EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

SUBGROUP ON ELECTRONIC CIGARETTES
DRAFT Summary record

Meeting date: 20 November 2015, 10.00 – 17:00
BRUSSELS

(1) Welcome and Introduction

The Chair opened the meeting of the Expert Subgroup on Electronic Cigarettes established by the Expert Group on Tobacco Policy and welcomed the participants.

(2) Commission work on implementation

A brief update on the implementation work in the area of e-cigarettes was given. DG SANTE explained that, following the vote in the Committee, the Commission Implementing Decision laying down the common format for e-cigarette notification was due to be adopted in coming days, in line with the time plan that has been published on the DG SANTE website. DG SANTE is also in the process of preparing the implementing act laying down technical standards for refill mechanisms, as well as the report on potential risks to public health related to refillables. It said that some key issues relating to these implementation tasks require discussion at today's meeting.

a) Common notification format for e-cigarettes (& related issues on common reporting format for tobacco products)

DG SANTE gave a presentation focusing on key issues relating to the notification of e-cigarettes and to the central entry gate being set up to facilitate this.

The first key points discussed were the reference tables. These list the possible answers to key fields in the notification format.

As regards the reference table for *submission type*, some discussion took place on the concept of "substantial modification". It was concluded that any change that may have an effect on the human body, such as a change of recipe or change to the hardware affecting emissions, should be considered a substantial change requiring six months prior notification. On the other hand the group considered that updates to information submitted e.g. on minor changes to production processes, should also be provided, but the six month period should not apply.

One participant asked whether a new notification would be needed if a product remains the same, but the company is bought by another company. The general view of the group was that this should not require a new notification, but would require an update. At the same time it was stressed that the company number forms part of the EC-ID, and this may be problematic. It was concluded that some more reflection is needed how to handle this issue from a technical perspective.

Regarding the reference table for product types, there was a discussion on products which are refillable but which do not have a tank. The key question was what category they should fall into. A more detailed description of the products in question was requested and it was decided to discuss this at the next Expert Group on 18 December. It was pointed out that regardless of category, authorities need to verify if these products are capable of complying with the safety requirements e.g. under Art. 20(3)(g).

A discussion on products capable of being used as both rechargeable and refillable products followed. There was consensus within the group these should be reported under the refillable category and the reference table adapted accordingly.

A discussion also took place regarding what might qualify as "other components" to be reported. Overall a pragmatic approach to this question was favoured, which would require notification of all components sold explicitly for e-cigarettes (e.g. mods capable of being used with different devices), but not other multi-use components such as batteries.

Regarding emissions to be notified, the group was asked which emissions it considers the most important/significant, on which information should most commonly be provided. The participants said they would require some time to reflect on this and it was agreed they would come back within two weeks. Formaldehyde and nitrosamines were already singled out as important.

It was explained that the reference tables will be published on the web and will be available to all stakeholders.

Regarding emission testing in general, there was general agreement that testing should be carried out with devices set at the highest range (voltage/wattage) that still produces palatable vapour. The tests will be an opportunity to learn more about these products, while not placing undue burden on manufactures/importers in the absence of agreed protocols. On the need to notify different flavours of the same products, it was pointed out that although there is an interest to limit unnecessary burden where possible, flavouring components could have different characteristics, having a potentially significant impact on emissions.

Regarding the information to be submitted on nicotine dose and uptake, there was consensus that full clinical tests would not be required, and chemical analysis, e.g. measuring of nicotine in the vapour could instead be conducted. One participant stated that the fields relating to wattage in the Implementing Decision should also apply to clearomizers.

Regarding supplementary fields which Member States can decide to require at national level, DG SANTE presented those currently envisaged and invited any further suggestions within 2 weeks. It clarified the notification format could also be used for nicotine-free liquids (indicating that nicotine content is 0), but that it is up to Member States to require this information.

On the subject of tolerance levels around nicotine in finished e-liquid products, the group generally agreed that the +/-5% allowed under pharmaceutical legislation could be acceptable, while one participant would potentially favour allowing a wider tolerance.

Some MS experts volunteered to examine some of the above topics and report back at the next Expert Group plenary meeting, so as to help foster common understanding. DG SANTE said it would be ready to facilitate the meetings/webinars of the group, if needed. There was consensus that the above clarifications are "work in process" that might evolve over time, eg. when international or European standards are developed.

b) Technical standards for refill mechanisms

DG SANTE gave a short overview of the background paper on technical specifications for e-cigarette refill mechanisms prepared by its contractor. This paper had also been shared with members of the Expert Group and stakeholders prior to the meeting. DG SANTE indicated that the background paper would provide the basis for the implementing act on technical standards for refill mechanisms it is currently preparing. It was agreed that DG SANTE would re-circulate the background paper and MS should then send any comments within two weeks.

c) Report on potential risks to public health related to refillable e-cigarettes

DG SANTE presented the timeline for the report on health risks of refillable e-cigarettes and indicated that feedback from MS will be sought early next year before publication in spring 2016. The report will present evidence from scientific literature, poison centre data and the results of chemical analyses regarding the risks of e-cigarettes in general and refillable e-cigarettes in particular. Some MS also volunteered to send in recent national studies on e-cigarette use that could be of relevance to the report.

(3) Discussion/update on other e-cigarette matters

Presentation by ECHA on reclassification of nicotine

ECHA[1] gave a presentation on the ongoing reclassification of CLP labelling for nicotine. ECHA's committee on risk assessment (RAC) has recently issued an opinion on the toxicity of nicotine based on a proposal from the Netherlands, including new scientific evidence and comments from stakeholders. The opinion recommends that pure nicotine be reclassified to level 2 acute toxicity by all routes of exposure (representing a reduced dermal exposure risk and an increased oral exposure risk, compared to the current classification). The classification and labelling requirements of mixtures (such as e-liquids) would depend on the nicotine concentration and presence of other compounds. Amending the CLP regulation to take into account this new recommendation is the responsibility of DG GROW, which means the current classification is still in force.

(4) Member State updates

[1] European Chemicals Agency

a) Presentation by NO on cross-border distance sales

Norway gave a presentation on its plans for implementing the TPD provisions on cross-border distance sales of tobacco and e-cigarette products. It intends to allow these sales, but will oblige distributors (such as postal services etc.) of these products to register and verify that consumers have respected the age limit requirements upon delivery of the products. This approach is based on the system already in place for alcohol products in Norway.

a) Other updates

One MS confirmed it has informed e-cigarette industry representatives of the position, endorsed at the last Expert Group meeting, that misleading descriptors on e-cigarettes should be prohibited. Another informed the group that it has sent a legislative proposal to have e-cigarettes incorporated into its national tobacco advertising ban, and the intention is also to incorporate them into existing smoke-free environment legislation.

One representative asked for the group's views regarding the potential consequences of allowing medically authorised e-cigarettes to be advertised when consumer products are not. Another representative said they don't consider this a risk as appropriate measures would be taken to ensure that such advertising is suitable and not directed at minors. DG SANTE added that the medical authorisation route allows advertising but the products must first meet the efficacy and other authorisation criteria it sets.

(5) Any other business

DG SANTE confirmed that it will circulate a list of interested e-cigarette competent authorities, in order to facilitate communication between MS, in early 2016.

DG SANTE also asked countries to reflect on whether they would like to take part in a potential Joint Action relating to tobacco products, one work package of which could focus on e-cigarettes. Joint Actions are led by Member States with approximately 60-80% co-financed via the Commission. Such a JA is yet to be confirmed, but interested countries were requested to come back within 2 weeks.

One MS asked whether the group shared its interpretation that tanks with volumes greater than 2ml will not be allowed under the new TPD. There was full agreement that this was the case.

The Chair thanked participants for a very useful meeting and for their contributions throughout.

List of Participants

Austria	(Federal Ministry of Health)
Belgium	(Federal Public Service Public Health)
Czech Republic	(Ministry of Health)
Denmark	(Danish Safety Technology Authority; Danish Health Authorities)
Finland	(National Supervisory Authority for Welfare and Health)
France	(LNE)

Hungary	(National Institute of Pharmacy and Nutrition)
Ireland	(Department of Health)
Latvia	(Health Inspectorate Latvia)
Luxembourg	(Ministry of Health)
Netherlands	(Ministry of Health)
Poland	(Bureau for Chemical Substances)
Romania	(National Institute of Public Health)
Slovakia	(Ministry of Health/Public Health Authority)
Sweden	(Public health Agency of Sweden)
United Kingdom	(MHRA)

Experts

Norway	(Norwegian Ministry of Health)

External

ECHA

Commission services

Mr Dominik Schnichels	DG SANTE D4 (Chair)
Ms Anna Eva Ampelas	DG SANTE D4
Mr Matus Ferech	DG SANTE D4
Ms Isabel Holmquist	DG SANTE D4
Ms Patricia Murray	DG SANTE D4
Mr Emmanouil Daskalakis	DG SANTE D4
Mr Markus Kalliola	DG SANTE A4