EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment
C6 - Health measures

Working group on harmonised data collection methods created by the Regulatory Committee under Article 10 of the Tobacco Products Directive

Mandate and Terms of Reference

i. Members

The Working Group ("WG") is composed of experts nominated by Members of the Regulatory Committee from NL AT BE ES DE FR PL UK (see details in the annex).

ii. Technical arrangements

Members give declaration of interests in writing.
The working language is English.
The Working Group is chaired by the Commission.
The secretariat will be assured by SANCO C6, J. Brodersen.
The Working Group can elect a rapporteur.

iii. Mandate

The tobacco products directive 2001/37/EC sets out in Art 6.1 " manufacturers and importers of tobacco products shall submit to Member States a list of all ingredients and quantities thereof, used in the manufacture of those tobacco products by brand name and type ". However, the directive is silent on the format of this reporting.

The first report on the implementation of the tobacco products directive concluded that the reporting from industry was varying to a large degree between Member States. This diversity of reporting poses a burden on industry and public administration to report, to analyse and to publish the data.

The regulatory committee therefore set up a working group to investigate possibilities and requirements for a single format of harmonised reporting of ingredients data according to Art 6.1 from manufacturers and importers to Member States, taking due account of the provisions of the directive, the associated objectives to inform the public and improve health as well as international experience.

The objective of the Working group is therefore to develop a draft of a harmonised reporting system for disclosure of ingredients and ingredients data by summer 2006 to be discussed and possibly adopted by the regulatory committee in September 2006.

iv **Terms of reference**

Leading questions during the elaboration of the harmonised reporting system should be:

- Develop a single electronic reporting format:
    - starting from the intended use of the data
    - taking into account data requirements set by the directive,
    - defining available data and gaps,
    - looking at different means to efficiently administer and verify the data.
    - taking into account best practice from food additives, pesticides/biocides or medicines as a reference point and reporting costs for industry
- Effects to be considered: addictiveness and health
- Compliance:
    - How can reporting from all be ensured?
    - Which level of verification of industry data is needed?
- Cost for studies /burden of proof:
    - Industry is to bear the burden of proof for demonstrating that ingredients do not increase toxicity or addictiveness. (This principle is already established in the General Product Safety Directive / EU Chemicals Bureau system or in the current REACH proposal.) But what is the level of evidence public authorities request?
    - Which tests are necessary?
- Publication:
    - Which information do consumers want? (quantities of an ingredient or smoke constituents, functions, maximum daily intake?)
    - Which practice do Member States use to ensure trade secrets while sticking to a high level of health protection?
    - What could be a joint approach to publish data, grouped by health effect?