



**EUROPEAN COMMISSION**

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products

**Substances of human origin and Tobacco control**

## **MEETING WITH STAKEHOLDERS ON SUBMISSION OF INFORMATION UNDER ARTICLE 20 OF DIRECTIVE 2014/40/EU**

### **SUMMARY RECORD**

**Date:** 29 June 2015

**Place:** CCAB-2C

#### **Background**

The meeting focused on the proposed technical solutions for submission and storage of information under Articles 20 of the Tobacco Products Directive 2014/40/EU (TPD) and to gather feedback from stakeholders, in particular concerning:

- the architecture and feasibility of the technical solutions being proposed by the Commission
- interest in participation in an industry ad-hoc technical working group with possible subsequent involvement in pilot testing

#### **Introduction**

DG SANTE welcomed the participants and introduced the Commission's team. The chair underlined that the purpose of the meeting was not to discuss the legality or the interpretation of the TPD, given that it has already been adopted and that court cases are pending. DG SANTE then briefly outlined the state of play regarding the common notification format for e-cigarettes to be established by means of an implementing act according to Art. 20 (13) TPD. An external study was launched in May 2014, carried out by an external contractor, the EUREST consortium. One of the key deliverables of the project is the data dictionary (draft reporting format). This document is being finalised taking into account input from stakeholders and Member States. On this basis a pilot notification platform is being developed. The adoption of the implementing act on the common notification format for e-cigarettes is foreseen for Q4 2015.

One of the key elements is that DG SANTE considers centralizing the data submission via an EU Common Entry Gate (EU-CEG), in order to ensure that harmonised data sets are transferred to Member States. Such a system would also limit the administrative burden for manufacturers, importers and national regulators and facilitate comparison of data.

To respond to request from some of the Member States, DG SANTE considers offering a data storage facility for Member States. Member States which are interested would be able to rent server capacity from the Commission by signing a Service Level Agreement. In this scenario the data would be stored by Member States in a national data repository hosted by the Commission. The alternative would be storing the data at national data repositories hosted by the Member States.

The Commission would fund the development and maintenance of the EU-CEG), but the responsibility for data processing remains with Member States

### **General comments**

Overall, stakeholders welcomed the approach and the development of a common entry gate for submission of data.

### **Discussion Points:**

#### **1) Submission and identification of confidential Data**

Some stakeholders asked which rules on confidentiality are applicable if a Member State goes for the option of storing data within the Commission premises. DG SANTE clarified that the responsibility of Member States will not change as a result of renting server capacity by the Commission services. Certain stakeholders expressed difficulties to notify all ingredients as a result of purchasing liquids or other components from a supplier who does not reveal exact information on ingredients because of trade secrets. DG SANTE explained that Art. 20(2)(b) of the TPD is clear in this respect and that the notification must contain a list of all ingredients

#### **2) Special impacts of the notification format for SMEs**

Some stakeholders expressed their wish to receive more information on submission via PDF-files and some further explanations on the operation of the IT platform. The discussion also focused on the question of whether a submission via PDF-files or a system to system submission is more complex and what might be better for SMEs as the number of notifications will ultimately depend on how many products each company markets/intends to market. DG SANTE indicated that the submission via PDF-files might be easier for companies with less extensive IT solutions because there are no session time-outs.

#### **3) Cost effects**

Stakeholders expressed some concerns about the cost impacts of the notification format when launching products in several Member States and submitting the data at different times, including for each nicotine level. DG SANTE explained that this should be discussed with the Member States, as they alone are entitled to charge fees. The current IT solution proposed by the Commission will help to reduce overall costs.

#### **4) Transitional period**

Stakeholders pointed out that it is very important for all e-cigarette manufacturers to know if Member States are making use of the exhaustion of stock provision in Art. 30 TPD.

#### **4) Pilot reporting platform and industry ad-hoc technical working group**

DG SANTE introduced the idea of an industry ad-hoc technical working group as well as a pilot testing of the notification format for stakeholders and explicitly invited smaller operators to participate because it is also a good opportunity for SMEs to express their concerns and provide feedback before actual notification is needed. The meetings of the ad-hoc technical working group will be held via web conferences so that there will not be a need to travel.

Stakeholders were invited to inform DG SANTE whether they wish to participate in the ad-hoc technical working group, the pilot reporting platform or both.

#### **5) Other technical issues**

Stakeholders asked whether there will be one database for conventional tobacco products and e-cigarettes or two separate ones. DG SANTE replied that this has not been decided yet.

Stakeholders also asked whether it is possible to delegate and outsource the submission process. DG SANTE indicated it will be possible to outsource submissions to third parties. For other technical questions raised stakeholders were referred to the ad-hoc technical working group.

#### **TPD implementation update on e-cigarettes**

At the end of the meeting DG SANTE briefly updated stakeholders on other implementation tasks relating to e-cigarettes. For the report on health risks related to refillable e-cigarettes (Art. 20.10 TPD) and for technical specification on refill mechanisms an external study (PRECISE) was launched in January 2015 to provide input to the Commission report and secondary legislation. DG SANTE indicated that the final report of the PRECISE contract is due in October 2015.

#### **Conclusions**

DG SANTE thanked stakeholders for their input and asked them to submit any additional comments relating to the proposed EU-CEG, ideally within one week of the meeting and at the latest within two weeks. During the same time period stakeholders should inform DG SANTE if they would like to participate in the technical ad-hoc working group and the pilot testing.

## **Annex I**

### **List of participants**

#### **Stakeholders:**

AIDUCE  
BLU  
British American Tobacco  
ECITA  
FIVAPE  
Flavourart  
Imperial Tobacco  
JTI

Nerudia  
Nicobrand  
Nicoventures  
NJOY  
Philip Morris International

Smart Evolution Trading (Puff)  
Tobacco Vaper Electronic Cigarette  
Association (TVECA)

Totally Wicked  
Totally Wicked E-Liquid

Alan Depauw  
Julian Shellard  
Darren Harris  
Thomas Pruen  
Arnaud Dumas de Raully  
Massimiliano Mancini  
Jonathan C. Davis  
Julia Wolf  
Joyce Cheuk Yi Cheung  
David Jones  
Mark McQuillan  
Francis Cheung  
David Graham  
Karsten Merkel  
Kristof Doms  
Umberto Roccatti

Renato Addis  
Ray Story  
Richard Hyslop  
Liam Humberstone

#### **Commission:**

DG SANTE D4

Dominik Schnichels (chair)  
Matus Ferech  
Isabel Holmquist  
Patricia Murray  
Herman Brand  
Markus Kalliola  
Kerstin Selbach