



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Expert Subgroup on the Technical Implementation of the Common Reporting/Notification Format Final Summary record

Webinar date: 29 February 2016, 10:00 – 12:00

(1) Welcome and Introduction

DG SANTE welcomed the participants. The Chair explained that following the legal adoptions the technical work is ongoing. The aim is to ensure that compliance with basic legal obligations will be possible in May 2016, and further refinements will follow. SANTE said it understands that all Member States intend to use Commission storage facilities and that if this is not the case, Member States should inform it as soon as possible. The Chair reminded participants that it is an obligation to have a system in place in May – either storage at Commission facilities or e-Delivery and national storage – that will allow the data submitted to be received. Storage at Commission facilities requires that a Service Level Agreement (SLA) is signed. SANTE is in the process of finalising this for MS signature. If a Member State has not signed an SLA or if it does not have an alternative (e-Delivery) system in place, any data submitted to it via the EU-CEG will need to be returned to submitters. The Chair informed that a new webpage¹ providing information on the EU-CEG has been launched and said that Member States should ensure that stakeholders at their national level are well informed of the requirements, including by referring them to this webpage.

(2) Update on the progress of the technical implementation of the common reporting/notification format

Presentation of general EU-CEG development progress

The general architecture of the system was presented and the various options for submitters were outlined. For Member States, ECAS and SAAS will be employed for identification and authentication.

¹<http://ec.europa.eu/health/euceg/>

Two URLs to test Member States TestaNG connectivity were provided. These are not EU-CEG-specific but are used for other Commission applications. By clicking on them however, Member States can verify their connection.

Member States were asked about the status of their TestaNG connections with many responding that the connection process was underway.

DG SANTE then presented a mock-up of the reporting tool that Member States will use to view their data, though further modifications are likely before the launch. New submissions will be visible by submission date and various filtering options will be possible. The content of the reporting tool – either a full or public version – will be downloadable. The reporting tool itself doesn't need to be downloaded as it will operate through a web browser.

SANTE also described how the section on submitter information has been separated from the section on product information in the XML schema. This will facilitate updates if company details change, as these can be updated separately. There will also be a viewable history to see past details, although the latest information will always be displayed first when viewing products.

The procedure for submission of attachments was also described. In order to facilitate the process and reduce the size of submissions it is foreseen that attachments will be uploaded in advance, and subsequently referred to in the submissions. If reference is made to an attachment that hasn't been uploaded, the submission will fail. Multiple references to uploaded files will be possible.

Regarding the size of files, estimates at this stage are difficult to make and sizes may differ depending on products. However, given the risk that they could be quite large, the method up uploading attachments described above will help to address this concern.

The roadmap for pilot testing was also described. The first phase of this is due to start for industry this week with connectivity testing for the e-Delivery platform. Testing with real data will begin in April and, based on this, modifications can be made if needed. SANTE said it would inquire with industry stakeholders whether this test data could be used for Member State training. SANTE reminded Member States that if any of them will choose the e-Delivery option for receiving data, now is the time to register for testing, as leaving it too late will be problematic. Testing and training for Member States: regarding the reporting tool is foreseen for late April/May and Member States were encouraged to communicate if they have any specific training needs in this respect.

It was clarified that it will be possible to use the EU-CEG for submission of information on novel products.

(3) Conclusions

The Chair said that the details of the new webpage will be circulated and reminded participants of the need to inform industry stakeholders at national level of this and of their obligations. It was pointed out that good progress had been made in terms of Member State connectivity to TestaNG, and that SANTE currently understands that all Member States will opt for storage of data at Commission facilities. In this respect, the Chair reminded Member States of the importance of preparing internally for signature of the SLA (e.g. by determining who will sign, who will act as national administrator for each sector etc.), as the timetable is tight. The text of the SLA is currently being finalised and will be circulated as soon as possible.

The next webinar will be held towards the end of March. In addition there will be some discussion on this topic in the Ingredients subgroup to be held on 22 April (invitation will be sent to members of the Ingredients Subgroup, and members of the current subgroup are requested to liaise with them regarding participation). Finally it was added that draft minutes and presentations given at today's webinar will be circulated as soon as possible and that relevant documents would be uploaded to CircaBC in the coming days.

Annex I – List of Participants

Member States:

Bulgaria
Czech Republic
Croatia
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Ireland
Malta
The Netherlands
Poland
United Kingdom

EEA countries:

Norway

Commission (DG SANTE):

Anna-Eva Ampelas (Chair)
Matus Ferech
Filip Borkowski
Markus Kalliola
Patricia Murray
Marta Legnaioli