EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

Brussels, 14 September 2015

FIRST MEETING OF THE STAKEHOLDER TECHNICAL WORKING GROUP ON REPORTING FORMAT UNDER ARTICLE 5 OF DIRECTIVE 2014/40/EU

SUMMARY RECORD

Date: **10 September 2015**

Place: **Adobe Connect WEBINAR**

Introduction

DG SANTE welcomed the participants and thanked them for joining the discussion. After a short "tour de table", it was highlighted that the role of the working group is to provide input to the IT related aspects of developing the reporting format under the TPD and that the purpose is not to discuss the legality or the interpretation of the TPD.

It was suggested that the working group would meet once a month via WEBINAR.

DG SANTE concluded that many companies had indicated interest in the foreseen pilot testing and suggested to refer discussion on practical arrangements to a later stage, closer to the testing.

Discussion

Two presentations were given to describe the business aspects and the IT aspects of the suggested (EU-CEG). The bullet points below summarise the discussion on the main topics:

- **Roadmap**: In terms of main delivery it was concluded that the intention is to have the EU-CEG up and running by 20 May 2016 as all new products placed on the market after this date shall require prior reporting via the system. It was noted, however, that the main bulk of reports is expected by 20 November 2016 (for products already on the market). DG SANTE also explained that the technical analysis is still going on and it is too early at this stage to share thoughts about the foreseen iterations. Participants asked whether the iteration

plan could be shared with manufacturers in a timely manner. SANTE replied that this is an internal document, but promised that the working group would be adequately informed. The duration of the working group was subject to a short discussion and some participants asked to continue the WG also during the pilot phase. DG SANTE confirmed that the idea is to continue the working group until the launch of the EU-CEG, but did not exclude a few meetings on a need basis even after the launch.

- **User interface:** DG SANTE explained that PDF technology is probably inadequate to comply with the foreseen reporting requirements. Two other technology options were presented for SMEs: a stand-alone application (which would allow saving past information locally) to be installed on the PC or a Web application (reporting starts always from a blank screen. Information can be exported to a local computer, but the process is complex). Stakeholders were asked to indicate their preferred solutions within two weeks. No firm positions were given at the meeting. Some participants indicated that for their SME members it is very important to understand how the proposed solutions would operate in a "real-life" environment and to be able to test those solutions in order to asses if they are fit for purpose without creating unnecessary burdens. SANTE confirmed that it would be possible within the pilot to test a suggested solution, but it would not be possible, from a resource point of view, to test many different options in the pilot.

- **Storage**: Following questions from the industry, it was clarified that many Member States had indicated interest in using the Commission facilities for storing data, but that no decisions had been taken by the Members States yet.

- **Security**: One participant asked whether there were any plans to perform independent security testing and share the outcome with the industry. DG SANTE explained that the security will be tested internally within the Commission and that this working group will be adequately informed. It was also indicated that the Member States are responsible for the security systems of their national systems.

- **Confidentiality:** One participant asked how the confidentiality claim should be justified by the industry and it was concluded that the exact format for this has not yet been decided, but that it is for Member States to assess whether the claims are justified or not.

- **Uploads**: It was discussed whether the attached files need to be re-attached every time they are to be included in a submission or whether the EU-CEG should foresee a possibility to keep copies of these files and allow for references to these in order to rationalise the process. It was concluded that references to previously submitted files could potentially be an option for those that are non-confidential. For confidential files, however, multiple uploads or encryption would be needed. Corrections were also subject to a short discussion, including how to distinguish between a new submission and a correction. DG SANTE responded that a "correction" field could be considered for the reference table under submission types. Participants indicated that it is very important (for traceability purposes) to receive a copy of all information submitted and a confirmation that the submission was successfully made. Errors should be clearly indicated by the system (including a reason for the error which should allow for efficient error

correction). DG SANTE confirmed that this is foreseen, but reminded that the system will only check errors from a technical point of view, with substance verification being the responsibility of Member States). In addition, it was pointed out that if a web application is chosen as a technology for SMEs to submit notifications, it will not keep the submitted data accessible for the submitter but it will be sent to the Member State database. Therefore it was said that submitters should save the notification receipt and data in local computers. It was stated that a checksum for the XML and also for file uploads may be necessary in the notification receipt, so that industry can check that their message was sent successfully. DG SANTE was in favour of adding it.

- **Data dictionary:** Following a question from one of the participants it was clarified that all the reporting fields in the legal act will be binding whilst the IT application will also include some optional reporting fields which could be useful for Member States/industry. Several participants requested the latest version of the data dictionary and in particular the XSD schema, acknowledging that it might not yet be finalised as it was critical information for preparing the industries' systems. SANTE referred to the draft Commission Decisions on reporting/notification which are both subject to TBT-notification. For additional non-mandatory fields and reference tables, reference was made to the previously shared data dictionary being the most recent version.

- **Annual data:** It was discussed that sales volume, ingredient actual quantities and other data to be submitted separately will require a different XML message, because it will be sent at different intervals and contains different data than the main notification of product data. Therefore it would not be necessary to send the rest of the data again when reporting these.

- **Language:** DG SANTE stated that the content based on the reference tables (Annex of Data dictionary) in the XML data will be translated to all EU languages and presented in the reporting tool with a language which is selected by the user. For files and studies they explained that it seems to be sufficient to provide this data in English, however the definitive decision will be with individual Member States.

Conclusions/Next steps

DG SANTE thanked stakeholders for their input and reassured that the slides will be shared together with the minutes of the meeting in coming days/week. A number of identified questions to the stakeholders will also be circulated for feedback within two weeks. The next webinar will take place in October (date tbc). The participants agreed to merge the working group with the parallel working group dealing with IT related aspects for electronic cigarettes' notification (TPD Article 20).

Annex I List of participants

Stakeholders:

Agio Cigars
British American Tobacco Germany
Bulgartabac
European Cigar Manufacturers Association
ESTA
House of Oliver Twist
Imperial Tobacco
Japan Tobacco International
J Cortès Cigars
Landewyck Tobacco
Philip Morris International
Pöschl Tabak
Protabacco
Scandinavian Tobacco Group
Swedish Match North Europe
Verband Deutscher Rauchtabakindustrie

Commission (DG SANTE)

Dominik Schnichels (chair)
Anna-Eva Ampelas
Matus Ferech
Markus Kalliola
Patricia Murray
Tommaso Maria Rinversi