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 INGREDIENTS ESTABLISHED BY THE EXPERT GROUP ON TOBACCO POLICY[1]

Summary record

Meeting date: 7 November 2014, 10.00 – 16:30
BRUSSELS

(1) Welcome and Introduction

This was the first meeting of the Expert Subgroup on Ingredients established by the Expert Group on Tobacco Policy.[1] The Chair opened the meeting and welcomed the participants. Following a short roundtable of introduction, the chair explained that the subgroup has been established to examine specific questions on ingredients. Aside from reporting to the Expert Group (plenary), deliberations at the Expert Subgroup should be kept confidential as appropriate. This is without prejudice to transparency obligations (e.g. publications of minutes). The chair also reminded that experts should declare any conflicts of interest. No expert declared such a conflict.

(2) Role of Expert Subgroup on Ingredients

The Commission briefly outlined the function of the Expert Group (plenary), explaining its advisory role in the preparation of Delegated Acts in the field of tobacco control and its role as a forum for all other exchanges on tobacco-related matters. The group and its subgroups might also be involved in the preparation of Implementing Acts, though it will be the Committee established under Article 25 of the Tobacco Products Directive (TPD) that will formally discuss and vote on these Acts.

Following its first meeting in June, the Expert Group established two sub-groups to work on more specific matters (this current sub-group on ingredients and another on illicit trade). The role of these sub-groups is to provide specific technical expertise and to report back to the Expert Group plenary sessions.

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

(3) Implementation of Tobacco Products Directive (TPD) (2014/40/EU) in the area of ingredients, emissions, and product characteristics

The Commission presented its work programme related to the implementation of the TPD in the areas of ingredients and emissions, outlining the various timelines and projects planned. Various studies and preparatory work relating to ingredient reporting and regulation are underway to ensure that the secondary legislation (Implementing and Delegated Acts) provided for in the TPD is adopted in a timely manner.

In response to questions, the Commission underlined that the essential elements of the new tobacco legislation are already established and that the text of the TPD should be taken as the basis for this. Therefore, transposition of the TPD into national law should not be delayed by the fact that secondary legislation is being prepared.

(4) Ongoing projects: presentation and discussion

a) Reporting of ingredients (presentation by the external contractor)

The Commission provided an overview of the reporting obligations under the new TPD which includes reporting on tobacco products and notification on electronic cigarettes. The Commission introduced the external contractor (EUREST) commissioned to carry out work on this. The EUREST consortium then provided an overview of what has been undertaken since the launch of the study in May 2014. It reported on the evaluation of existing reporting formats derived in particular from Member State and stakeholder surveys and presented a first draft outline of a new reporting format.

The discussion focussed on the structure and content of the data dictionaries as well as on the practical challenges involved in maximizing the utility of the reporting system (e.g. classification and nomenclature of ingredients and products, unique identifiers allowing identification of identical ingredients/products across manufacturers/Member States, the concept of product modification, frequency of reporting, measurement approaches and values to be reported, mandatory or optional nature of certain fields for various types of products etc.). The need for an encompassing and harmonized reporting system that would allow meaningful cross-country comparison was emphasized.

b) Priority list of additives

The Commission presented a progress report on the establishment of a priority list of additives. In particular, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) has been asked to prepare an opinion for such a list on the basis of publicly available data.[2] The Commission encouraged experts to support the SCENIHR via submission of relevant data.

The Commission is also considering launching a request for service under its Framework Contract to assess industry data on toxicity, addictiveness and attractiveness received in the context of reporting obligations under Directive 2001/37/EC. Following a discussion on various options, Member State experts indicated a preference for creating a database of submitted information that would be accessible also to Member State regulators. Member State experts expressed a wish to be informed on progress.

[2] http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_q_037.pdf

c) Determination of characterising flavours (presentation by the external contractor)

The Commission provided an overview of the implementation tasks and introduced the work being carried out by an external contractor (HETOC) that began in August 2014. The HETOC consortium reported on its work, most notably on the literature review, complemented by a consultation of regulators and sensory experts. A first set of methods which can be used to determine whether a product has a characterising flavour was presented.

The discussion focused on the characteristics of these approaches and the methodologies to be used (e.g. type, composition and size of population (experts/consumers/age groups), reference products, testing concepts (sensory/instrumental/combination)) as well as the products to be included in the pilot testing. There was consensus that a uniform decision-making mechanism would be essential for taking regulatory decisions on products with characterising flavours.

(5) Any other business

The Commission thanked participants and indicated that the next meeting of the Expert Subgroup on Ingredients is likely to take place in spring 2015. A further consultation of Member States / Expert Group / Expert subgroup on the ongoing implementation work is envisaged.

Annex I – List of Participants

Members of Expert subgroup

Austria	(Federal Ministry of Health)
Belgium	(Federal Public Service of Health, Food safety and Environment)
Croatia	(Croatian Institute of Public Health/Division of Environmental Health)
Denmark	(The Danish Health and Medicines Authority)
Finland	(Ministry of Social Affairs and Health – National Supervisory Authority for Welfare and Health)
France	(Laboratoire national de métrologie et d'essais)
Germany	(Federal Office of Consumer Protection and food Safety – BVL)
Latvia	(Centre for Disease Prevention and Control)
Lithuania	(Drug, Tobacco and alcohol control Department)
Poland	(The Bureau for Chemical Substances)
Romania	(Ministry of Health)
Spain	(Ministry of Health, Social Affairs and Equal opportunities)
Sweden	(Public Health Agency of Sweden)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(UK Department of Health)

Consortia

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

Commission services

Mr Dominik Schnichels	DG SANCO D4 (Chair)
Ms Katja Bromen	DG SANCO D4
Mr Matus Ferech	DG SANCO D4
Ms Patricia Murray	DG SANCO D4
Ms Ingrida Pucinskaite-Kubik	DG SANCO D4
Mr Emmanouil Daskalakis	DG SANCO D4
Mr Stefano Delle Chiaie	DG SANCO D4
Ms Ana Mancho Rojo	CHAFEA

Observers

Greece	Permanent Representation to the EU