EUROPEAN COMMISSION

HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

**C6 – Health Law and International**

AM/TPE/D(2008) 360238

# 8th Meeting of the REGULATORY COMMITTEE established under Article 10 of the Tobacco Products Directive 2001/37/EC
# Summary record

**Meeting date: 16 April 2008, 9.30 – 17.30**
**Centre de Conference Albert Borschette, meeting room 3C**

## 1. Welcome and apologies

The Commission (TE) welcomed the participants and explained that no observers are invited as the discussion will be mainly on the possible changes in the Directive. The observers are always invited if the discussion is on the implementation of the Directive.

Apologies were received from Latvia, Luxembourg and Slovakia.

TE asked whether the participants agree to disclose their names if the Commission is asked. None of the participants was against the disclosure.

## 2. Adoption of the draft agenda

The draft 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. Opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) on health risks of smokeless tobacco products

Prof. J. Bridges (chair of the SCENIHR) presented the Opinion which was adopted 6 February 2008.

Member States would expect further work on NRTs.

The Commission explained that it is currently analysing different risk management options.

One Member State said that the ban on snus is discriminating compared to other similar tobacco products that are allowed in the EU.

None of the other Member States indicated to have a problem in case the ban on snus would not be lifted.

## 5. 2nd Report on the implementation of the Tobacco Products Directive 2001/37/EC

Definitions (Article 2)

In the 2nd implementation report the Commission proposed to include the tobacco leaf and other natural or unprocessed tobacco plant parts in the definition of ingredient.

A number of Member States supported the change in the definition and the inclusion of the leaf in ingredients.

Measurement method and yield labelling (Article 4)

In general Member States supported the extension of the Commission regulatory powers to the adoption of the criteria for laboratory approval and making these criteria binding.

Labelling (Article 5)

In the 2nd implementation report, the Commission proposed possible further actions such as to examine the possibilities to replace the TNCO data on the cigarette packages with information on help-lines and/or other substances in tobacco products (e.g. labelling the use of GMOs) and to have combined warnings with increased size on both sides of the package to be mandatory in all EU countries.

These proposals were welcomed by many Member States.

Several Member States supported the idea to remove TNCO data from the package and to make pictorial warnings compulsory. There was also some criticism on the removal of TNCO data from packages, GMO labelling and mandatory pictorial warnings.

Some member States found the idea of GMO labelling interesting, but noted that it should be avoided that tobacco companies use it for promoting their products.

Ingredients (Article 6)

Member States supported the proposal, made by the Commission in the 2nd implementation report, to make the new reporting formats on ingredients compulsory.

The Commission repeated that it is necessary to prepare a strategy on how to deal with ingredients and possible future developments on this. The strategy depends greatly on our own work on ingredients as well as on the work done by the FCTC Working Group on Articles 9 and 10.

Common list of ingredients (Article 12)

One of the possible areas for change as the Commission proposed in the 2nd implementation report includes the ban on substances enhancing addictiveness and which are carcinogenic, mutagenic or toxic for reproduction (CMR) as such or upon pyrolysis and substances for which complete data sets are not submitted. However it should be clarified what is meant by a complete data set.

In general there was support to the ideas listed under this point, especially the penalties on incomplete data and ban on CMR substances.

Import, sale and consumption of tobacco products (Article 13)

In general there was a cautious support for looking further on the issue of generic packages. This issue will be discussed again after CoP3 or in spring 2009.

Emerging issues

The Commission informed that the new legislative proposal on new tobacco taxation is expected to be adopted in July-August this year.

With regard to the new products the Commission recognised that there is an imbalance in legislation.

Member States were invited to submit their views on how to better balance tobacco and pharmaceutical legislation.

Liability

The Commission intends to have a study on liability. This area needs a long term work and therefore is not likely to be a part of the revision of the Directive.

**Conclusion:**

Member States expressed their strong support to a number of changes proposed in the 2nd Report.

## 6. State of play of tobacco products ingredients reporting

The Commission gave an overview of the work done in after the Regulatory Committee Meeting in December. The Commission met on its own initiative several experts following the publication of the literature study on tobacco products ingredients in Denmark in November 2007. These were experts from Danish Cancer Society, German Cancer Research Centre and RIVM (NL). The purpose of the meeting was to share experience on the work on ingredients. Expert's opinions will be presented and discussed during the next ingredients Working Group meeting.

Prof Per Kim Nielsen (DK) presented a literature study "Tilsætningsstoffer i cigaretter".

Member States supported the Commission proposal to continue the work of the ingredients Working Group, in particular, the work on reporting formats for the general public. The Working Group can be expanded in case there is an interest to join the group.

NL gave an overview of the use of new reporting formats. Several Member States reported about the confidentiality issue which is still main obstacle for industry to fulfil the legal requirement to submit information on all ingredients. Industry is pushing Member States to sign the confidentiality agreements. Also, industry has several times asked for an overview on how the confidential information is handled in the Member States' competent authorities.

Several Member States have asked the industry to start using the new formats, but this is not legally binding.

**Conclusions:**

Several Member States have asked the industry to start using the new reporting formats.

An electronic database is expected to be up and running in 2009. This is expected to solve some confidentiality issues.

The Working Group on ingredients will be reconvened in 2008 to continue work on public formats.

## 7. Pictorial warnings

Member States reported about the recent developments in the work on pictorial warnings.

## 8. New products

The Commission pointed out that the orientation note on electronic cigarettes is in preparation but is not yet ready for distribution.

Several Member States welcomed the upcoming note as a basis for their actions.

The Commission outlined the EC legal framework for nicotine drinks.

Nicogel will be discussed during the next Regulatory Committee meeting.

**Conclusion:**

Orientation note on e-cigarettes will be sent out as soon as it is finalised.

Issues on Nicogel will be discussed during the next Regulatory Committee meeting.

This agenda point remains permanent in the agenda. Member States are asked to report on new products at each committee meeting.

## 9. Debriefing on the GoToLab Network activities

Mr Jürgen Hahn gave an overview of the GoToLab network activities. In his presentation Mr Hahn emphasised that the laboratory work done in EU can feed well into the work of WHO FCTC the same way as the work done outside the EU contributes our work. The GoToLab Network is already supported by DG SANCO and DG JRC. In order to start the work on validating some testing methods financial support from the Member States is of utmost importance.

The Commission endorsed the plea from GoToLab network to support the work of GoToLab network and testing so that EU can participate in the world-wide process.

## 10. Recent developments with RIP cigarettes

The Commission gave an overview on the recent developments with RIP cigarettes.

## 11. Close of the meeting

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

## Annex I - Summary of conclusions

- In general the Member States have no problem in case the ban on snus will not be lifted.
- Member States expressed their strong support to a number of changes proposed in the 2nd Report.
- Several Member States have asked the industry to start using the new reporting formats.
- An electronic database is expected to be up and running in 2009. This is expected to solve some confidentiality issues.
- The Working Group on ingredients will be reconvened in 2008 to continue work on public formats.
- Orientation note on e-cigarettes will be sent out as soon as it is finalised.
- Issues on Nicogel will be discussed during the next Regulatory Committee meeting.
- The discussion on new products remains permanent in the agenda. Member States are asked to report on new products at each committee meeting.

## Annex II – List of participants

**Committee members:**

| | |
|---|---|
| Austria | (Ministry of Health, Family and Youth) |
| Belgium | (Ministry of Health) |
| Bulgaria | (Ministry of Health) |
| Czech Republic | (Ministry of Health) |
| Cyprus | (Ministry of Health) |
| Denmark | (National Board of Health) |
| Estonia | (Ministry of Social Affairs) |
| Finland | (National Product Control Agency for Welfare 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) |
| Italy | (Ministry of Health) |
| Lithuania | (Ministry of Health) |
| Malta | (Permanent Representation of Malta) |
| The Netherlands | (Ministry of Health, Welfare and Sport, RIVM) |
| Poland | (Ministry of Health) |
| Portugal | (Ministry of Health) |
| Romania | (Ministry of Health) |
| Slovenia | (Ministry of Health) |
| Spain | (Ministry of Health and Consumer Affairs) |
| Sweden | (National Institute of Public Health) |
| United Kingdom | (Department of Health) |

**Experts**

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|---|---|
| Prof Jim Bridges | Chair of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) |
| Mr Per Kim Nielsen | (Danish Cancer Society) |
| Ms Nina Lei | (Danish Cancer Society) |
| Mr Jürgen Hahn | (Chair of the GoToLab Network) |

**Commission services:**

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|---|---|---|
| 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 | |
| Mr Eddy Parijs | DG SANCO C6 | (Secretariat) |
| Ms Urszula Baranik | DG SANCO C6 | (Secretariat) |
| Mr Jürgen Vogelgesang | DG SANCO B3 | |
| Ms Diana Rembges | DG JRC, IHCP | |