



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  
DRAFT Summary record**

**Webinar date: 14 June 2016, 11.00 – 13:00**

**(1) Welcome and Introduction**

DG SANTE welcomed the participants. The Chair briefly summarised the work to date and informed the group that all 28 Member States had by now signed the Service Level Agreement for storage of data at Commission facilities. No submissions to individual Member States would therefore be blocked as a result of non-signature of the SLA.

**(2) Pre-stage procedure and Member State reporting too**

DG SANTE outlined the temporary pre-stage procedure, which was opened in an initial phase in order to manage as efficiently as possible, minimise disruptions and ensure that secure data transfer would be possible. It was also intended to prevent any possible negative consequences in terms of timely placing on the market of new products.

SANTE further highlighted that participation/non-participation in the pre-stage procedure should have no consequences for existing products (i.e. those already on the market on 20 May 2016), for which the deadline for submission remains 20 November 2016.

It was explained that products for which pre-stage information was submitted, and for which full submissions are subsequently made (via the EU-CEG) within the given deadline, will have their provisional submission date confirmed in the system. DG SANTE therefore encouraged the companies concerned to complete full submissions as early as possible and not to wait until the final moment before expiry of the deadline.

**(3) Technical update from the Commission**

DG SANTE explained that the layout of documents on CIRCABC has been reorganised, with the latest data dictionary versions uploaded on 07/06. The major changes in these versions include corrections to CLP fields and to business rules relating to ingredients for e-cigarette products. Participants were informed that advance notice will always be given in the case of future changes, which will be uploaded in advance in acceptance, with a clear release date for production communicated to users. DG SANTE further explained that it is not the intention to

make frequent changes to technical documents/the XML generator, but rather to integrate necessary changes in batches.

It was explained that the technical documents relating to message encryption (which concerns only AS4 users, not users of the XML generator) were updated on 10/06 on CIRCABC. It is possible to test encryption in acceptance.

Regarding any issues or difficulties companies may be experiencing, DG SANTE advised to contact the IT Support team as a first point of contact. This team is working in close collaboration with DG DIGIT and will attempt to resolve the problem.

DG SANTE reminded companies still experiencing difficulties with system-to-system submissions that the XML generator tool remains available as an alternative option. One company asked whether a different Submitter ID is required for submissions from system-to-system and for submissions from the XML generator. SANTE said no, explaining that a single Submitter ID should be used by each company (i.e. regardless of submission method).

Another company suggested that a document be compiled and uploaded to CIRCABC including the most frequently asked technical questions and their responses, as well as updates where needed, so that companies could consult it as a resource. SANTE indicated that it is working on such a document, and that a first list of such FAQs is already published on the EU-CEG webpage.

Another company inquired what the procedure would be in the case of a new version of the XML generator being published. SANTE assured participants that it would provide adequate advance notice in such cases and provide a clear date on which production would begin. In principle, old data should be copied to the new future versions.

Regarding the annual sales data field for e-cigarette products, SANTE confirmed that this remains optional, even if it remains an obligation (under Art. 20(7) TPD) to submit such data to Member States. Submitters of information on e-cigarette products may choose to submit this information via the EU-CEG.

For all new products, submitters were advised to enter zero values in the annual sales data fields.

It was clarified that the intention to provide a dedicated 'annual sales volume' submission type in subsequent releases remains in place.

As a general point, SANTE encouraged companies to contact the competent authorities of Member States in order to gain further information and advice regarding the content of their submissions. It said a list of Member State contact points would soon be published on the EU-CEG page.<sup>1</sup>

#### **(4) Update from users and Q&A**

One company asked how Member States will be informed when successful submissions are made to them. SANTE clarified that it is the responsibility of the authorities in question to check their databases and they are being encouraged to do this regularly.

Another company asked if stress testing with companies is foreseen and SANTE informed that internal stress testing will be carried out. In general companies were encouraged not to wait till the last minute but to complete submissions in a timely manner.

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<sup>1</sup> [http://ec.europa.eu/health/euceg/docs/contact\\_point\\_en.pdf](http://ec.europa.eu/health/euceg/docs/contact_point_en.pdf)

It was confirmed that submitters will receive a check-sum file which will provide them with a record of what they have submitted. The algorithm for this check-sum is published along with the other technical documentation.

SANTE confirmed that the SLAs signed with Member States govern only the storage of submitted data, and do not cover the functioning of the EU-CEG itself.

One participant asked whether it would be possible to share information regarding timelines for breakdown/maintenance procedures. SANTE said it would look into this.

In response to further questions relating to changes/future releases, SANTE clarified that its first priority is to rectify blocking issues. Aside from this, ideas and proposals for improvements/non-blocking issues will be collected over coming weeks/months, and a list compiled. These will then be implemented in batches, and users will be kept informed of this process with adequate advance notice.

It was confirmed that industry systems will not be subject to audit by the EU.

Finally there was a question regarding how Member States will handle information marked as confidential and whether companies will be informed if a decision is taken to publish it. SANTE said that such decisions are the competence of Member States alone, and confirmed that it may be possible that Member States request further justification for certain confidential markings. It highlighted that in the Implementing Decisions laying down a common format for tobacco reporting and e-cigarette notification, the Commission provided some guidance as to what it will consider as non-confidential information, and Member States may choose to follow this. The group was also informed that SANTE facilitates discussion on this topic in meetings with Member States in order to encourage a common approach.

## **(5) Conclusions**

SANTE thanked participants. It said it is very important to continue to cooperate in this task, and that IT Support colleagues remain ready to assist where possible in resolving remaining issues. Further webinars to discuss companies' experience and gain feedback will be planned towards the end of the summer.

## **List of Participants**

Cuts Ice E-liquids  
Imperial Tobacco Limited  
Scandinavian Tobacco Group  
BAT  
ESTA  
Nerudia  
JTI  
Danneman  
Pöschl Tobacco  
Nobacco  
ECMA  
Nicobrand  
ELDA  
Heupink & Bloemen Tabak  
Continental Tobacco  
Karelia Tobacco  
Oettinger Davidoff  
PMI  
Concept Liquids  
V2 Tobacco  
TDR  
Swedish Match  
Totally Wicked  
Agio Cigars  
House of Oliver Twist  
J. Cortès Cigars  
Fem 2 ambiente  
Traditab  
Ritchy EU  
Arnold André  
Landewyck Tobacco  
Fivape

## **Commission services**

Anna Eva Ampelas, Filip Borkowski, Matus Ferech, Jan Hoffmann, Marta Legnaioli, Patricia Murray, Markus Kalliola, Christophe Dumont, Renaud Subiger