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**WP5– D5.1 Report on what  
data is public and non-  
confidential in EU-CEG**

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## 1. Introduction

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According to the European Union (EU) Tobacco Products Directive (2014/40/EU), manufacturers and importers of tobacco products, electronic cigarettes (e-cigarettes) and refill containers are required to report comprehensive information to the European Commission (EC) and Member States (MS) on products which they intend to place on the market. Such information is the ingredients, the emissions and detailed toxicological data, with the specific parameters defined in the Annexes to Commission Implementing Decision (EU) 2015/2186 for tobacco products and Commission Implementing Decision (EU) 2015/2183 for e-cigarettes and refill containers. For the submission of the above-mentioned data, the Information Technology (IT) tool entitled EU Common Entry Gate (EU-CEG) has been developed with a standard format for manufacturers and importers. The EU-CEG has been operational since May 2016 and it is frequently updated according to the feedback of industry stakeholders. This tool is necessary for the EC and MS to reduce administrative burdens to regulators, to have data easily comparable and monitor the tobacco product landscape in Europe. According to articles 5(4), 20(8) and 22(2) of Directive 2014/40/EU, Member States shall ensure that the information submitted through the EU-CEG is made publicly available on a website. They have to take into account the need to protect trade secrets when making that information publicly available. Therefore, when submitting information, manufacturers and importers (and third parties) can specify which information they consider confidential. During the submission process, they have the option to indicate for all submitted data fields the confidentiality level they claim with regards to national rules on trade. However, Member States have the authority to determine whether the claims around confidentiality are valid. There are some data which even if they can be submitted as confidential by the manufacturers and importers, they can be easily revealed through plain logic, observation, internet research, chemical analysis or other types of analysis. The fact that information which can be submitted as confidential, can be also found in the public domain, negates its confidentiality and indicates that there is no reason for such kind of data to be indicated as not public in the submission process.

Within WP5, this report outlines the parameters to be used to define the level of confidentiality of the data submitted through EU-CEG taking into account the available legislation and international evidence.

## 2. Data Sources

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For the creation of this document the following resources were used – presented with their hyperlinks

### **EU Legislative Sources:**

- DIRECTIVE (EU) 2016/943 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure Directive 2016/943/EU; (Online Access),
- 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 Article 5.1.a, 14, 20.2b-f, 20.3 (Online Access),
- EU Approved Additives and E Numbers; List (Website including its base EU document REGULATION (EC) No 1333/2008 (Website))
- 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 (Text with EEA relevance) (Online Access),
- Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products (notified under document C(2015) 8162) (Online Access),
- 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) (Online Access)

#### Other EU Sources:

- EC; Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). Final Opinion on Additives used in tobacco products (Opinion 1). Tobacco Additives I SCENIHR; Additives Used in Tobacco Products; Tobacco Additives II (Online Access),
- EC; DG SANTE website. Electronic cigarettes; Packaging and Labelling Rules for E-Cigarettes (Website)
- Study on the development of a EU common reporting format for submission of data on ingredients contained in tobacco and related products, and disclosure of the collected data to the public. European Regulatory Science on Tobacco Consortium (EUREST) (Online Access)

#### International Sources:

- **USA:** FDA Listing of Ingredients in Tobacco Products: Guidance for Industry; (Online Access),
- **USA:** FDA; Listing of Ingredients in Tobacco Products as Established by the Tobacco Control Act (Online Access),
- **Canada:** Tobacco Reporting Regulations: Tobacco and Vaping Products Act; SOR2000-273; Section 11.5 (Online Access), Tobacco Reporting Regulations for Canadian Manufacturers and Importers (Website)
- **Netherlands:** NIPHE; RIVM; Filter Ventilation (Website)
- **France:** ANSES; Public Data Excel Sheets (Website)

#### Example Industry Sources:(A list of indicative websites used)

- BAT Company Information (Website), BAT Kool Filters Ingredient Specification (Website), PMI Company Information (Website), PMI; "Making Heated Tobacco Products" Article (Website), PMI; Product Ingredient Finder (Website), PMI; IQOS Product Page (Website), Totally Wicked; Arc Evo User Manual (Online Access), Nobacco; Vype ePen 3 Starter Kit (Website), Nobacco; Technical Characteristics (Website)

#### Scientific Journals (Indicative):

- BMJ Journals; Article; Electronic Cigarettes: Product Characterisation and Design Considerations; Product Design Diagram (Online Access)
- BMJ Journals; Article; Cigarette company trade secrets are not secret: an analysis of reverse engineering reports in internal tobacco industry documents released as a result of litigation (Online Access)

#### EU MS Sources of already released data

- Denmark: (Online Access)
- UK: (Online Access)
- France: (Online Access)

### 3. Generalized Groupings

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There are three types of data category clarifications

- 1) **Public Data:** Data which are to be fully disclosed to the public.
- 2) **Conditionally Public Data:** Data which are conditionally public based on specific criteria i.e. a threshold in ingredient quantity.
- 3) **Confidential Data:** Data which are to be regarded as trade secrets and not to be disclosed to the public.

There are two types of pdf file category clarifications

- 1) **Conditionally Public PDF files:** Submitters should deliver a ready-to-publish version (unlocked).

Files which are deemed to be public, however due to their large file size may be handled centrally and not at the EU MS level. The technical solution for the presentation and release of such data to the public will be assessed later within the context of the JATC.

- 2) **Confidential PDF files:** These are pdf files regarded as confidential. Should an EU MS wish to disclose the file to the public this is on a case by case basis and after discussion/agreement with the manufacturer. In the case of disagreement an edited version that can be disclosed to the public may be requested by the EU MS.

## 4. Variables for all products

The below variables are presented as per the Commission Implementing Decision 2016/2186.

### 4.1 Submitter/Manufacturer/Enterer Characteristics

Field	Description	Status	Description of Reasoning/Related Notes
Submitter_ID	This is the submitter ID; it is the first part of the (TP-ID).	Public	The TP-ID (and EC-ID) are also noted on the packaging of some products – this information is publicly available in some EU MS.
Submitter_Name	Official name of the submitter at the MS level, as linked to the VAT number requested below.	Public	This is the official name of the submitter – which is publicly available in some EU MS.
Submitter_SME	Verification if the Submitter, or parent company if it exists, is an SME as defined in EU recommendation 2003/361.	Conf.	Whether or not a company is a small-medium enterprise depends upon the balance sheet and the number of employees - two publicly available metrics. <i>EC; Explanation of an SME (Website)</i>
Submitter_VAT	The VAT number of the Submitter of the product.	Public	Publicly available on industry websites or in national company registers.
Submitter_Type	Indication whether the submitter is a manufacturer or importer.	Conf.	With the submitter's name, it can be determined whether or not they are producing/manufacturing the products or solely importing. The nature of the operations is a public matter.
Submitter_Address	The address of the Submitter associated with the VAT.	Conf.	Publicly available on industry websites or in national company registers.
Submitter_Country	The country of the Submitter in which the company is based.	Conf.	Publicly available on industry websites or in national company registers.
Submitter_Phone	The business phone of the Submitter with international codes.	Conf.	Contact information to communicate with public companies is available on their website or in national company registers.
Submitter_Email	The business email address of the Submitter. Only functional addresses should be used.	Conf.	Contact information to communicate with public companies is available on their website or in national company registers.
Submitter_Has_Parent_Company	Checkbox if the submitter has a parent company.	Conf.	Private information of the submitter
Submitter_Has_Subsiidiary_Company	Checkbox if the submitter has a subsidiary company.	Conf.	Private information of the submitter
Submitter_Has_Affiliate_Company	Tick the box if the submitter has an affiliate company	Conf.	Private information of the submitter
Submitter_Appoints_enterer	Checkbox if the submitter has appointed a third party to submit its data on its behalf (enterer).	Conf.	Private information of the submitter
Submitter_Parent_ID	The Submitter ID of the parent company should one exist.	Conf.	Private information of the submitter

Submitter_Parent_Name	Official name of the parent company.	Conf.	Private information of the submitter
Submitter_Parent_Address	The address of the parent company.	Conf.	Private information of the submitter
Submitter_Parent_Country	The country in which the parent company is based.	Conf.	Private information of the submitter
Submitter_Parent_Phone	The business phone of the parent company with international codes.	Conf.	Private information of the submitter
Submitter_Parent_Email	The business email address of the parent company. Only functional addresses should be used.	Conf.	Private information of the submitter
Submitter_Subsiidiary_ID	The Submitter ID of the subsidiary company should one exist.	Conf.	Private information of the submitter
Submitter_Subsiidiary_Name	Official name of the subsidiary company.	Conf.	Private information of the submitter
Submitter_Subsiidiary_Address	The address of the subsidiary company.	Conf.	Private information of the submitter
Submitter_Subsiidiary_Country	The country in which the subsidiary company is based.	Conf.	Private information of the submitter
Submitter_Subsiidiary_Phone	The business phone of the subsidiary company with international codes.	Conf.	Private information of the submitter
Submitter_Subsiidiary_Email	The business email address of the subsidiary company. Only functional addresses should be used.	Conf.	Private information of the submitter
Submitter_Principal_ID	The Submitter ID of the company on whose behalf the submission takes place (so called Principal).	Conf.	Private information of the submitter
Submitter_Principal_Name	Official name of the principal company.	Public.	Similar to the Submitter Name
Submitter_Principal_Address	The address of the principal company.	Conf.	Private information of the submitter
Submitter_Principal_Country	The country in which the principal company is based.	Conf.	Private information of the submitter
Submitter_Principal_Phone	The business phone of the principal company with international codes.	Conf.	Private information of the submitter
Submitter_Principal_Email	The business email address of the principal company. Only functional addresses should be used.	Conf.	Private information of the submitter
Product_Manufacturer_Identification	If the submitter is NOT the manufacturer of the tobacco product, then here he would state the official company name of the manufacturer of the product and other information that would aid the identification of the manufacturer.	Public	Similar to Submitter Name

## 4.2 Product Information Submission and Description

Field	Description	Status	Description of Reasoning/Related Notes
Submission_Type	The type of submission for the product.	Public	This should be used as a filter variable used with only the most recent version of the products currently on the market (at the time of data extraction) selected for sharing with the public.
Submission_Start_Date	The submission date will be calculated by the system when the user submits the product. Date will have the following format: dd/mm/yyyy.	Public	This would indicate the data since which the above product is on the market (provided the current date is after the Launch_Date AND six months after the First_Submission_Date for EC and Novel TP at the time of data extraction)
Product ID (TP-ID or EC-ID accordingly)	The unique ID is given to each product.	Public	This is the public identifier of that specific product.
Product_ID_Other	Additional "Product_ID" fields for when the same product (same recipe and design characteristics) is marketed in another EU MS. The submitter reports which other Product_IDs exist for this identical product in other MS. Each additional ID is separated with semicolons (;).	Public	This is the public identifier of that specific product.
Product_Same_Composition_Exist_Other	List Product_ID of the product(s) with the same proportion of ingredients in the tobacco blend composition.	Public	This is the public identifier of that specific product that provides information on the producer, the year and the product.
Product_Type	The type of tobacco product concerned.	Public	Can be found on the packaging of the product or website. This is used to differentiate which variables that are product specific are also mandated as public.
Product_Length	Average length of the product unit in mm.	Public	This can be measured.
Product_Diameter	Average diameter (measured at the point with maximal diameter) of the product unit in mm.	Public	This can be measured.
Product_Weight	Weight of one unit of product, including the specified moisture for one unit of product, and expressed in mg.	Public	This can be measured.
Product_Tobacco_Weight	Weight of the tobacco in one unit of the product.	Public	This can be measured. A unit of product is one cigar, one cigarillo, one cigarette, one pouch/bit, etc. of SLT. One unit for all loose products is 1 g including the moisture content and expressed in mg.
Product_Filter	Existence of a filter in the product.	Public	Can see this if you were to take apart the product and often is externally visible and advertised on the packaging
Product_Filter_Length	Length of the product filter in mm.	Public	Can be measured.
Product_Brand_Name	The "product brand name" as marketed in the MS.	Public	Consumer would already know this information when purchasing the product

Product Production Site	The complete address of the sites where product production is completed.	Conf.	May effect market practices.
Product_Brand_subtype_name	The product "subtype name" as marketed in the MS.	Public	Consumer would already know this information when purchasing the product
Product_Launch_Date	Date on which the submitter plans to launched the product on the market	Conditionally public	Information is available to the consumer via internet search. Only launch dates that are in the past are to be released to the public. Note: If technically feasible we may have only active products (not withdrawn) in the public version released.
Product_Withdrawal_Indication	Indication that the submitter plans to withdraw/withdrew the products from the market	Conf.	This could have implications for market reasons, of use to the regulator.
Product_Withdrawal_Date	Date on which the submitter plans to withdraw/withdrew the product from the market	Conditionally public	This could have implications for the internal markets, of primary use to the regulator. Only withdrawal dates that are in the past are to be released to the public. Note: If technically feasible we may have only active products (not withdrawn) in the public version released.
Product_Submitter_Number	ID number used internally by the submitter.	Conf.	Not of use to the general public as the name of the product as marketed is released along with the TP-ID.
Product_UPC_Number	The UPC-12 (Universal Product Code) for the product.	Public	Available on the barcode visible on the packaging.
Product_EAN_Number	The EAN-13 or EAN-8, (European Article Number) for the product.	Public	Available on the barcode visible on the packaging.
Product_GTIN_Number	The GTIN (Global Trade Identification Number) for the product.	Public	Available on the barcode visible on the packaging. Not all products have all three of these but whichever they have is public <i>Global Trade Item Number Implementation Guide; Page 5 (Online Access)</i>
Product_SKU_Number	The SKU (Stock Keeping Unit) number(s) for the product.	Public	Available on the barcode visible on the packaging. ANSES publishes the SKU numbers for companies for which they are available <i>France; ANSES; Public Data Excel Sheets (Website)</i>
Product_National_Market	The Member state for which the product information below is being provided. The EU MS is selected from a dropdown list.	Public	The data are EU MS specific and each EU MS is responsible for its data and hence apriori this information is public.
Product_Package_Type	The type of the Product Package	Public	Publicly viewable
Product_Package_Units	The number of individual units of product in the package.	Public	Publicly viewable Directive 2014/40/EU; TPD2; Article 14 (Online Access)
Product_Package_Net_Weight	Net Weight of the product contained within one package in g.	Public	Already on the packaging and could be measured <i>Directive 2014/40/EU; TPD2; Article 14 (Online Access)</i>



### 4.3 Description of Ingredients: Tobacco

Field	Description	Status	Description of Reasoning/Related Notes
Tobacco_Quantity	The quantity of each of the tobacco parts noted below (Type, leaf, cure method) Reported per product unit in mg.	Conditional Public	Conditionally public based on a proposed cut-off of 0.5% of product weight. <b><i>This variable should be the weight of tobacco in mg, by leaf cure method, leaf type, and part type</i></b>
Tobacco_Part_Type	The type of tobacco part as noted in Table 3.4 of the Reference Data section. Each specific type should be reported separately.	Conditional Public	Conditionally public based on a proposed cut-off of 0.5% of product weight.
Tobacco_Part_Type_Other	The name of the tobacco part type if "other" is selected from Table 3.4 of the Reference Data Section.	Conditional Public	Conditionally public based on a proposed cut-off of 0.5% of product weight.
Tobacco_Part_Manufactured_Source	The manufacturer/source of the manufactured tobacco.	Conf.	Trade secret possibly (also incriminating of trade secret if a shared manufacturer). If released it may possibility to breach a confidentiality agreement between manufacturer and importer
Tobacco_Leaf_Type	The type of tobacco leaf used.	Conditional Public	Conditionally public based on a proposed cut-off of 0.5% of product weight.
Tobacco_Leaf_Type_Other	The name or description of the tobacco leaf type if "other" or "unspecified" is selected from Table 3.5 of the data reference section.	Conditional Public	Conditionally public based on a proposed cut-off of 0.5% of product weight.
Tobacco_Leaf_Cure_Method	The method used to cure the tobacco leaf.	Conditional Public	Conditionally public based on a proposed cut-off of 0.5% of product weight.
Tobacco_Leaf_Cure_Method_Other	The name/description of the cure method used if "other" is selected from Table 3.6 of the Reference Data section.	Conditional Public	Conditionally public based on a proposed cut-off of 0.5% of product weight.

### 4.4 Description of ingredients: Additives and other substances/elements

Field	Description	Status	Description of Reasoning/Related Notes
Ingredient_Category	Category of the product component or material to which the ingredient is added to as described in Table 3.7 of the Reference Data section.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the agreed threshold described in Annex 1.
Ingredient_Category_Other	The category of the product component or material to which the ingredient is added in text format if the response to Item# 5.10 is "other".	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the agreed threshold described in Annex 1.
Ingredient_Name	Chemical name of the ingredient.	Conditionally public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the agreed threshold described in Annex 1. For e-cigarettes all ingredients should be listed on the package (TPD art. 20.4 (b)), and therefore Ingredient_Name can be fully public regardless of the %.

Ingredient_CAS	The CAS registry number used to identify the ingredient.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the agreed threshold described in Annex 1. Research using EU-CEG data has noted that this variable is of high quality and would be the predominant chemical identifier.
Ingredient_CAS_Additional	The additional CAS registry numbers provided.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the agreed threshold described in Annex 1.
Ingredient_FEMA_Number	Flavour and Extract Manufacturers Association	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the agreed threshold described in Annex 1.
Ingredient_Additive_Number	If the ingredient is a food additive, its food additive number should be stated using the Commission Regulation (EU) No 1130/2011 and Regulation (EC) No 1333/2008.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the threshold described in Annex 1.
Ingredient_FL_Number	European flavouring (FL) number of ingredients, if one has been granted for the ingredient based on the commission Implementing Regulation (EU) No 872/2012.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the threshold described in Annex 1.
Ingredient_EC_Number	European Community (EC) number, if one has been granted for the ingredient.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the threshold described in Annex 1.
Ingredient_Recipe_Quantity	The weight of the ingredient included in one unit of product in mg according to recipe.	Conditional Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the 0.1% for RYO and cigarettes and 0.5% of the total tobacco product weight for other tobacco products BAT provides the exact quantity of each ingredient to the hundredths decimal place <i>Example of BAT Kool Filter Ingredients (Website)</i>
Ingredient_Recipe_Min_Level	When the declared quantity of the additive fluctuates in order to adjust for the natural variations of tobacco leaf, the manufacturer should declare lowest range in weight (mg) of the specific ingredient in one unit of the product. This used weight should NOT be lower.	Conf.	Fluctuations of production batch recipes from the standard recipe may not be relevant information for the public, but more for the regulator. Based on 2015/2186 this information would not be regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the 0.1% for RYO and cigarettes and 0.5% of the total tobacco product weight for other tobacco products FDA shares this online. <i>USA; FDA; Listing of Ingredients in Tobacco Products as Established by the Tobacco Control Act (Online Access);</i> <i>BAT; Ingredient Identifier (Website)</i>

Ingredient_Recipe_Max_Level	When the declared quantity of the additive fluctuates in order to adjust for the natural variations of tobacco leaf, the manufacturer should declare the upper range in weight (mg) of the specific ingredient in one unit of the product. This weight should NOT be exceeded. This field can be used to differentiate the ingredient information below into either "Confidential" or "Public" on the basis of agreed cut-offs.	Conf.	Fluctuations of production batch recipes from the standard recipe may not be relevant information for the public, but more for the regulator. Based on 2015/2186 this information would not be regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the 0.1% for RYO and cigarettes and 0.5% of the total tobacco product weight for other tobacco products FDA shares this online. <i>USA; FDA; Listing of Ingredients in Tobacco Products as Established by the Tobacco Control Act (Online Access)</i> <i>BAT; Ingredient Identifier (Website)</i>
Ingredient_Measured_Mean_Quantity	The measured mean (average) weight of the ingredient in mg that was added to one unit of the product during the previous reporting period. This "Measured Mean Quantity" is to be calculated based on the average of the quantity of that ingredient added within each standardised batch.	Conf.	Fluctuations of production batch recipes from the standard recipe may not be relevant information for the public, but more for the regulator. For regulators to assess if the measured concentrations match the reported concentrations noted in EU-CEG.
Ingredient_Measured_SD	The statistically derived standard deviation of the mean quantity of ingredient added to one unit of the product within each standardized batch during the previous reporting period.	Conf.	Fluctuations of production batch recipes from the standard recipe may not be relevant information for the public, but more for the regulator. For regulators to assess if the measured concentrations match the reported concentrations noted in EU-CEG.
Ingredient_Measured_Number	Number of measurements considered	Conf.	Fluctuations of production batch recipes from the standard recipe may not be relevant information for the public, but more for the regulator. For regulators to assess if the measured concentrations match the reported concentrations noted in EU-CEG.
Ingredient_Function	Function of the ingredient. If an ingredient has multiple functions, all the function codes should be stated and are to be separated by semicolons (;).	Public	Based on 2015/2186 this information is not regarded as a trade secret. Values from fields with possible multiple entries should be merged in the public dataset.
Ingredient_Function_Other	The function of the ingredient in text format if the response to Item# 5.60 is "other".	Public	Based on 2015/2186 this information is not regarded as a trade secret
Ingredient_Priority_Additive	Indication if the ingredient is a priority additive	Public	Of significant interest to public health
Ingredient_Unburnt_Status	Dropdown on the existence of information if the ingredient in unburnt status is characterised by any known type of toxicity or has CMR properties.	Public	Based on 2015/2186 this information is not regarded as a trade secret
Ingredient_REACH_Registration	Notification if the ingredient has been registered under REACH (1907/2006), regardless of its registration type.	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, REACH status can be identified via the public domain through the site: <a href="http://echa.europa.eu/information-on-chemicals/registered-substances">http://echa.europa.eu/information-on-chemicals/registered-substances</a> <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i> <i>European Chemicals Agency; Registered Substances; REACH (Website)</i>

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 and is in the classification and labelling inventory	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6,
Ingredient_CLP_Classification	Notification if the ingredient has been CLP classified (1272/2008) and is in the C&L Inventory (A yes vs. no response).	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, Can look online at the CLP Classification site to determine this. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i> <i>European Chemicals Agency; C&amp;L Inventory; CLP Classification (Website)</i>
Ingredient_Tox_Data	Existence of toxicological data available, for either as an individual substance or as part of a mixture and in burnt or unburnt form.	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 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 <i>Commission Implementing Decision 2015/2186/EU; Article 6.2.B (Online Access)</i>
Ingredient_Tox_Emission	Existence of studies that indicate the chemistry and/or toxicity of emissions	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 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 <i>Commission Implementing Decision 2015/2186/EU; Article 6.2.B (Online Access)</i>
Ingredient_Tox_CMV	Existence of any CMR related study	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 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 <i>Commission Implementing Decision 2015/2186/EU; Article 6.2.B (Online Access)</i>
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.	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 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 <i>Commission Implementing Decision 2015/2186/EU; Article 6.2.B (Online Access)</i>

Ingredient_Tox_Addictive	Existence of an analysis of the possible addictive properties of the ingredient, i.e. whether the ingredient promotes dependence.	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 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 <i>Commission Implementing Decision 2015/2186/EU; Article 6.2.B (Online Access)</i>
Ingredient_Tox_Other	Existence of any other toxicological data not stated above.	Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 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 <i>Commission Implementing Decision 2015/2186/EU; Article 6.2.B (Online Access)</i>

#### 4.5 TNCO and other emissions

Field	Description	Status	Description of Reasoning/Related Notes
Emission_Tar	For cigarettes, Tar according to the ISO standard 4387 with the accuracy measurements determined in accordance with ISO standard 8243.	Public	This is routinely provided public data of public health interest.
Emission_Nicotine	Nicotine yield according to the ISO standard 10315 with the accuracy measurements determined in accordance with ISO standard 8243.	Public	This is routinely provided public data of public health interest.
Emission_CO	CO yield according to the ISO standard 8454 with the accuracy measurements determined in accordance with ISO standard 8243.	Public	This is routinely provided public data of public health interest.
Emission_TNCO_Lab	The identification of the laboratories used to measure each of the above TNCO emissions from the list of the laboratories used by manufacturers and communicated to the commission. In case of multiple entries, they should be separated by semi- columns (;).	Conf	The name of the exact laboratories is more of interest to the regulators and not a priori of use for the general public
Emission_Other_Available	Filter variable for notification of the existence or not of information on other emissions and their levels.	n/a	Filter variable (not applicable)
Emission_Other_Name	Chemical name of the emissions produced during the testing of the product.	Conditionally public	Of public health interest. Measurable in a laboratory. The actual disclosure of this data should be performed after the JATC overview of the value of this field is provided.

Emission_Other_CAS	The individual emission's Chemical Abstract Service (CAS) registry number.	Conditionally public	With emission name, CAS can be derived online <i>Directive 2014/40/EU; TPD2; Article 20.2.B; Page 26 (Online Access)</i>
Emission_Other_IUPAC	The emission's IUPAC name, should a CAS number not exist.	Conditionally public	Above reasoning <i>Directive 2014/40/EU; TPD2; Article 20.2.B; Page 26 (Online Access)</i>
Emission_Other_Quantity	The quantity of the emission produced during the process of using the product.	Conditionally public	"including quantities thereof" <i>Directive 2014/40/EU; TPD2; Article 20.2.B; Page 26 (Online Access)</i>
Emission_Other_Units	The units in which the emission is measured.	Conditionally public	"including quantities thereof" → this is necessary to express quantity with clarity <i>Directive 2014/40/EU; TPD2; Article 20.2.B; Page 26 (Online Access)</i>

#### 4.6 Additional Cigarette specific

Field	Description	Status	Description of Reasoning/Related Notes
Cigarette_Characterising Flavour	Classification of the cigarette as having a characterising flavour	Public	Of significant public health interest as products that are marked as having a characterizing flavor should be removed from the market based on the 2014/40/EU.
Cigarette_Filter_Ventilation	Total Ventilation of the filter (0-100%).	Public	This website comments on the efficiency of filters, validating the importance of the differences in size of the ventilation holes (thereby making it in the interest of public health to disclose). This is also routinely measured with the use of appropriate lab equipment available in smoking labs. Additional reading: <i>Netherlands; NIPHE; RIVM; Filter Ventilation (Website)</i> <i>France; ANSES; Public Data Excel Sheets (Website)</i>
Cigarette_Filter_Drop Pressure_Closed	Drop of Pressure with closed vents (mmH2O).	Public	Of public health interest. This is also routinely measured with the use of appropriate lab equipment available in smoking labs. France already has this information published for public viewing
Cigarette_Filter_Drop Pressure_Open	Drop of Pressure with open vents; (mmH2O).	Public	Of public health interest. This is also routinely measured with the use of appropriate lab equipment available in smoking labs. France already has this information published for public viewing

#### 4.7 Additional Smokeless, Finecut and Roll-your-own specific

Field	Description	Status	Description of Reasoning/Related Notes
Smokeless_pH	The pH of the product.	Public	Of public health interest. This can be measured in a lab. Toxicokinetics: Nicotine, the main addictive substance in tobacco products, is a weak base with a pKa of 8.0 (Fowler 1954). At pH 6.5 and higher, a considerable part of nicotine is in its unionised, free base form which readily crosses biological membranes. Chewing tobacco and snuff are buffered to alkaline pH to facilitate absorption of nicotine through the oral mucosa (Benowitz 1999a) Additional Reading: <i>EC; SCENIHR; Health Effects of Smokeless Tobacco Products Preliminary Report; Page 46 (Online Access)</i> <i>PubMed; Journal; USA; Surveillance of Smokeless Tobacco Nicotine, pH, Moisture, and Unprotonated Nicotine Content (Online Access)</i>
Smokeless_Nicotine_Content	Total nicotine content of the product per unit.	Public	Of public health interest. This can be measured in a lab.
Roll-you-own/pipe_Total_Nicotine_Content	Total Nicotine Content of the loose product per product unit	Public	Of public health interest. Easily measurable in a laboratory
Finecut/pipe_Unionised_Nicotine_Content	Unionised nicotine content of the loose content.	Public	Based on 2015/2183 this information is not regarded as a trade secret.
Smokeless_Total_Moisture	Total moisture of the product per unit.	Public	Measurable
Smokeless_Unionised_Nicotine_Content	Unionised nicotine content of the product per unit.	Public	Based on 2015/2186 this information is not regarded as a trade secret.
Smokeless_Analysis_Methods	Brief Text description of the methods used to measure the above variables	Confidentially Public	Of interest to the general public – for transparency reasons the industry should indicate the analysis methods used. As this is a text field it should be explored if this should become a pdf file – following the detailed JATC analysis of EU-CEG data.

#### 4.8 Additional on electronic cigarettes and their refill containers

For variables that have the similar naming as in the EU notification format for implementing decision 2015/2183, the interpretation is the same. Below are the variables that are unique to electronic cigarettes and their refill containers as per Commission Implementing Decision 2015/2186

Field	Description	Status	Description of Reasoning/Related Notes
Product_Weight_E-liquid	Total weight of e-liquid in one product unit in mg.	Public	Is measurable within a lab and/or included in the packaging of the product.
Product_Volume_E-liquid	Total volume of e-liquid in one product unit in ml.	Public	Is measurable in a lab and/or included in the packaging of the product.

Ingredient_Non_Vaporized_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	Public	Of public health interest, additionally supported by COM 2015/2183, Art 6 as it is linked to the existence of information on toxicity.
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	Public	Not a trade secret because it would be public information that these products need to be used together (not a legally controlled piece of information, this is just something you would know) <i>Directive 2016/943/EU; Trade Secrets; Article 2; Page 9 (Online Access)</i>
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	Public	Of public health interest. Emissions are measurable in a lab with appropriate equipment
E-Cigarette_Liquid_Volume	Volume/capacity in ml	Public	The capacity is measurable
E-cigarette_Nicotine Concentration	The nicotine concentration of the liquid in the e-cigarette or refill container in mg/ml.	Public	This is defined on the packaging
E-Cigarette_Battery_Type	Description of the type of battery used including its chemical composition (type).	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Battery_Type Capacity	Indication of the battery capacity in mAh.	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Volt Watt_Adjustable	Verification that the e-cigarette is either voltage/wattage adjustable.	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Voltage	The stable voltage of the e-cigarette	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Voltage_Lower Range	Lower voltage obtainable	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Voltage_Upper Range	Upper voltage obtainable if response	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Wattage	Steady wattage output	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Wattage_Lower Range	Lower wattage obtainable	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.
E-Cigarette_Wattage_Upper Range	Upper wattage obtainable	Public	Battery specifications are noted within the packaging during purchase and in the accompanying battery safety guides and/or user manuals.



E-cigarette_Airflow Adjustable	Indication if the airflow of the e-cigarette is adjustable.	Public	Airflow adjustment will be noted within the packaging during purchase and/or user manuals.
E-Cigarette_Wick Changeable	Indication that the consumer may adjust/alter/replace the wick.	Public	Wick adjustment will be noted within the packaging during purchase and/or user manuals.
E-Cigarette_Microprocessor	Indication of the existence of a microprocessor in the e-cigarette.	Public	This is identifiable through basic reverse engineering.
E-Cigarette_Coil_Composition	Chemical composition of the wiring (coil) in the atomiser.	Public	Coil composition is of public health interest as it may be related to emission or by product production. Coil Composition may also be noted within the packaging during purchase and/or user manuals.
E-Cigarette_Production Conformity	Declaration that the production process ensures conformity	Public	Of interest primarily to the regulator at the EU and EU MS level as it is a declaration of compliance to the TPD requirement “a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;” <i>Directive 2014/40/EU; TPD2; Article 20. (Online Access)</i>
E-Cigarette_Quality_Safety	A declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when used under normal or reasonably foreseeable conditions.	Public	Of interest primarily to the regulator at the EU and EU MS level as it is a declaration of compliance to the TPD requirement “a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;” <i>Directive 2014/40/EU; TPD2; Article 20. (Online Access)</i>
E-cigarette_Consistent Dosing	Declaration of nicotine dosing at consistent levels during product use and across batches under normal or reasonably foreseeable conditions.	Public	Of interest primarily to the regulator at the EU and EU MS level as it is a declaration of compliance to the TPD requirement “a description of the production process, including whether it involves series production, and a declaration that the production process ensures conformity with the requirements of this Article;” <i>Directive 2014/40/EU; TPD2; Article 20. (Online Access)</i>
E_Cigarette_Child_Tamper_Proof	Declaration that the product is child resistant and tamper proof, is protected against breakage and leakage and have a mechanism that ensures refilling without leakage (where applicable).	Public	Declarations of interest to regulators
E-cigarette_High_Purity	Declaration that only ingredients of high purity are used in the manufacture of the liquid.	Public	Declarations of interest to regulators

## 5. Pdf file variables

Product_Technical_File	Pdf file as the relative technical document setting out a general description of the additives used and their properties.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 2(a) – as long as the additives described are above the designated threshold. Note: Pending the technical ability to publish pdf files
Product_Market_Research_File	Internal and external 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.	Conditionally Public	May be public based on 2015/2186, Art 6, (e) if they refer to ingredients and emissions in light of the release of information for toxicity and addictiveness. Note: Pending the technical ability to publish pdf files
Product_Mode_Of_Sales	Relevant pdf document describing the mode of sale of the products.	Conf.	This is their proprietary research on the market and is easily defended as a trade secret: not generally known, not readily accessible, has commercial value because it's secret, subject to reasonable steps to be kept secret <i>Directive 2014/40/EU; TPD2; Article 20.7; Page 28 (Online Access)</i> <i>Directive 2016/943/EP (Online Access)</i>
Tobacco_Part_Description_File	Pdf including the overall description of the manufactured part type in the recipe. The description should provide detailed information on the quantitative and qualitative consistency of the manufactured tobacco.	Conf.	Trade secret possibly (also incriminating of trade secret if a shared manufacturer). It may possibility to breach a confidentiality agreement between manufacturer and importer
Ingredient_Priority_Additive_Files	Pdf files of the report 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.	Conditionally Public	Such files are common for all MS (at the Product level and not at the Presentation level), a common publication of these common files should be agreed by the Expert Group on Tobacco Policy and released at the EU level.
Ingredient_Tox/Addictive_File	Files related to the relevant toxicological data above in items (#5.140-5.144) referring in particular to their effects on the health of consumers and taking into account, inter alia, any addictive effects.	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret under Art6, 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 <i>Commission Implementing Decision 2015/2186/EU; Article 6.2.B (Online Access)</i>
Emission_Other_Methods_File	Description of the measurement methods used to assess the other emission	Conditionally Public.	A methods file. <i>Canada; Tobacco Reporting Regulations for Canadian Manufacturers and Importers (Website)</i>

Emission_Methods_File	Pdf file on the production and measurement methods used to assess the emissions. The file should contain substantial information for the regulator to understand and duplicate if necessary, the emission test and also include where the emission testing took place.	Conditionally Public	Of public health interest. Emissions are measurable in a lab with appropriate equipment.
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)	Public	This is dependent on the detail of the information provided in the pdf. Information available on the website, the user manual and information that can be detected through reverse engineering should be noted. <i>For instance: Totally Wicked; Arc Evo User Manual (Online Access)</i>
Novel_Risk/Benefit_File	Pdf file on the Risk/Benefit analysis of the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption and predicted consumer perception.	Public	"1. The manufacturers and importers submitting a notification of a novel tobacco product shall also provide the competent authorities with: c. other available and relevant information, including a risk/benefit analysis of the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption and predicted consumer perception." <i>Directive 2014/40/EU; TPD2; Article 19; Page 25 (Online Access)</i>
E-Cigarette_Nicotine_Dose/Uptake_File	Pdf document for the nicotine dosing/uptake studies.	Public	Related to public health. Research on 107 post TPD products has indicated that this information is commonly presented in the packaging/instructions/leaflets of e-cigarette refill vials
E-Cigarette_Production_File	Pdf file with the description of the final production process, including series production.	Conf.	The production file may be regarded as a trade secret.
E_Cigarette_Opening Refill_File	Pdf file with the description of the opening and refill mechanism, where applicable.	Public	The opening/refill file is noted within the packaging during purchase and/or user manuals.
Product_Unit_Picture_File	The relevant picture of the individual unit in pdf form. The picture should be clear enough to view details and aid in unique product identification.	Conditionally Public	As the products are available on the public market, a picture could be taken and thereby distributed; making this a public submission component.
Product_Package_Picture_File	The relevant picture of the package in pdf form. The picture should be clear enough to view details and aid in unique product identification.	Public	Also can see at the retailer (same reasoning as for Product_Unit_Picture_File)

E_Cigarette_Leaflet_File	Pdf file for the uploading of the scanned file of the leaflet of information for consumers that will include: Instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers; contra-indications; warnings for specific risk groups; possible adverse effects; addictiveness and toxicity; and contact details of the manufacturer or importer and a legal or natural contact person within the Union.	Public	Can be found on the packaging of the product or website
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## 6. Variables Specific to the EU-CEG Reporting format and not 2015/2183 and 2015/2186

This section contains the definitions and explanation of the variables included in the EU-CEG reporting system, but not covered under the 2015/2183 or 2015/2086 Commission Implementing Decisions.

Field	Description	Status	Description of Reasoning/Related Notes
Product_Multiple_Presentation	A dropdown if the unique TP-ID product is marketed with different presentations. This is the "key" to product description Part B.	Public	Publicly identifiable at the point of sale.
Product_Maximum_Sales_Price	The highest (maximum) retail sale price per package of the specific product in the local currency in the country for which the product is being reported.	Public	Publicly identifiable at the point of sale. (Preliminary assessment of the EU-CEG data indicate that this is not always reported)
Ingredient_CLP_Acute_Tox_Oral	Ingredient Classification with regards to acute oral toxicity based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Acute_Tox_Dermal	Ingredient Classification with regards to acute dermal toxicity based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Acute_Tox_Inhalation	Ingredient Classification with regards to acute inhalation toxicity based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Skin_Corrosive / Irritant	Ingredient Classification as a skin corrosive/irritant based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Eye_Damage/ Irritation	Ingredient Classification as responsible for eye damage/irritation based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Respiratory_Sensitisation	Ingredient Classification with regards to respiratory sensitisation based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>

Ingredient_CLP_Skin_Sensitisation	Ingredient Classification with regards to skin sensitisation based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Mutagen/Genotox	Ingredient Classification with regards mutagenicity/genotoxicity based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Carcinogenity	Ingredient Classification with regards to its carcinogenity based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Reproductive_Tox	Ingredient Classification with regards to its reproductive toxicity based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_STOT	Ingredient Classification with regards to its specific target organ toxicity based on Regulation (EC) No 1272/2008. Responses are selected from the dropdown list provided.	Public	Based on 2015/2183 this information is not regarded as a trade secret. TPD - reads: "toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;" <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_STOT_Description	Reference to the specific organ(s) affected in text format based on the above classification.	Public	Based on 2015/2183 this information is not regarded as a trade secret. TPD - reads: "toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;" <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Ingredient_CLP_Aspiration_Tox	Ingredient Classification with regards to aspiration toxicity based on Regulation (EC) No 1272/2008.	Public	Based on 2015/2183 this information is not regarded as a trade secret. TPD - reads: "toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, inter alia, any addictive effect;" <i>Directive 2014/40/EU; TPD2; Article 20.2.C (Online Access)</i>
Product_CLP_Classification	Overall Product classification as a mixture of substances based on Regulation (EC) No 1272/2008 and as described in the "Guidance on the Application of the CLP Criteria". This takes into account collectively the potential toxicity at the "product level".	Conditionally Public	Based on 2015/2186 this information is not regarded as a trade secret. <i>NOTE: Due to the potential errors with the variable – it potentially should be reassessed after the JATC data analysis is completed ECHA; Guidance on the Application of the CLP Criteria; to Regulation 1272/2008/EC; Version 5.0 (Online Access)</i>

## 7. Submission of annual product data

Field	Description	Status	Description of Reasoning/Related Notes
Product_Annual_Reporting_Section	Verification if the submitter would like also to submit their annual information noted in TPD Art20.7 via the current submission system. Checking this box activates the below reporting requirements.	Conf.	This is their proprietary research on the market and is easily defended as a trade secret: not generally known, not readily accessible, has commercial value because it's secret, subject to reasonable steps to be kept secret <i>Directive 2014/40/EU; TPD2; Article 20.7; Page 28 (Online Access)</i> <i>Directive 2016/943/EP (Online Access)</i>
Product_Sales_Volume	Information on annual sales volume of the reported product in the country at the submitter level. Sales volume reporting to be reported in pieces (for devices) and/or ml (for e-liquids).	Conf.	This is their proprietary research on the market and is easily defended as a trade secret: not generally known, not readily accessible, has commercial value because it's secret, subject to reasonable steps to be kept secret <i>Directive 2014/40/EU; TPD2; Article 20.7; Page 28 (Online Access)</i> <i>Directive 2016/943/EP (Online Access)</i>
Product_Other_Market_Data	Other market data that may be available to the submitter.	Conf.	For use by the regulator and may impact market research firms who collect this information unless it contains information on studies of toxicity addictiveness. The information could be released case by case, on request, in an aggregate form after having informed the manufacturers
Product_Other_Market_Data	Supplementary market data that may be available to the submitter.	Conf.	This is their proprietary research on the market and is easily defended as a trade secret: not generally known, not readily accessible, has commercial value because it's secret, subject to reasonable steps to be kept secret <i>Directive 2014/40/EU; TPD2; Article 20.7; Page 28 (Online Access)</i> <i>Directive 2016/943/EP (Online Access)</i>

### ANNEX –Proposal for a technical interpretation of the provisions laid on Art.6(2) of Decision of execution 2015/2186 (tobacco products).

A same ingredient might be split into different burnt or unburnt categories. In such a situation and due to many errors in reporting ingredients, it is impossible to identify this and sum the quantities (or the weight fraction) for the ingredient whatever its categories. Splitting an ingredient into different categories as it stands prevents substances and their actual quantities to be published. Hence the following solution is proposed.

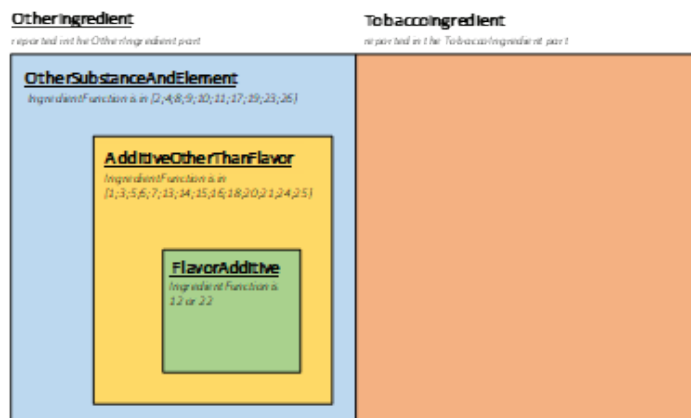
Art.6(2) of Decision of 2015/2186 provides a set of rules based on product type, ingredient type and ingredient weight fraction to set cut-off values under which information is considered to be a trade secret and should not be disclosed to the public. Regulatory rules are as follows:

6(2). When using the information transmitted for the purposes of applying Directive 2014/40/EU and Regulation (EC) No 1049/2001 of the European Parliament and of the Council (4), the Commission shall, in principle, not consider the following information to be confidential or a trade secret:

- (a) for all tobacco products, inclusion and quantity of additives other than flavourings;
- (b) for all tobacco products, inclusion and quantity of ingredients other than additives used in quantities above 0,5 % of the total tobacco product unit weight;
- (c) for cigarettes and roll-your-own tobacco, inclusion and quantity of individual flavourings used in quantities above 0,1 % of the total tobacco product unit weight;
- (d) for pipe tobacco, cigars, cigarillos, smokeless tobacco products and all other tobacco products inclusion and quantity of individual flavourings used in quantities above 0,5 % of the total tobacco product unit weight.

Any ingredient of a tobacco product (tobacco ingredient, additive, flavor, other substance and element, as defined in TPD Art.2) can be related to one of the ingredient type described in Figure 1.

Figure 1. Proposal for a partition of tobacco ingredients with regards of their nature and their technological function as categorized in the TPD Data Dictionary for Tobacco Products.



Therefore, we propose to translate the regulatory provisions into the following business rules for publishing, using the terms defined in Figure 1:

Ingredient Type (Fig.1)	Product Type	WeightFraction Threshold
Tobacco Ingredient	All tobacco products	0.5%
Other elements		
Flavor Additive	Tobacco products other than Cigarette and RYO	0.1%
	Cigarette and RYO	
Additives Other Than Flavors	All tobacco products	Null or 0.0%