EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 – Health Law and International

12th Meeting of the REGULATORY COMMITTEE established under Article 10 of the Tobacco Products Directive 2001/37/EC

Summary record

Meeting date: 25 October 2010, 10.00 – 17.00
Centre de Conference Albert Borschette, meeting room 0C

1. Welcome and introduction

The Commission welcomed the participants and introduced new members of the tobacco control team.

2. Adoption of the draft agenda

With following changes the draft agenda was adopted.

- To add presentation on reduced ignition propensity (RIP) cigarettes under point 6 – AOB.
- To discuss new products and RIP cigarettes as first items in the agenda.

3. Declaration of interests

No conflicts of interests according to Art 12.2 of the Rules of Procedures (RoP) were signalled by the participants.

4. Reduced ignition propensity (RIP) cigarettes

The Commission gave a presentation on the recent developments regarding RIP-cigarettes. The work in the European Committee for Standardization (CEN) finished in October 2010

and the final document EN 16156 "Cigarettes Assessment of the ignition propensity – Safety requirement" will be published in November 2010. Member States' standardisation organisations will have 6 months to include EN 16156 in their national standards collection. Publication of a reference to EN 16156 (and EN ISO 12863) in the Official Journal is expected in the 2nd half of 2011 or 1st quarter of 2012. Enforcement of fire safety requirement by Member States' authorities is expected as of the publication date.

One of the Member States asked when the RIP cigarettes will have to be put on the market and how this will be achieved. The Commission clarified that there will be a transitional period of 6 months during which RIP should become national standard. Test method including the technical aspects is described in the ISO standard.

5. New products

The Commission invited the Member States to present any experience of new products or information on new products which have not yet been discussed. The Commission stressed the importance of reporting new products as there is an ongoing public consultation regarding the possible revision of the Tobacco Products Directive.

The following new products were presented:

- A bar of dried fruits/ nuts and tobacco. The product is banned as it is similar to snus.

- "Similar", a product similar to e-cigarettes, except they are not electronic. The nicotine level is the same as in cigarettes. The product is marketed as an alternative to cigarettes to use in airplanes and bars where there is a smoking ban.

- "Smokers' choice" which is a cigarette-imitation. The "cigarettes" contain some kind of filler and smell menthol. They are not made for smoking and their purpose is unclear.

Member States stressed that there is still a lot of confusion around new products as most of them are not covered by the Directive, and only some of them are classified as pharmaceutical products. Most of the new products are consequently not included under any existing regulation.

Some Member States reported that the use of herbal cigarettes and water pipes has increased as they are not currently covered by the smoking ban. One Member States reported that they have introduced a ban on smoking e-cigarettes in public places.

6. Review of the textual and pictorial warnings

The Commission gave a short presentation on the review of the textual and pictorial warnings. The study on the evaluation of the proposed new text warnings has been sent to the Member States. A vote on the new text warnings is expected at the next meeting of the Regulatory Committee.

The contractor (TNS Opinion) presented the Qualitative Eurobarometer. The purpose of the study was to evaluate the 24 proposed new text warnings and identify which 14 would be the most effective.

Upon request from the Member States, the report will be re-circulated together with a translation of the warnings into the EU official languages. It was further agreed that Member States can send comments and suggestions on minor changes (linguistic) within two weeks.

Several Member States requested clarification on the procedure involved with the development and implementation of the new warnings, the transitional period and the effect of the new warnings in Member States where pictorial warnings are mandatory. The Commission explained that as a first step there will be a vote on the new text warnings, following which the work on developing new pictures will start. The transitional period will be sufficient to make sure that Member States that already use pictorial warnings have time to adapt to the new warnings. The length of the transitional period will be decided in the Regulatory Committee.

Two Member States asked whether the implementation of the new warnings would require a change in national law and in that case whether this could be done together with the revision of the Directive. The Commission explained that the new warnings require a change of Annex I to the Directive. The Annex needs to be transposed by Member States. These are two separate procedures, as revision of textual and pictorial warnings is a process for the Regulatory Committee while a revision of the Directive is a procedure involving the Council and the Parliament.

The question regarding the future library of pictorial warnings was raised by one Member State. The Commission answered that rather than extending the current picture library there will be two sets of pictures during the transitional period. Some of the pictures might remain the same as the ones in the old library, although combined with new texts. The Member States will be regularly informed of the work on new pictures.

Member States also asked whether the Commission is planning to propose mandatory pictorial warnings, whether the two general warnings will also be reviewed and whether there will be (new) health warnings also for other types of products (smokeless tobacco, herbal water pipes). The Commission answered that these items will be considered in the Impact Assessment for the possible revision of the Directive.

7. Impact assessment on the possible revision of the Tobacco Products Directive

The Commission gave a short presentation on the study "Assessing the impacts of revising the Tobacco products Directive" prepared by RAND Europe and explained the ongoing work on the impact assessment on the possible revision of the Directive. The Commission has organised a number of meetings with stakeholders to discuss the study prepared by RAND Europe. The Commission expects to receive additional comments on the study by the end of December 2010.

In addition, a public consultation on the possible revision of the Directive will run until 17 December 2010. The objective of the consultation is to get the views of all stakeholders on the

problem definitions and options for addressing these problems effectively.

Overall, Member States expressed a concern as in their opinion the RAND study contains inaccurate data in several areas such as employment in tobacco sector, illicit trade, use of pictorial warnings, and oral tobacco.

On a question from Member States on whether the RAND report will be amended, the Commission replied that the study is final; it has already been published and will not be formally changed. The Commission underlined that it is an independent study not expressing the views of the Commission. The Impact Assessment report will however be a Commission document and, therefore, comments from the Member States and other stakeholders are very important and will be carefully analysed.

8. Close of the meeting

The Commission thanked the participants for a useful meeting and the active participation.

The date of next meeting of the Regulatory Committee will be communicated later.

Annex I - Summary of conclusions

- The Commission invited Member States to send their comments on translations of new text warnings within two weeks.
- The voting on new text warnings is expected at the next Regulatory Committee meeting.
- The Commission invited Member States to send their comments on the study "Assessing the impacts of Revising the Tobacco products Directive" by 31 December 2010.

Annex II – List of Participants

Committee members:

Austria	(Federal Ministry of Health)
	(Medical University Vienna)
Belgium	(FPS Public Health)
Bulgaria	(Ministry of Health)
Czech Republic	(Ministry of Agriculture)
	(Ministry of Health)
Cyprus	(Ministry of Health, Public Health Services)
Denmark	(National Board of Health)
Estonia	(Ministry of Social Affairs)
Finland	(Ministry of Social Affairs and Health)
France	(Ministère de la Santé et des Sports)
Germany	(BMELV)
Greece	(Ministry of Health, Tobacco Institute)
Hungary	(National Institute of Health Development)
	(Ministry of National Resources)
Ireland	(Department of Health and Children)
Italy	(Ministry of Health)
Latvia	(Ministry of Health)
Lithuania	(Ministry of Economy)
Luxembourg	(Permanent Representation to the EU)
Malta	(Ministry of Health)
Poland	(Ministry of Health)
Portugal	(Ministry of Health)
Romania	(Ministry of Health)
Slovakia	(Permanent Representation to the EU)
Sweden	(Swedish National Institute of Public Health)
The Netherlands	(RIVM)
	(Ministry of Health, Welfare and Sport)
United Kingdom	(Department of Health)

Observers

Norway	(Ministry of Health)
Turkey	(Tobacco and Alcohol Market Regulatory Authority)

Commission services:

Mr Antti Maunu	DG SANCO C6 (Chair)
Ms Terje Peetso	DG SANCO C6
Ms Anna Eva Ampelas	DG SANCO C6
Ms Anna Jassem-Staniecka	DG SANCO C6
Ms Magdalena Ahlberg	DG SANCO C6
Ms Antonella Correra	DG SANCO B3
Ms Rita Poleczki	DG SANCO C6 (Secretariat)
Mr Eddy Parijs	DG SANCO C6 (Secretariat)