Tobacco and related products: manufacture, presentation and sale

2012/0366(COD) - 19/12/2012 - Legislative proposal

PURPOSE: to revise Directive 2001/37/EC on tobacco products in order to improve the functioning of the internal market and ensure a high level of health protection.

PROPOSED ACT: Directive of the European Parliament and of the Council.

BACKGROUND: tobacco is the most significant cause of premature death in the EU, **responsible for almost 700 000 deaths every year**. More than ten years have passed since the adoption of the Directive 2001/37/EC on tobacco products. In line with market, scientific and international developments, it has become necessary to **update and complement this Directive**.

The overall objective of the revision is to **improve the functioning of the internal market**. In particular, the proposal aims to:

- **update already harmonised areas,** in order to overcome obstacles encountered by Member States in bringing their national legislation in line with new market, scientific and international developments;
- **address product related measures** not yet covered by the Directive;
- ensure that provisions of the Directive are **not circumvented** by the placing on the market of products not compliant with the Directive;
- ensure a **harmonised implementation of international obligations following from the WHO Framework Convention on Tobacco Control (FCTC)**, which is binding for the EU and all Member States.

With regard to **health protection**, the proposed revision:

- seeks to regulate tobacco products in a way that reflects their specific characteristics (nicotine has addictive properties) and the **negative consequences of their consumption** (mouth, throat and lung cancer, cardiovascular problems including heart attacks, strokes, clogged arteries, increased risk of blindness, impotence, lower fertility, impact on the unborn child etc);
- focuses on initiation of tobacco consumption, **in particular by young people**, taking into account that 70% of the smokers start before the age of 18 and 94% before the age of 25;
- create conditions which allow all citizens across the EU to **take informed decisions** about the products, based on accurate information on the health consequences of consuming tobacco products.

The Commission's proposal for a Regulation of the European Parliament and of the Council on establishing a Health for Growth Programme contains measures which have as their direct objective the protection of public health regarding tobacco products and advertisement required by or contributing to the objectives of EU legislation in this field.

IMPACT ASSESSMENT: the Commission undertook an impact assessment which accompanies the proposal. A high level of health protection has been taken as the basic criteria amongst the different strategic options that were considered during the review of the Directive.

LEGAL BASIS: **Article 114** of the Treaty on the Functioning of the European Union (TFEU).

CONTENT : the revision of Directive 2001/37/CE focuses on the following areas:

1) Ingredients and emissions: the maximum yields of tar, nicotine and carbon monoxide as well as the measurement methods remain the same as in Directive 2001/37/EC.

The proposal:

- keeps in place the **mandatory reporting system** of ingredients and, in addition, provides that a common electronic format for the reporting and manufacturers are required to provide supporting data (e.g. marketing reports);

- provides that placing on the market of new or modified tobacco products must not take place before the submission of **ingredients data**. Reported data, excluding confidential information, must be published;

- prohibits tobacco products with **characterising flavours**, such as fruit flavours or chocolate, and prohibits flavourings in filters, papers or packages;

- forbids **additives** associated with energy and vitality (e.g. caffeine and taurine), or creating the impression that products have health benefits (e.g. vitamins);

- **exempts tobacco products** other than cigarettes, roll-your own tobacco and smokeless tobacco products, i.e. cigars, cigarillos and pipe tobacco from some provisions such as the prohibition of products with characterising flavours. The exemption shall be removed if there is a substantial change of circumstances (in terms of sales volume or prevalence level among young people).

2) Labelling and packaging: the proposal seeks to ensure that the appearance of the package reflects the characteristics of the product inside the package - a product that has negative health consequences, is addictive, and is not for the consumption of children and teenagers. In concrete terms, the proposal:

- provides that that **combined warnings** (picture plus text) of 75% should be displayed on both sides of the packages of tobacco products, presented in rotation;

- replaces tar, nicotine and carbon monoxide (TNCO) levels on the packages with an **information message** referring to harmful substances of tobacco;

- ensures that display **of cessation information** (e.g. quit-lines, websites) is added to the packages;

- states that neither packaging of tobacco products, nor the products themselves, shall include any elements that promote tobacco products or mislead consumers into believing that the product is less harmful than others, refers to flavours or tastes or resembles a food product;

- exempts tobacco products other than cigarettes and roll-your own tobacco from larger health warnings;

- provides that in order to increase the visibility of the health warnings on **smokeless tobacco products**, these will have to be put on both sides of the package according to the proposal, but their size will remain unchanged compared to Directive 2001/37.

3) Traceability and security features: the proposal:

- provides for an **EU tracking and tracing system** at packet level for tobacco products throughout the supply chain (excluding retail). Tobacco products other than cigarettes and roll-your-own-tobacco are granted a transitional period of five years;

- provides that **technical standards** to ensure compatibility between the tracking and tracing systems used as well as for the contracts with third parties shall be adopted by delegated acts. Technical standardisations for security features shall also be adopted through delegated acts.

4) Tobacco for oral use: the ban of placing on the market (including cross-border distance sale) of tobacco for oral use as set out in Directive 2001/37/EC is maintained (except for Sweden which has an exemption in its Accession Treaty).

5) Cross-border distance sales of tobacco products: cross-border distance sales of tobacco products fall outside the scope of Directive 2001/37/EC. The proposal:

- includes a **notification obligation** for retailers of tobacco products intending to engage in cross-border distance sales;

- allows Member States to require the retailer to appoint a **natural person, who ensures compliance with the Directive** of products delivered to customers in the Member States concerned;

- provides a **mandatory age verification mechanism**.

6) Novel tobacco products (do not fall within any of the established product categories): these products will have to respect requirements of the Directive (e.g. in terms of labelling and ingredients) to ensure a level playing field, and the applicable rules will depend on whether the product involves a combustion process or not.

The proposal also provides a notification obligation for novel tobacco products and the Commission will issue a report on market development in these products five years after the transposition deadline of the Directive.

7) Nicotine containing products (NCP): bearing in mind the novelty and the rapid growth of the market in NCP, the proposal removes current legislative divergence between Member States and the differential treatment between Nicotine Replacement Therapies and Nicotine Containing Products. The proposal provides that:

- NCP that either have a nicotine level exceeding 2 mg, a nicotine concentration exceeding 4 mg per ml or whose intended use results in a mean maximum peak plasma concentration exceeding 4 ng per ml may be placed on the market only if they have been authorised as medicinal products on the basis of their quality, safety and efficacy, and with a positive risk/benefit balance;

- NCP with nicotine levels below this threshold can be sold as consumer products provided they feature an adapted health warning.

8) Herbal products for smoking: herbal products for smoking fall outside the scope of Directive 2001/37 /EC and Member States regulate these products in different ways.

The proposal provides for **adapted health warnings** for herbal products for smoking to inform consumers about the adverse health effects of these products. In addition, no promotional or misleading elements are allowed on the packages.

BUDGETARY IMPLICATIONS: the estimated impact on expenditure (operational appropriations, human resources and other administrative expenditure) amounts to EUR 7,888 millions for the period 2014-2018.

DELEGATED ACTS: the proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU).