European Network for Smoking Prevention

ENSP | Position Paper | Article 11 Directive 2001/37/EC

Article 11 of Directive 2001/37/EC of 5 June 2001 (OJ L 194) on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products requires that the Commission shall regularly report to the European Parliament, the Council and the Economic and Social Committee on the application of the Directive.

The EC published the report on 27 July 2005, which aimed at providing the first assessment of the application of the Directive.

Unfortunately, the report has no real value for policy or evaluation purposes. Since no real data were presented (list of emissions, ingredients etc), it is difficult to assess the situation other than the fact that a number of Member States are following some parts of the Directive in some areas, but not all. Without a checklist of countries and what they are doing, it is hard to reach any conclusion.

1) Introduction

The report states that there is no information on oral use or roll-your-own tobacco products, as there was no new information. Information on roll-your-own tobacco use is readily available and has been shown to be growing in Germany and other Member States.

Conclusion:

It should have been important to include some comments about labelling, testing and ingredients on oral use or roll-your-own tobacco products.

2) Measurement methods (3.2):

A) The report states that 13 countries have notified approved laboratories. ENSP would have liked to know which countries these are and where the laboratories are and also the date of the publication of the list of approved laboratories.

B) Even knowing that the emission nicotine yields have no relationship to exposure and health impact, the report still concludes that it is not necessary to revise the standards until better methods are available. This is wrong since the standard is misleading and, as the industry will tell you, the industry's ability to meet the standard has been based upon slight modifications to the ventilation without changing the cigarette's ability to deliver nicotine to the smoker. This is referred to as "cigarette elasticity".

C) The report states that the Directive will be adapted once more realistic methods have been developed. This probably means that the Commission will continue to set a performance standard based upon some test method that more adequately reflects a smokers' normal smoking behaviour but that will have no bearing on individual smoking behaviour, exposure and risk. Any smoking standard will only provide information on how a cigarette performs under a specific set of conditions and in no way reflects individual smoking behaviour.

Conclusion:

The ISO method is useless in epidemiological terms, as it has been shown that mortality of smokers does not depend on tar and nicotine 'values'.
The limits of toxic constituents established and controlled by the existing ISO machine-smoking regime are meaningless and deceiving. They will need to be replaced by meaningful limits.
Latest debate focuses on the 'Canadian regimen', which even if it is closer to the smoker it still shares the same basic shortcomings of the old ISO regime in that it does not sufficiently take compensatory smoking into consideration.
If used, the yields derived from this system should not only be used to 'inform' consumers, as they will not profit from this information) but to adjust to the current limits.
At present a new smoking regime, which is adjusted for compensatory smoking, has recently been developed and might be the right alternative for both systems above if 'values' are indeed needed.
As the report states that '*the EC will encourage the scientific and technological development in this area'*, the ENSP strongly supports EC leadership on the matter and encourages the Commission to organise a meeting on the ISO debate to discuss the above considerations.
The report also calls for measured yields to remain on the packs. This decision will lead to some debate and we propose to set it up as an additional point of the agenda for discussion.

3) Labelling Section (3.3):

A) The report would have been very useful if this section had contained a list of each country and their current labels.

B) The data presented in this section seem to indicate that the labels are leading to some behavioural change. It is subtle but, the primary purpose of the labels is to inform and that behavioural change is a secondary effect. We cannot attribute cessation of reduction directly to the labels, but we can attribute knowledge growth to the labels.

4) Ingredients Section (3.4):

A) This is one of the most problematic areas. The report quite rightly states that there is a lack of capacity to analyse the data. We would also add that there is a lack of capacity to collect and store the data in a usable format. Transfer of technology from more advanced regulatory systems becomes a necessity here.

B) There is a need for the EC to harmonise procedures related to the transmission of information, for the sake of coherence and comparability and also to improve definitions.

C) ENSP is wary of industry "help" on this issue.

Conclusion:

There is an obvious necessity to further develop Article 6. The ENSP welcomes the proposal of the Commission to organise an expert consultation concerning this point, but given the amount of work still to be done, an early 2006 consultation will be most pertinent.

5) Common list of ingredients section (3.5):

A) This may be an issue that will cause trouble in the future. While a common list is a good idea, one should be very careful as to its purpose. It is not possible to tell from the report if this will be either a list of ingredients that are found in all products (a good idea) or a list of "approved" products (a bad idea). Any "approved" ingredients puts the regulatory agency at a disadvantage, as the industry can say "it was not my fault", thus adding to the tobacco industry's sustainability in the future.

The only use for a common list is to give the industry a break from full reporting. So, instead of giving all of the details on toxicity, etc, all the industry reports is the name and amount of the chemical used. Besides there is no adequate scientific studies for the approval or prohibition of neither ingredients nor the inter alia effects and their changing physical and chemical properties following pyrolisis.

B) For how the industry will use the common list: In America, for instance, they deal with large list of ingredients that were used in all bands and that were so highly secret that only a few people were allowed to look at the list and were subjected to heavy penalties if they ever disclosed anything. This could end up being the scenario in Europe.

<u>Conclusion:</u>

Tobacco products themselves are dangerous to health. It is the exposure to the entity that determines its harmfulness, not only qualities or quantities of individual components. Tobacco smoke is a carcinogen and a toxic product per se, we are concerned that the Directive is concentrating on the toxicology data.
The product is toxic and, while some additives may add to the overall toxicity, in some countries like Canada, where few, if any, additives are used, the toxicity of the product is high.