EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Health in all Policies, Global Health, Tobacco Control

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

Webinar date: 08 September 2016, 14.00 – 16:00

(1) Welcome and Introduction

DG SANTE welcomed the participants and informed them that a webinar with Member States had taken place earlier on the same day. The Chair said that a lot of progress had been made since the last webinar, when the pre-stage procedure was still open. This has since been closed, and both submission options are in place. The majority of submissions are currently being made via the XML creator, but system-to-system information has been successfully submitted by some companies. SANTE offered support to any company still in the process of preparing to submit via system-to-system. It also informed that notifications for all new documents uploaded in CIRCABC have been set up, but that companies must change their CIRCABC settings in order to receive these notifications. In addition, a new webpage is being developed, containing an extended FAQ section and further guidance for users. Most parts of the webpage will be made available in the Commission's three official languages.

(2) Technical update from the Commission

DG SANTE provided some figures and statistics regarding the submissions successfully received via the EU-CEG to date and informed participants that the Member State reporting tool (to view submitted data) is accessible for national administrators.

The procedure for future updates to the system and how these will be implemented was then outlined. Each time an update is planned for release, envisaged changes will be noted in the latest version of the 'general release note' on CIRCABC. SANTE explained that two new releases ahead of 20 November are foreseen: the first will be in mid-September and is expected to have no impact for submitters; the second will be in mid-October. This will have some impact for submitters, but it is expected to be low as most changes will relate to a relaxation of business rules, meaning that submissions under the old XSD will still be accepted by the system. The changes being prepared have been decided based on user feedback received to date. Further updates are foreseen for after November and will relate to business rule improvements.

In terms of the deployment procedure updates, SANTE will first publish the XSD release candidates on CIRCABC. Some weeks after this, it will release the changes in acceptance. Finally, three weeks following this, the updates will be released in production. SANTE said it

will aim to publish all release candidates as early as possible so that companies have sufficient time to prepare. It further explained that improvements to the XML creator will be bundled into update packages that are released in intervals once available.

(3) Update from users and Q&A

Participants asked a series of questions relating to the operation of the system as well as the content of submissions. Responses can be summarised as follows:

- A simplified process to submit annual sales volume is foreseen. The decision as to when this information is required each year is up to Member States, but the relevant Commission Implementing Decisions recommend that this information should be submitted in the first half of the subsequent calendar year (i.e. in the first half of 2017, sales data for 2016 should be provided. In 2016, data from the 2015 sales year should be given, which for new products will be '0').
- It was clarified that the field 'package units' refers to the number of individual units in the unit packet (i.e. the number of sticks in an individual cigarette pack).
- The choice of file format is up to submitters, but SANTE agreed that PDF format is likely to prove reliable. More unusual file types may have a higher likelihood of causing technical problems.
- Regarding the possibility for companies to check whether certain products have already been notified, no specific tool is currently foreseen by SANTE. In this respect SANTE reminded participants that the reporting/notification procedure is not an authorisation procedure, and as such no formal acceptance or rejection of submissions should be expected (in the case of problems with individual submissions, Member State authorities will of course take contact with companies).
- SANTE also said that although it understands that certain information related to each notification is likely to be confidential, there have been some reports from Member States of very frequent confidentiality markings. Companies are asked to ensure that all confidentiality claims they make are well justified and limited to the extent possible.
- For non-compliant products/products benefiting from the exhaustion of stock clause provided for under the TPD (Art. 30), SANTE agreed that it is difficult to complete the required information and said that it understands most Member States will not require such products to be reported/notified via the EU-CEG.
- Though there is currently no copy option, SANTE explained that submitters can copy the XML to a local folder in order to reduce some burden (participants may email the IT Support address for instructions on how to do this). Attachments need to be uploaded only once. Thereafter submitters may re-attach them by selecting the ID under which they were filed.
- Regarding REACH reference numbers, SANTE said these can be found on the ECHA website.[1]
- SANTE clarified that for all new submissions, including for products already on the market but submitted via the EU-CEG for the first time, submission type 1 (new product) should be chosen.
- On the issue of language, SANTE reiterated that the EU-CEG cannot translate text, but that most elements of the submission are dealt with via codes, which facilitate translation, and that the free text fields remain limited. It reported that in meetings

[1] https://echa.europa.eu/regulations/reach

with Member States there has been a common understanding that most studies would be received and accepted in English. On SANTE's side, as mentioned, it is working on the translation of the website and of certain key documents.

- It was explained that in order to add a national market to a notification, submitters should add a 'Product Presentation', and fill in the information required in this section. Companies should note that, in the case of e-cigarettes, the addition of a Member State will trigger the required 6 months advance notice before the product can be placed on the market of the Member State in question.

(4) AOB

Some participants informed SANTE that they are planning a stress test of the EU-CEG system, to ensure it is in a position to receive large quantities of data. SANTE said that it welcomed this as an additional opportunity to ensure the system is working well and that it would be interested to share experiences on both sides following this.

(5) Conclusions

SANTE thanked participants. It said that minutes of the webinar and the date of the next webinar would be communicated shortly to participants.

List of Participants

Cutsice
ELDA
ST Group
FEM2 AMBIENTE
JTI
PÖSCHL TABAK
BAT
ECMA
PMI
Landewyck
Oliver Twist A/S
NOBACCO
Arnold Andre
Oettinger Davidoff
Continental Tobacco Corporation
Joh. Wilh. von Eicken GmbH
Dannemann
Agio Cigars
J. Cortès Cigars
Mac Baren Tobacco Company A/S
Imperial Tobacco Limited
Karelia Tobacco Company
Traditab
German Smoking Tobacco Association
Robert Demeter
CECCM
Swedish Match
Concept Liquids

Commission services

Anna Eva Ampelas, Filip Borkowski, Matus Ferech, Jan Hoffmann, Patricia Murray, Caroline Fabre, Markus Kalliola.