

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 II

TOBACCO PRODUCTS

CHAPTER I

Ingredients and emissions

Article 5

Reporting of ingredients and emissions

1 Member States shall require manufacturers and importers of tobacco products to submit to their competent authorities the following information by brand name and type:

- a a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products, in descending order of the weight of each ingredient included in the tobacco products;
- b the emission levels referred to in Article 3(1) and (4);
- c where available, information on other emissions and their levels.

For products already placed on the market that information shall be provided by 20 November 2016.

Manufacturers or importers shall also inform the competent authorities of the Member States concerned, if the composition of a product is modified in a way that affects the information provided under this Article.

For a new or modified tobacco product the information required under this Article shall be submitted prior to the placing on the market of those products.

2 The list of ingredients referred to in point (a) of paragraph 1 shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in the tobacco products concerned. That list shall also indicate the status of the ingredients, including whether they have been registered under Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁽¹⁾ as well as their classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁽²⁾.

3 The list referred to in point (a) of paragraph 1 shall also be accompanied by the relevant toxicological data regarding the ingredients in burnt or unburnt form, as appropriate, referring in particular to their effects on the health of consumers and taking into account, inter alia, any addictive effects.

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Furthermore, for cigarettes and roll-your-own tobacco, a technical document setting out a general description of the additives used and their properties, shall be submitted by the manufacturer or importer.

Other than for tar, nicotine and carbon monoxide and for emissions referred to in Article 4(4), manufacturers and importers shall indicate the methods of measurement of emissions used. Member States may also require manufacturers or importers to carry out studies as may be prescribed by the competent authorities in order to assess the effects of ingredients on health, taking into account, inter alia, their addictiveness and toxicity.

4 Member States shall ensure that the information submitted in accordance with paragraph 1 of this Article and of Article 6 is made publicly available on a website. The Member States shall take the need to protect trade secrets duly into account when making that information publicly available. Member States shall require manufacturers and importers to specify, when submitting the information pursuant to paragraph 1 of this Article and Article 6, the information which they consider to constitute trade secrets.

5 The Commission shall, by means of implementing acts, lay down and, if necessary, update the format for the submission and the making available of information referred to in paragraphs 1 and 6 of this Article and Article 6. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2).

6 Member States shall require manufacturers and importers to submit internal and external studies available to them on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys they carry out when launching new products. Member States shall also require manufacturers and importers to report their sales volumes per brand and type, reported in sticks or kilograms, and per Member State on a yearly basis starting from 1 January 2015. Member States shall provide any other sales volume data that is available to them.

7 All data and information to be provided to and by Member States under this Article and under Article 6 shall be provided in electronic form. Member States shall store the information electronically and shall ensure that the Commission and other Member States have access to that information for the purposes of applying this Directive. Member States and the Commission shall ensure that trade secrets and other confidential information are treated in a confidential manner.

8 Member States may charge manufacturers and importers of tobacco products proportionate fees for receiving, storing, handling, analysing and publishing the information submitted to them pursuant to this Article.

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- (1) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([OJ L 396, 30.12.2006, p. 1](#)).
- (2) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ([OJ L 353, 31.12.2008, p. 1](#)).