EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

MEETING OF THE EXPERT SUBGROUP ON THE TECHNICAL IMPLEMENTATION OF THE COMMON REPORTING/NOTIFICATION

SUMMARY RECORD

Date: **20 January 2016**

Place: **Centre Albert Borschette (Rue Froissart, 36) room 3A**

Introduction

DG SANTE welcomed the participants and thanked them for them taking part in the meeting and sharing their views concerning the development of the EU-CEG to date.

It was explained that this meeting follows a series of webinars over previous months. A brief summary of the background to this work was given, including the related implementing acts, the ongoing creation of an EU common entry gate (EU-CEG) for submission of reporting/notification information and the possibility for Member States to choose to store submitted data at Commission facilities.

The chair outlined the agenda for the day and encouraged MS in general to ensure that all industry actors are well informed of their obligations concerning reporting and notification via the EU-CEG ahead of the May 2016 deadline. Efforts will continue to be made by DG SANTE in this respect but it was highlighted that support at MS level is essential.

EU-CEG

DG SANTE then gave an update on the progress of the technical implementation of the common reporting/notification format.

A submission tool mock-up was also presented. Representatives from DG DIGIT informed the participants about both TestaNG and e-Delivery tools. MS choosing to store their data within the Commission facilities have to establish a connection to TestaNG while MS opting to store at national level will need to install e-Delivery. Storage within Commission facilities will be regulated by a Service Level Agreement (SLA). DG SANTE updated MS concerning the work on the final version of the agreement. The main points discussed during the meeting are summarised in bullet points below:

- DG SANTE encouraged MS to provide the Commission as soon as possible with their decision regarding their option for storage (preferably within two weeks). DG SANTE can then provide MS with more information and where possible help them to make necessary arrangements. In this context DG SANTE informed the participants that a list of national TestaNG contact points will be circulated electronically and it is important to identify and contact the persons that are responsible for TestaNG in each MS.

- The chair also encouraged MS who have not yet done so to submit the entity form setting out which entities will be responsible for tobacco reporting and e-cigarette notifications respectively. It was clarified that it is also possible to have one entity responsible for both.

- Regarding the general architecture of the EU-CEG, MS were informed that the viewing tool "Qlikview" is not yet feasible in the secure environment foreseen for the data storage. . The Commission will instead provide MS with a different kind of viewing tool which it is currently developing. This tool will provide all basic functions necessary to view data and will be secure.

- In terms of division of tasks, it was highlighted that once the EU-CEG is operational technical support to industries and importers will be provided by the Commission, while all substance/content-related questions relating to submissions will be the responsibility of Member States.

- It was clarified that it will be technically possible to submit data on products such as herbal and novel tobacco products via the EU-CEG, and that the SLA for storage at Commission facilities will also cover these products.

- During the meeting DG SANTE took note that MS requested further documentation regarding some of the computer systems that are already in use within the Commission (ECAS, SAAS etc.), in order to decide whether further tests need to be carried out by MS themselves concerning computer systems that might be necessary for implementation of the EU-CEG, as well as to assist in their decision regarding storage at Commission facilities. DG SANTE will provide MS with any such documentation available. Concerning updates to submitted information in the system, MS expressed interest in having notifications each time an update is received. DG SANTE took note of this opinion and said it is an important issue that it will look into, even if such a function may not be possible at the first launch. MS also expressed an interest in creating a forum where they can cooperate in information exchange/work-sharing regarding tasks related to reporting/notification, as well as in a potential future Joint Action linked to these tasks. DG SANTE encouraged this idea and will also endeavour to facilitate MS in the creation of such a forum.

Conclusions/Next Step

DG SANTE thanked MS for their participation in the meeting and said that slides, other documents and minutes will be shared in coming weeks. The next meeting will take place

in webinar format and will likely be next month. DG SANTE will inform MS as soon as a date and time have been confirmed. DG SANTE also informed MS that the next meeting of the Expert Group on Tobacco Policy will take place on 24 February 2016.

Annex I – List of Participants

Member States:

Austria	(Federal Ministry of Health)
Belgium	(Federal Public Service Public Health)
Bulgaria	(Ministry of Agriculture and Food)
Cyprus	(Ministry of Health – Medical and Public Health)
Czech Republic	(Ministry of Health)
Croatia	(Ministry of Health
Cyprus	(Ministry of Health; Department of Information Technology Services)
Czech Republic	(Czech Agriculture and Food Inspection Authority; Ministry of Health)
Denmark	(Danish Safety Technology Authority)
Estonia	(Ministry of Social Affairs)
Finland	(National Supervisory Authority for Welfare and Health)
France	(Direction Générale de la Santé)
Germany	(Federal Ministry of Food and Agriculture)
Greece	(Permanent Representation of Greece to the EU)
Hungary	(National Institute of Pharmacy and Nutrition; Ministry of Agriculture)
Ireland	(Department of Health; Health Service Executive)
Italy	(Ministry of Health)
Latvia	(Ministry of Health, Health Inspectorate)
Lithuania	(Ministry of Health)
Malta	(Ministry for Energy and Health, Environmental Health)
Poland	(Ministry of Health/Bureau for Chemical Substances)
Portugal	(Ministry of Health)
Slovakia	(Ministry of Agriculture and Rural Development)
Slovenia	(National Laboratory of Health, Environment and Food)
Sweden	(Public Health Agency of Sweden)
The Netherlands	(RIVM)
United Kingdom	(Department of Health; MHRA)

EEA countries:

Norway	(Norwegian Medicines Agency; Norwegian Directorate of Health)

Commission (DG SANTE):

Anna-Eva Ampelas (Chair)

Matus Ferech

Filip Borkowski

Markus Kalliola

Patricia Murray

Marta Legnaioli

Christoph Dumont