EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C6 - Health Law and International

Brussels, 18 May 2010

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11th Meeting of the REGULATORY COMMITTEE established under Article 10 of the Tobacco Products Directive 2001/37/EC

Summary record

Meeting date: 18 May 2010, 10.00 – 17.00
Committee of the Regions, meeting room VM1

1. Welcome

The Commission welcomed the participants.

2. Adoption of the draft agenda

With following additions the draft agenda was adopted.

- debriefing on the preparatory work of the WHO FCTC CoP4 and presentation on draft partial guidelines on the FCTC Articles 9&10 to point 6
- presentation from Jürgen Hahn (chair of the GoToLab Network) on water pipes and the work of the GoToLab Network under point 8 – AOB.
- discussion point on tobacco sales to minors and problems with retail sector under point 8 - AOB
- debriefing on the state of play with the Commission report on snus and the publication of the Eurobarometer 2009 under point 8 - AOB

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. Impact Assessment on the possible revision of the Tobacco Products Directive

The Commission gave a short overview on the ongoing work on the Impact Assessment on the revision of the Tobacco Products Directive. Following the consultation with the Member States, NGOs and tobacco industry in December 2009 on the baseline scenario, an external contractor, will finalise the report on the impacts of possible changes by summer 2010. A document by the Commission analysing these impacts will thereafter be published for public consultation.

Member States will be informed about the publication of the consultation document.

5. State of play of the work on tobacco products ingredients

5.1. Debriefing on the Working Group meeting on harmonised data collection methods for tobacco products ingredients on 30 March 2010

The Commission briefed the Member States on the meeting of the Working Group on harmonised data collection methods. Main items discussed during the meeting were (1) implementation of the electronic model for ingredients data submission and harmonised reporting formats, (2) state of play on analysing toxicological information on selected ingredients, (3) possible changes in the reporting formats and (4) analysis of ingredients data.

5.2. Debriefing on the status of the EMTOC project

Mr van Amsterdam (NL, RIVM) provided an update on the Electronic Model Tobacco Control (EMTOC) project. The project was finished in February 2010, the system is ready for use and Member States are invited to start using it actively. Currently, the EMTOC system is obligatory for manufacturers and importers only in Austria. Austria will be willing to share their legislation with interested Member States. In some Member States, industry may use the system for the data submission, but it is not obligatory.

Austria presented their experience on using the EMTOC system. Although less than half of products (414 out of 2548) were reported via EMTOC by the deadline of 15 March 2010, Austria found the system useful because it allows to

- check easily which companies have reported,
- check which products are reported,
- assess the quality of reports,
- analyse submitted data and
- transmit data to the European Commission

Austria will engage with industry to ascertain why there was a low level of compliance using the EMTOC system in 2010 and try to help resolve any problems. However, stringent procedures will be put in place, as non-compliance will not be tolerated in 2011.

Austria is preparing an analysis of costs of using the system for the Member States authorities and for the tobacco industry.

The Commission encouraged the Member States to learn from the Austrian experience and start using the system as it facilitates the data submission and analysis.

5.3 Guiding Questions to Regulators

The Commission encouraged Member States to use the guiding questions on the analysis of tobacco ingredient data, which was circulated to Member States at the 7th Meeting of the Tobacco Regulatory Committee. A few Member States have attempted to use these questions and found them useful. Other Member States were encouraged to use the questions and feed back to the Commission. The Commission will re-circulate the questions for the benefit of those who do not have the questions.

Member States are invited to use the questions and send their experiences to the Commission.

6. Preparations for the FCTC 4th Conference of Parties

The Commission gave an overview on the timetable of the preparatory work and invited the Member States to start work on preparing their comments on the draft guidelines on Articles 9&10, 12 and 14 that will be presented in November 2010 to the 4th Conference of Parties in Uruguay.

The Commission presented the outcome of INB4 on the FCTC Art 15 Illicit trade protocol in March 2010. The Commission encouraged the Members of the Regulatory Committee to liaise with their colleagues responsible for customs.

The Commission gave a short overview on the contents of the draft partial guidelines on Articles 9&10 (product regulation and disclosure).

7. Review of the text and picture warnings

The Commission presented an update on the developments since the Regulatory Committee meeting in April 2009. Translations of text warnings had been sent to the Member States. All comments received have been taken into account. The Commission invited Member States to finalise the revision of the translations by the end of May 2010.

A testing of the effectiveness of the possible new text warnings will be carried out within the Eurobarometer Qualitative Studies framework. The testing methodology was explained to the Member States: a range of groups will be covered by the study, including young people and both smokers and non-smokers. . The report will be presented to the Regulatory Committee in autumn 2010.

The Commission underlined the importance of introducing pictorial warnings in all Member States as soon as possible and not wait until new warnings will be made available.

The Commission took note of the wish of some Member States to revise both text and picture warnings simultaneously.

The Commission recalled that revision of the text and picture warnings is independent from the revision of the Directive. However, warnings will be discussed in the Impact Assessment of the Directive in the context of possible making picture warnings mandatory.

8. New products

The Commission thanked Member States for sending information on the availability on the market of electronic and herbal cigarettes and the relating legislation.

The Commission debriefed the Member States on the work on electronic cigarettes undertaken by the WHO. The Commission has participated in discussions organised by the WHO. Main concerns raised were lack of evidence regarding the safety of e-cigarettes and use of unsubstantiated claims in marketing.

Some Member States expressed their wish to include electronic and herbal cigarettes in the scope of the Tobacco Products Directive.

9. Any other business

9.1. Information on the Focal Points

The Commission recalled that according to point 6 of the Council Recommendation on smoke-free environments, Member States have to communicate to the Commission the details of their national focal points for tobacco control by 30 May 2010.

The Commission thanked those Member states which have already done so.

9.2. Information about water-pipe tobacco

Mr J. Hahn (Chair of the GoToLab Network) presented results of a study on the emissions of water-pipe tobacco. Mr Hahn noted that emissions and puffs from water pipes, relative to conventional cigarettes, are significantly higher. Therefore, Member States needed to raise awareness to educate people.

Member States asked whether it would be possible to include water –pipe tobacco in the scope of the Tobacco Products Directive. The Commission said that an inclusion of water-pipe tobacco in the scope of the Directive is analysed in the Impact Assessment of the revision of the Directive.

9.3. Work of the Network of the EU Governmental tobacco laboratories.

Mr J. Hahn gave an overview of the work of the GoToLab Network, its objectives and plans for next years.

The Commission reminded the Member States that the FCTC 3rd Conference of Parties decided to work on the validation of the testing and measurement methods for selected contents and emissions. It is important that the EU governmental tobacco laboratories participate in this work.

9.4. The Commission Report on the availability of snus in the Member States

The Commission thanked Member States for sending their contributions and Sweden and Finland, in particular, for sending written replies to the additional questions.
The report is expected to be adopted by the Commission by the end of 2010.

9.5. Eurobarometer 2009

The Commission informed the Member States that the Eurobarometer 2009 on tobacco control will be published on 27 May 2010.

10. Close of the meeting

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

The next meeting of the Regulatory Committee will be held in autumn 2010.

Annex I - Summary of conclusions

- Report on the impacts of possible changes of the Tobacco Products Directive is expected to be published for consultation in summer 2010. The Member States will be informed by e-mail.

- EMTOC is up and running since the beginning of 2010. The Commission invited Member States to learn from the Austrian experience and join the EMTOC.
- The Commission invited Member States to send their comments on translations of new text warnings by 21 May 2010.

- The Commission encourages starting using picture warnings now and not wait until the revised warnings will be made available.

Annex II – List of participants

Committee members:

Austria	(Ministry of Health)
Belgium	(Ministry of Health)
Bulgaria	(Permanent Representation of Bulgaria to the EU)
Czech Republic	(Ministry of Agriculture)
Denmark	(National Board of Health)
Estonia	(Ministry of Social Affairs)
Finland	(Ministry of Social and Health Affairs)
France	(Direction général de la santé)
Germany	(Ministry of Nutrition, Agriculture and Consumer Protection)
Greece	(Ministry of Health - Tobacco Institute)
Hungary	(Ministry of Health)
Ireland	(Department of Health and Children)
Italy	(Ministry of Health)
Latvia	(Ministry of Health)
Lithuania	(Ministry of Economy)
Malta	(Department of Environmental Health within the Ministry for Social Policy)
Netherlands	(Ministry of Health, RIVM)
Poland	(Ministry of Health)
Portugal	(General Directorate for Health)
Romania	(Ministry of Health)
Slovenia	(Ministry of Health)
Slovakia	(Ministry of Health)
Spain	(General Directorate on Public Health and Health Foreign Affairs)
Sweden	(National Institute of Public Health)
United Kingdom	(Department of Health)

Observers

Mr Jürgen Hahn	(GoToLab Network)
Norway	(Ministry of Health)
Turkey	(Tobacco, tobacco products and alcoholic beverages market regulatory authority)

Experts

Mr Paul Stamper	TNS

Commission services:

Ms Patricia Brunko	DG SANCO C6	(Chair)
Ms Terje Peetso	DG SANCO C6	
Mr Antti Maunu	DG SANCO C6	
Ms Sigrid Wimmer	DG SANCO C6	
Ms Pilar Lacruz	DG SANCO C6	
Ms Ming-Mei Wu	DG SANCO C4	
Mr Daniel Vanderelst	DG AGRI.DDG2.C.3	
Ms Rita Poleczki	DG SANCO C6	(Secretariat)

Mr Eddy Parijs	DG SANCO C6	(Secretariat)