EUROPEAN
COMMISSION

Brussels, XXX
[…](2015) XXX draft

ANNEX 1

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1. FIELD DESCRIPTIONS

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

Filter 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.

Item #	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	

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 e-mail 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 e-mail 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 e-mail address.

[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).

3. PRODUCT INFORMATION SUBMISSION AND DESCRIPTION – PART A

Item #	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	
	E-Cigarette_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	
	E-cigarette_Product_ID_Other_Exist	Indication whether the submitter is aware of another product with the same design and composition that is marketed in the EU using a different EC-ID	M	
	E-cigarette_Product_ID_Other	EC_ID of the product(s) with same design and composition known to the submitter	F	
	E-cigarette_Product_ID_Other2	If EC_ID of the product(s) with same design and composition is not known to the submitter, indicate brand name and Member State(s) where product is placed on the market	F	
	E-cigarette_Product_Same_Composition_Exist	Indication whether the submitter is aware of another product with the same composition of e-liquid, but different design	M	
	E-cigarette_Product_Same_Composition_Other	EC_ID of the product(s) with the same composition of e-liquid but different design known to the submitter	F	
	E-cigarette_Product_Same_Composition_Other2	If EC_ID of the product(s) with the same composition of e-liquid but different design is not known to the submitter, indicate brand name and Member State(s) where product is placed on the market	F	
	Product_Type	Type of e-cigarette or refill liquid 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.		
	Product_Manufacturer_Identification	If the submitter is not the manufacturer, the official company name of the manufacturer of the product including its contact details (multiple entries possible if the product is manufactured by multiple companies)[2]	F	
	Product_Production_Multiple_Sites	Indication if the product is produced in multiple sites	M	
	Product_Production_Site_Address	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[3] and as described in the "Guidance on the Application of the CLP	F	

[2] For each manufacturer, the following information is to be provided: ID number if any, official name, address, country, business phone and functional business e-mail.

[3] 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).

		Criteria"*(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, the following variables must be completed for each format.

Item #	Field	Description	Reporting	Submitter considers information confidential
	Product_Brand_Name	Brand name under which the product is marketed in the Member State(s) to which information is being submitted.	M	
	Product_Brand_subtype_name	Product "subtype name" (if any) as marketed in the Member State(s) to which the product information is being submitted.	M	
	Product_Unit_Packet_Picture_File	Picture of the unit packet (multiple entries possible). The picture must be clear enough to view details and to assist in the identification of unique products	M	
	E-cigarette_launch_date	The date on which the submitter plans to launch/launched the product on the market	M	
	E-cigarette_withdrawal_indication	Indication that the submitter plans to withdraw/withdrew the product from the market	M	
	E-cigarette_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(s) to which the product information below 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.[4]

Item #	**Field**	**Description**	**Reporting**	**Submitter considers information confidential**
	Ingredient_Name	Chemical name of the ingredient	M	
	Ingredient_CAS	CAS (Chemical Abstracts Service) number	M	

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

	Ingredient_CAS_Additional	Additional CAS numbers if applicable	F	
	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 [5]		
	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[6])		
	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 mg according to recipe.	M	
	Ingredient_ non-vaporised_Status	Indication whether the ingredient in non-vaporised status 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[7] , if any.	M	
	Ingredient_CLP_Classification	Indication whether the ingredient has a harmonised classification and labelling under Regulation (EC) No 1272/2008 and is included in the Classification and labelling Inventory (Article 42 Regulation (EC) No 1272/2008)	M	
	Ingredient_CLP_Acute_Tox_Oral	Ingredient classification with regard to acute oral toxicity based on Regulation (EC) No 1272/2008	F	
	Ingredient_CLP_Acute_Tox_Dermal	Ingredient classification with regard to acute dermal toxicity based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_Acute_Tox_Inhalation	Ingredient classification with regard to acute inhalation toxicity based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_Skin_Corrosive/Irritant	Ingredient classification as a skin corrosive/irritant based on Regulation (EC) No 1272/2008		

5 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).

6 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).

7 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).

	Ingredient_CLP_Eye_Damage/Irritation	Ingredient classification as responsible for eye damage/irritation based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_Respiratory_Sensitisation	Ingredient classification with regard to respiratory sensitisation based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_Skin_Sensitisation	Ingredient classification with regard to skin sensitisation based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_Mutagen/Genotox	Ingredient classification with regard to mutagenicity/genotoxicity based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_Carcinogenity	Ingredient classification with regard to its carcinogenity based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_Reproductive_Tox	Ingredient classification with regard to its reproductive toxicity based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_STOT	Ingredient classification with regard to its specific target organ toxicity based on Regulation (EC) No 1272/2008		
	Ingredient_CLP_STOT_Description	Explanations with regard to specific organ(s) affected based on the above classification (in text format)		
	Ingredient_CLP_Aspiration_Tox	Ingredient classification with regard to aspiration toxicity based on Regulation (EC) No 1272/2008		
	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 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	

5. EMISSIONS

Where multiple emissions have been measured, variables in the following sections are requested for each individual emission.

Item #	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	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	F	

		emissions, should a CAS number not exist		
	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

Item #	Field	Description	Reporting for e-cigarettes	Submitter considers information confidential	Reporting for e-cigarette refill container	Submitter considers information confidential
	E-Cigarette_Description	Description of the e-cigarette or refill container to facilitate unique product identification, including a description of 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	Lower voltage obtainable	F		N/A	
	E-Cigarette_Voltage_Upper_Range	Upper 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	Lower wattage obtainable	F		N/A	
	E-Cigarette_Wattage_Upper_Range	Upper 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	
	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 consisting 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	