EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

EXPERT SUBGROUP WEBINAR ON INGREDIENTS
Final Summary record

Webinar date: 22 April 2016, 9.30 – 12:30

(1) Welcome and Introduction

The Chair opened the meeting and welcomed all participants. The group was informed that the Implementing Decision on technical standards for the refill mechanism of electronic cigarettes was adopted on 14 April and that the vote on the secondary legislation on characterising flavours (concerning both the panel and the procedure) had been closed now. With respect to the Joint Action on Tobacco and e-cigarettes, which would be discussed in the second half of the webinar, the Chair remarked that an Expert Group meeting on tobacco policy will take place on 15 June. On a general note, it was stressed that SANTE still had the ambition to have a basic EU-CEG up and running on time. The system will receive continuous improvements, following its launch, based on the input received.

(2) Reporting on ingredients

An update on the EU-CEG testing phase and the acquisition of a Submitter ID was provided by the DG SANTE IT representative. A roadmap was presented outlining the timeline until the launch. It was noted that the final integration will be based on the test results received. SANTE IT received a high number of registrations for the testing phase both concerning the standalone client and system-to-system. Also, all company accounts had been created and the test packages were ready to be sent out. Finally, the participants were informed that testing for the acquisition of a Submitter ID was now using real information.

SANTE explained that the EU-CEG website had received a comprehensive update and now contained, *inter alia,* a sub-section with instructions on how to apply for a Submitter ID as well as a section with Frequently Asked Questions (FAQ). The latter would be updated on a regular basis with more questions and answers. Following a question from one of the participants, it was clarified that, for the time being, the Submitter ID application form would be made available in the English language only, but that translations were considered.

Outlining the process of the Service Level Agreement (SLA), SANTE thanked Member States (MS) for their cooperation. It was SANTE's understanding that all MS decided to opt for the Commission storage facilities, which required MS to sign the SLA as soon as possible. The

Chair stressed that MS were asked to inform the Commission, if they decided not to make use of the Commission facilities. If the SLA was not signed on time, MS cannot retrieve the data and an alternative solution would have to be agreed upon as soon as possible. Concerning a question on the National Administrator (NA) and his/her role, SANTE clarified that this person is responsible for accessing tobacco and/or e-cigarettes data in the storage facilities. He/she also needs to manage further users at MS level which, however, would not require specific IT knowledge. Lastly, it was clarified that the designated NA would only have access to the sections of his/her MS, but not to data of other MS.

In line with what had already been discussed with industry, SANTE suggested to the group that, in order to unify the process as much as possible, submissions will be recorded on the date of submission. SANTE encouraged MS to accept this submission date as it will have legal implications for the industry. No objections were raised by MS to this suggestion.

Another presentation was given by the SANTE IT representative on TestaNG. It was explained that no connection to the EU-CEG was possible without a TestaNG connection in place. However, it would still be possible in these cases for the data to be stored at the Commission facilities, but the NA will not have access to it.

The Chair informed that the training for MS will take place on 10 May in the form of a webinar in which SAAS and the tool for viewing submissions are addressed. SANTE would also look into the possibility to provide MS with a manual on SAAS.

(3) Joint Action on Tobacco and E-cigarettes

SANTE gave a short presentation on the planned Joint Action, which was based on a co-funding principle: 60% (Commission) and 40% (MS). It was stressed that this was a non-competitive process where decision-making takes place by consortium. The sharing of the overall budget of €2.3b will be subject to negotiations among the MS. SANTE explained that areas of collaboration will contain: (a) peer-review and follow-up of studies on priority additives; (b) EU-CEG extraction, processing and reporting; (c) building up of appropriate lab capacity to verify submitted data. Furthermore, the Joint Action will aim at the further facilitation of the implementation of the Directive.

(4) AOB

The Chair let the participants know that nominations for subgroup members should come either via the official expert group member or via the already nominated subgroup member.

Lastly, MS were reminded to submit their comments on the Commission report on potential risks of refillable e-cigarettes as soon as possible.

List of Participants

Austria

Belgium

Bulgaria

Czech Republic

Denmark

Estonia

Finland

France

Hungary

Ireland

Latvia

Lithuania

Netherlands

Poland

Sweden

UK

EEA

Norway

Commission (DG SANTE):

Anna Eva Ampelas, Jerome Boehm, Filip Borkowski, Federica Bruno, Christoph Dumont, Caroline Fabre, Matus Ferech, Jan Hoffmann, Marta Legnaioli, Patricia Murray, Markus Kalliola