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STATUTORY INSTRUMENTS

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**2016 No. 507**

**The Tobacco and Related Products Regulations 2016**

**PART 6**

**Electronic cigarettes**

**Notification about electronic cigarettes and refill containers**

**31.**—(1) A producer who supplies or intends to supply electronic cigarettes or refill containers must notify the Secretary of State in accordance with this regulation.

(2) Where an electronic cigarette or refill container is substantially modified (“a modified product”) a producer must comply with paragraph (1) in respect of the modified product.

(3) A notification under paragraph (1) must contain the following information (so far as relevant to the product concerned)—

- (a) the name and contact details of the person who manufactures the product, the importer (if applicable) and, if neither is based in a member State, a responsible person within a member State;
- (b) a list of all ingredients contained in, and emissions resulting from the use of, the product by brand and variant name, including quantities;
- (c) toxicological data regarding the product’s ingredients (including in heated form) and emissions, referring in particular to their effects on the health of consumers when inhaled and taking into account, amongst other things, any addictive effect;
- (d) information on the nicotine dose and uptake when consumed under normal or reasonably foreseeable conditions;
- (e) a description of the components of the product including, where applicable, the opening and refill mechanism of the electronic cigarette or refill container;
- (f) a description of the production process and a declaration that the production process ensures conformity with the requirements of this Part; and
- (g) a declaration that the producer bears full responsibility for the quality and safety of the product when supplied and used under normal or reasonably foreseeable conditions.

(4) Paragraph (1) does not apply to an importer in respect of a product if—

- (a) another producer has notified the Secretary of State in respect of that product; and
- (b) the information submitted by that producer has been published in accordance with regulation 34(a).

(5) Paragraph (1) does not apply to a producer in respect of a product if the producer intends to withdraw the product from the market by 20th November 2016.

(6) Notification under paragraph (1) must be submitted in respect of a product—

- (a) at least one day before the day the producer first supplies the product, where—

- (i) a producer intends to first supply a product which is not a modified product during the period beginning with 20th May 2016 and ending with 19th November 2016 (“a new transitional product”), or
- (ii) a producer intends to first supply a modified new transitional product during the period beginning with 20th May 2016 and ending with 19th November 2016;
- (b) on or before 19th November 2016, where—
  - (i) a producer first supplied a product before 20th May 2016 (“an existing product”) and intends to continue to supply that product on or after 20th November 2016, or
  - (ii) a producer intends to first supply a modified existing product during the period beginning with 20th May 2016 and ending with 19th May 2017; or
- (c) in any other case, at least six months before the date on which the producer intends to first supply a product or a modified product.

(7) Unless the Secretary of State directs otherwise, notification is not regarded as submitted for the purposes of paragraph (6) until any fee which may be payable in connection with the notification has been paid.

(8) A producer must notify the Secretary of State before, or as soon as reasonably practicable after, the producer withdraws a product that has been notified under paragraph (1) from the market.

(9) Paragraph (8) does not apply to an importer in respect of a product if another producer has notified the Secretary of State that the product has been withdrawn from the market.

(10) Where the Secretary of State considers that the information submitted under this regulation is incomplete, the Secretary of State may request the producer concerned to provide the complete information.

(11) A producer must comply with a request under paragraph (10) by the date reasonably required by the Secretary of State.

### **Annual reporting requirement**

**32.—**(1) A producer of electronic cigarettes or refill containers must submit the following information to the Secretary of State—

- (a) comprehensive data on the producer’s sales volumes in the United Kingdom, by brand and variant name;
- (b) any information available to the producer, whether published or not, on the preferences of consumer groups in the United Kingdom, including young people, non-smokers and the main types of current users;
- (c) the mode of sale of the producer’s products in the United Kingdom; and
- (d) executive summaries of any market surveys carried out by the producer in respect of paragraphs (a) to (c).

(2) The information listed in paragraph (1)(a) to (d) must be submitted annually on or before 20th May each year, and must relate to the preceding calendar year.

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

(4) The information listed in paragraph (1)(a) to (d) relating to the period beginning with 20th May 2016 and ending with 31st December 2016 must be submitted on or before 20th May 2017.

(5) The Secretary of State must monitor the market developments concerning electronic cigarettes and refill containers, including any evidence that their use is a gateway to nicotine addiction and ultimately traditional tobacco consumption amongst young people and non-smokers.

### **Submission of information**

**33.**—(1) This regulation applies to a person who notifies the Secretary of State under regulation 31 or submits any information under regulation 32.

(2) Information must be submitted to the Secretary of State—

- (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) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers<sup>(1)</sup>;
- (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) A person submitting information under regulation 31 must specify any information which that person considers to constitute a trade secret.

### **Secretary of State duty to publish notifications etc.**

**34.** The Secretary of State must—

- (a) ensure that information submitted under regulation 31 is made publicly available on a website, taking the need to protect trade secrets duly into account;
- (b) provide the European Commission and the competent authorities of other member States with access to information submitted in accordance with any provision of this Part on request, ensuring that trade secrets are treated in a confidential manner.

### **No supply of product where notification not complied with**

**35.** A producer who is required to submit a notification under regulation 31(1) in respect of any electronic cigarettes or refill containers but fails to do so in accordance with that regulation and regulation 33 may not supply those electronic cigarettes or refill containers until—

- (a) the producer has submitted the information listed in regulation 31(3) in respect of that product to the Secretary of State in accordance with regulation 33;
- (b) the producer has paid any fee payable in connection with notification; and
- (c) the information submitted by that producer has been published in accordance with regulation 34(a).

### **Product requirements**

**36.**—(1) No person may produce or supply an electronic cigarette or refill container unless it complies with paragraphs (2) to (8), so far as relevant to the product concerned.

(2) Nicotine-containing liquid which is presented for retail sale must be in—

- (a) a dedicated refill container in a volume not exceeding 10 millilitres; or
- (b) a disposable electronic cigarette, a single use cartridge, or a tank, in a volume not exceeding 2 millilitres.

(3) The capacity of the tank of a refillable electronic cigarette must not exceed 2 millilitres.

(4) Nicotine-containing liquid which is presented for retail sale in an electronic cigarette or refill container must not contain nicotine in excess of 20 milligrams per millilitre.

(5) Nicotine-containing liquid in an electronic cigarette or refill container—

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(1) OJ L 309, 26.11.2015, p 15.

- (a) must not contain any additive referred to in regulation 16 (no vitamins, colourings or prohibited additives in tobacco products);
  - (b) must be manufactured using only ingredients of high purity;
  - (c) must not contain substances other than the ingredients notified under regulation 31, unless present in trace levels, where such trace levels are technically unavoidable during manufacture; and
  - (d) must not include ingredients (except for nicotine) which pose a risk to human health in heated or unheated form.
- (6) An electronic cigarette must be able to deliver a dose of nicotine at consistent levels under normal conditions of use.
- (7) An electronic cigarette or refill container must be—
- (a) child-resistant and tamper-evident; and
  - (b) protected against breakage and leakage.
- (8) An electronic cigarette or refill container must have a mechanism for ensuring re-filling without leakage (unless it is a disposable electronic cigarette).
- (9) For the purposes of paragraph (7), a product is tamper-evident if it has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that the product (or its packaging) has been opened.
- (10) For the purposes of paragraph (8), a product has a mechanism for ensuring re-filling without leakage if the mechanism—
- (a) entails—
    - (i) the use of a refill container possessing a securely attached nozzle at least 9 millimetres long which is narrower than, and slots comfortably into, the opening of the tank of the electronic cigarette, and
    - (ii) in the case of refill containers, a flow control mechanism that emits no more than 20 drops of refill liquid per minute when placed vertically and subjected only to atmospheric pressure at a temperature between 15 and 25 degrees Celsius; or
  - (b) operates by means of a docking system which only releases refill liquids into the tank of an electronic cigarette when the electronic cigarette and refill container are connected.

### **Product information and labelling requirements**

**37.**—(1) No person may produce or supply an electronic cigarette or refill container unless it complies with paragraphs (2) to (6).

(2) Each unit packet of the electronic cigarette or refill container must include a leaflet with information on—

- (a) instructions for use and storage of the product, including a reference that the product is not recommended for use by young people and non-smokers;
- (b) contra-indications;
- (c) warnings for specific risk groups;
- (d) possible adverse effects;
- (e) addictiveness and toxicity;
- (f) contact details of the producer; and
- (g) if the producer is not based in a member State, a contact person within a member State.

(3) Each unit packet and any container pack must include—

- (a) a list of all ingredients contained in the product set out in descending order by weight;
  - (b) an indication of the nicotine content of the product and the delivery per dose;
  - (c) the batch number; and
  - (d) a recommendation to keep the product out of reach of children.
- (4) Each unit packet and any container pack must carry a health warning consisting of the text: “This product contains nicotine which is a highly addictive substance”.
- (5) The health warning must—
- (a) appear on both the front and back surfaces of the unit packet and any container pack;
  - (b) cover 30% of the area of each of those surfaces, calculated in relation to the area of the surface concerned when the pack is closed;
  - (c) be in black Helvetica bold type on a white background;
  - (d) be in a font size which ensures that the text occupies the greatest possible proportion of the surface area reserved for it; and
  - (e) appear at the centre of that area.
- (6) The health warning must be parallel to the main text on the surface concerned.
- (7) For the purposes of paragraph (2)(a), the instructions for use must—
- (a) include appropriate instructions for refilling, including diagrams; and
  - (b) comply with paragraph (8).
- (8) Instructions for use comply with this paragraph where—
- (a) if the refill mechanism is as described in regulation 36(10)(a), the instructions for use indicate the width of the nozzle or the width of the opening of the tank (as appropriate) in a manner that enables consumers to identify the compatibility of refill containers and electronic cigarettes; or
  - (b) if the refill mechanism is as described in regulation 36(10)(b), the instructions for use specify the type or types of docking system with which the electronic cigarette or refill container is compatible.
- (9) Paragraph (7) does not apply to instructions for use that relate to disposable electronic cigarettes.

### **Product presentation requirement**

**38.**—(1) No person may produce or supply an electronic cigarette or refill container unless it complies with paragraphs (2) to (4).

(2) The unit packet and any container pack of the electronic cigarette or refill container may not include any element or feature falling within paragraph (3).

(3) An element or feature falls within this paragraph if it—

- (a) promotes an electronic cigarette or refill container, or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;
- (b) suggests that a particular electronic cigarette or refill container—
  - (i) is less harmful than other electronic cigarettes or refill containers,
  - (ii) has vitalising, energising, healing, rejuvenating, natural or organic properties, or
  - (iii) has other health or lifestyle benefits;

- (c) refers to taste, smell or other additives (except flavourings) or the absence of any such thing;
- (d) resembles a food or a cosmetic product; or
- (e) suggests that a particular electronic cigarette or refill container has improved biodegradability or other environmental advantages.

(4) The unit pack or container pack in which an electronic cigarette or refill container is, or is intended to be, presented for retail sale may not contain any element or feature which suggests economic advantage by including printed vouchers or offering discounts, free distribution, two-for-one or other similar offers.

(5) The elements and features referred to in paragraphs (2) to (4) include (but are not limited to) text, symbols, names, trademarks, figurative or other types of sign.

### **Vigilance requirements**

**39.**—(1) A producer of electronic cigarettes or refill containers must establish and maintain a system for collecting information about all of the suspected adverse effects on human health of the product.

(2) Paragraphs (3) and (4) apply where a producer of electronic cigarettes or refill containers considers or has reason to believe that an electronic cigarette or refill container which is in its possession and is intended to be supplied, or which has been supplied, is not—

- (a) safe;
- (b) of good quality; or
- (c) in conformity with this Part of the Regulations.

(3) The producer must (as appropriate)—

- (a) immediately take the corrective action necessary to bring the product into conformity with this Part of the Regulations;
- (b) withdraw the product;
- (c) recall the product.

(4) The producer must immediately inform the Secretary of State and the competent authority of any other member State in which the product has been supplied or is intended to be supplied, giving details of, in particular—

- (a) the risk to human health and safety;
- (b) any corrective action taken; and
- (c) the results of any corrective action taken.

(5) The Secretary of State or the competent authority of any other member State may request additional information from a producer of electronic cigarettes or refill containers, including information on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers.

(6) A producer must comply with a request made of it under paragraph (5) by the date reasonably required by the Secretary of State.

### **Action to protect human health**

**40.**—(1) This regulation applies where the Secretary of State has reasonable grounds to believe that an electronic cigarette or refill container, or a type of electronic cigarette or refill container, could present a serious risk to human health.

(2) The Secretary of State may take appropriate provisional measures to address the risk to human health.

(3) The measures that the Secretary of State may take include, but are not limited to—

(a) prohibiting the supply of the electronic cigarette or refill container, or the type of electronic cigarette or refill container;

(b) requiring each supplier of the electronic cigarette or refill container, or the type of electronic cigarette or refill container, to recall the product.

(4) The Secretary of State may take appropriate follow-up measures to implement any conclusions of the European Commission in relation to the matter.

(5) Any producer or supplier of a product that is the subject of a provisional measure or a follow-up measure must comply with the measure insofar as it applies to that producer or supplier.