



**MEETING OF TECHNICAL WORKING GROUP ON REPORTING AND NOTIFICATION
FORMAT UNDER ARTICLE 5 AND ARTICLE 20 OF DIRECTIVE 2014/40/EU**

SUMMARY RECORD

Date: 24 November 2015

Place: Adobe Connect WEBINAR

Introduction

DG SANTE welcomed the participants and thanked them for joining the discussion through WEBINAR.

The Chair explained that as no further comments were received on the summary record of the last meeting of 12 October 2015 they would be published on DG SANTE website.

Discussion – EU-CEG

A presentation was given by DG SANTE to provide an update on the recent progress related to the IT development of the EU-CEG. In addition, several related working documents were shown on screen (Use case model; Sequence diagram; XSD document). The bullet points below summarise the discussion on the main topics:

- **E-delivery:** E-delivery will be the means by which information will be transmitted for system-to-system submissions. Information on its technical requirements (specifications, licensing etc.) is publically available and companies could use this to decide which submission system to opt for (system-to-system or 'client'/stand-alone system). Security certificates will be needed for system-to-system submissions. The process for granting these will be defined. Following a question regarding the timing, it was pointed out that one option may be for companies to begin by using the 'client'/stand-alone system and then moving to system-to-system once they have completed the necessary technical preparations. At the next meeting (likely in January) DG SANTE will request information form companies as to their likely system choices.
- **Reference tables:** Following a question on the reference tables that will accompany the reporting/notification format. DG SANTE said a useful reference

point is the last version of the data dictionary circulated in June. The same applies for the business rules, which are currently being worked on.

- **Timeline:** A first in-house prototype is foreseen by the end of this year. Before May pilot testing will have taken place (likely March/April). DG SANTE agreed that deadlines are tight but reiterated that the main priority is to have architecture in place by 20 May 2016 that will allow industry to fulfil the basic reporting/notification requirements expected of it (for both system-to-system and 'client'/stand-alone submissions).
- **Translations:** A participant asked for confirmation as to whether it will be possible for submissions to be made in English, including in ingredients fields and free text fields. DG SANTE said it expects most of the data e.g. CAS and FEMA to be submitted as numbers or codes. The intention is to translate field headings into all languages, but this may not be for the first launch.
- **Sequence diagram; Use case model; XSD document:** Draft versions of these documents were presented. The Use Case model defines the actors and their actions in EU-CEG according to the current requirement analysis.
A participant asked if the Commission or the Member State will be able to delete/modify incorrect information. DG SANTE clarified that neither the Commission, nor the Member State are empowered to modify the content of the submission. Therefore a re-submission from the industry will be necessary.

Conclusions/Next Step

DG SANTE thanked participants for their input and said that the slides and documents presented will be shared shortly together with the minutes of the meeting. Comments would be welcome within a deadline of 2 weeks of receipt of these documents. Participants were also invited to suggest questions and discussion points for coming meetings. It was suggested that the next meeting would take place in in January. Relevant documents will be circulated for this. DG SANTE will confirm a date and time as soon as possible.

Annex I – List of Participants

Stakeholders:

Arnold André Cigars	Nerudia
British American Tobacco	Nicobrand
Concept Liquids	Nicoventures
ECMA	Nobacco
ESTA	Oliver Twist
FlavourArt	Philip Morris International
German Smoking Tobacco Association	Ritchy EU
Imperial Tobacco Limited	
JTI	Scandinavian Tobacco Group

Commission (DG SANTE):

Anna-Eva Ampelas (Chair)
Matus Ferech
Markus Kalliola
Patricia Murray
Marta Legnaioli
Renaud Subiger
Christoph Dumont
Foucart Michèle