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Directorate C - Public Health and Risk Assessment

C6 - Health measures

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Summary information

5th Meeting of the REGULATORY COMMITTEE established under Article 10 of the Tobacco Products Directive 2001/37/EC

Brussels, 16 October 2006

PARTICIPANTS

Commission Services

Ms Thea Emmerling	DG SANCO C6	(Chair)
Ms Terje Peetso	DG SANCO C6	
Mr Antti Maunu	DG SANCO C6	
Ms Anna Jassem	DG SANCO C6	
Ms Lourdes Chamorro	DG SANCO C6	
Mr Eddy Parijs	DG SANCO C6	
Ms Jen Yang	DG SANCO C6	
Mr Stefano Soro	DG SANCO B3	
Mr Michael Hübel	DG SANCO C4	

Committee members

Austria	(Ministry of Health and Women)
Belgium	(Ministry of Health)
Cyprus	(Ministry of Health)
Czech Republic	(Ministry of Agriculture)
Denmark	(National Board of Health)
Estonia	(Permanent Representation of Estonia to EU)
Finland	(Ministry of Social Affairs and Health)
Germany	(Ministry of Nutrition, Agriculture and Consumer Protection)
Greece	(Tobacco Institute of Greece)
Hungary	(National Institute for Health Development)
Italy	(Ministry of Health)
Ireland	(Department of Health and Children)
Lithuania	(Ministry of Economy; Ministry of Health)
Malta	(Permanent Representation of Malta to EU)
Netherlands	(Ministry of Health, Welfare and Sport)
Poland	(Ministry of Health)
Portugal	(Ministry of Health)
Spain	(Ministry of Health and Consumer Affairs)
Sweden	(National Institute of Public Health)
United Kingdom	(Department of Health)

Observers:

Bulgaria	(Ministry of Health)
Switzerland	(Federal Office for Public Health)
Turkey	(Tobacco Regulatory Authority)
Norway	(Ministry of Health and Care Services)
Iceland	(Ministry of Health)

Absent: Latvia, Luxembourg, Slovakia, Slovenia

Summary Information

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Tobacco Products Regulatory Committee

Brussels, 16 October 2006

Summary Report

The Regulatory Committee established under Article 10 of the Tobacco Products Directive 2001/37/EC of the European Parliament and the Council was convened on 16 October 2006 by the Chair Ms Thea Emmerling, Deputy Head of Unit, SANCO C6. All member states were present at the meeting with the exception of Latvia, Luxembourg, Slovakia and Slovenia.
The topics for the discussion were mainly on the results of two working groups: on ingredients reporting formats and on laboratory cooperation. Other items are mentioned in the agenda.
All Member States welcomed the work done by the working groups and encouraged the Commission to go ahead with the documents.

1 Welcome and apologies

The Commission (TE) welcomed the participants and introduced the current tobacco control team of the Commission.
Apologies were received from Croatia, Latvia, Luxembourg, Slovakia and Slovenia as well as from Romania and Liechtenstein.

2 Adoption of the draft agenda

The draft agenda was adopted with modification to the order of proceedings.

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 Tobacco product regulation

4.1. Information on developments since the last meeting

REACH regulation

The Commission (AM) explained the current state of negotiations for the Reach system, outlined the link between the REACH system and the works on tobacco ingredients under the tobacco products directive.

FCTC guidelines for testing and measuring of contents and emissions of tobacco products

The Commission (TE) gave an overview of the state of play of the work for the development of FCTC guidelines on testing and measurement of the contents and emissions of tobacco products, for which the Community acts as one of the key facilitators.

4.2. Results of the working group on ingredients reporting formats and discussion

Draft Harmonised Reporting Format to national authorities

The Commission (TE) thanked the Member States for their extremely valuable input and cooperation in the working groups. She reported on the work done by the Working Group on ingredients reporting formats and explained the logic of the two draft formats, one for reporting to the authorities, one for reporting to the public.

The Commission announced that recommendation/guidelines will also include a reminder to Member States that they are dealing with information which contains trade secrets. Therefore, appropriate procedures for handling the data should be applied.

Member Sates backed the Commission by insisting to ask for exact ingredients data instead of maximum quantities or a range.

It was agreed that the Member States mandate the working group to finalise the draft with the Commission in a follow-up meeting.

Draft Harmonised Reporting Format to the general public

The Commission explained the logic of the draft reporting format designed for the general public and informed participants about the results of the consultation with industry on draft formats. The current text suggests that flavourings used in quantities below 0.1% of the total tobacco unit weight would be considered as trade secrets. During the 2nd consultation with industry exceptions for pipe tobacco and oral tobacco products with the quantities below 0.5% were proposed.

One Member State stressed that the industry should not be allowed to disseminate unapproved information to the general public. Two Member States also pointed out that in order not to send the wrong signal to the public, any public disclosure of ingredient information must be prefaced by a statement that clearly explains that all smoking is dangerous and no cigarette is better for one's health than another.

It was agreed that the Member States mandate the working group to finalise the draft with the Commission in a follow-up meeting.

Electronic system for reporting formats

The Commission asked the Member States about their opinion on how and by whom the electronic formats should developed.

The general consensus among Member States was that forming partnership with the tobacco industry would be against the spirit of the tobacco directives and FCTC.

Conclusion: Working group is on good way; one more meeting needed to finalise the formats; Member States to give written feedback on industry proposal in 2 weeks.

4.3. Results of the working group on laboratory cooperation and discussion

The Commission (TE) reported on the work done by the Working Group on laboratory cooperation and presented the papers prepared by the Working Group. The Working Group suggests that there should be a clear distinction between testing and verifying laboratories and that verification should be done by independent laboratories.

The delegations made certain modification proposals on the meaning and criteria for verification.

The Commission said it would check the proposals and take them into account, if appropriate.

Conclusion: The Commission should go ahead with a recommendation on laboratory cooperation on this basis, it will clarify the interpretation of maximum limits and confidence intervals.

4.4. Relation of Regulatory Committee and Commission to European Network of Governmental Laboratories

The Chairman of the European Network of Governmental Laboratories gave a general overview over the work of the network and expressed the willingness of the network to be closer linked to the regulatory work.

The Commission asked Member States for their comments on the idea of linking the GoToLab network closer to the Committee work. The Member States demonstrated strong support for this proposal and unanimously agreed that forming a working relationship with the GoToLab would be a good idea.

Conclusion: The Commission will develop a draft 'Memorandum of understanding' for setting the relationship between the Commission, the Regulatory Committee and GoToLab.

5 Colour photographs

5.1. Information on the Commission's work since the last meeting

The Commission (AJ) informed that the amending decision on pictorial warnings was adopted in April 2006.

Furthermore, the Commission informed that licence agreements have been concluded with New Zealand, Switzerland and Romania, which will allow these countries to use the EU library of warnings.

5.2. Pictorial warnings

Member States debriefed on their state of play of their introduction of pictorial warnings.

Conclusion: The Commission appreciated the work done by the Member States that intend to introduce pictorial warnings and stressed that it will provide within its possibilities all possible help to support them.

6 Oral tobacco: Information by the Commission on the state of play

Following the conclusion of the last Regulatory Committee to ask the scientific committees of DG SANCO for an opinion on oral tobacco, the Commission asked the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for an opinion on health effects of smokeless tobacco products in November 2005, the terms of reference are available at:
http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_004.pdf

The members of the SCENIHR identified the needs for the expertise and invited external experts to participate in the Working Group accordingly.

The preliminary opinion is expected to be published in January 2007. A six-week public consultation period will follow, which will give various stakeholders the opportunity to express their views on the draft. The final opinion is expected to be adopted during the SCENIHR Plenary Meeting in May 2007.

Member States raised concerns about new technologies and harm-reduced products that were developed after the Directive was formulated, such as nicotine drinks or smokeless and electric cigarettes. The main concerns were about how such products should be defined and dealt with.

The Commission outlined the regulatory environment for nicotine drinks. The question of tobacco intended for chewing was also discussed and the need for further clarification was identified.

Several Member States wished to hold a specific meeting on discussing the issue of new tobacco products. The Commission was ready to look into the possibility for a supplementary meeting of the Committee in spring next year.

7 RIPS: Information by the Commission on state of play of work on RIPs

The Commission (SS) reported its work on RIPs under the General Product Safety Directive. Several Member States expressed their interest to participate in the preparatory work which might take several years before EU standards will be in place.

8 Any other business

8.1 Smoke free environments

The Commission (AJ) reported on the findings from the recent Eurobarometer survey on the attitudes towards smoking. According to the survey, over 85% of EU citizens are in favour of smoke-free workplaces and public places.

http://ec.europa.eu/health/ph_information/documents/ebs_239_en.pdf

The Commission is in the final stages of drafting a Green Paper on smoke-free environments which is currently being negotiated with other Commission's departments.

8.2. Help campaign: Information by the Commission

The Commission (MH) drew attention to a number of highlights of the Help Campaign. In particular, the Commission reported that the Campaign's website received very positive responses from the public. Furthermore, its achievement in forming partnership with influential youth organisations, such as Youth Forum, is likely to strengthen the Campaign's cause.

No comments from Member States on this part.

8.3. Council recommendation on smoking prevention

The Commission (LC) announced it would start to monitor the implementation of the Council Recommendation on the prevention of smoking (2004/54/EC). It had therefore prepared a draft questionnaire to survey the implementation of the measures. The participants were asked to submit their comments on the format and content of the questionnaire via e-mail by 19 October. As no comments on the draft questionnaire were received, the Commission sent it out to Member States end of October with a six weeks deadline.

9 Close of the meeting

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

Conclusions

- Ingredients formats will be further discussed in the next meeting of the ingredients working group. The next meeting is likely to be scheduled for sometime in mid-November.

- Rather than industry involvement, the Commission will investigate other possible ways to develop the electronic system.

- Amendments requested by certain delegations with regard to laboratory cooperation will be taken under consideration.

- Member States wished to closer link the European Network of Governmental Laboratories to the work of the Regulatory Committee. The Commission will develop an arrangement.

- Member States should send comments on the draft questionnaire to survey the implementation of the measures proposed by the Council Recommendation on the prevention of smoking to the Commission within the next three days. If no comments arrive, the Commission will convert the draft into a final questionnaire and send it to Member States for response.

Chair of the Committee

signed

Thea Emmerling