EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems and products
Substances of human origin and Tobacco control

4TH MEETING OF THE EXPERT GROUP ON TOBACCO POLICY

SUMMARY RECORD

Date: **15 October 2015**

Place: **CCAB**

1. Introduction

The meeting focused on the transposition and implementation of the Tobacco Products Directive 2014/40/EU (TPD).

2. Implementation update

a) A member of SCENIHR presented the preliminary opinion on priority additives, finalised in July 2015, and the results of the public consultation on the draft opinion. SCENIHR's final opinion is expected in November. The work of SCENIHR will provide important input to the Commission's development of an implementing act on the priority list. In the subsequent discussion it was further clarified that the additives on the list established by the implementing act will not be banned or regulated as such, but will be subject to additional reporting obligations according to the TPD, which might trigger further action.

The Commission also explained that an external contractor (DIRECT) is assessing the available evidence on toxicity, addictiveness and attractiveness of ingredients on the basis of the information submitted by the industry according to TPD1 (Directive 2001/37/EC).

b) The Commission presented possible areas of strengthened cooperation between MS and indicated that this could be particularly relevant as regards ingredients/priority additives/e-cigarettes/laboratory capacity. MS were asked to consider other areas of close cooperation and to indicate whether they would be interested to actively engage in such cooperation, possibly also within a more formalised framework with financial support from the Commission.

c) The Commission updated MS on the technical developments regarding the establishment of the Common Entry Gate ("EU-CEG) for the submission of data on

tobacco products and e-cigarettes. In this context the Commission reported from recent meetings (webinars) with industry stakeholders and national regulators. It was also stressed that the Commission is working on a Service Level Agreement, which should be signed by MS interested in storing data at Commission facilities. The participants also agreed to establish a separate EU-CEG subgroup reporting to the Expert Group.

3. Implementation and transposition in Member States

a) The Commission presented the results of a questionnaire circulated to MS prior to the meeting in relation to the regulation of electronic cigarettes. The subsequent discussion revealed that for a number of MS national regulation of electronic cigarettes is challenging. For example, some MS had been challenged in the courts on smoke-free environments legislation. Issues that were highlighted were enforcement problems, risk of renormalisation and emerging evidence on risks associated with second hand vape. Some MS are currently conducting research on e-cigarettes and agreed to share their studies with the group when published.

Member States reported that age-verification or cross-border bans on the sale of electronic cigarettes are also a challenge. In particular, it is difficult to enforce bans when products are sold by retailers in other EU MS or from third countries. In this context, one MS informed that it has strengthened its ban of cross-border sales of tobacco by introducing fines for citizens that purchase products from abroad. Another participant explained that they will mirror the rules they use for alcohol purchasing, which require that delivery firms check the age of the final consumer.

b) The scope of the transposition period for tobacco products with characterising flavours with a market share exceeding 3% of the EU market (TPD Article 7(14)) was discussed. None of the participants questioned the interpretation that the ban on caffeine, taurine etc. in Article 7(6) applies as of 20 May 2016 also in products benefitting from the transitional period. As regards the ban of flavourings in components, such as capsules or filters, a small number of experts expressed doubts whether it is possible to ban flavour capsules in products covered by the transitional period in Article 7(14), while the others who took the floor were in favour of an interpretation resulting in a ban of all flavour capsules as of May 2016. The capsules would be a design feature that could render the products more attractive to young people. It was stressed in that context, that Article 7(14) TPD should be read in the light of recital 16. It was also argued that some Member States had banned capsules prior to the adoption of TPD2 and these MS should not be obliged to revisit their decision. Some Member States called for a non-paper.

Furthermore it was concluded that the annual rotation period of the combined health warnings should be counted from May to May, and should begin with the first set of images.

The group also discussed the printing of combined health warnings on cigarette packages with bevelled or rounded edges on the basis of the non-paper paper prepared by the Commission services. Some Member States asked for clarifications on the interpretation in relation to bevelled edges. The Commission clarified that Canada is not a good example for countries banning printing on bevelled edges, but Singapore is. Most Member States, which took the floor, generally agreed that the warnings should not be printed across the bevelled and rounded edges. The group requested that a revised version of the non-paper be prepared based on the discussions.

The implication of Article 13 TPD on brand names of some electronic cigarettes was discussed. The group agreed that Article 13 means that brand names with misleading descriptors cannot be used on electronic cigarettes' packaging.

The Commission also asked participants how they would classify smokeless tobacco products marketed as 'chew bags', as oral tobacco or chewing tobacco. If considered oral tobacco, the marketing of these products would be prohibited in the EU (with the exception of Sweden). Member States reported that the assessment of such products is often difficult. It was, however, concluded that the basis for assessment should be the intended actual use and in this perspective an appearance, consistency and composition similar to oral tobacco should be taken into account. Some MS reported explicitly that they would consider "chew bags" as oral tobacco, while other MS did not participate in the discussion. No MS reported explicitly that they would consider these products as chewing tobacco.

One MS informed the group that a new heated tobacco product has been launched and the classification of this product was subject to some discussion in the group. It was agreed that any product that falls outside the existing product categories and was first marketed in the EU after 19 May 2014 is to be considered a novel tobacco product.

AOB

The Commission updated MS on the work of the FCTC Working Group on Article 9 and 10 of the FCTC and on the ratification of the Illicit Trade Protocol which is being prepared in the Council. The Commission also encouraged MS to ratify the Protocol.

The proposed development of standards on tracking and tracing in CEN-CENELEC was also brought up and the group expressed concerns about this initiative as it would impede the work on Article 15 and 16 of TPD. A number of Member States indicated that they would raise the matter (again) with the national standardisation bodies.

Annex I

List of participants

Members of the Expert Group on Tobacco control:

Austria	(Federal Ministry of Health)
Belgium	(FPS Public Health)
Bulgaria	(Permanent Representation of the Republic of Bulgaria to the EU)
Cyprus	(Permanent Representation of Cyprus to the EU)
Croatia	(Ministry of Health)
Czech Republic	(Ministry of Agriculture/Ministry of Health)
Denmark	(Ministry of Health)
Estonia	(Permanent Representation of Estonia to the EU)
Finland	(Ministry of Social Affairs and Health)
France	(Direction Générale de la Santé)
Germany	(Federal Ministry of Food and Agriculture)
Greece	(Ministry of Health /Permanent Representation of Greece to the EU)
Hungary	(National Institute for Health Development)
Ireland	(Department of Health)
Italy	(Ministry of Health)
Latvia	(Ministry of Health)
Lithuania	(Drug, tobacco and alcohol control department)
Luxembourg	(Ministry of Health)
Malta	(Environmental Health Directorate Ministry for Energy and Health)
Poland	(Ministry of Health/Bureau for Chemical Substances)
Portugal	(General Directorate of Health)
Romania	(Ministry of Health)
Slovakia	(Public Health Authority)
Slovenia	(Ministry of Health of the Republic of Slovenia)
Spain	(Ministry of Health)
Sweden	(Ministry of Health and Public Affairs/Public Health Agency of Sweden)
The Netherlands	(Ministry of Health, Welfare and Sport)
United Kingdom	(Department of Health)

Observers:

Norway	(Ministry of Health)
Iceland	(Ministry of Welfare)
EFTA Secretariat	
Turkey	(Tobacco and Alcohol Market Regulatory Authority)

Private Expert:

KU Leuven

Commission:

DG SANTE D4	Dominik Schnichels (chair)
	Anna-Eva Ampélas
	Katja Bromen
	Isabel Holmquist
	Patricia Murray
	Matus Ferech
	Marta Legnaioli