EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
D.4 Substances of human origin and Tobacco control

1st MEETING of the SUBGROUP ON ELECTRONIC CIGARETTES
Summary record

Meeting date: 29 May 2015, 10.00 – 16:30
BRUSSELS

(1) Welcome and Introduction

This was the first meeting of the Expert Subgroup on Electronic Cigarettes established by the Expert Group on Tobacco Policy.[Error! Bookmark not defined.] The Chair opened the meeting and welcomed the participants. He underlined that the subgroup on e-cigarettes was created at the request of Member States. The Chair presented the colleagues from DG SANTE which was followed by a short roundtable of introduction of Member State representatives.

(2) E-cigarettes implementation update

2.1.1 Commission work on implementation

DG SANTE introduced the Commission's implementation tasks regarding the Tobacco Products Directive 2014/40/EU (TPD) related to e-cigarettes. These tasks include a Commission Report on the potential risks to public health associated with refillable e-cigarettes, as well as two Implementing Acts on technical specifications for the refill mechanism and a common format for notification of e-cigarettes.

Two external contracts are running to assist the Commission in these tasks. One is the development of the e-cigarette notification format (EUREST) and the second relates to refillable e-cigarettes (health risks and technical standards) (PRECISE).

a) Risks for public health associated with refillable products

The current progress was presented by work package. The consortium has separated risks by refillable and non-refillable e-cigarettes and has also grouped these risks into sub-categories. Member States are encouraged to provide data from their poison centres to assist the work.

DG SANTE also presented responses to the Member State questionnaire on the risks to public and/or human health from refillable e-cigarettes. The main Member State concerns are nicotine poisoning, accidental overdose, dermal exposure, the potential for increased toxicity of the vapour components and the potential increased attractiveness of these products to young people/non-smokers. The Member State responses will be shared with the contractor.

The Commission Report must be submitted to the European Parliament and Council before 20 May 2016.

b) Technical standards for refill mechanisms

The state-of-play on the development of proposals for technical specifications for e-cigarette refill mechanisms was then presented. The consortium is currently collecting e-cigarette industry stakeholder feedback. Further involvement of Member States and stakeholders will also be sought. The responses to the Member State questionnaire on the subject will be shared with the contractor. The adoption of the implementing act on technical specifications for e-cigarette refill mechanisms is foreseen for quarter 2 of 2016.

c) Common notification format for e-cigarettes

The common notification format was presented. The work of the contractor is almost completed and the work in the Commission laying down an implementing act is ongoing. The adoption of the implementing act is foreseen for the end of 2015. The consortium gave an overview of the study, including the data dictionary, which has also been sent to Member States for comments.

The discussions focused mainly on product design reporting, ingredients reporting, emission measurement methods and substantial modification. On substantial modification, National experts argued that this concept would at least encompass any change that would affect the health of the user or the human body, as well as any change related to aspects fixed in the TPD text. On ingredients reporting experts raised the issue of natural extracts and the need to report components of extracts which could be very toxic. The Commission reminded the group that Art. 20. 2 (c) of the TPD requires manufacturers to submit toxicological data. DG SANTE offered experts a possibility to send further comments in writing within two weeks.

DG SANTE also presented their work on the IT implementation of the notification format. In particular, DG SANTE is considering establishing a common entry gate through which all notifications should be submitted to Member States. This will be linked to a Commission-based data storage facility. Member States that do not wish to create their own data storage could "rent" server capacity after having signed a Service Level Agreement. DG SANTE will prepare a concept paper to provide further details to Member States.

2.1.2 Member State updates

(a) Transposition efforts by Member States

DG SANTE summarised the implementation plans reported by Member States in advance of the meeting. One Member State asked which e-cigarette components should carry health warnings. Participants agreed that Art. 20.4 (b) TPD foresees warnings for all unit packets and any outside packaging and that the warning makes sense for all items that contain nicotine.

(b) Areas not regulated in the TPD

Member States presented regulatory actions in areas outside the scope of the TPD. The experts from the Netherlands presented the results of RIVM-research on the health risks of e-cigarettes for users and the envisaged policy measures for nicotine containing and nicotine-free e-cigarettes, including an age limit and an advertising ban. Austria presented their new

draft law restricting points of sale for e-cigarettes. The intention is also to bring e-cigarettes under the new smoke-free laws it hopes to pass. A presentation of a report from the Norwegian Public Health Institute on health risks from e-cigarette vaping and second-hand vaping, which found that vaping produces the same nicotine-related effects as conventional tobacco use and that second-hand vaping can result in similar high nicotine levels in the blood to that from second-hand tobacco smoke, with the same harmful nicotine-related negative effects, was also given.

(3) Any other business

(a) DG TAXUD presentation on e-cigarettes taxation

DG TAXUD presented ongoing reflections regarding the taxation of e-cigarettes in the EU. There are currently no EU rules, but the possibility to include e-cigarettes in the scope of excisable products will be analysed and discussed with experts from Member States.

(b) Update on e-cigarette court case

DG SANTE gave a short overview of the e-cigarette court case. A UK-based manufacturer and retailer of e-cigarettes has brought national action against Art. 20 of the TPD which was referred to the Court of Justice (ECJ) in November 2014. The hearing might take place in autumn.

(c) Standardisation

The work of the CEN Technical Committee on e-cigarettes and the Commission's involvement in this work were briefly presented and discussed. The first meeting of the CEN Technical Committee will take place in Paris on 22 June 2015. It is foreseen that the Commission will be represented by JRC, which has an observer status. DG SANTE encouraged Member States to follow closely and participate where possible.

The Commission thanked participants and indicated that the next meeting of the Expert Subgroup on E-Cigarettes will take place in October 2015.

Annex I – List of Participants

Members of Expert subgroup

Austria	(Federal Ministry of Health/Centre for Public Health, Institute for social medicine of the Medical University of Vienna)
Belgium	(Permanent Representation of Belgium to the EU)
Croatia	(Croatian Institute of Public Health)
Czech Republic	(Ministry of Agriculture)
Denmark	(Ministry of business and growth)
Estonia	(Ministry of Social Affairs)
Finland	(Ministry of Social Affairs and Health)
France	(Permanent Representation of France to the EU)
Greece	(Ministry of Health and Social Insurance/Permanent Representation)

Hungary	(National Institute for Health Development/Permanent Representation)
Ireland	(Department of Health)
Latvia	(The Center for Disease Prevention and Control)
Luxembourg	(Ministry of Health)
Netherlands	(Ministry of Health, Welfare and Sport/National Institute for Public Health and the Environment (RIVM))
Poland	(The Bureau for Chemical Substances)
Romania	(Ministry of Health)
Slovakia	(Public Health Authority/Permanent Representation)
Slovenia	(Agency for Medicinal Products and Medical Devices of the Republic of Slovenia)
Spain	(Ministry of Health, Social Affairs and Equal opportunities)
United Kingdom	(MHRA)

Experts

Norway	(Norwegian Ministry of Health)

Consortia

EUREST (European Regulatory Science on Tobacco)

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
Ms Ingrida Pucinskaite-Kubik	DG SANTE D4
Mr Emmanouil Daskalakis	DG SANTE D4
Mr Stefano Delle Chiaie	DG SANTE D4
Mr Markus Kalliola	DG SANTE A4
Ms Annerie Bouw	DG TAXUD
Mr Thomas Wenzl	EC-JRC