STATUTORY INSTRUMENTS

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.