

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 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 (Text with EEA relevance)

TITLE I

COMMON PROVISIONS

Article 1

Subject matter

The objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States concerning:

- (a) the ingredients and emissions of tobacco products and related reporting obligations, including the maximum emission levels for tar, nicotine and carbon monoxide for cigarettes;
- (b) certain aspects of the labelling and packaging of tobacco products including the health warnings to appear on unit packets of tobacco products and any outside packaging as well as traceability and security features that are applied to tobacco products to ensure their compliance with this Directive;
- (c) the prohibition on the placing on the market of tobacco for oral use;
- (d) cross-border distance sales of tobacco products;
- (e) the obligation to submit a notification of novel tobacco products;
- (f) the placing on the market and the labelling of certain products, which are related to tobacco products, namely electronic cigarettes and refill containers, and herbal products for smoking;

in order to facilitate the smooth 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, and to meet the obligations of the Union under the WHO Framework Convention for Tobacco Control ('FCTC').

Article 2

Definitions

For the purposes of this Directive, the following definitions shall apply:

- (1) 'tobacco' means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;
- (2) 'pipe tobacco' means tobacco that can be consumed via a combustion process and exclusively intended for use in a pipe;

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- (3) 'roll-your-own tobacco' means tobacco which can be used for making cigarettes by consumers or retail outlets;
- (4) 'tobacco products' means products that can be consumed and consist, even partly, of tobacco, whether genetically modified or not;
- (5) 'smokeless tobacco product' means a tobacco product not involving a combustion process, including chewing tobacco, nasal tobacco and tobacco for oral use;
- (6) 'chewing tobacco' means a smokeless tobacco product exclusively intended for the purpose of chewing;
- (7) 'nasal tobacco' means a smokeless tobacco product that can be consumed via the nose;
- (8) 'tobacco for oral use' means all tobacco products for oral use, except those intended to be inhaled or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of those forms, particularly those presented in sachet portions or porous sachets;
- (9) 'tobacco products for smoking' means tobacco products other than a smokeless tobacco product;
- (10) 'cigarette' means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 3(1) of Council Directive 2011/64/EU⁽¹⁾;
- (11) 'cigar' means a roll of tobacco that can be consumed via a combustion process and is further defined in Article 4(1) of Directive 2011/64/EU;
- (12) 'cigarillo' means a small type of cigar and is further defined in Article 8(1) of Council Directive 2007/74/EC⁽²⁾;
- (13) 'waterpipe tobacco' means a tobacco product that can be consumed via a waterpipe. For the purpose of this Directive, waterpipe tobacco is deemed to be a tobacco product for smoking. If a product can be used both via waterpipes and as roll-your-own tobacco, it shall be deemed to be roll-your-own tobacco;
- (14) 'novel tobacco product' means a tobacco product which:
 - (a) does not fall into any of the following categories: cigarettes, roll-your-own tobacco, pipe tobacco, waterpipe tobacco, cigars, cigarillos, chewing tobacco, nasal tobacco or tobacco for oral use; and
 - (b) is placed on the market after 19 May 2014;
- (15) 'herbal product for smoking' means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process;
- (16) 'electronic cigarette' means a product that can be used for consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank. Electronic cigarettes can be disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges;
- (17) 'refill container' means a receptacle that contains a nicotine-containing liquid, which can be used to refill an electronic cigarette;

- (18) 'ingredient' means tobacco, an additive, as well as any substance or element present in a finished tobacco product or related products, including paper, filter, ink, capsules and adhesives;
- (19) 'nicotine' means nicotinic alkaloids;
- (20) 'tar' means the raw anhydrous nicotine-free condensate of smoke;
- (21) 'emissions' means substances that are released when a tobacco or related product is consumed as intended, such as substances found in smoke, or substances released during the process of using smokeless tobacco products;
- (22) 'maximum level' or 'maximum emission level' means the maximum content or emission, including zero, of a substance in a tobacco product measured in milligrams;
- (23) 'additive' means a substance, other than tobacco, that is added to a tobacco product, a unit packet or to any outside packaging;
- (24) 'flavouring' means an additive that imparts smell and/or taste;
- (25) 'characterising flavour' means a clearly noticeable smell or taste other than one of tobacco, resulting from an additive or a combination of additives, including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla, which is noticeable before or during the consumption of the tobacco product;
- (26) 'addictiveness' means the pharmacological potential of a substance to cause addiction, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both;
- (27) 'toxicity' means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure;
- (28) 'substantial change of circumstances' means an increase of the sales volumes by product category by at least 10 % in at least five Member States based on sales data transmitted in accordance with Article 5(6) or an increase of the level of prevalence of use in the under 25 years of age consumer group by at least five percentage points in at least five Member States for the respective product category based on the Special Eurobarometer 385 report of May 2012 or equivalent prevalence studies; in any case, a substantial change of circumstances is deemed not to have occurred if the sales volume of the product category at retail level does not exceed 2,5 % of total sales of tobacco products at Union level;
- (29) 'outside packaging' means any packaging in which tobacco or related products are placed on the market and which includes a unit packet or an aggregation of unit packets; transparent wrappers are not regarded as outside packaging;
- (30) 'unit packet' means the smallest individual packaging of a tobacco or related product that is placed on the market;
- (31) 'pouch' means a unit packet of roll-your own tobacco, either in the form of a rectangular pocket with a flap that covers the opening or in the form of a standing pouch;
- (32) 'health warning' means a warning concerning the adverse effects on human health of a product or other undesired consequences of its consumption, including text warnings,

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- combined health warnings, general warnings and information messages, as provided for in this Directive;
- (33) ‘combined health warning’ means a health warning consisting of a combination of a text warning and a corresponding photograph or illustration, as provided for in this Directive;
- (34) ‘cross-border distance sales’ means distance sales to consumers where, at the time the consumer orders the product from a retail outlet, the consumer is located in a Member State other than the Member State or the third country where that retail outlet is established; a retail outlet is deemed to be established in a Member State:
- (a) in the case of a natural person: if he or she has his or her place of business in that Member State;
 - (b) in other cases: if the retail outlet has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that Member State;
- (35) ‘consumer’ means a natural person who is acting for purposes which are outside his or her trade, business, craft or profession;
- (36) ‘age verification system’ means a computing system that unambiguously confirms the consumer's age electronically in accordance with national requirements;
- (37) ‘manufacturer’ means any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under their name or trademark;
- (38) ‘import of tobacco or related products’ means the entry into the territory of the Union of such products unless the products are placed under a customs suspensive procedure or arrangement upon their entry into the Union, as well as their release from a customs suspensive procedure or arrangement;
- (39) ‘importer of tobacco or related products’ means the owner of, or a person having the right of disposal over, tobacco or related products that have been brought into the territory of the Union;
- (40) ‘placing on the market’ means to make products, irrespective of their place of manufacture, available to consumers located in the Union, with or without payment, including by means of distance sale; in the case of cross-border distance sales the product is deemed to be placed on the market in the Member State where the consumer is located;
- (41) ‘retail outlet’ means any outlet where tobacco products are placed on the market including by a natural person.

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- (1) Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco ([OJ L 176, 5.7.2011, p. 24](#)).
- (2) Council Directive 2007/74/EC of 20 December 2007 on the exemption from value added tax and excise duty of goods imported by persons travelling from third countries ([OJ L 346, 29.12.2007, p. 6](#)).