
STATUTORY INSTRUMENTS

2016 No. 507

The Tobacco and Related Products Regulations 2016

PART 4

Reporting about tobacco products

Specified information about tobacco products

18.—(1) A producer of a tobacco product must submit the following information relating to the product to the Secretary of State—

- (a) the ingredients information specified in regulation 19; and
- (b) the emissions information specified in regulation 20.

(2) The information required by paragraph (1) must be submitted—

- (a) on or before 19th November 2016, in the case of a tobacco product which a producer first supplied before 20th May 2016 and continues to supply on or after that date; or
- (b) where paragraph (a) does not apply, at least one day before the day the producer first supplies a tobacco product.

(3) Where the composition of a tobacco product is modified in a way that would affect the information required by paragraph (1) (“a modified product”), a producer must comply with that paragraph in respect of the modified product at least one day before the producer first supplies the modified product.

(4) A producer of a tobacco product must also—

- (a) carry out such further studies as the Secretary of State may reasonably require in order to assess the effects of ingredients on health, and such studies must take into account, among other things, the addictiveness and toxicity of the ingredients; and
- (b) report the results of such studies to the Secretary of State by the date reasonably required by the Secretary of State.

(5) A producer of a tobacco product must notify the Secretary of State before, or as soon as reasonably practicable after, the producer withdraws a product from the market.

(6) A producer is not required by paragraph (1) to re-submit information which the producer has submitted under regulation 22 or 24 (notification of novel tobacco products).

Ingredients information

19. The ingredients information relating to a tobacco product means the following information, by brand and variant name—

- (a) a list of all ingredients in the product, and the quantity of each ingredient, set out in descending order by weight;
- (b) a statement setting out the reasons for the inclusion of each ingredient in the product;

- (c) a statement setting out the status of each ingredient including whether or not it has been registered under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals⁽¹⁾;
- (d) each ingredient's classification under Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures⁽²⁾;
- (e) any available toxicological data regarding each ingredient in burnt or unburnt form as appropriate, referring in particular to the effect of the ingredient on the health of consumers and taking into account, among other things, any addictive effects; and
- (f) in the case of cigarettes and hand rolling tobacco and where the ingredient is an additive, a general description of the additive and its properties.

Emissions information

20.—(1) In the case of cigarettes, the emissions information means—

- (a) the tar, nicotine and carbon monoxide emission levels (“TNCO emissions”) by brand and variant name, measured in compliance with regulation 14(1) and (2); and
- (b) where available to a producer, information on other emissions and their levels (“non-TNCO emissions”), by brand and variant name.

(2) In the case of a tobacco product other than cigarettes, the emissions information means information about the product's TNCO and non-TNCO emissions by brand and variant name, so far as the information is available to the producer.

(3) The emissions information must set out a description of the methods of measurement used for measuring emissions for the purposes of paragraphs (1)(b) and (2).

Sales data and market research information

21.—(1) A producer of a tobacco product must submit the following information to the Secretary of State—

- (a) that producer's sales volumes in the United Kingdom by brand and variant name, reported in sticks or kilograms (“sales volume data”);
- (b) any studies available to the producer, whether published or not, on market research and preferences of consumer groups (including in particular young people and current smokers), relating to ingredients and emissions in tobacco products (“market research data”); and
- (c) executive summaries of any market surveys the producer carries out when launching a new product.

(2) The information listed in paragraph (1)(a) to (c) must be submitted annually on or before 20th May each year and must relate to sales conducted, market research data that became available, and surveys carried out, during the preceding calendar year.

(3) The first submission under paragraph (2) must be made on or before 20th May 2018 in respect of the calendar year 2017.

(4) Sales volume data relating to sales conducted during the period beginning with 20th May 2016 and ending with 31st December 2016, and any market research data and market surveys relating to the same period must be submitted on or before 20th May 2017.

(1) OJ L 396, 30.12.2006, p.1.

(2) OJ L 353, 31.12.2008, p.1.

- (5) So far as the information is available to a producer of a tobacco product—
 - (a) sales volume data relating to sales conducted during the calendar year 2015, and any market research data and market surveys relating to the same period, must be submitted on or before 19th November 2016; and
 - (b) sales volume data relating to sales conducted during the period beginning with 1st January 2016 and ending with 19th May 2016, and any market research data and market surveys relating to the same period, must be submitted on or before 20th May 2017.
- (6) A producer is not required by this regulation to re-submit information which the producer has submitted under regulation 22 or 24 (notification of novel tobacco products).

Notification of novel tobacco products

22.—(1) A producer who supplies or intends to supply a novel tobacco product must notify the Secretary of State in accordance with this regulation.

- (2) The notification must be accompanied by the following information regarding the product—
 - (a) a detailed description of the product;
 - (b) instructions for the use of the product;
 - (c) the ingredients information specified in regulation 19;
 - (d) the emissions information specified in regulation 20;
 - (e) available studies on the toxicity, addictiveness and attractiveness of the product, in particular as regards its ingredients and emissions;
 - (f) any available studies, executive summaries or market research on the preferences of consumer groups, including young people and current smokers, in respect of the product;
 - (g) any other available information relating to the product, including—
 - (i) the risks and benefits of the product,
 - (ii) the expected effects of the product on the cessation of tobacco consumption,
 - (iii) the expected effects of the product on the initiation of tobacco consumption,
 - (iv) the predicted perception of the product by consumers and potential consumers.
- (3) The detailed description required by paragraph (2)(a) must include, but is not limited to, a description of—
 - (a) the components of the product;
 - (b) the mechanism by which any emission or vapour is generated; and
 - (c) the means by which nicotine is absorbed by the consumer.

Deadline for notification of novel tobacco products

23.—(1) Notification under regulation 22(1) must be given at least six months before the date on which a producer intends to first supply the product concerned, unless paragraph (2) or (3) applies.

(2) This paragraph applies where a producer first supplied a novel tobacco product before 20th May 2016 and continues to supply it on or after that date.

(3) This paragraph applies where a producer intends to first supply a novel tobacco product during the period beginning with 20th May 2016 and ending with 19th November 2016.

(4) Where paragraph (2) or (3) applies, notification under regulation 22(1) must be given on 20th May 2016.

Further information about novel tobacco products

24. A producer of a novel tobacco product must—

- (a) carry out such additional studies or tests as the Secretary of State may reasonably require;
- (b) report the results of such studies or tests to the Secretary of State by the deadline reasonably required by the Secretary of State; and
- (c) submit to the Secretary of State any new or updated information on the matters referred to in regulation 22(2)(e) to (g), which becomes available to the producer after the producer has notified a novel product, and must make such a submission on or before the 20th May that follows such new or updated information becoming available.

Submission of information

25.—(1) This regulation applies to a person who submits information to the Secretary of State in accordance with any provision of this Part.

(2) Information must be submitted—

- (a) in electronic form;
- (b) by means of the entry gate for data submission referred to in Article 2.2 of Commission Implementing Decision (EU) 2015/2186 of 25th November 2015 establishing a format for the submission and making available of information on tobacco products⁽³⁾;
- (c) in accordance with the administrative requirements set out in that Decision; and
- (d) in the format specified in the Annex to that Decision.

(3) For the purposes of paragraph (2)(b), any reference in Commission Implementing Decision (EU) 2015/2186 to a “subtype” in relation to a particular product, is to be construed as a reference to a variant name of that product.

(4) A person submitting information under regulation 18 (specified information) must specify any information which that person considers to constitute a trade secret.

Use of information

26. The Secretary of State must—

- (a) store electronically the information which is submitted in accordance with any provision of this Part;
- (b) provide the European Commission and the competent authorities of other member States with access to information submitted in accordance with regulations 18 (specified information) and 21 (sales data etc.), ensuring that trade secrets and other confidential information are treated in a confidential manner; and
- (c) ensure that information submitted in accordance with regulation 18 is made publicly available on a website, taking the need to protect trade secrets duly into account.

No supply of tobacco product where reporting obligation not complied with

27. A producer who fails to submit information in accordance with any provision of this Part in respect of any tobacco product, must not supply the tobacco product concerned until the producer submits the required information in accordance with regulation 25.

(3) OJ L 312, 27.11.2015, p.5.