



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products

Health in all Policies, Global Health, Tobacco Control

Expert Subgroup Group on the Technical Implementation on the Common Reporting and Notification Formats under Articles 5 and 20 of Directive 2014/40/EU (webinar)

DRAFT Summary record

Webinar date: 08 September 2016, 10.00 – 12:00

(1) Welcome and Introduction

DG SANTE welcomed the participants and said that a lot of progress had been made since the last webinar with Member States, when the pre-stage procedure was still open. This has since been closed and both submission options – system to system and XML Creator – are in place and working well. 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 said that where possible Member States should encourage industry to prepare for system to system submissions in good time, and contact the IT Support in case of problems being experienced. It also said that the Member State reporting tool is now in place and that all Member States should be in a position to view the data that has been submitted to them. Additional functionalities for the tool are foreseen at a later stage. SANTE then informed that notifications for all new documents uploaded in CIRCABC have been set up. In order to receive them users from Member State must be members of the CIRCABC group and ensure that the notification settings are turned on. 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.

Member States were also informed that some updates to the system are planned and SANTE presented a timetable for their release. Some of these have been based on user feedback and are intended to improve the business rules so as to make the system more user-friendly. The first update is planned for mid-September. The procedure for each time there is an update will be explained to industry in detail and SANTE said it will aim to give notice of all planned updates as early as possible so that companies have sufficient time to prepare.

Regarding the Member State reporting tool, as mentioned basic functionality is in place and further updates are planned, including the possibility to download zip files containing submissions and their attachments. Further improvements are also foreseen at later stages.

It was explained that Member States will need to regularly look at their data in order to determine whether new submissions have been received. There will however be a specific flag indicating the most recent incoming submissions.

Regarding the possibility for Member States to download a version of the submission for publication on national websites in order to comply with the requirements of the TPD, SANTE said it is working on the possibility of allowing users to extract information marked as non-confidential for download in file format. However, it also pointed out that the responsibility to assess the confidentiality claims made by companies will be with Member States. SANTE said that such assessment merits further reflection amongst Member States, in particular as some have already noted a heavy use of confidentiality claims within their submissions. If a common understanding is reached in the future by Member States on what they deem to be non-confidential information, it may be possible to develop an extraction function based on this. The Joint Action on tobacco and e-cigarettes currently underway may be one forum in which this subject could be discussed. In cases where excessive confidentiality claims have been identified, SANTE pointed out that Member States should take contact with companies outside the EU-CEG system, as reverting to them via the system will not be possible.

It was clarified that the data dictionaries for herbal products and for non-nicotine containing e-cigarettes (should Member States be requiring submissions on these via the EU-CEG) are contained within the tobacco and e-cigarette data dictionaries respectively.

SANTE explained that it is currently receiving a lot of emails containing interpretation/policy questions for which it has been necessary to refer to Member States. SANTE asked Member States to be aware that they are often best placed to respond to these questions, as they frequently relate to the practical implementation in Member States. SANTE also said it would like to hear whether Member States are receiving similar questions and suggested that a discussion among Member States could be facilitated if needed. It clarified that it will not be able to add interpretation questions to the new batch of FAQs that is being developed, as Member States are responsible for transposing the TPD.

Regarding procedures for the next webinar, SANTE said it intends to set new password codes and will consider setting specific rules on Member State identification within the webinar in order to ensure only national representatives are present.

Member States asked with whom the notification responsibility should lie in the case of manufacturers located in third countries, with several importers located in the EU. SANTE said that in this case Article 23 TPD clarifies that the primary responsibility should lie on the importers located in the EU, and that in principle one notification is enough per product, should the various importers of the product choose to cooperate on this (the different brand names/formats of the product should then simply be noted in the 'product presentation' section, and other importers should be identified as "associate company"). If the importers are unaware of each other, different notifications can be introduced.

(3) Conclusions

SANTE thanked participants. It said that minutes of the webinar and the date of the next webinar would be communicated shortly to participants. It informed Member States that a webinar with industry was scheduled for the afternoon.