EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

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

2nd MEETING of the SUBGROUP ON INGREDIENTS ESTABLISHED BY THE EXPERT GROUP ON TOBACCO POLICY[1]

Summary record

Meeting date: 01 June 2015, 10.00 – 16:30
BRUSSELS

(1) Welcome and Introduction

The Chair opened the meeting and welcomed the participants. He explained that the main focus of this meeting was the progress made in the area of ingredients

(2) Update on implementation of Tobacco Products Directive (TPD) (2014/40/EU) in the area of ingredients, emissions and product characteristics

DG SANTE presented its implementation tasks under the Tobacco Products Directive (TPD) (2014/40/EU) in the area of ingredients regulation. These tasks include establishing a procedure for determining characterising flavours, setting up an advisory panel (flavour testing), establishing the list of priority additives as well as establishing the reporting format for tobacco ingredients and emissions.

(3) Ongoing projects: presentation and discussion

(a) Priority list of additives

First, DG SANTE reported on the progress made regarding the priority list of additives. which should take into account, as appropriate, the opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) the ongoing project assessing the toxicological data submitted by industry (DIRECT) and other relevant information. Member States were encouraged to take part in the public consultation on the preliminary opinion of SCENIHR which will be held in July/August 2015. The Commission implementing legislation on the priority list of additives is expected to be adopted in Q1 2016.

The subsequent discussion focused mainly on the selection of additives, the design for comprehensive studies, enhanced reporting obligations and possibilities for collaboration

[1] established under Commission Decision C(2014) 3509

between Member States as well as the language to use. While all dimensions (i.e. toxicity, addictiveness and attractiveness) as well as interaction effects need to be considered in the assessment, it was stated that the data currently available focused mostly on toxicity.

Concerning the study design for comprehensive studies the Member Sate experts agreed that guidance on study design would be useful to ensure the possibility of comparisons between Member States and between studies. Relevant study designs for further consideration will be suggested by SCENIHR and DIRECT. Suggestions from Member States are also welcome.

Regarding the enhanced reporting obligations, it was concluded that close cooperation is needed and a group of experts from different Member States and the Commission could evaluate the data jointly. This way a duplication of effort could be avoided. Member States were asked to check if they have the capacity to contribute to this work and promised to report back to the Commission. The participants agreed that the preferred language for the studies is English.

(b) Determination of characterising flavours

DG SANTE introduced the HETOC-consortium as the external contractor carrying out a study on the determination of characterising flavours. The project was launched in August 2014 and is now in its final phase. The HETOC consortium presented the pilot study on setting up a sensory panel and its conclusions. It was stressed that sensory testing complemented by chemical analysis was an appropriate method to determine characterising flavours. The pilot had confirmed that an expert panel is a good approach, but the training phase needs to be more extensive when the real panel is set up. Smelling is the preferred starting point for determining characterising flavours and it was recommended to consider, as a future step, whether a smoking experiment was needed. It was concluded that specific reference spaces for cigarettes and RYO are needed. The HETOC consortium also reported about the pilot study on the chemical analysis. The conclusions of the study were broadly endorsed by the group.

A short discussion was also held on the procedure for determining tobacco products with characterising flavours. The group generally supported to establish key principles such as how to avoid diverging decisions and duplication of procedures as well as the right for manufacturers/importers to be heard before a decision is adopted.

(c) Reporting of ingredients

DG SANTE introduced the EUREST-consortium as the external contractor carrying out a study on a common format for reporting of tobacco ingredients and emissions. The study was launched in May 2014 and is almost finished. The adoption of the implementing act is foreseen for Q4 2015. EUREST presented the different work packages with a focus on the development of a data dictionary (format for reporting). Some key questions were pointed out in relation to the data dictionary, including the tobacco products ID-number facilitating identification of the same product placed on several markets, tobacco leaf descriptors, definitions of a standardised batch and data storage after product cancellation. The participants agreed that manufacturers should be asked for the recipe rather than the actual ingredients in each individual batch. With regard to the time period for reporting certain

information where continuous update may be foreseen, Member States were in favour of a period of one year. Regarding data storage after product cancellation, some were in favour of a uniform threshold of 5-10 years, while others considered it important to keep the data on a long term basis for scientific research purposes. Some Member States argued this should be left to the national legislators. EUREST also presented a cost/benefit analysis and encouraged Member States to provide feedback on their administrative burden.

Subsequently, DG SANTE presented some orientations as regards technical solutions for submission of information through a common electronic entry gate. In terms of data storage, it was also indicated that Member States which are interested should be able to rent server capacity from the Commission by signing a Service Level Agreement. The Commission was asked to draft a concept paper on the IT reporting architecture. Member States welcomed, in general, the orientations presented and promised to indicate whether they would be interested to make use of the offer to store data at Commission servers, whilst maintaining full responsibility for collecting, analysing, storing and disseminating the data collected.

(4) Any other business

The Commission thanked participants and indicated that the next meeting of the Expert Group on Tobacco Policy will take place on July 2nd essentially on labelling and packaging.

Annex I – List of Participants

Members of Expert subgroup

Austria	Federal Ministry of Health
Belgium	FPS Public Health – Food Chain Safety and Environment
Denmark	The Danish Health and Medicines Authority
Finland	National Supervisory Authority for Welfare and Health
Germany	Federal Office of Consumer Protection and Food Safety – BVL
Greece	Permanent Representation of Greece to the EU
Latvia	Centre for Disease Prevention and Control
Lithuania	Drug, Tobacco and alcohol control Department
Netherlands	Ministry of Health, Welfare and Sport
Poland	The Bureau for Chemical Substances
Slovenia	National Institute of Public Health of the Republic of Slovenia
Spain	Ministry of Health, Social Affairs and Equal opportunities
Sweden	Public Health Agency of Sweden
United Kingdom	UK Department of Health

Consortia

EUREST (European Regulatory Science on Tobacco)
HETOC (Health Effects Tobacco Composition)

Commission services

Mr Dominik Schnichels	DG SANTE D4 (Chair)
Ms Anna Eva Ampelas	DG SANTE D4
Ms Katja Bromen	DG SANTE D4
Mr Matus Ferech	DG SANTE D4
Mr Markus Kalliola	DG SANTE A4