STATUTORY INSTRUMENTS

2016 No. 507

CONSUMER PROTECTION

The Tobacco and Related Products Regulations 2016

Made - - - -	*18th April 2016*
Laid before Parliament	*22nd April 2016*
Coming into force - -	*20th May 2016*

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(**1**).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 ("the 1972 Act") in relation to tobacco, tobacco products, nicotine, nicotine products and herbal products for smoking(**2**).

PART 1

Introduction

Citation and commencement

1.—(1) These Regulations may be cited as the Tobacco and Related Products Regulations 2016.

(2) These Regulations come into force on 20th May 2016.

Interpretation

2.—(1) In these Regulations—

"the 2002 Regulations" means the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002(**3**);

(**1**) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative Reform Act 2006 (c.51) and section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7). Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (c.51) and amended by section 3(3) of and Part 1 of the Schedule to the European Union (Amendment) Act 2008. Under section 57(1) of the Scotland Act 1998 (c.46), despite the transfer to Scottish Ministers of functions in relation to implementing obligations under Community law in relation to devolved matters, the functions of the Secretary of State in relation to implementing these obligations continues to be exercisable by him as regards Scotland.

(**2**) S.I. 2014/2705.

(**3**) S.I. 2002/3041.

"addictiveness" means the pharmacological potential of a substance to cause addiction, that is, a state which affects an individual's ability to control his or her behaviour, typically by instilling a reward or a relief from withdrawal symptoms, or both, and "addictive" is to be construed accordingly;

"additive" means a substance, other than tobacco, that is added to a tobacco product, unit pack or container pack;

"brand name", in relation to a particular product, means the primary name by which the product is known;

"calendar year" means a period of 12 months beginning with 1st January and ending with 31stDecember;

"characterising flavour" means a smell or taste other than one of tobacco which—

(a) is clearly noticeable before or during consumption of the product; and

(b) results from an additive or a combination of additives,

including, but not limited to, fruit, spice, herbs, alcohol, candy, menthol or vanilla;

"cigarette" means a tobacco product that can be consumed by means of a combustion process and which is either—

(a) a roll of tobacco (or of tobacco and another substance) capable of being smoked as it is, but which is not a cigar; or

(b) a roll of tobacco (or of tobacco and another substance) which is designed to be, by simple non-industrial handling—

  (i) wrapped in cigarette paper, or

  (ii) inserted into a cigarette-paper tube;

"cigar" means a tobacco product that can be consumed by means of a combustion process and, given its properties and normal consumer expectations, is exclusively intended to be smoked as it is, and which is either—

(a) a roll of tobacco (or of tobacco and another substance) which has an outer wrapper of natural tobacco; or

(b) a roll of tobacco (or of tobacco and another substance) which—

  (i) has an outer wrapper—

    (aa) of the normal colour of a cigar,

    (bb) made of reconstituted tobacco, and

    (cc) covering the product in full (including the filter but not, in the case of a cigar with a mouthpiece, the mouthpiece),

  (ii) is filled with a threshed blend of tobacco (or of tobacco and another substance),

  (iii) has a unit weight, not including any filter or mouthpiece, of not less than 2.3 grams and not more than 10 grams, and

  (iv) has a circumference, over at least one third of its length, of not less than 34 millimetres;

"cigarillo" means a cigar with a unit weight of not more than 3 grams;

"chewing tobacco" means a smokeless tobacco product which is exclusively intended for the purpose of chewing;

"CMR properties" means properties which are carcinogenic, mutagenic or toxic for reproduction;

"consumer" means a natural person who is acting for purposes which are outside that person's trade, business, craft or profession;

"container pack" has the meaning given to it in regulation 4(2);

"cross border distance sale" has the meaning given to it in regulation 3(4);

"electronic cigarette" means a product that—

(a) can be used for the consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank (regardless of whether the product is disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges); and

(b) is not a medicinal product or medical device;

"emissions" means substances that are released when a tobacco product or related product is consumed as intended;

"hand rolling tobacco" means a tobacco product which is not a cigarette and can be used after retail sale for making cigarettes;

"herbal product for smoking" means a product based on plants, herbs or fruits which contains no tobacco and that can be consumed via a combustion process;

"ingredient" means the tobacco, any additive, as well as any other substance or element present in a finished tobacco product or related product, including paper, filter, ink, capsules and adhesives;

"ISO 4387" means the international standard entitled "Cigarettes: Determination of total and nicotine-free dry particulate matter using a routine analytical smoking machine", ISO 4387:2000, third edition, published by the International Organisation for Standardisation on 1st April 2000 and amended by Amendment 1:2008 dated 15th September 2008;

"ISO 10315" means the international standard entitled "Cigarettes: Determination of nicotine in smoke condensates. Gas chromatographic method", ISO 10315:2013, third edition, published by the International Organisation for Standardisation on 31st March 2013, and corrected by Corrigendum dated 1st November 2014;

"ISO 8243" means the international standard entitled "Cigarettes: Sampling", ISO 8243:2013, fifth edition, published by the International Organisation for Standardisation on 31stJuly 2013;

"ISO 8454" means the international standard entitled "Cigarettes: Determination of carbon monoxide in the vapour phase of cigarette smoke: NDIR method", ISO 8454:2007, third edition, published by the International Organisation for Standardisation on 1st June 2007 and amended by Amendment 1:2009 dated 15th October 2009;

"medical device" has the meaning given to it by regulation 2 of the Medical Devices Regulations 2002(**4**);

"medicinal product" has the meaning given to it by regulation 2 of the Human Medicines Regulations 2012(**5**);

"nasal tobacco" means a smokeless tobacco product that can be consumed via the nose;

"nicotine" means nicotinic alkaloids;

"novel tobacco product" means a tobacco product which—

(a) is not a cigarette, hand rolling tobacco, pipe tobacco, waterpipe tobacco, a cigar, a cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use; and

(b) is first supplied by the producer after 19th May 2014;

(**4**) S.I. 2002/618, amended by S.I. 2008/2936; there are other amending instruments but none are relevant.
(**5**) S.I. 2012/1916, to which there are amendments not relevant to these Regulations.

"pipe tobacco" means tobacco that—

(a) can be consumed by means of a combustion process; and

(b) is exclusively intended for use in a pipe;

"pouch" means a unit pack of hand rolling tobacco either in the form of a rectangular pocket with a flap that covers the opening or in the form of a standing pouch;

"produce" and "producer" have the meaning given to them by regulation 3(1);

"refill container" means a receptacle that—

(a) contains a nicotine-containing liquid, which can be used to refill an electronic cigarette; and

(b) is not a medicinal product or medical device;

"related product" means a herbal product for smoking, an electronic cigarette or a refill container;

"retailer" has the meaning given to it by regulation 3(4);

"retail sale" means sale to a consumer;

"smokeless tobacco product" means a tobacco product that is consumed in a way which does not involve a combustion process (including chewing tobacco, nasal tobacco and tobacco for oral use);

"supply" and "supplier" have the meaning given to them by regulation 3(2);

"tar" means the raw anhydrous nicotine-free condensate of smoke;

"tobacco" means leaves and other natural processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco;

"tobacco for oral use" means a tobacco product which is—

(a) intended for oral use, unless it is intended to be inhaled or chewed; and

(b) in powder or particulate form or any combination of these forms, whether presented in a sachet portion or a porous sachet, or in any other way;

"tobacco product" means a product that can be consumed and consists, even partly, of tobacco;

"tobacco product for smoking" means a tobacco product other than a smokeless tobacco product;

"Tobacco Products Directive" means Directive 2014/40/EU of the European Parliament and the Council 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(**6**);

"toxicity" means the degree to which a substance can cause harmful effects in the human organism, including effects occurring over time, usually through repeated or continuous consumption or exposure, and "toxic" is to be construed accordingly;

"travel retail sector" means retail outlets in the United Kingdom at which tobacco products or related products may be purchased only by people travelling on journeys to destinations outside the United Kingdom;

"unit pack" has the meaning given to it in regulation 4(1);

"variant name", in relation to a particular product, means any name by which that product is distinguished from other products under the same brand name;

"waterpipe tobacco" means a tobacco product that can be consumed by means of a waterpipe, and for the purposes of these Regulations—

(**6**) OJ L 127, 29.4.2014, p.1 as amended by Commission Delegated Directive 2014/109/EU, OJ L 360, 17.12.2014.

(a) waterpipe tobacco is deemed to be a tobacco product for smoking; and

(b) a product which may either be consumed via a waterpipe, or used as hand rolling tobacco, is deemed to be hand rolling tobacco.

(2) For the purposes of these Regulations, data or information are available to a person if that person is able, by reasonable endeavour, to identify their existence and obtain a copy.

Meaning of producer and supplier etc.

3.—(1) For the purposes of these Regulations a person produces a tobacco product or related product if in the course of a business and with a view to the product being supplied for consumption in the United Kingdom or through the travel retail sector, the person—

(a) manufactures the product;

(b) puts a name, trade mark or other distinguishing mark on it by which the person is held out to be its manufacturer or originator; or

(c) imports it into the United Kingdom,

and the terms "producer" and "importer" are to be construed accordingly.

(2) For the purposes of these Regulations a person supplies a tobacco product or related product if, in the course of a business, the person—

(a) supplies the product—

(i) for consumption in the United Kingdom or through the travel retail sector, or

(ii) with a view to the product being supplied for consumption in the United Kingdom or through the travel retail sector;

(b) offers or agrees to supply it in those circumstances; or

(c) exposes or possesses it for supply in those circumstances,

and "supplier" is to be construed accordingly.

(3) In the case of a cross-border distance sale of a product to a consumer located in the United Kingdom, the product is to be treated for the purposes of these Regulations as supplied, and presented for retail sale, in the United Kingdom.

(4) In these Regulations, "cross-border distance sale" means a distance sale to a consumer where, at the time the consumer orders a product from a retailer, the consumer is located in a member State other than the member State or third country where the retailer is established, and for these purposes—

(a) a retailer means a person who sells, or offers or agrees to sell, a tobacco product or related product to a consumer; and

(b) a retailer is deemed to be established in a member State—

(i) in the case of a retailer who is a natural person, if that person's place of business is in that member State, and

(ii) in any other case, if the retailer has its statutory seat, central administration or place of business, including a branch, agency or any other establishment, in that member State.

Meaning of unit and container pack and the surfaces of a pack

4.—(1) In these Regulations, a "unit pack", in relation to a tobacco product or related product, means the smallest individual packaging in which that product is, or is intended to be, presented for

retail sale (regardless of whether it is presented inside a container pack), but does not include any transparent wrapper.

(2) In these Regulations, a "container pack", in relation to a tobacco product or related product means any packaging—

(a) in which that product is, or is intended to be, presented for retail sale; and

(b) which contains (whether fully or partially enclosing)—

(i) a unit pack of that product, or

(ii) an aggregation of such unit packs,

and where there is more than one separate layer of such packaging, each layer is to be regarded as a separate container pack, but a transparent wrapper alone is not a container pack.

(3) References in these Regulations to the front and back surfaces of a unit pack or container pack are to the two largest surfaces of the pack (of the surfaces that are visible before the pack is opened).

(4) References in these Regulations to the secondary surfaces of a unit pack or container pack are to the next two largest surfaces of the pack after the front and the back surfaces (again of the surfaces that are visible before the pack is opened).

PART 2

Labelling of tobacco products

Combined health warnings on tobacco products for smoking

5.—(1) No person may produce or supply a tobacco product for smoking unless it complies with this regulation.

(2) A unit pack and any container pack of a tobacco product for smoking must carry a combined health warning**.**

(3) A combined health warning must consist of—

(a) one of the text warnings listed in Annex 1 to the Tobacco Products Directive together with a corresponding colour photograph, as specified in the picture library in Annex II to that Directive(**7**); and

(b) the following smoking cessation information: "Get help to stop smoking at www.nhs.uk/quit".

(4) A combined health warning must appear on both the front and back surfaces of the unit pack and any container pack, and the same text warning and corresponding colour photograph must appear on both surfaces.

(5) A combined heath warning must—

(a) cover 65% of the area of each surface on which it appears;

(b) appear at the top edge of the surface concerned;

(c) be positioned in the same direction as any other information on that surface; and

(d) comply with the conditions set out in regulation 11.

(6) A combined health warning must be reproduced in accordance with the layout, design and proportions specified in Commission Implementing Decision (EU) 2015/1842 of 9th October 2015

(**7**) See Commission Delegated Directive 2014/109/EU of 10 October 2014 (OJ L 360, 17.12.2014, p.22), amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products.

on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking(**8**) ("the Combined Health Warnings Decision").

(7) For the purposes of this regulation, any reference in the Combined Health Warnings Decision—

(a) to a manufacturer or an importer is to be construed as a reference to a producer; and

(b) to outside packaging is to be construed as a reference to a container pack.

(8) In the case of a unit pack of cigarettes, a combined health warning must be not less than—

(a) 44mm high; and

(b) 52mm wide.

(9) In the case of a cylindrical pack, references in this regulation to the front and back surfaces are to the two opposite halves of the curved surface of the pack that is visible before the pack is opened, if the curved surface is divided equally along a vertical plane.

(10) This regulation does not apply to a unit pack or container pack to which regulation 9 (large cigars and individually wrapped cigars and cigarillos) applies.

Range and rotation of combined health warnings

6.—(1) A producer of a tobacco product for smoking (other than an importer) must select the photograph used for the purposes of regulation 5(3)(a)—

(a) from the set of photographs which is specified for the production year during which the pack is produced; and

(b) so that each of the 14 photographs in a specified set appears on between 1/24 and 1/12 of the total number of packs under each brand name produced by that producer within that production year.

(2) An importer of a tobacco product for smoking must use the importer's best endeavours to ensure that the obligations in paragraph (1) are complied with.

(3) For the purposes of this regulation—

(a) the set of photographs contained in Set 1 of Annex II to the Tobacco Products Directive is specified for the production year 2016-2017 and every third production year thereafter;

(b) the set of photographs contained in Set 2 of Annex II to that Directive is specified for the production year 2017-2018 and every third production year thereafter;

(c) the set of photographs contained in Set 3 of Annex II to that Directive is specified for the production year 2018-2019 and every third production year thereafter; and

(d) "production year" means a period of 12 months beginning with 20th May and ending with 19th May.

General warnings and information messages on tobacco products for smoking

7.—(1) No person may produce or supply a tobacco product for smoking unless it complies with this regulation.

(2) A unit pack and any container pack of a tobacco product for smoking must carry the following health warnings—

(a) a general warning consisting of the text: "Smoking kills – quit now"; and

(b) an information message consisting of the text: "Tobacco smoke contains over 70 substances known to cause cancer".

(**8**) OJ L 267, 14.10.2015, p.5.

(3) Each of the health warnings referred to in paragraph (2) must—

(a) cover 50% of the area of each surface on which it appears;

(b) be in black Helvetica bold type on a white background;

(c) be in a font size which ensures that the text occupies the greatest possible proportion of the surface area reserved for it;

(d) appear at the centre of that area;

(e) in the case of a cuboid shaped unit pack and any container pack, be oriented parallel to the longest edge of the surface on which it appears;

(f) comply with the conditions set out in regulation 11; and

(g) in the case of a unit pack of cigarettes or hand rolling tobacco, appear in the manner specified in regulation 8.

(4) This regulation does not apply to a unit pack or container pack to which regulation 9 (large cigars and individually wrapped cigars and cigarillos) applies.

Position of general warning and information message on cigarettes and hand rolling tobacco

8.—(1) This paragraph applies to—

(a) a unit pack of cigarettes, other than a shoulder box(**9**); and

(b) a unit pack of hand rolling tobacco which is cuboid in shape, but not a shoulder box.

(2) Where paragraph (1) applies to a unit pack—

(a) the general warning must appear on one of the secondary surfaces of the pack;

(b) the information message must appear on the other secondary surface; and

(c) each of those health warnings must be—

(i) positioned at the bottom edge of the surface on which it appears, and

(ii) at least 20mm wide.

(3) In the case of a unit pack of cigarettes or hand rolling tobacco in the form of a shoulder box—

(a) the general warning must appear in its entirety on the larger of the two split parts of one of the secondary surfaces of the shoulder box;

(b) the information message must appear in its entirety on the larger of the two split parts of the other secondary surface of the shoulder box; and

(c) the general warning must also appear on the inside of the lid, such that it is visible when the pack is open.

(4) In the case of a unit pack of hand rolling tobacco which is cylindrical, with a lid—

(a) the general warning must appear on the outside surface of the lid; and

(b) the information message must appear on the inside surface of the lid.

(5) A unit pack of hand rolling tobacco in the form of a rectangular pouch must carry a general warning and an information message in accordance with Article 2.1 of Commission Implementing Decision (EU) 2015/1735 of 24th September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches(**10**) ("the Pouches Decision").

(**9**) Regulation 4(3) of the Standardised Packaging of Tobacco Products Regulations 2015 (S.I.2015/829), which implements Article 14.1 of the Tobacco Products Directive provides that a unit pack of cigarettes must be cuboid in shape.

(**10**) OJ L 252, 29.9.2015, p.49.

(6) Paragraph (5) does not apply to a unit pack of hand rolling tobacco which is in the form of a wraparound rectangular pouch made from polythene, polypropylene or laminate material where the product—

(a) is manufactured or released for free circulation in the European Union before 20th May 2018;

(b) is supplied before 20th May 2019; and

(c) carries a general warning and an information message in accordance with Article 2.2 of the Pouches decision.

(7) A unit pack of hand rolling tobacco in the form of a standing pouch, must carry a general warning and an information message in accordance with Article 3 of the Pouches Decision.

(8) For the purposes of this regulation, any reference in the Pouches Decision to roll-your-own tobacco is to be construed as a reference to hand rolling tobacco.

(9) In this regulation, a "shoulder box" means a unit pack which is cuboid in shape with a hinged lid that results in the secondary surfaces being split into two when the pack is opened.

Labelling of large cigars and individually wrapped cigars and cigarillos

9.—(1) This regulation applies to a unit pack or container pack which contains—

(a) a single cigar or cigarillo; or

(b) two or more cigars each with a unit weight of more than 3 grams.

(2) No person may produce or supply a pack to which this regulation applies unless the pack carries—

(a) the general health warning: "Smoking kills – quit now" together with the smoking cessation information: "Get help to stop smoking at www.nhs.uk/quit"; and

(b) one of the text warnings listed in Annex 1 to the Tobacco Products Directive ("the Annex").

(3) A producer (other than an importer) must select the text warning referred to in paragraph (2)(b) so that each of the text warnings listed in the Annex appears on between 1/24 and 1/12 of the total number of packs under each brand name produced by that producer within that production year.

(4) An importer must use the importer's best endeavours to ensure that the obligation in paragraph (3) is complied with.

(5) The general health warning referred to in paragraph (2)(a) must—

(a) appear on the most visible surface of the pack; and

(b) cover 30% of the area of the surface on which it appears.

(6) The text warning referred to in paragraph (2)(b) must—

(a) appear on the next most visible surface of the pack or, if the pack has a hinged lid, the surface that appears when the pack is opened; and

(b) cover 40% of the area of the surface on which it appears.

(7) Paragraphs (5)(b) and (6)(b) are subject to paragraph (8).

(8) Where one of the health warnings referred to in paragraph (2) is to appear on a surface with an area which is greater than 150 square centimetres, the health warning must cover at least 45 square centimetres of that surface.

(9) Each of the health warnings referred to in paragraph (2) must—

(a) be in black Helvetica bold type on a white background;

(b) be in a font size which ensures that the text occupies the greatest possible proportion of the surface area reserved for it;

(c) appear at the centre of that area; and

(d) comply with the conditions in regulation 11.

(10) The warning must be parallel to the main text on the surface concerned.

(11) For the purposes of this regulation "production year" has the same meaning as in regulation 6(3)(d).

Health warning on smokeless tobacco products

10.—(1) No person may produce or supply a smokeless tobacco product unless it complies with this regulation.

(2) A unit pack and any container pack of a smokeless tobacco product must carry a health warning consisting of the text: "This tobacco product damages your health and is addictive".

(3) The health warning referred to in paragraph (2) must—

(a) appear on both the front and the back surfaces of the pack;

(b) cover 30% of the area of each of those surfaces;

(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;

(e) appear at the centre of that area; and

(f) comply with the conditions in regulation 11.

(4) The health warning must be parallel to the main text on the surface concerned.

General conditions applicable to all health warnings on tobacco products

11.—(1) The general conditions referred to in regulations 5(5)(d), 7(3)(f), 9(9)(d) and 10(3)(f) are as follows.

(2) A health warning must cover the entire area that is reserved for it, and must not be commented on or paraphrased.

(3) The dimensions of a health warning must be calculated in relation to the area of the surface concerned when the pack is closed.

(4) A health warning must be—

(a) in English;

(b) fully visible;

(c) indelible;

(d) irremovably printed;

(e) printed on the pack, subject to paragraph (7); and

(f) surrounded by a black border of a width of 1mm inside the area which is reserved for it.

(5) A health warning must remain intact when the pack is opened, subject to paragraph (8).

(6) A health warning must not—

(a) be partially or totally hidden or interrupted by wrappers, jackets or boxes (except in the case of a unit pack presented inside a container pack);

(b) be partially or totally hidden or interrupted by any other item (such as a tax stamp, price mark or security feature); or

(c) partially or totally hide or interrupt any tax stamp, price mark, tracking and tracing mark, security feature or any other marking which is required under or by virtue of any enactment.

(7) In the case of a unit pack of a tobacco product other than cigarettes and hand rolling tobacco in a pouch, the warning may be printed on a sticker affixed to the pack, provided that the sticker is irremovable.

(8) In the case of a unit pack with a flip-top lid, a combined health warning may be split when the pack is opened, but only in a manner which ensures the graphical integrity and visibility of the text, photograph and smoking cessation information in accordance with Article 4 of the Combined Health Warnings Decision(**11**).

Images of tobacco products targeted at consumers

12.—(1) No person may publish or cause to be published in the course of a business an image of a unit pack or container pack of a tobacco product in connection with an offer for sale to a consumer (in circumstances which are not otherwise made unlawful by the provisions of the Tobacco Advertising and Promotion Act 2002(**12**)) unless the image complies with paragraph (2).

(2) An image of a unit pack or container pack of a tobacco product complies with this paragraph if the pack depicted in the image complies with the labelling and packaging requirements for the lawful supply of the product concerned which are imposed by—

(a) this Part; and

(b) regulations 4, 8 and 10 of the Standardised Packaging of Tobacco Products Regulations 2015(**13**).

PART 3

Emissions, additives and other prohibited ingredients and products

Maximum emission levels of cigarettes

13.—(1) No person may produce, supply or manufacture for export any cigarettes with emission levels greater than—

(a) 10 milligrams of tar per cigarette;

(b) 1 milligram of nicotine per cigarette;

(c) 10 milligrams of carbon monoxide per cigarette.

(2) For the purposes of this regulation and regulation 14, a person manufactures a product for export if, in the course of a business and other than with a view to the product being supplied for consumption in the United Kingdom or through the travel retail sector, the person—

(a) manufactures the product; or

(b) puts a name, trade mark or other distinguishing mark on it by which the person is held out to be its manufacturer or originator.

(**11**) See regulation 5(5).
(**12**) 2002 c. 36. The Tobacco Advertising and Promotion Act 2002 makes provision about the advertising of tobacco products.
(**13**) S.I. 2015/829.

Measurement and verification of emission levels

14.—(1) The tar, nicotine and carbon monoxide emissions from cigarettes must be measured in accordance with standards ISO 4387 for tar, ISO 10315 for nicotine, and ISO 8454 for carbon monoxide.

(2) The accuracy of tar, nicotine and carbon monoxide measurements must be determined in accordance with standard ISO 8243.

(3) The Secretary of State must—

(a) approve and monitor one or more laboratories ("approved laboratories") which must not be owned or controlled directly or indirectly by the tobacco industry; and

(b) arrange for an approved laboratory to verify the measurements referred to in paragraphs (1) and (2).

(4) For the purpose of enabling the Secretary of State to perform functions under paragraph (3)(b), a person who produces cigarettes, or manufactures cigarettes for export must provide to the Secretary of State (or to such person as the Secretary of State may specify) such samples, at such times and intervals and from such sources, as the Secretary of State may reasonably require.

No flavoured cigarettes or hand rolling tobacco etc.

15.—(1) No person may produce or supply cigarettes or hand rolling tobacco with a characterising flavour.

(2) No person may produce or supply cigarettes or hand rolling tobacco with—

(a) a filter, paper, package, capsule or other component containing flavourings;

(b) a filter, paper or capsule containing tobacco or nicotine; or

(c) a technical feature allowing the consumer to modify the smell, taste, or smoke intensity of the product.

No vitamins, colourings or prohibited additives in tobacco products

16.—(1) No person may produce or supply a tobacco product containing—

(a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;

(b) caffeine, taurine or other additives and stimulant compounds that are associated with energy and vitality;

(c) additives which have colouring effects on emissions; or

(d) in the case of tobacco products for smoking, additives that facilitate inhalation or nicotine uptake.

(2) No person may produce or supply a tobacco product containing—

(a) additives that have CMR properties in unburnt form; or

(b) additives in quantities that increase, to a significant or measurable degree, the toxic or addictive effect or CMR properties of the product when it is consumed.

(3) Nothing in this regulation prohibits the use of an additive which is essential for the manufacture of a tobacco product (for example, sugar when it is used to replace sugar that is lost during the curing process), provided that the additive does not result in a product with a characterising flavour, and does not increase to a significant or measurable degree, the toxic effect, addictive effect or CMR properties of the product when it is consumed.

Tobacco for oral use

17. No person may produce or supply tobacco for oral use.

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(**14**);

(**14**) OJ L 396, 30.12.2006, p.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(**15**);

(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.

(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

(**15**) OJ L 353, 31.12.2008, p.1.

(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(**16**);

(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.

(**16**) OJ L 312, 27.11.2015, p.5.

PART 5

Herbal products for smoking

Labelling and presentation of herbal products for smoking

28.—(1) No person may produce or supply a herbal product for smoking unless it complies with paragraphs (2) to (5).

(2) A unit pack and any container pack of a herbal product for smoking must carry a health warning consisting of the text: "Smoking this product damages your health".

(3) The health warning must—

(a) appear on both the front and back surfaces of the unit pack 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.

(4) A unit pack and any container pack of a herbal product for smoking must not—

(a) state that the product is free of additives or flavourings; or

(b) include any element or feature that falls within paragraph (5).

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

(a) promotes a herbal product for smoking or encourages its consumption by creating an erroneous impression about its characteristics, health effects, risks or emissions;

(b) includes any information about the nicotine, tar or carbon monoxide content of a herbal product for smoking;

(c) resembles a food or a cosmetic product; or

(d) suggests that a particular herbal product for smoking—

(i) is less harmful than other herbal products for smoking,

(ii) aims to reduce the effect of some harmful components of smoke,

(iii) has vitalising, energising, healing, rejuvenating, natural or organic properties, or

(iv) has other health or lifestyle benefits.

(6) The elements and features referred to in paragraphs (4)(b) and (5) include (but are not limited to) texts, symbols, names, trade marks, figurative signs or other types of sign.

Ingredients information for herbal products for smoking

29.—(1) A producer of a herbal product for smoking must submit to the Secretary of State a list of all the ingredients of the product, by brand and variant name, and the quantity of each ingredient.

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

(a) on or before 19th November 2016 in the case of a herbal product which a producer first supplied before 20th May 2016 and continues to supply on or after that date; or

(b) in any other case, at least one day before the day a producer first supplies a herbal product for smoking.

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

Herbal products for smoking - supplementary

30.—(1) Regulations 25 (submission of information) and 26 (use of information) apply in relation to information provided in accordance with regulation 29 as they apply in relation to information provided in accordance with regulation 18 (information about tobacco products).

(2) A producer who fails to submit information in accordance with regulation 29 in respect of a herbal product for smoking may not supply the product concerned until the producer submits the required information in accordance with regulation 25.

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 20thMay 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 20thMay 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(**17**);

(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

(**17**) OJ L 309, 26.11.2015, p 15.

(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—

(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.

PART 7

Electronic cigarette advertising

Interpretation of Part 7

41.—(1) In this Part "electronic cigarette advertisement" means an advertisement with—

(a) the aim of promoting an electronic cigarette or refill container; or

(b) the direct or indirect effect of promoting one.

(2) In this Part—

"the E-Commerce Directive" means Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce)(**18**);

"information society services"—

(a) has the meaning given in Article 2(a) of the E-Commerce Directive (which refers to Article 1(2) of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations(**19**)); and

(b) is summarised in recital 17 of the E-Commerce Directive as covering "any service normally provided for remuneration, at a distance, by means of electronic equipment for the processing (including digital compression) and storage of data, and at the individual request of a recipient of a service";

"recipient" means a person who (whether for professional purposes or otherwise) uses an information society service, in particular for seeking information or making it accessible;

"service provider" means a person providing an information society service;

"the Union market" means the market of one or more member States; and

"third country" means a state which is not a member State.

(**18**) OJ L 178, 17.7.2000, p.1.
(**19**) OJ L 204, 21.7.1998, p.37, as amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p.18).

(3) For the purposes of this Part, a service provider is established in a particular EEA State, if the service provider—

(a) effectively pursues an economic activity in that EEA State using a fixed establishment for an indefinite period; and

(b) is a national of an EEA State, or a company or firm as mentioned in Article 54 of the Treaty on the Functioning of the European Union (**20**).

(4) The presence or use in a particular place of equipment or other technical means of providing an information society service is not itself sufficient to constitute the establishment of a service provider.

(5) Where it cannot be decided from which of a number of establishments a given information society service is provided, that service is to be regarded as provided from the establishment at the centre of the service provider's activities relating to that service.

No advertising of electronic cigarettes in the press etc.

42.—(1) No person may in the course of a business publish, or procure the publication of, an electronic cigarette advertisement in a newspaper, periodical or magazine.

(2) No person may in the course of a business sell, offer for sale or otherwise make available to the public a newspaper, periodical or magazine containing an electronic cigarette advertisement.

(3) Paragraphs (1) and (2) do not apply—

(a) to a newspaper, periodical or magazine which is intended exclusively for professionals in the trade of electronic cigarettes or refill containers; or

(b) to a newspaper, periodical or magazine which is printed and published in a third country and is not principally intended for the Union market.

No advertising of electronic cigarettes in information society services

43.—(1) No person may in the course of a business include, or procure the inclusion of, an electronic cigarette advertisement in an information society service provided to a recipient in the United Kingdom.

(2) No service provider established in the United Kingdom may in the course of a business include an electronic cigarette advertisement in an information society service provided to a recipient in an EEA State other than the United Kingdom ("a non-UK-EEA-State").

(3) No proceedings for an offence for breach of paragraph (1)(**21**) may be instituted against a service provider who is established in a non-UK-EEA-State, unless the derogation condition mentioned in paragraph 4 is satisfied.

(4) The derogation condition is satisfied where the institution of proceedings—

(a) is necessary for the purposes of public policy, the protection of public health or the protection of consumers ("the objective");

(b) relates to an information society service that prejudices the objective or presents a serious and grave risk of prejudice to the objective; and

(c) is proportionate to the objective.

(5) Paragraphs (1) and (2) do not apply—

(a) to an information society service which is intended exclusively for professionals in the trade of electronic cigarettes or refill containers; or

(**20**) Cm 7310.
(**21**) See regulation 48(e).

(b) to an electronic cigarette advertisement which is not principally intended for the Union market.

(6) Schedule 1 (liability of intermediary information society service providers) has effect.

Sponsorship of events etc.

44.—(1) No person may in the course of a business provide electronic cigarette sponsorship to—

(a) an event or activity which takes place in or has an effect in two or more member States ("a cross-border event or activity"); or

(b) an individual taking part in a cross-border event or activity.

(2) In this regulation "electronic cigarette sponsorship" means any form of public or private contribution to any event, activity or individual, with the aim or direct or indirect effect of promoting an electronic cigarette or refill container.

Amendment of section 319 of and Schedule 11A to the Communications Act 2003 (product placement of electronic cigarettes on television)

45.—(1) Section 319 of the Communications Act 2003(**22**) (OFCOM's standards code) is amended as follows—

(a) at the beginning of subsection (9) insert "Subject to subsection (10),";

(b) after subsection (9) insert—

"(10) So far as relating to product placement falling within paragraph 4(ba) of Schedule 11A (electronic cigarettes and electronic cigarette refill containers), subsection (2)(fa) applies only in relation to programmes the production of which begins after 19th May 2016.".

(2) In Schedule 11A (Restrictions on Product Placement)—

(a) at the end of paragraph 4(b) omit "or";

(b) after paragraph 4(b) insert—

"(i) (ba) of electronic cigarettes or electronic cigarette refill containers; or";

(c) in paragraph 6(2)(a) omit "electronic or smokeless cigarettes, ";

(d) in paragraph 9 after the definition of "connected" insert—

""electronic cigarette" has the meaning given in section 368R;

"electronic cigarette refill container" has the meaning given in section 368R;".

Amendment of Part 4A of the Communications Act 2003 (on-demand programme services)

46.—(1) Part 4A of the Communications Act 2003(**23**) (on-demand programme services) is amended as follows.

(2) In section 368F (advertising) after subsection (1)(a) insert—

"(aa) electronic cigarettes or electronic cigarette refill containers;".

(3) In section 368G (sponsorship) after subsection (1) insert—

"(1A) An on-demand programme service or a programme included in an on-demand programme service must not be sponsored for the purpose of promoting electronic cigarettes or electronic cigarette refill containers.".

(**22**) 2003 c.21. Relevant amendments were made by S.I. 2010/831.
(**23**) Part 4A was inserted by S.I. 2009/2979. There have been subsequent amendments, but none is relevant.

(4) In section 368H (product placement)—

(a) at the end of subsection (4)(b) omit "or";

(b) after subsection (4)(b) insert—

"(ba) it is of electronic cigarettes or electronic cigarette refill containers, or";

(c) at the beginning of subsection (15) insert "Subject to subsection (15A),";

(d) after subsection (15) insert—

"(15A) Subsection (4)(ba) applies only in relation to programmes the production of which begins after 19th May 2016.".

(5) In section 368R (interpretation of Part 4A) in subsection (1) after the definition of "children's programme" insert—

""electronic cigarette" means a product that—

(a) can be used for the consumption of nicotine-containing vapour via a mouth piece, or any component of that product, including a cartridge, a tank and the device without cartridge or tank (regardless of whether the product is disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges), and

(b) is not a medicinal product within the meaning of regulation 2 of the Human Medicines Regulations 2012 (S.I. 2012/1916) or a medical device within the meaning of regulation 2 of the Medical Devices Regulations 2002 (S.I. 2002/618);

"electronic cigarette refill container" means a receptacle that—

(a) contains a nicotine-containing liquid, which can be used to refill an electronic cigarette, and

(b) is not a medicinal product within the meaning of regulation 2 of the Human Medicines Regulations 2012 or a medical device within the meaning of regulation 2 of the Medical Devices Regulations 2002;".

PART 8

Distance sales to consumers

Cross-border distance sales of tobacco products and electronic cigarettes etc.

47.—(1) The following persons must register with the Secretary of State—

(a) a retailer established in the United Kingdom who engages or intends to engage in a cross-border distance sale of a relevant product with a consumer located in any other member State; and

(b) a retailer who is established elsewhere than in the United Kingdom who engages or intends to engage in a cross-border distance sale of a relevant product with a consumer located in the United Kingdom.

(2) A person seeking registration must submit to the Secretary of State—

(a) the information specified in paragraph (3) ("the retailer information");

(b) in the case of a retailer who falls within paragraph (1)(a), the information specified in paragraph (4) ("the additional information"); and

(c) such other information as the Secretary of State may reasonably require.

(3) The retailer information is—

(a) the retailer's name;

(b) the retailer's trading name, if different;

(c) the address of each place of business used by the retailer for the supply of a relevant product;

(d) the date on which the retailer first supplied or, if the retailer has not yet so supplied, intends to supply a relevant product via a cross border distance sale;

(e) the address of any website on which the retailer offers or intends to offer to supply a product, together with any other information required to identify the website; and

(f) a description of the details and functioning of the retailer's age verification system (see paragraph (6)(b)).

(4) The additional information is—

(a) confirmation of any registration provided by the competent authority of any member State in which the retailer is registered to supply products via a cross-border distance sale to a consumer located in that member State; and

(b) the name of any other member State to which the retailer has applied, or is intending to apply, for registration.

(5) The Secretary of State must—

(a) provide confirmation of registration to a retailer who complies with paragraph (2);

(b) publish a list of retailers registered with the Secretary of State.

(6) A retailer must not supply a relevant product to a consumer via a cross-border distance sale unless—

(a) the retailer has received confirmation of registration from the Secretary of State and from the competent authority of any member State in which the consumer is located or in which the retailer is established;

(b) the retailer operates an age verification system; and

(c) prior to, or at the time of sale, the retailer's age verification system confirms that the consumer's age is not lower than the minimum age applicable for the purchase of the product in the member State in which the consumer is located.

(7) A retailer must not supply a relevant product via a cross-border distance sale to a consumer located in a member State in which cross border distances sales are prohibited in accordance with Article 18(1) of the Tobacco Products Directive.

(8) In this regulation—

"age verification system" means a computing system that confirms the consumer's age electronically; and

"confirmation of registration" means written confirmation provided by the competent authority of any member State in accordance with the requirements in that member State which implement Article 18 of the Tobacco Products Directive; and

"relevant product" means a tobacco product, an electronic cigarette or a refill container.

PART 9

Penalties and enforcement

Offences

48. A person is guilty of an offence if that person—

(a) breaches a provision of

(i) Part 2 (labelling),

(ii) Part 3 (emissions, additives etc.) except regulation 14(3) (approved laboratories), or

(iii) regulation 27 (no supply of products where reporting obligations not complied with);

(b) fails to submit information to the Secretary of State in accordance with a provision of Part 4 (reporting about tobacco products) or regulation 29 (ingredients information for herbal products for smoking);

(c) breaches regulation 28 (labelling and presentation of herbal products for smoking) or regulation 30(2) (no supply where reporting obligation not complied with);

(d) breaches any provision of Part 6 (electronic cigarettes) except regulations 32(5) (annual reporting requirement) and 34 (Secretary of State duty to publish notifications);

(e) breaches any provision of regulations 42, 43 or 44 (advertising and sponsorship); or

(f) supplies a product in breach of regulation 47 (cross border distance sales of tobacco products and electronic cigarettes etc.).

False or misleading information

49. A producer or retailer is guilty of an offence if that producer or retailer provides information to a person pursuant to any obligation in these Regulations if—

(a) the information is false or misleading in a material particular; and

(b) the producer or retailer who provides the information either knows it to be false or misleading in a material particular, or is reckless as to whether it is false or misleading in a material particular.

Defences

50.—(1) In any proceedings for an offence under these Regulations brought against a person who supplies any tobacco product or related product in breach of these Regulations, it is a defence that the supplier exercised all due diligence to avoid committing the offence.

(2) In any proceedings for an offence against a person under regulations 42, 43 or 44 (advertising and sponsorship) it is a defence that the person exercised all due diligence to avoid committing the offence.

(3) In any proceedings for an offence against a person under regulations 42(1) or 43 it is a defence that the person did not know and had no reason to suspect that the advertisement was an electronic cigarette advertisement.

(4) In proceedings for an offence against a person under regulation 42(2), it is a defence that the person did not know and had no reason to suspect that the newspaper, periodical or magazine contained an electronic cigarette advertisement.

(5) A defendant may not, without permission of the court, rely on the defence provided by paragraph (1) or (2) on the basis that the commission of the offence was due to the act or default of another person or the defendant's reliance on information given by another person, unless the defendant has served on the prosecutor the notice mentioned in paragraph (6).

(6) That notice is notice in writing, giving such information identifying or assisting in the identification of that other person as is in the defendant's possession and which is served not less than seven clear days before the date of the hearing.

(7) A defendant may not rely on the defence provided by paragraph (1) or (2) by reason that the defendant relied on information given by another person, unless the defendant shows that it was reasonable in all the circumstances to have relied on that information.

Penalties

51. A person guilty of an offence under these Regulations is liable—

(a) on summary conviction—

(i) in England and Wales to imprisonment for a term not exceeding three months, or a fine or both, or

(ii) in Scotland, to imprisonment for a term not exceeding twelve months, or a fine not exceeding level 5 on the standard scale, or both;

(iii) in Northern Ireland, to imprisonment for a term not exceeding three months, or a fine not exceeding level 5 on the standard scale, or both; or

(b) on conviction on indictment to imprisonment for a term not exceeding 2 years, or a fine, or both.

Offences by bodies corporate and Scottish partnerships

52.—(1) If an offence under these Regulations committed by a body corporate is proved—

(a) to have been committed with the consent or connivance of an officer; or

(b) to be attributable to any neglect on the officer's part,

the officer as well as the body corporate is guilty of the offence and liable to be proceeded against and punished accordingly.

(2) In paragraph (1) "officer", in relation to a body corporate, means a director, manager, secretary or other similar officer of the body, or a person purporting to act in any such capacity.

(3) If the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with the member's functions of management as if that person were a director of the body corporate.

(4) If an offence under these Regulations committed by a partnership in Scotland is proved—

(a) to have been committed with the consent or connivance of a partner; or

(b) to be attributable to any neglect on the partner's part,

the partner as well as the partnership is guilty of the offence and is liable to be proceeded against and punished accordingly.

(5) In paragraph (4) "partner" includes a person purporting to act as a partner.

Enforcement

53.—(1) It is the duty of each weights and measures authority in Great Britain and each district council in Northern Ireland to enforce these Regulations within their area.

(2) Paragraph (1) is subject to paragraphs (6) and (7).

(3) For the purposes of paragraph (1) and (6) to (8), the provisions of parts 2, 4 and 5 (enforcement) of the Consumer Protection Act 1987(**24**) ("the 1987 Act"), except for sections 12, 13 and 27, are to apply to these Regulations as if—

(a) these Regulations were safety regulations(**25**) within the meaning of that Act; and

(b) the persons on whom functions are conferred by this regulation were enforcement authorities within the meaning of that Act.

(**24**) 1987 c.43. Relevant amendments are made by the Consumer Rights Act 2015 c. 15.
(**25**) The expression "safety regulations" is defined by section 45 of the Consumer Protection Act 1987.

(4) The reference to six months in section 14(6) of the 1987 Act (imprisonment on summary conviction not to exceed six months), as that section has effect by virtue of paragraph (1), is to be read in its application to England and Wales and Northern Ireland as a reference to three months.

(5) In determining how to comply with paragraph (1) in relation to regulations 42 and 43 (electronic cigarette advertising), every enforcement authority must have regard to the desirability of encouraging control of advertising by such established means as it considers appropriate, having regard to all the circumstances of the particular case.

(6) The duty under paragraph (1) in relation to the following provisions is transferred to the Secretary of State, and each weights and measures authority in Great Britain and each district council in Northern Ireland is relieved of that duty—

(a) regulation 14(4) (measurements and verifications of emission levels);

(b) Part 4 (Reporting), except for regulation 27;

(c) regulation 29 (ingredients information for herbal products for smoking);

(d) regulation 31 (notification provisions for electronic cigarettes); and

(e) regulation 32 (annual reporting for electronic cigarettes).

(7) The duty under paragraph (1) in relation to the following provisions is transferred to the Secretary of State, but each weights and measures authority in Great Britain and district council in Northern Ireland is not relieved of that duty—

(a) regulation 27 (supply of tobacco products);

(b) regulation 30(2) (supply of herbal products for smoking);

(c) regulation 35 (supply of electronic cigarettes etc.); and

(d) regulation 40(5) (action to protect public health).

(8) Where paragraph (6) or (7) does not apply, the Secretary of State may direct, in relation to cases of a particular description or a particular case, that the enforcement duty is to be discharged by the Secretary of State or by the appropriate minister.

(9) In this regulation—

"appropriate minister" means—

(a) in relation to England, means the Secretary of State,

(b) in relation to Wales, means the Welsh Ministers,

(c) in relation to Northern Ireland, means the Department of Health, Social Services and Public Safety, and

(d) in relation to Scotland, means the Scottish Ministers.

PART 10

Miscellaneous provisions

Revocation

54. The following regulations are revoked (although see regulations 55 and 56 (savings and transitional provisions))—

(a) the Tobacco for Oral Use (Safety) Regulations 1992(**26**);

(b) the 2002 Regulations; and

(**26**) S.I. 1992/3134.

(c) the Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007(**27**).

Saving for tobacco product identification marking

55.—(1) Regulation 10 (product identification markings) of the 2002 Regulations continues to have effect in relation to the code marking of tobacco products until the relevant date, despite the revocation made by these Regulations.

(2) For the purposes of paragraph (1) —

(a) the reference in regulation 10(2) of the 2002 Regulations to the Secretary of State's functions under those Regulations, is to be read as a reference to the Secretary of State's functions under these Regulations; and

(b) the 2002 Regulations continue to apply as if they (as amended by the Regulations referred to in regulation 54(c)) had not been revoked.

(3) The relevant date for the purposes of paragraph (1) is—

(a) 20th May 2019 in the case of cigarettes and hand rolling tobacco; and

(b) 20th May 2024 in the case of any other tobacco product.

Transitional provisions

56.—(1) The provisions of Part 2 (labelling) and Part 3 (emissions and ingredients) do not apply to the supply of a tobacco product where—

(a) the product was produced before 20th May 2016, or released for free circulation within the European Union before that date;

(b) the supply takes place before 20th May 2017; and

(c) the product complies with the 2002 Regulations at the time of supply.

(2) For the purposes of paragraph (1)(c) the 2002 Regulations continue to apply as if they (as amended by the Regulations referred to in regulation 54(c)) had not been revoked.

(3) The provisions of regulation 15 (flavoured cigarettes etc.) do not apply to menthol cigarettes until 20th May 2020.

(4) The provisions of regulation 28 (labelling and presentation of herbal products for smoking) do not apply to the supply of a herbal product for smoking where—

(a) the product was produced before 20th May 2016, or released for free circulation within the European Union before that date; and

(b) the supply takes place before 20th May 2017.

(5) The provisions of regulations 36 to 38 (product requirements etc. of electronic cigarettes) do not apply to the production of an electronic cigarette or a refill container until 20th November 2016.

(6) The provisions of regulations 36 to 38 do not apply to the supply of an electronic cigarette or a refill container where—

(a) the electronic cigarette or a refill container was produced before 20th November 2016, or released for free circulation within the European Union before that date; and

(b) the supply takes place before 20th May 2017.

(7) Regulation 42(2) (sale etc. of newspaper, periodical or magazine) does not apply to a newspaper, periodical or magazine which was published before 20thMay 2016.

(**27**) S.I. 2007/2473.

Saving for product placement of electronic cigarettes in television programmes the production of which began before 20th May 2016

57. In the case of a programme the production of which began before 20th May 2016, section 319 of and Schedule 11A to, the Communications Act 2003 apply as if they had not been amended by these Regulations.

Review

58.—(1) The Secretary of State must from time to time—

(a) carry out a review of the regulatory provision made by these Regulations; and

(b) publish a report setting out the conclusions of the review.

(2) The review must have regard to how the Tobacco Products Directive is implemented in other member States.

(3) The report must, in particular—

(a) set out the objectives intended to be achieved by the regulatory provision made by these Regulations;

(b) assess the extent to which those objectives are achieved; and

(c) assess whether those objectives remain appropriate, and

(d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.

(4) The first report under this regulation must be published before 20th May 2021.

(5) Subsequent reports must be published at intervals not exceeding five years.

(6) In this regulation "regulatory provision" has the meaning given in section 32(4) of the Small Business, Enterprise and Employment Act 2015(**28**).

Signed by authority of the Secretary of State for Health.

Jane Ellison
Parliamentary Under-Secretary of State,
Department of Health

18th April 2016

(**28**) 2015 c.26.

SCHEDULE Regulation 43

Liability of intermediary information society service providers

Mere conduits

1.—(1) A service provider does not contravene regulation 43 only by providing access to a communication network, or by transmitting, in a communication network, information provided by a recipient of the service, if the service provider does not—

(a) initiate the transmission;

(b) select the recipient of the transmission; or

(c) select or modify the information contained in the transmission.

(2) For the purposes of sub-paragraph (1), the provision of access to a communication network and the transmission of information in a communication network include the automatic, intermediate and transient storage of the information transmitted if—

(a) the storage is solely for the purpose of carrying out the transmission in the network; and

(b) the information is not stored for longer than is reasonably necessary for the transmission.

Caching

2.—(1) A service provider does not contravene regulation 43 only by storing information provided by a recipient of the service for transmission in a communication network if the first and second conditions are met.

(2) The first condition is that the storage of the information—

(a) is automatic, intermediate and temporary; and

(b) is solely for the purpose of making more efficient the onward transmission of the information to other recipients of the service at their request.

(3) The second condition is that the service provider—

(a) does not modify the information;

(b) complies with any conditions attached to having access to the information; and

(c) in a case to which sub-paragraph (4) applies, promptly removes the information or disables access to it.

(4) This sub-paragraph applies if the service provider obtains actual knowledge that—

(a) the information at the initial source of the transmission has been removed from the network or access to it has been disabled; or

(b) a court or administrative authority has required the removal from the network of, or the disablement of access to, the information.

Hosting

3.—(1) A service provider does not contravene regulation 43 only by storing information provided by a recipient of the service, if—

(a) when the information was provided, the service provider had no actual knowledge that it was, or contained, an electronic cigarette advertisement; and

(b) where the service provider subsequently obtained such actual knowledge, the service provider promptly removed the information or disabled access to it.

(2) Sub-paragraph (1) does not apply if the recipient of the service is acting under the authority or control of the service provider.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement Directive 2014/40/EU of the European Parliament and the Council 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 ("the Tobacco Products Directive"), other than articles 6, 13 to 16, one element of article 9.3, and certain aspects of article 20.5. Articles 13, 14 and the element of article 9.3 are implemented by S.I 2015/829; certain aspects of article 20.5 are implemented by statutory code.

These Regulations also implement:

- Commission Delegated Directive 2014/109/EU of 10 October 2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products;
- Commission Implementing Decision (EU) 2015/1735 of 24 September 2015 on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches;
- Commission Implementing Decision (EU) 2015/1842 of 9 October 2015 on the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking;
- Commission Implementing Decision (EU) 2015/2183 of 24 November 2015 establishing a common format for the notification of electronic cigarettes and refill containers;
- Commission Implementing Decision (EU) 2015/2186 of 25 November 2015 establishing a format for the submission and making available of information on tobacco products;
- Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes; and
- Directive 2001/31/EC of the European Parliament and Council of 8 June 2000 on certain legal aspects of information society service, in particular electronic commerce, in the Internal Market ("the e-commerce directive") in relation to electronic cigarette advertising.

These regulations revoke and replace the Tobacco for Oral Use (Safety) Regulations 1992 (SI 1992/3134) and the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 (SI 2002/3041) as amended by SI 2007/2473, which implemented Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products, the precursor to the Tobacco Products Directive.

Part 2 deals with the labelling of tobacco products. Regulation 5 requires tobacco products for smoking to carry a health warning label including a colour photograph on the front and back surfaces and regulations 7 and 8 require a general warning and information message on other surfaces. Regulation 9 makes special provision for the labelling of large cigars and individually wrapped

cigars and regulation 10 for the labelling of smokeless tobacco products. Images of tobacco products targeted at consumers must comply with regulation 12.

Part 3 deals with emissions and additives. Regulation 13 sets maximum tar, nicotine and carbon dioxide levels for cigarettes. Regulation 15 prohibits cigarettes and hand rolling tobacco with a characterising flavour, although it does not apply to menthol cigarettes until 20th May 2020 (see regulation 56(3)). Regulation 16 prohibits the use of certain additives and regulation 17 prohibits tobacco for oral use.

Part 4 deals with reporting of information about tobacco products. Producers of tobacco products are required to submit ingredients information (regulation 19), emissions information (regulation 20), sales data and market research information (regulation 21) to the Secretary of State. Novel tobacco products are to be notified to the Secretary of State in accordance with regulation 22 to 24. Regulation 27 prohibits a producer who has failed to comply with reporting obligations from supplying the product concerned.

Part 5 deals with herbal products for smoking. Regulation 28 requires herbal products for smoking to carry a health warning label and regulation 29 requires producers to report ingredients information.

Part 6 deals with electronic cigarettes. Producers of electronic cigarettes and refill containers are required by regulations 31 and 32 to submit product information, sales and other data to the Secretary of State. Regulation 36 sets out product requirements for electronic cigarettes and refill containers including maximum nicotine concentration. Electronic cigarettes are required to be labelled and presented in accordance with regulations 37 and 38. Regulation 39 sets out vigilance requirements including actions to be taken where an electronic cigarette or refill container is believed to be unsafe and the Secretary of State may take appropriate provisional measures under regulation 40 to address serious risks to human health.

Part 7 deals with electronic cigarette advertising. Regulations 42 and 43 prohibit electronic cigarette advertising in the press and information society services ("ISS") subject to limited exceptions. ISS are regulated on a "country of origin" basis in accordance with the e-commerce directive. Regulation 44 prohibits electronic cigarette sponsorship of cross-border events. Regulations 45 and 46 amend the Communications Act 2003 to prohibit electronic cigarette advertising, sponsorship and product placement on-demand television and electronic cigarette product placement on broadcast television. (Electronic cigarette advertising and sponsorship on broadcast television and radio is prohibited by means of amendments to the OFCOM Broadcasting Code and the UK Code of Broadcast Advertising.)

Part 8 (regulation 47) places requirements on retailers engaging in cross-border distance sales to consumers.

Part 9 deals with penalties, enforcement and defences. Part 10 contains transitional provisions, savings provisions and revocations.

Regulation 58 requires the Secretary of State to review the operation and effect of these Regulations and publish a report within five years after they come into force and within every five years after that. Following a review it will fall to the Secretary of State to consider whether the Regulations should remain as they are, or be revoked or be amended. A further instrument would be needed to revoke the Regulations or to amend them.

An impact assessment of the effect that these Regulations will have on the costs of business and the voluntary sector has been prepared. As these Regulations transpose a Directive, a transposition note setting out how the Government has transposed the Directive into UK law has been prepared.

Copies of the impact assessment and the transposition note have been placed in the libraries of both Houses of Parliament and are also annexed to the Explanatory Memorandum which is available alongside the instrument on the www.legislation.gov.uk website. Copies of the International Standards referred to in this instrument are available for purchase on line from bsigroup.com or by post from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.