EUROPEAN COMMISSION

HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C6 - Health Law and International

Brussels, 30 November 2009

SANCO C6/TP/ D(2009)/

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

C6 notes

Meeting dates: 30 November 2009, 10.00 – 16.30
Centre de Conference Albert Borschette, meeting room 1B

1. Welcome

The Commission welcomed the participants.

2. Adoption of the draft agenda

With following changes the draft agenda was adopted.

- to delete the review of the textual and pictorial warnings due to the ongoing work and add the Commission presentation on the Commission Working Document on the implementation of the Council Recommendation on the prevention of smoking (2003/54/EC) and debriefing on the Council Recommendation on smoke-free environments to the agenda
- to add presentation on the evaluation of the EMTOC project
- to add presentation on some issues regarding product labelling under AOB
- to move point 6. on the illicit trade protocol under 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 work done until now – 2nd implementation report adopted on 27 November 2007 followed by the discussions in the Regulatory Committee in December 2007 and April 2008.

First meeting of the Impact Assessment Steering Group (IASG) took place on 5 March 2009; external consultant started the work in June 2009. Interim report on the baseline scenario was presented to the IASG on 26 November; meetings with stakeholders are scheduled for 3 and 4 December.

The draft Interim Report was presented.

Some Member States recommended to include in the calculations of costs more diseases attributable to smoking than only lung cancer, COPD and cardiovascular diseases. It was also underlined that the productivity aspects and gender differences should also be reflected in the analysis.

The Commission informed that consultations on the final report will take place in the first half 2010.

Conclusion:

Member States were invited to send their written comments on the Interim Report by 6 January 2010.

5. New products

Member States informed about new developments on electronic and herbal cigarettes in their markets. Several Member States reported having classified electronic cigarettes as pharmaceutical products. Some Member States told they had banned electronic cigarettes altogether. Internet sales were reported as a major challenge. The majority of Member States reported existence of herbal cigarettes on their market, but did not consider that this was an issue. Following a request for clarification from one Member State, the Commission advised that electronic cigarettes should be regulated as a pharmaceutical product.

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

6.1. Debriefing on DG SANCO request for a scientific opinion on the attractiveness and addictiveness of tobacco products additives

The Commission briefed the Member States on the work of the Working Group established by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for preparing a scientific opinion on attractiveness and addictiveness of tobacco products additives. The mandate and call for additional information are published on DG SANCO website:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_020.pdf

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/scenihr_call_info_08_en.htm

To the questions from on how to define the "attractiveness" and whether the products with less additives are less attractive, the Commission replied that these questions are part of the terms of reference in the mandate to the SCENIHR.

One Member State asked for more information on the project PITOC (analysis of toxicological information on tobacco products ingredients). Mr. van Amsterdam explained that the project starts on 1 December 2009 and will be finalised by the end of 2010. Results of the project may be used for informing public about toxicological effects of tobacco ingredients.

6.2. Debriefing on the status of the EMTOC project

Mr van Amsterdam (NL, RIVM) provided an update on the Electronic Model Tobacco Control (EMTOC) project. Currently 11 Member States participate in the project, which is in its final stage. Discussions with tobacco industry on some technical problems are expected to be finalised by January 2010.

Some Member States expressed concerns regarding the financing of the project as there is a lack of legal basis for getting financing from tobacco industry. One Member State would prefer the Commission as a trust centre fro the EMTOC.

The Commission reminded that it is a collection of information on ingredients and dissemination of it to public is a legal obligation of the Member States. The Commission has facilitated the harmonisation of reporting formats and provided financial help for setting up the system. There is no legal basis for the Commission to provide resources for the maintenance of the system. Member States were reminded to check with their legal departments already existing possibilities of involving industry in the financing of similar procedures e.g. for pharmaceutical products.

Mr. van Amsterdam explained that the biggest costs will occur during the first year of the implementation of the project as a 'Help Desk' needs to be set up for answering questions that may emerge during first months. For the maintenance of the system and issuing smart cards the annual costs will be significantly lower.

6.3. Evaluation of the EMTOC project.

One Member State presented an evaluation of the project based on the questionnaire filled by the participants of the EMTOC. Majority of respondents appreciated the work done and intend to implement the system in 2010 or 2011. Several Member States would expect the EU to absorb the costs of the system.

Conclusion:

EMTOC is expected to be up and running in the beginning of 2010 and the project is thus finalised. The Commission invited Member States to join the EMTOC project as the development of any other IT system would also bear costs.

7. Report on the implementation of the Council recommendation on the prevention of smoking (2003/54/EC)

The Commission recalled the relevance of the Council Recommendation 2003/54 as complementary element to the binding legislative instruments which was adopted at the time between the Tobacco Products and the Tobacco Advertising Directives. Although many developments had taken place since its adoption – at national, European and international level – the recommendation was still a good overview of some essential measures in tobacco control.

The report was in a generic and factual manner presenting the information received from Member States. The structure of the report followed the recommendation and was thus centred on the areas: measures to better protect minors, advertising and promotion, protection from environmental smoke and other flanking measures.

The degree of implementation was generally satisfactory.

Progress had been made as concerns in particular the requirement to verify the minimum age for the purchase of tobacco products (all Member States have minimum age limits). The rules in Member States as regards the sale of cigarettes individually or in packets of fewer than 19 cigarettes and with regard to the sale of sweets and toys which resemble tobacco products vary considerably and are not fully implemented. The same is the case for the rules concerning distant sales.

While the provisions related to the prohibition of certain forms of advertising and promotion, are almost fully implemented, some issues remained as regards the points of sale.
In the area of smoke free environments, while all Member States have some legislation, comprehensive bans in particular in workplaces (notably in the hospitality sector) remained a challenge. Price measures of tobacco products to discourage tobacco consumption have not been widely used, but this will change given the recent agreement of Finance Ministers to increase the minimum excise duties.

8. Debriefing on the adoption of the Council Recommendation on Smoke-free Environments

The Commission informed the Member States that the Recommendation had been adopted during the day in the Council. Member States are now expected to designate focal points to define benchmarks, definitions and indicators. It could be envisaged that the focal points would also deal with other aspects of tobacco control, not only smoke-free environments.

On the question from a Member State on whether plain packaging was included the Commission replied that according to its information plain packaging has been included as an invitation for the Commission to further assess the issue.

9. Availability of snus in the Member States

The Commission thanked those 17 Member States who had sent their replies by the deadline of 25 November. The rest of the Member States were asked to reply by 10 December 2009.

Conclusions:

The Commission will produce a report on the situation.. The Commission also encouraged Sweden and Finland to negotiate bilaterally.

10. Any other business

10.1. Implementation of pictorial warnings in Member States

Several Member States informed the Commission on the legislative plans towards the adoption of pictorial warnings.

10.2. Debriefing on the state of play of the FCTC Art. 15 Illicit trade protocol

The Commission reminded that the negotiations on a protocol on illicit trade were entering a decisive phase and that it hoped that INB 4 in March 2010 could conclude work on the protocol.

The positions of the EU were co-ordinated in Brussels (for all substance related issues) in the Customs Union Group and in Geneva (for institutional and financial matters). The lead service in the Commission was OLAF, SANCO was closely associated. The Commission encouraged the Members of the Regulatory committee to liaise with custom colleagues and to support the protocol from public health angle.

The main features of the future protocol were mentioned: Licences, Customer Identification and Verification, Tracking and Tracing, Record Keeping, Internet and other telecommunication sales, Free Trade Zones and duty-free sales. This part was complemented by parts on criminal Law and on institutional rules.

10.3. Tobacco product labelling

One Member State presented number of problematic cases on product labelling, advertising and promotion.

Several Member States shared the concerns, reported about developments regarding display-ban and emphasised that serious considerations should be given to the plain packaging.

11. 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 in April 2010.

Annex I - Summary of conclusions

- Member States are invited to send their written comments on the Interim Report by 6 January 2010.
- EMTOC is expected to be up and running in the beginning of 2010 and the project is thus finalised. The Commission invited Member States to join the EMTOC project as the development of any other IT system would also bear costs.
- The Commission will prepare a report on the situation regarding the availability of snus. The Commission also encouraged Sweden and Finland to negotiate bilaterally.

Annex II – List of participants

Committee members:

Austria	(Ministry of Health)
Belgium	(Ministry of Health)
Bulgaria	(Ministry of Health)
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 Agriculture and Rural Development) (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) (Ministry of Health and Social Affairs)
United Kingdom	(Department for Tobacco Policy)

Observers

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

Experts

Mr Jan Tiessen	RAND
Ms Priscillia Hunt	RAND

Commission services:

Ms Patricia Brunko	DG SANCO C6	(Chair)
Ms Terje Peetso	DG SANCO C6	
Mr Antti Maunu	DG SANCO C6	
Mr Dimitios Kotzias	DG JRC	
Ms Diana Rembges	DG JRC	

Ms Rita Poleczki	DG SANCO C6	(Secretariat)
Mr Eddy Parijs	DG SANCO C6	(Secretariat)