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## **The Danish Government's Contribution to the possible Revision of the Tobacco Products Directive 2001/37/EC**

### **General remarks**

The Danish Government welcomes the Commission's efforts to take the regulation of tobacco products into a new decade, taking into account that the current Directive (2001/37/EC) has been in place for almost 10 years.

In general, the Danish Government sees it as important, that the Directive upholds the proper balance between protecting consumers from the negative health aspects of tobacco on the one hand and facilitating the free movement of goods in the Internal Market on the other.

The Danish Government has within recent years increased its efforts with regards to tobacco consumption, balancing the freedom of choice and personal responsibility of the individual and the aim to protect young people and potential new smokers as well as the general public from the harmful effects of smoking,

In 2007, the Danish Government introduced new comprehensive legislation on smoke-free environments and in 2008, put forward legislation to prevent young people from smoking by raising the minimum purchasing age for tobacco products from 16 to 18 years.

Furthermore, a national campaign in 2009/10 using the Australian concept "Every Cigarette is Doing You Damage" has contributed to the significant decrease in the number of every day smokers in Denmark. In 2000, 33 percent of the adult population in Denmark smoked. Today this figure has decreased to 24 percent. The campaign will be repeated in 2011.

In 2011, the Danish Government introduces pictorial warnings on cigarette packages.

At European level, the Danish Government – in the meetings of the Council (Employment, Social Policy, Health and Consumer Affairs) in June and December 2009 – advocated for regulatory measures on tobacco ingredients and excessive flavourings to be taken in the framework of the revision of the Tobacco Products Directive.

The Danish Government is concerned about the appearance of new tobacco products on the European market that seem to have as their main purpose to attract new smokers. Potential new users are often young and may often not

be fully aware of the short term and long term harmful effects of smoking. The revision of the Directive should focus especially on the regulation of products targeting new users and on the use of ingredients in tobacco products in general.

The Danish Government takes note of the fact that, pursuant to Article 13 of the existing Directive (2001/37), Member States may maintain or introduce more stringent rules concerning the manufacture, import, sale and consumption of tobacco products which they deem necessary in order to protect public health as long as the rules comply with the Treaty. Such rules may include measures concerning tobacco ingredients and new products such as cigarettes with excessive flavourings.

However, taking into account the cross border aspects of tobacco products and in order to protect in particular children and young people from the harmful effects of smoking, measures on tobacco ingredients and excessive flavourings should be taken at European level by way of a revision of the Tobacco Products Directive.

Thus, Denmark would welcome the inclusion of inter alia the following elements in the upcoming Commission proposal for a revised Directive:

- A common European list of tobacco ingredients
- A ban on cigarettes with excessive flavourings ie. so-called candy cigarettes.

#### **Specific remarks:**

##### (1) Scope of the Directive

The Danish Government is of the view that the scope of the Tobacco Products Directive should include products containing *tobacco* and products that can be *smoked* and thus attract the same users as tobacco products, such as herbal cigarettes.

Denmark would welcome European regulation of other nicotine products that do not contain tobacco, but considers that these products should not be dealt with within the framework of the Tobacco Products Directive.

As regards electronic nicotine delivery systems ('e-cigarettes') that contain nicotine, these products are regarded by the Danish authorities as pharmaceutical products and regulated as such. At this stage, no marketing authorisation for e-cigarettes that contain nicotine has been granted and thus such products cannot be marketed legally in Denmark.

##### (2) Smokeless tobacco products

The Danish Government does not see a need to change the provisions of the current Directive as regards tobacco products for oral use.

The Danish Government takes note of the Swedish response to the Commission consultation on this matter.

### (3) Consumer information

The Danish Government finds it very important to strengthen consumer information and would suggest a revision of the existing provisions of the Directive in this regard. Denmark would agree that information on packages should focus on general information on health consequences and harmful substances in tobacco products rather than the content of specific substances, such as tar, nicotine and carbon monoxide. In this regard, the Danish Government would not consider the provision of very detailed information on ingredients, for instance in the form of inserts in packages, as an efficient instrument in communicating the health risks of tobacco consumption to consumers.

The Danish Government sees the use of pictorial warnings as an important step forward in the ongoing process of preventing children and young people from taking up smoking and getting more people to quit.

The Danish Government has therefore decided as of February 2011 to introduce pictorial warnings on tobacco products sold in Denmark in accordance with the existing Directive. Pictorial warnings are to be added to tobacco packages by mid 2012 at the latest. Danish Government supports that the use of pictorial warnings becomes mandatory in all Member States.

Given that pictorial warnings would become mandatory for all Member States, the Danish Government sees no need for introducing generic packaging, taking into account the very limited space left on the individual package for branding purposes. In addition, important legal constraints in relation to trademarks and intellectual property rights may need to be taken into account.

### (4) Reporting and registration of ingredients

The Danish Government supports the establishment of a common compulsory reporting format at European level. The tobacco industry should as a result of a revised Directive in the future be obliged to use one harmonised reporting format, ideally combined with the electronic submission of data. This could be based on the voluntary reporting format developed by the Commission in May 2007 on how industry could report to Member States (EMTOC).

The Danish Government encourages the Commission to consider a reporting system, where the tobacco industry would report directly to the Commission in order to enable the further development of European legislation in this field.

It is important to stress however, that Denmark would not consider an improved registration mechanism to be a sufficient measure at this stage. In our view, there is an urgent need to introduce legislation on the use of ingredients in tobacco products at European level, focussing on substances that enhance the addictiveness and attractiveness of tobacco products in general – and cigarettes with excessive flavourings in particular.

The Danish Government furthermore invites the Commission to consider a tobacco manufacturer-financed mechanism to provide for independent research on the toxicity and addictiveness of tobacco ingredients.

### (5) Regulation of ingredients

The Danish Government strongly supports European regulation of ingredients

added in tobacco products and favours the establishment of a common list of tobacco ingredients. The future regulation in this field should allow for the continuous up-dating of such a list in order to improve as far as possible consumer protection as well as to ensure fair conditions for the manufacturers of tobacco products.

The aim of a common European list should be to regulate the use of ingredients in tobacco products and to introduce a European ban on cigarettes with excessive flavourings. The Danish Government encourages the Commission to take the experiences from other EU countries as well as the United States' "Family Smoking Prevention and Tobacco Control Act" of June 22 2009 (H.R. 1256) into consideration on this point. A similar EU initiative would constitute an important supplement to other measures at European and national level aimed at reducing smoking prevalence, especially among young people.

In this context, the Danish Government would invite the Commission to consider how best to achieve these objectives, including the ban of and/or setting of maximum levels for the use of certain ingredients, such as sweeteners and vanilla to be added to tobacco products.

Furthermore, the Danish Government is open to consider regulation of water pipe tobacco, since water pipe tobacco contains excessive flavourings that attract new and often young consumers, who are often unaware of the short and long term harmful effects of tobacco consumption.

#### (6) Access to tobacco products

Due mainly to the lack of cross border aspects the Danish Government is of the opinion that the competence to regulate access to tobacco products, such as measures relating to vending machines and the display of tobacco products at sales venues, should remain at the level of the Member States

In Denmark, the Act on the ban of Tobacco Advertising of 2001 (Act 492/2001) as amended in 2008 (Act 536/2008) introduces a comprehensive ban on tobacco advertising and sets out regulation of the display and visibility of tobacco products at the point of sale.

As for sales of tobacco products via the internet, the Danish Government does not see a need to introduce new regulation, considering that advertising aspects of internet sales are already covered by the Tobacco Advertising Directive (2003/33) whereas decisions to regulate or ban internet sales of tobacco products as such should be taken at the national level.