Tobacco and related products: manufacture, presentation and sale

2012/0366(COD) - 03/04/2014 - Final act

PURPOSE: to improve the functioning of the internal market for tobacco and related products, taking as a base a high level of protection of human health, especially for young people.

LEGISLATIVE ACT: Directive 2014/40/EU of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

CONTENT: this Directive replaces Directive 2001/37/EC and aims to approximate the laws, regulations and administrative provisions of the Member States **concerning the manufacture, presentation and sale of tobacco and related products**, that is, electronic cigarettes and refill containers, and herbal products for smoking.

Maximum emission levels for tar, nicotine, carbon monoxide and other substances: by virtue of the new Directive, the emission levels from cigarettes placed on the market or manufactured in the Member States shall not be greater than: a) 10mg of tar per cigarette; b) 1mg of nicotine per cigarette; c) 10mg of carbon monoxide per cigarette.

The accuracy of the measurements shall be determined in accordance with **ISO standard 8243**.

The measurements shall be verified by **laboratories which are approved** and monitored by the competent authorities of the Member States. Those laboratories shall not be owned or controlled directly or indirectly by the tobacco industry.

Reporting of ingredients and emissions: the Directive shall require manufacturers and importers of tobacco products to declare the ingredients contained in all tobacco products, as well as the tar, nicotine and carbon monoxide emissions of cigarettes. **Additional enhanced** reporting obligations should be provided for in respect of additives contained in cigarettes and roll-your-own tobacco included on a **priority list**. A first list of additives, containing at least 15 additives, shall be adopted no later than two years after the entry into force of the Directive.

Ingredients: the Directive prohibits the placing on the market of tobacco products containing **characterising flavour** (perfume of fruit, spices, aromatic plants, alcohol, sweets, menthol or vanilla). Furthermore, additives such as vitamins, taurine or caffeine, as well as additives having colouring properties for emissions, as well as additives that facilitate inhalation or nicotine uptake, and that have CMR properties in unburnt form.

Additives which are essential for the manufacture of tobacco products, for example, sugar, shall, however, be authorised.

In the case of tobacco products with a characterising flavour, **whose Union-wide sales volumes represent 3% or more in a particular product category**, the provisions of this Directive shall **apply from 20 May 2020**.

The prohibition on tobacco products with a characterising flavour shall not apply to other tobacco products such as **cigars, cigarillos and smokeless tobacco products**. In addition, this Regulation shall not apply to tobacco for oral use (snus).

Labelling and packaging: cigarette packets shall carry **combined health warnings** containing a colour photograph and a text warning covering **65%** of both the external front and back surface of the unit packet and any outside packaging. Health warnings will also cover **50%** of the lateral surfaces of packets (such as 'Smoking kills – quit now' or 'Tobacco smoke contains over 70 substances known to cause cancer.')

Unit packets of cigarettes shall have a **cuboid shape** and shall include **at least 20 cigarettes.** A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30g.

The health warnings should be **irremovably printed, indelible and fully visible** in the official language or languages of the Member State where the product is placed on the market.

Member States may **exempt** tobacco products for smoking other than cigarettes, roll-your-own tobacco and waterpipe tobacco from the obligations to carry the information message and the combined health warnings In that event, they will be required to ensure that a general warning with reference to smoking cessation services and one of the text warnings appears on the products.

Each unit packet of **smokeless tobacco products** shall carry the following health warning: 'This tobacco product damages your health and is addictive.' In addition, each unit packet of **herbal products for smoking** shall carry the following health warning: 'Smoking this product damages your health.'

The labelling of unit packets shall not include **any element or feature** that: i) promotes a tobacco product or encourages its consumption; ii) suggests that a particular tobacco product has other health or lifestyle benefits; iii) resembles a food or a cosmetic product; iv) suggests that a certain tobacco product has improved biodegradability.

Traceability: Member States shall ensure that all unit packets of tobacco products are marked with a **unique identifier**. This identifier shall allow the following to be determined, among others, the date and place of manufacturing, the manufacturing facility, the product description, the intended market of retail sale, and the intended shipment route. All unit packets of tobacco products, which are placed on the market, should carry a **tamper proof security feature**.

Tobacco for oral use and cross-border distance sales: the Directive provides that the Member States prohibit the sale of tobacco for oral use, without prejudice to the Act of Accession of Austria, Finland and Sweden. Member States should, therefore, be allowed to prohibit cross-border distance sales. Member States should cooperate with each other in order to prevent such sales.

Notification: the Directive requires the manufacturers and importers of novel tobacco products to submit a notification to the competent authorities of Member States of any such product they intend to place on the national market concerned.

Electronic cigarettes: electronic cigarettes should be regulated like medicinal products if they permit smoking cessation or as tobacco products. In the second case, their **nicotine concentration should not exceed 20mg/ml**.

Manufacturers and importers of electronic cigarettes and refill containers should be required to submit a **notification** of the relevant products before they are placed on the market.

Electronic cigarettes should be banned for children and carry **health warnings**. They shall be subject to the same restrictions as tobacco products as regards advertising.

The Commission shall submit a **report** on the potential risks to public health associated with the use of refillable electronic cigarettes by 20 May 2016 and whenever appropriate thereafter.

Where the placing on the market of specific electronic cigarettes or refill containers, or a type of electronic cigarette or refill container has been prohibited on duly justified grounds in at least three Member States, **the Commission shall be empowered to extend such a prohibition to all Member States**.

ENTRY INTO FORCE: 9.05.2014.

TRANSPOSITION: no later than 20.05.2016. The measures shall apply from this date.

DELEGATED ACTS: the Commission may adopt delegated acts in order to adapt the Directive to technical, scientific and international developments in tobacco manufacture, consumption and regulation. The power to adopt such acts shall be conferred on the Commission for a period of **five years from 19 May 2014**. The European Parliament or the Council may object to a delegated act within a period of two months from the date of notification (this period can be extended for two months). If the European Parliament or the Council make objections, the delegated act will not enter into force.