EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
D.4 Substances of human origin and Tobacco control

Stakeholder Technical Working Group on Reporting and Notification Formats under Articles 5 and 20 of Directive 2014/40/EU
FINAL Summary record

Meeting date: 21 January 2016, 10.00 – 12:00
BRUSSELS

(1) Welcome and Introduction

DG SANTE welcomed the participants. The Chair outlined the agenda for the day and explained that as in previous meetings the focus will be purely on IT aspects. It was highlighted that though much progress has been made to date, the timeline is tight, and the intention is to have basic functionality in place by 20 May enabling the key requirements to be met. SANTE will continue to work with stakeholders beyond this to further refine the system.

The Chair recalled that there will be a need for all submitters to register for submitter IDs from the Commission and said that more information will be communicated as soon as possible, including on a dedicated webpage.[1] For this, an ECAS authentication will be needed and this can already be acquired.[2]

(2) Update from the Commission

General progress report: EU-CEG

DG SANTE gave an update on the progress of the EU-CEG development, including the roadmap for development, general architecture and the timeline for pilot testing. As the timeline is ambitious stakeholders requested further details relating to the planning and relevant documents as soon as possible. SANTE noted the comments and said it would endeavour to provide these.

A submission tool mock-up was also presented and there was a presentation on the functionality of e-Delivery, to which companies intending to make system-to-system submissions will need to ensure access (establishing the access point is already possible and support is provided on the dedicated webpage[3]). The main points discussed during the meeting are summarised in bullet points below:

[1] http://ec.europa.eu/health/euceg/.
[2] https://webgate.ec.europa.eu/cas
[3] https://joinup.ec.europa.eu/software/cipaedelivery/home

- The intention is to begin pilot testing for companies opting for system-to-system submissions in March (connection testing only). Relevant Integration documents for testing (including XSDs and error messages) will be provided at the end of February. In April a second phase of testing will be done. The second phase will be done with validation and success/error messages. If necessary the technical specifications will be adjusted according to the feedback from testing. Some stakeholders asked about stress testing under heavy payload. DG SANTE noted the query. It said currently foresees that the majority of submissions will be made towards the 20 November 2016 deadline, even if some submissions will need to be made as soon as the tool is launched.

- For standalone client users there will be testing in April. Standalone client users will be authenticated via ECAS and system-to-system users will be authenticated by certificates.

- DG SANTE asked participants to reflect on which option they would go for, both for the pilot testing phase and after 20 May, and to let it know, preferably ahead of next month's webinar (opting for one pilot test option does not exclude choosing the other option in May). Specific webinars may be proposed to each of the user groups (i.e. the system-to-system and the stand-alone client users). Relevant integration documents for testing (including XSDs and error messages) will be provided at the end of February.

- It was highlighted that companies who do not manage to set in place the relevant IT structures for system-to-system submissions by 20 May 2016 may consider using the stand-alone client option initially as a transitional solution and switching over at a later date,

- Concerning preparation for system-to-system pilot testing companies should consult the e-Delivery webpage in conjunction with the documents and sample XML previously circulated.

- It was clarified that the format for the stand-alone client and system-to-system are exactly the same: both create a zip package, they just deliver them via different channels. Regarding a question as to whether the industry can create the XML using another application than the EC-created standalone client, SANTE responded that it is theoretically possible but recommended to use the stand-alone application.

- It was explained that some additions to the reference table for submission type could still be done, e.g. an annual data submission type and a correction submission type. Participants agreed that these modifications would be useful and requested that the revised reference tables be circulated as soon as possible, to which SANTE agreed.

- In relation to the mock-up screens from the submission tool, it was explained that a section for general comments has been foreseen, and submitters are encouraged to specify here what changes are being made, e.g. to previously reported/notified products when re-submitting. It was clarified that certain fields have been foreseen to allow Member States to use the submission tool for the submission of other information e.g. on novel products (to fulfil Article 19 TPD requirements), herbal products for smoking (Article 22 TPD), and the annual data required for e-cigarettes

and refill containers (Article 20(7) TPD), even if these are not specifically addressed in the implementing acts (it is expected that most Member States will require submission of this information via the EU-CEG). It was further clarified that the 'Product presentation' section is the section in which submissions to individual MS can be added or withdrawn. One participant said that there are some discrepancies between the mock-up screenshots and the final implementing decision and that this would be a concern for the industry. SANTE explained that though the layout may be somewhat different, the mock-up tool had been designed taking the implementing act as a basis.

- It was noted that, where possible, the addition of a copy/duplicate function for automatic re-entry of repeated data would be welcomed by participants. SANTE noted the request and said it had already been foreseen for certain sections of the stand-alone tool.

- Regarding submission of annual data, SANTE encouraged this where possible to be done around the same time of the year in all relevant Member States. The implementing act provides some suggestions as to when this could be. It was also mentioned by DG SANTE that some MSs may ask for annual sales data submissions, as well as information on actual use of additives in the case fluctuation. An appropriate submission type should in these cases be selected.

- For notification of e-cigarettes and refill containers, it was clarified that if only notifying a liquid/device, emissions testing must be performed with another 'test' product. If the liquid and device are sold together, they should be tested together.

- On system-to-system usage, it was explained that a Commission-led (DG DIGIT) secure access point called e-Delivery, which is used to send documents between parties, is foreseen to be used. With system-to-system you must create your own zip file, then use the e-Delivery access point to send it to the EC access point. Users will have to install and operate an e-Delivery access point based on an AS4 profile. This can be done with open source software offered by the Commission (called Domibus) or with other open source and proprietary solutions offered by various vendors.

- It was confirmed that after successful validation of the submitted information by the system (i.e. format validation only), a success message will be delivered to submitters. If submissions contain format errors, this will be communicated to the submitter. An XML for these error messages was requested by participants and SANTE said this could be provided along with the other technical specifications at the end of February. One of the participants asked for clarification as to whether or not the system would automatically generate a copy of the submitted document as received by the Member State authority, which can be used as proof of which data were uploaded, and stressed the importance of this. SANTE replied that the success messages would contain a check-sum of submitted information.

(3) Conclusions

SANTE thanked participants for their input and said that though timelines are very tight every effort is being made to make progress. The chair noted the request by participants to receive updated documents as soon as possible, and receive more documentation relating to pilot testing. On its side SANTE reminded that it would like to know as soon as possible which

submission system (system-to-system or stand-alone) companies will opt for, both for the pilot testing and in May 2016. SANTE agreed to circulate general information on e-Delivery and contact information for support on this, and said the next webinar will likely take place in 1 month (date to be confirmed).

Annex I– List of Participants

Stakeholders:

Arnold AndréCigars

British American Tobacco

Bulgartabac

ECMA

ESTA

Freshcig

German Smoking Tobacco Association

Imperial Tobacco

JTI

Karelia Tobacco

Nerudia

Nicopure Labs

Nicoventures

Nobacco

PMI

Pöschl Tabak

Ritchy EU

Scandanavian Tobacco

Swedish Match

Totally Wicked

TVECA

Cuts Ice

FlavourArt

Nerudia

Nicobrand

Landewyck Tobacco

House of Oliver Twist

Commission (DG SANTE):

Anna-Eva Ampelas (Chair)

Matus Ferech

Filip Borkowski

Patricia Murray

Markus Kalliola

Caroline Fabre

Christophe Dumont