EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C6 - Health measures

Brussels,

SANCO C6//TPE/ub / D(2007) 360261

Summary information

6th Meeting of the REGULATORY COMMITTEE established under Article 10 of the Tobacco Products Directive 2001/37/EC

Brussels, 20 April 2007

PARTICIPANTS

Commission services:

Ms Thea Emmerling	DG SANCO C6	(Chair)
Mr Tapani Piha	DG SANCO C6	
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	(Secretariat)
Ms Urszula Baranik	DG SANCO C6	(Secretariat)
Mr Dimitrios Kotzias	DG JRC I5	
Ms Anne Deltour	DG ENTR F2	

Committee members:

Austria	(Ministry of Health and Women)
Belgium	(Ministry of Health)
Bulgaria	(Ministry of Health)
Czech Republic	(Ministry of Agriculture)
Denmark	(National Board of Health)
Finland	(Ministry of Social Affairs and Health)
France	(Direction général de la santé)
Germany	(Ministry of Nutrition, Agriculture and Consumer Protection)
Greece	(Tobacco Institute of Greece)
Hungary	(National Institute for Health Development)
Ireland	(Department of Health and Children)
Latvia	(Ministry of Health)
Lithuania	(Ministry of Economy; Ministry of Health)
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)

Guests:

Denis Choinière	(Ministry of Health of Canada)
Murray Kaiserman	(Ministry of Health of Canada)
Julie Fillion	(Ministry of Health of Canada)
Mathew Cook	(Ministry of Health of Canada)

Observers:

Jürgen Hahn	(GoToLab Network)
Iceland	(Ministry of Health)
Norway	(Ministry of Health and Care Services)
Switzerland	(Federal Office for Public Health)
Turkey	(Tobacco Regulatory Authority)

Summary Information

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1 Welcome and apologies

The Commission (TE) welcomed the participants and introduced the current tobacco control team of the Commission (DG SANCO and DG JRC), four guests from Health Canada and observers from European Governmental Tobacco Laboratories (GoToLab) Network, EEA, EFTA and candidate countries.

Apologies were received from Estonia, Italy, Cyprus, Luxembourg, Malta and Slovakia as well as from Croatia and Liechtenstein.

2 Adoption of the draft agenda

The following items were added as 'any other business' to the agenda: waterpipe issues, RIP cigarettes, recent developments in the preparation of the scientific opinion on smokeless tobacco products; state of play of the Tobacco Products Directive 2nd implementation report.

The draft amended agenda was adopted.

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 State of play of harmonised reporting formats for tobacco products ingredients and tobacco laboratory cooperation

The Commission (TPE) explained that due to the need for a stakeholder consultation on the TNCO measurements and the criteria for the laboratory approval DG SANCO decided to separate it from the document on the ingredients reporting formats.

Reporting on tobacco product ingredient – practical guide

The Commission (TPE) informed that the guide will be published as DG SANCO document within a few weeks on DG SANCO's website.

The Commission stressed that although the document is not legally binding the use of the common reporting formats is important for the future analyses of the data submitted by industry.

Cigarette yield measurement and some basic steps for laboratory approval – practical guide

The Commission (TPE) gave an overview of the outcome of consultation meetings with NGOs and the tobacco industry. The Commission (TE) asked Member States to send their comments about the proposal within the next 2 weeks.

Administrative arrangement between DG SANCO and DG JRC

The Commission (TPE) informed that DG SANCO and DG JRC concluded a three year cooperation agreement on tobacco ingredients. The agreement mainly covers:

- analysis and assessment of certain tobacco ingredients and TNCO data received by DG SANCO from the Member States;
- checking which ingredients will be covered by REACH and summarise this information;
- scientific support to DG SANCO on the issues relevant to the regulatory process and in its role as key facilitator in the FCTC Working Group on art.9;
- support to the European Governmental Tobacco Laboratories (GoToLab) Network.

Conclusion: The Commission will inform Member States about the publication of the practical guide on ingredients reporting on DG SANCO website.

5 Introduction to Canadian tobacco product regulation, Canadian tobacco industry and Canadian political system

The Canadian delegation presented the Canadian political system, the main items in the tobacco product regulation, data on smoking habits and tobacco consumption in Canada and the principles of their data collection and analysis.

Conclusion: Health Canada is currently working on a national tobacco products data repository. After the completion of the work some data exchange with the Commission and Member States might be possible.

6 Analysis of tobacco ingredients and smoke emissions data

DG Joint Research Centre

DG JRC presented the activities done so far within the administrative arrangement between DG SANCO and DG JRC. The main work consists of the analysis of the data submitted to the Commission by the Member States.

Conclusion: The Commission will set up a working group consisting of DG SANCO, DG JRC and the chairman of the GoToLab network. The group will draft a set of guiding questions which will be discussed during one of the next Regulatory Committee meetings.

7 Pictorial warnings

Participants presented the state of play as regards their plans or measures taken to introduce pictorial warnings.

BE presented the first experience in the EU of introducing pictorials. Pictorial warnings were introduced last November and, as of 10 June 2007, will feature on all cigarette packets sold in Belgium. The implementation so far has been rather smooth. Producers have the choice to either use all 42 pictures from the beginning or to introduce the whole set - divided into three series - over a three-year period (the solution chosen by most producers)

In RO, pictorials will become mandatory on all cigarette packs in July 2008. A public consultation, which selected one of three images for each of the 14 additional warnings, was carried out last December.

Conclusion: An update on pictorial warnings will be a standard point at each of the future Regulatory Committee meetings

The Commission will be happy to provide Member States with technical or legal assistance needed for introducing pictorial warnings.

8 New products

Participants described their experience with various new types of tobacco and nicotine products on the market.

Thereafter, the Commission gave an overview of the present EC regulatory environment for new types of tobacco and nicotine products (tobacco product regulation, food legislation and pharmaceutical legislation). The Commission stressed that it is for the Member States to classify each product and the Commission can only give general orientation.

As for the Tobacco Products Directive, it should be studied case-by-case whether it is applicable and, if yes, which of its articles are applicable. As for the EU food legislation, it excludes tobacco products from its scope. Nicotine products not containing tobacco could potentially fall under its scope.

A product containing tobacco can also fall under the EU pharmaceutical legislation if it fulfils the criteria of a human medicine. Human medicines are subject to pre-marketing authorisation that requires effectiveness to be shown. No human medicine can be put on the EU market without such authorisation.

In accordance with Directive 2001/83/EC two criteria are relevant to define whether a product must be considered as human medicine:

- **Human medicine by function**: It includes all substances endowed with pharmacological properties with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions. The ECJ has expressly ruled that this covers all products which alter physiological functions and which may thus have an effect on health in general, even in the absence of a disease. The following criteria have been identified by the ECJ as relevant: the pharmacological properties of the product to the extent to which they have been established in the present state of scientific knowledge, its composition, the way in which it is used, the risks which may

be associated with consumption, the extent to which it is sold and the consumers familiarity with it.

The existence of health risks is traditionally one of the criteria employed by the ECJ for classifying a product as medicinal. It follows from the aim of health protection pursued by the Community pharmaceutical legislation that products presenting health risks should be covered by the rigorous requirements of that legislation in case of doubt as to their classification.

- **Human medicine by presentation:** A product expressly indicated or recommended as having therapeutic or prophylactic properties has to be regarded as a medicinal product by virtue of its presentation even if it has no known therapeutic effect. A product is deemed to be presented for treating or preventing disease within the meaning of Directive 2001/83/EC not only when it is expressly indicated or recommended as such, but also whenever any averagely well-informed consumer gains the impression that the product in question should have such an effect. Regard should be had to the product's form and the manner in which it is packaged, and to the information provided to the consumer. Reference to research by pharmaceutical laboratories or to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product in question can lead to the classification of the product as medicinal.

Conclusion: This agenda point will be made permanent. Member States are asked to report on new products at each committee meeting.

9 Smoke emission measurement methods

The representative from Norway presented the work of the FCTC Working Group on guidelines for the implementation of the FCTC tobacco product regulation provisions.

The chairman of the GoToLab network presented the ISO and compensatory method.

A representative from Canada presented the Canadian intense and Massachusetts method.

DG JRC presented the pro's and con's on different methods prepared by the GoToLab Network members.

Conclusion: Different methods were discussed. No conclusion was made.

10 Any other business

10.1 Smokeless Tobacco Products

In the context of the discussion on snus, the Commission (TPE) informed about the recent developments and timeframe in the work of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on smokeless tobacco products.

10.2 Taxation

The Commission (LC) presented the process of the review of the tobacco taxation directive and made delegates aware of the on-line open consultation on this issue. The link to the consultation web-page and the contact details of the officials in charge in TAXUD and SANCO were distributed.

http://ec.europa.eu/taxation_customs/common/consultations/tax/article_3835_en.htm

The Commission stressed that there is a lot of evidence available on how increased taxation affects the demand for cigarettes and other tobacco products.

10.3 RIPs

The Commission (LC) informed the participants about the current situation in this issue under the GPSD.

10.4 Water-pipe

Several delegations noted the increasing use of water-pipes among young people.

The Commission (AM) explained that it must be regarded as a tobacco product under the Tobacco product Directive.

10.5 2nd implementation report

The Commission (TE) outlined the main items to be covered.

Conclusion: The Commission will inform Member States about the launch of the public consultation on the scientific opinion on smokeless tobacco products as soon as it is published on DG SANCO website.

The Commission will keep the water-pipe issue under the review of the committee.

11 Close of the meeting

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

Annex I - Summary of conclusions

- The Commission will inform Member States about the publication of the practical guide on ingredients reporting on DG SANCO website.

- The Health Canada is currently working on a national tobacco products data repository.

- The Commission will set up a working group consisting of the DG SANCO, DG JRC and the chairman of the GoToLab network. The group will draft a set of guiding questions for the ingredients data analysis which will be discussed during one of the next Regulatory Committee meetings.

- An update on pictorial warnings will be a standard point at each of the future Regulatory Committee meetings

- The Commission will be happy to provide Member States with technical or legal assistance needed for introducing pictorial warnings.

- Discussion on new tobacco products will be made permanent in the agenda of the Regulatory Committee meetings. MS are asked to report on new products at each committee.

- The Commission will inform Member States about the launch of the public consultation on the scientific opinion on smokeless tobacco products as soon as it is published on DG SANCO website.

- The Commission will keep the water-pipe issue under the review of the committee.