
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.

[^{F1}(2A) If a fee which is payable under regulation 3 of the Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017 in respect of a submission under paragraph (1) of this regulation is not paid by the date specified in the invoice for that fee, for the purposes of regulation 48(b) (offences), the submission is to be regarded as not having been made in accordance with paragraph (2)(b) until the fee has been paid.]

(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).

<p>F1 Reg. 18(2A) inserted (6.4.2017) by The Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017 (S.I. 2017/409), regs. 1(1), 8(2)</p>
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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 [^{F2}or, in relation to an NI tobacco product, that Regulation as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement];
- (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 [^{F3}or, in relation to an NI tobacco product, that Regulation as it has effect by virtue of the Protocol on Ireland/Northern Ireland in the EU withdrawal agreement];
- (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.

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| F2 | Words in reg. 19(c) inserted (31.12.2020) by S.I. 2019/41, reg. 6(15A)(a) (as inserted by The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1316) , regs. 1(3), 3(18) (with reg. 5)) |
| F3 | Words in reg. 19(d) inserted (31.12.2020) by S.I. 2019/41, reg. 6(15A)(b) (as inserted by The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1316) , regs. 1(3), 3(18) (with reg. 5)) |

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).

[^{F4}Priority list of additives - enhanced reporting

20A.—(1) A producer of cigarettes or hand rolling tobacco which contain an additive listed in Schedule 2 must—

- (a) carry out the study specified in regulation 20B in respect of that additive; and

- (b) on or before the relevant deadline, submit a report on the results of the study to the Secretary of State [^{F5}and, where the product is an NI tobacco product, to] the European Commission.
- (2) The report must include—
 - (a) an executive summary;
 - (b) a comprehensive overview—
 - (i) compiling the available scientific literature on the additive concerned; and
 - (ii) summarising the data, whether published or not, which is available to the producer on the effects of that additive; and
 - (c) such supplementary information regarding the additive as the [^{F6}appropriate authority may request].
- (3) The relevant deadline is—
 - (a) 1st July 2018 where paragraph (1) applies to a producer on 1st January 2017; or
 - (b) in any other case, 18 months after the day paragraph (1) first applies to a producer in respect of a particular additive.
- (4) A producer must cooperate with a requirement of the [^{F7}appropriate authority] for the report submitted under paragraph (1)(b) to be peer reviewed by an independent scientific body.
- (5) This regulation does not apply to a person who produces cigarettes or hand rolling tobacco containing an additive listed in Schedule 2 where—
 - (a) the person is a small or medium sized enterprise as defined in the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises [^{F8}but, for the purposes of this regulation as it applies in Great Britain, with the modifications in paragraph (7)]; and
 - (b) the additive concerned is the subject of a report which has been submitted to the [^{F9}appropriate authority] by another producer.
- [^{F10}(6) Regulations may amend the list of additives in Schedule 2 as it applies in Great Britain, which list must contain additives—
 - (a) for which initial indications, research, or regulation in jurisdictions outside Great Britain exist suggesting that they have one of the properties set out in regulation 20B(1)(a) to (d); and
 - (b) which are amongst the most commonly used additives by weight or number according to the reporting of ingredients pursuant to regulation 18.
- (7) For the purposes of this regulation as it applies in Great Britain, the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises is to be read as if—
 - (a) in Article 2—
 - (i) in paragraph 1, for “EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million” there were substituted “£44,000,000, and/or an annual balance sheet not exceeding £38,000,000”;
 - (ii) in paragraph 2, for “EUR 10 million” there were substituted “£8,800,000”;
 - (iii) in paragraph 3, for “EUR 2 million” there were substituted “£1,750,000”;
 - (b) in Article 3—
 - (i) in paragraph (2)(a), for “EUR 1 250 000” there were substituted “£1,100,000”;

- (ii) in paragraph (2)(d), for “EUR 10 million” there were substituted “£8,800,000”;
 - (iii) in paragraph 5, for “by national or Community rules” there were substituted “under the law of Great Britain (or any part of it)”;
 - (c) in Article 5, in paragraph (b), for “national law” there were substituted “the law of Great Britain (or any part of it)”.
- (8) In this regulation “appropriate authority”—
- (a) where the product is a GB tobacco product, means the Secretary of State;
 - (b) where the product is an NI tobacco product, means—
 - (i) the Secretary of State, or
 - (ii) the European Commission.]]

- F4** Regs. 20A, 20B inserted (1.1.2017) by [The Tobacco and Related Products \(Amendment\) Regulations 2016 \(S.I. 2016/1127\)](#), reg. 2(2)(3)
- F5** Words in [reg. 20A\(1\)\(b\)](#) substituted (31.12.2020) by S.I. 2019/41, reg. 6(16)(a) (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(19)** (with reg. 5))
- F6** Words in [reg. 20A\(2\)\(c\)](#) substituted (31.12.2020) by S.I. 2019/41, reg. 6(16)(b) (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(19)** (with reg. 5))
- F7** Words in [reg. 20A\(4\)](#) substituted (31.12.2020) by S.I. 2019/41, reg. 6(16)(c) (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(19)** (with reg. 5))
- F8** Words in [reg. 20A\(5\)\(a\)](#) inserted (31.12.2020) by S.I. 2019/41, reg. 6(16)(d)(i) (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(19)** (with reg. 5))
- F9** Words in [reg. 20A\(5\)\(b\)](#) substituted (31.12.2020) by S.I. 2019/41, reg. 6(16)(d)(ii) (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(19)** (with reg. 5))
- F10** Reg. 20A(6)-(8) inserted (31.12.2020) by S.I. 2019/41, **reg. 6(16)(e)** (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(19)** (with reg. 5))

[^{F4}Research study into additives

20B.—(1) The study referred to in regulation 20A(1)(a) must be a comprehensive study which examines whether an additive—

- (a) contributes to the toxicity or addictiveness of the product concerned, and whether this has the effect of increasing the toxicity or addictiveness of the product to a significant or measurable degree;
 - (b) results in a characterising flavour;
 - (c) facilitates inhalation or nicotine uptake;
 - (d) leads to the formation of substances that have CMR properties, and if so—
 - (i) in what quantities; and
 - (ii) whether this has the effect of increasing the CMR properties of the product concerned to a significant or measurable degree.
- (2) The study must also—
- (a) take into account the intended use of the product concerned;

- (b) examine in particular the emissions resulting from the combustion process involving the additive concerned; and
 - (c) examine the interaction of that additive with other ingredients contained in the product concerned.
- (3) Two or more producers who use the same additive in their products, in a comparable product composition, may carry out a joint study.]

F4 Regs. 20A, 20B inserted (1.1.2017) by [The Tobacco and Related Products \(Amendment\) Regulations 2016 \(S.I. 2016/1127\)](#), reg. 2(2)(3)

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 [^{F11}the relevant part of 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.
- (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).
- [^{F12}(7) In this regulation “the relevant part of the United Kingdom”—
- (a) in relation to a tobacco product which is a GB tobacco product, means Great Britain;
 - (b) in relation to a tobacco product which is an NI tobacco product, means Northern Ireland.]

F11 Words in [reg. 21\(1\)\(a\)](#) substituted (31.12.2020) by S.I. 2019/41, reg. 6(16A)(a) (as inserted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(20)** (with [reg. 5](#)))

F12 Reg. 21(7) inserted by S.I. 2019/41, **reg. 6(16A)(b)** (as inserted by The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1316), regs. 1(3), **3(20)** (with reg. 5))

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.

[^{F13}(5) If a fee which is payable under regulation 3 of the Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017 in respect of a notification under regulation 22 of these Regulations is not paid by the date specified in the invoice for that fee, for the purposes of regulation 48(b) (offences), the notification is to be regarded as not having been given in accordance with paragraph (1) until the fee has been paid.]

F13 Reg. 23(5) inserted (6.4.2017) by [The Tobacco Products and Herbal Products for Smoking \(Fees\) Regulations 2017 \(S.I. 2017/409\)](#), regs. 1(1), **8(3)**

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.

[^{F14}(1A) Information which relates to a GB tobacco product must be submitted—

- (a) in electronic form, and
- (b) having regard to such technical requirements and procedures as may be specified in guidance issued by the Secretary of State.]

(2) Information [^{F15}which relates to an NI tobacco product] 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 ^{M1};
- (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) [^{F16} or 20A (priority list of additives)] must specify any information which that person considers to constitute a trade secret.

F14 Reg. 25(1A) inserted (31.12.2020) by [S.I. 2019/41](#), **reg. 6(17)(a)** (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(21)** (with [reg. 5](#)))

F15 Words in [reg. 25\(2\)](#) inserted (31.12.2020) by [S.I. 2019/41](#), [reg. 6\(17\)\(b\)](#) (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(21)** (with [reg. 5](#)))

F16 Words in [reg. 25\(4\)](#) inserted (1.1.2017) by [The Tobacco and Related Products \(Amendment\) Regulations 2016 \(S.I. 2016/1127\)](#), [reg. 2\(2\)\(4\)](#)

Marginal Citations

M1 OJ L 312, 27.11.2015, p.5.

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) [^{F17}provide the European Commission and the competent authorities of the member States with access to information submitted about any NI tobacco product in accordance with regulation 18, 20A or 21, 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 [^{F18} and 20A] is made publicly available on a website, taking the need to protect trade secrets duly into account.

F17 Reg. 26(b) substituted (31.12.2020) by S.I. 2019/41, reg. 6(18) (as substituted by [The Tobacco Products and Nicotine Inhaling Products \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1316\)](#), regs. 1(3), **3(22)** (with reg. 5))

F18 Words in reg. 26(c) inserted (1.1.2017) by [The Tobacco and Related Products \(Amendment\) Regulations 2016 \(S.I. 2016/1127\)](#), reg. 2(2)(6)

[^{F19}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—

- (a) the producer has submitted the required information in accordance with regulation 25; and
- (b) any fee payable in respect of the submission of that information under regulation 3 of the Tobacco Products and Herbal Products for Smoking (Fees) Regulations 2017 has been paid.]

F19 Reg. 27 substituted (6.4.2017) by [The Tobacco Products and Herbal Products for Smoking \(Fees\) Regulations 2017 \(S.I. 2017/409\)](#), regs. 1(1), **8(4)**

Changes to legislation:

There are currently no known outstanding effects for the The Tobacco and Related Products Regulations 2016, PART 4.