130	Company_Address	Address of the company.	Text (300)	Simple	М	
131	Company_Country	Country in which the company has its seat/domicile.	List	Simple	M	All countries
132	Company_Phone	Business phone of the company.	Phone	Simple	M	
133	Company_Email	Functional business email address of the company.	Email	Simple	M	

9.2 Production site data

Item #	Field	Description	Data Type	Cardinality	Priority	Values
134	Production_Site_Address	The address of the production site.	Text (300)	Simple	М	
135	Production_Site_Country	The country in which production site has its seat/domicile.	List	Simple	М	All countries
136	Production_Site_Phone	The business phone of the production site with international codes.	Phone	Simple	0	
137	Production_Site_Email	The functional business email address of the production site, only functional addresses should be used.	Email	Simple	0	

10. Reference Data

10.1 Submitter Type

Value	Name
1	Importer
2	Manufacturer

10.2 Submission Type

Value	Name
1	Notification of information on a new product (new EC-ID).
2	Substantial modification of information on a previously notified product leading to a new EC-ID (with a link to the previous EC-ID).
3	Addition of product presentation (e.g. national market) to an existing product submission.
4	Removal of product presentation, including product withdrawal, from an existing product submission.
5	Update of information on a previously notified product submission at product and/or presentation level not leading to a new EC-ID.
6	Update of information required to be submitted for notified products in regular intervals (annually), such as sales data or actual quantities of ingredients.
7	Correction of clerical/administrative errors in existing product submission.

10.3 Product Type

1	Electronic cigarette – Disposable
2	Electronic cigarette – Rechargeable, placed on the market with one type of e-liquid (fixed combination). Any rechargeable which can also be used as a refillable should be reported under the refillable category
3	Electronic cigarette – Rechargeable, device only. <i>Any rechargeable which can also be used as a refillable should be reported under the refillable category</i>
4	Electronic cigarette – Refillable, placed on the market with one type of e-liquid (fixed combination).
5	Electronic cigarette – Refillable, device only
6	Kit – Pack containing more than one different e-cigarette device and/or more than one different refill container/cartridge
7	Refill container/cartridge containing e-liquid
8	Individual part of electronic cigarette capable of containing e-liquid
9	Other

10.4 Emission Name

Value	Name
1	Nicotine

2	Ethylene glycol
3	Diethylene glycol
4	Formaldehyde
5	Acetaldehyde
6	Acrolein
7	Crotonaldehyde
8	TSNA: NNN
9	TSNA: NNK
10	Cadmium
11	Chromium
12	Copper
13	Lead
14	Nickel
15	Arsenic
16	Toluene
17	Benzene
18	1,3-Butadiene
19	Isoprene
20	Diacetyl
21	Acetyl Propionyl
22	Other

10.5 E-cigarette Voltage/Wattage Adjustable

Value	Name
1	Yes, voltage and wattage adjustable
2	Yes, only voltage adjustable
3	Yes, only wattage adjustable
4	No, un-adjustable

10.6 Marketing Data Available

Value	Name
1	No marketing data available
2	Marketing data is available but not new
3	New marketing data has been obtained since the last reporting period

10.7 Ingredient Function

Value	Name
1	Addictive Enhancer
2	Adhesive
3	Binder
4	Carrier
5	Colour
6	Combustion Modifier
7	Casing
8	Fibre
9	Filler
10	Filter Component
11	Filtration Material
12	Flavour and/or Taste Enhancer
13	Humectant
14	pH Modifier
15	Plasticiser
16	Preservative
17	Solvent - Processing Aid
18	Reduced Ignition Propensity Agent
19	Sizing Agent
20	Smoke Enhancer
21	Smoke Colour Modifier
22	Smoke Odour Modifier
23	Wrapper
24	Water-Wetting Agents
25	Viscosity Modifier
26	Other

10.8 Ingredient Non-Vaporised Status

Value	Name
0	No available information on the ingredient's toxicity in non-vapourised form.
1	Not toxic and without CMR properties in non-vapourised form.
2	Identified as toxic and or with CMR properties in non-vapourised form.

10.9 Toxicological Data Available

Value	Name
1	No toxicological data available.
2	Toxicological data is available but not new.
3	New toxicological data has been obtained since the last reporting period.

10.10 National Markets

Value	Name
AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DK	Denmark
DE	Germany
EE	Estonia
GR	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland
IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	Netherlands
PL	Poland
PT	Portugal
RO	Romania
SI	Slovenia
SK	Slovakia
SE	Sweden
GB	United Kingdom