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CONSUMER PROTECTION

The Tobacco and Related Products Regulations 2016

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SCHEDULE — Graphical health warning library

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of and paragraph 1A of Schedule 2 to, the European Communities Act 1972(**a**) and sections 27(2) and (3) of the Consumer Protection Act 1987(**b**).

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(**c**).

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Secretary of State that it is expedient for references in these Regulations to the following instruments to be construed as references to those instruments as amended from time to time:

- (a) Article 4.1 of Directive 2014/40/EU(**d**) 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;
- (b) Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises(**e**);
- (c) Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals(**f**);
- (d) Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures(**g**);

(a) 1972 c.68. Section 2(2) was amended by section 27(1)(a) of the Legislative and Regulatory 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.

(b) 1987 c.43.

(c) S.I. 2014/2705.

(d) OJ L 127, 29.4.2014, p.1.

(e) OJ L 124, 20.5.2003, p.36.

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

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

- (e) [Reference to instrument to be adopted under Article 6.1 (priority list of additives) to be inserted]

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Tobacco and Related Products Regulations 2016 and come into force on 20th May 2016.

Interpretation

2.—(1) In these Regulations—

“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 the period beginning with 1st January and ending on 31st December;

“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;

“Classification, Labelling and Packaging Regulation” means Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures^(a);

“consumer” means an individual who is acting for purposes which are outside the individual’s trade, business, craft or profession;

“container pack” has the meaning given to it in regulation 4;

“cross border distance sale” has the meaning given to it in regulation 3;

“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 it is disposable or refillable by means of a refill container and a tank, or rechargeable with single use cartridges), but

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

“emissions” means substances that are released when a tobacco 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;

“importer” has the meaning given to it by regulation 3;

“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;

“manufacture for export” has the meaning given to it by regulation 3;

“medical device” has the meaning given to it by regulation 2 of the Medical Devices Regulations 2002^(b);

“medicinal product” has the meaning given to it by regulation 2 of the Human Medicines Regulations 2012^(c);

“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, water pipe tobacco, a cigar, a cigarillo, chewing tobacco, nasal tobacco or tobacco for oral use, and

(b) is first supplied by the producer after 19 May 2016;

“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;

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

(b) S.I. 2002/618, amended by S.I. 2008/2936; there are other amending instruments but none is relevant.

(c) S.I. 2012/1916, to which there are amendments not relevant to these Regulations.

“pouch” means a unit pack of 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;

“refill container” means a receptacle that—

- (a) contains a nicotine-containing liquid, which can be used to refill an electronic cigarette, but
- (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” means a person who supplies a tobacco or related product to a consumer;

“retail sale” means sale otherwise than to a person who is acting in the course of a business which is part of the tobacco trade;

“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;

“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(a) 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.

‘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 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;

“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—

- (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.

(a) OJ L 127, 29.4.2014, p.1.

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

Meaning of producer and supplier etc.

3.—(1) For the purposes of these Regulations a person produces a tobacco 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 “producer” is to be construed accordingly.

(2) For the purposes of these Regulations a person supplies a tobacco 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) References in these Regulations to an “importer” are to a person who 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, imports a tobacco or related product into the United Kingdom.

(5) For the purposes of these Regulations 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.

(6) 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 an EEA state other than the EEA state or third country where the retailer is established; and for the purposes of this definition a retailer is deemed to be established in an EEA state—

- (a) in the case of a retailer who is an individual, if the individual’s place of business is in that EEA state, and
- (b) 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 EEA state.

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

4.—(1) References in these Regulations to the front and back surfaces of a unit pack or container pack of a tobacco or related product are to the two largest surfaces of the pack (of the surfaces that are visible before the pack is opened).

(2) References in these Regulations to the secondary surfaces of a unit pack or container pack of a tobacco or related product 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).

(3) In these Regulations, a “container pack”, in relation to a tobacco or related product means any packaging in which that product is, or is intended to be, presented for retail sale, and which contains (whether fully or partially enclosing)—

- (a) a unit pack of that product; or
- (b) 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 for the purposes of these Regulations, but a transparent wrapper alone is not a separate container pack.

(4) In these Regulations, a “unit pack”, in relation to a tobacco 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.

PART 2

Labelling of tobacco products

Graphical health warnings on tobacco products for smoking

5.—(1) No person may produce or supply a tobacco product for smoking unless the unit pack and any container pack carries a graphical health warning in accordance with this regulation.

(2) A graphical health warning must consist of one of the graphics contained in the Schedule (graphical health warning library) which has been selected in accordance with regulation 6 (range and rotation of graphical health warnings).

(3) A graphical health warning must appear on the front and back surfaces of the unit pack and any container pack and the same graphic must appear on both surfaces.

(4) A graphical health warning must—

- (a) cover 65% of the area of each surface on which it appears, calculated in relation to the area of the surface concerned when the pack is closed;
- (b) be positioned at the top edge of the surface concerned;
- (c) be positioned in the same direction as any other information on that surface (or if more than one piece of information appears on that surface, the most prominent one);
- (d) be reproduced in accordance with the layout, design and proportions specified in [reference to technical specifications to be set out in instrument to be adopted under article 10 (4) to be inserted]; and
- (e) comply with the conditions set out in regulation 10 (general conditions).

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

- (a) 44mm high, and
- (b) 52mm wide.

(6) In the case of a cylindrical shaped pack, references in this regulation to the front and back surfaces of a unit pack or container pack 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.

Range and rotation of graphical health warnings

6.—(1) A producer of a tobacco product for smoking (other than an importer) must select the graphic referred to in regulation 5(2)—

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

- (b) so that each of the 14 graphics in that 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 graphics contained in Part 1 of the Schedule is specified for the production year 2016-2017 and every third production year thereafter;
 - (b) the set of graphics contained in Part 2 of the Schedule is specified for the production year 2017-2018 and every third production year thereafter;
 - (c) the set of graphics contained in Part 3 of the Schedule 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 20 May and ending with 19 May.

Text health warnings on tobacco products for smoking

7.—(1) No person may produce or supply a tobacco product for smoking unless the unit pack and any container pack carries both of the following text health warnings in accordance with this regulation and regulation 8 (position of text health warning)—

- (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".
- (2) Each text health warning must—
- (a) appear on the surfaces of the unit pack or container pack in the manner specified in regulation 8;
 - (b) cover 50% of the area of each surface on which it appears, 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;
 - (e) appear at the centre of that area; and
 - (f) comply with the conditions set out in regulation 10 (general conditions).

Position of text health warning on tobacco products for smoking

8.—(1) In the case of a unit pack or container pack of cigarettes or hand-rolling tobacco which is cuboid shaped but is not a shoulder box—

- (a) the general warning must appear on one of the secondary surfaces;
- (b) the information message must appear on the other secondary surface; and
- (c) each text health warning must be—
 - (i) positioned at the bottom edge of the surface on which it appears,
 - (ii) at least 20mm wide, and
 - (iii) orientated parallel to the longest edge of that surface.

(2) In the case of a unit pack or container pack which is cuboid shaped with a hinged lid that results in the secondary surfaces being split into two when the pack is opened ("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;
 - (c) the general warning must also appear on the inside of the lid, such that it is visible when the pack is open; and
 - (d) each text health warning must be orientated parallel to the longest edge of the surface on which it appears.
- (3) In the case of a unit pack or container pack of hand-rolling tobacco which is cylindrical shaped, 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.
- (4) In the case of a unit pack or container pack of hand rolling tobacco which is in the form of a pouch—
- (a) [implement technical specifications to be defined by instrument to be adopted under article 9.6 of the Directive]
- (5) In the case of a unit pack or container pack of any other shape—
- (a) the general warning must appear on one of the secondary surfaces, and
 - (b) the information message must appear on the other secondary surface.

Text health warning on smokeless tobacco products

9.—(1) No person may produce or supply a smokeless tobacco product unless the unit pack and any container pack carries a health warning consisting of the text: “This tobacco product damages your health and is addictive”.

- (2) The health warning 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, 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;
 - (e) appear at the centre of that area; and
 - (f) comply with the conditions in regulation 10 (General conditions).
- (3) Where any other text appears on the surface concerned, the health warning must be parallel to that text, or if there is more than one item of text, parallel to the most prominent item.

General conditions applicable to health warnings on tobacco products

10.—(1) The general conditions referred to in regulations 5(4)(e), 7(2)(f) and 9(2)(f) are as follows.

- (2) A health warning must not be commented on, paraphrased or referred to in any form.
- (3) A health warning must be—
- (a) in English;
 - (b) visible;
 - (c) indelible;
 - (d) irremovably printed;
 - (e) printed on the pack, subject to paragraph (6); and
 - (f) surrounded by a black border of a width of 1mm inside the area which is reserved for it.
- (4) A health warning must remain intact when the pack is opened, unless paragraph (7) applies.

(5) 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 tax stamp, price mark, 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.

(6) 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.

(7) In the case of a unit pack with a flip-top lid, a graphical 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, photographs and cessation information.

(8) In this regulation “cessation information” means information informing consumers about programmes to support persons who want to stop smoking.

Labelling on images of tobacco products

11.—(1) No person may publish or cause to be published in the course of business an image targeting consumers in the United Kingdom, of a unit pack or container pack of a tobacco product, unless the image carries health warnings that would be consistent with the requirements of this Part for the lawful supply of that product.

(2) [Exceptions and defences – to be completed following consultation]

PART 3

Emissions and ingredients in tobacco products

Maximum emission levels of cigarettes

12. 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.

Measurement and verification of emission levels

13.—(1) The tar, nicotine and carbon monoxide emissions from cigarettes must be measured in accordance with the standards specified at the first indent of Article 4(1) of the Tobacco Products Directive.

(2) The accuracy of tar, nicotine and carbon monoxide measurements must be determined in accordance with the standard specified at the second indent of Article 4(1) of the Tobacco Products Directive.

(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 the Secretary of State with 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.

14.—(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 certain other additives in tobacco products

15. No person may produce or supply a tobacco product containing—

- (a) vitamins or other additives that create the impression (or would create the impression if the consumer were made aware of their inclusion in the product) 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;
- (d) in the case of tobacco products for smoking, additives that facilitate inhalation or nicotine uptake; or
- (e) additives that, in unburnt form, meet (or contain substances or mixtures which meet) the criteria for classification as a category 1A, 1B or 2 carcinogen, mutagen or reprotoxin in accordance with the criteria in Annex 1 to the Classification, Labelling and Packaging Regulation.

Prohibited additives in tobacco products

16. No person may produce or supply a tobacco product containing additives in quantities that increase, to a significant or measurable degree, the toxicity, addictiveness or carcinogenic, mutagenic or reprotoxic properties of the product when it is consumed.

PART 4

Reporting about tobacco products

Specified information about tobacco products

17.—(1) A producer of a tobacco product must on or before the relevant deadline submit to the Secretary of State the following information relating to the product, by brand and variant name—

- (a) the ingredients information specified in regulation 18; and
- (b) the emissions information specified in regulation 19.

(2) Paragraph (1) also applies to a producer where the composition of a tobacco product is modified in a way that affects the information provided in accordance with that paragraph (“a modified product”).

(3) The relevant deadline—

- (a) in the case of a product which a producer has supplied before 20th May 2016 and continues to supply on or after that date, is 19th November 2016;
 - (b) in any other case, is at least one day before the day a producer first supplies a product, or a 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 deadline reasonably required by the Secretary of State.

Ingredients information

18.—(1) The ingredients information regarding 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) [implement data dictionary as defined by instrument to be adopted under article 5.5 of the Directive];
 - (d) 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^(a);
 - (e) each ingredient's classification under the Classification, Labelling and Packaging Regulation;
 - (f) any available toxicological data regarding each ingredient in appropriate forms, referring in particular to its effects on the health of consumers and taking into account, among other things, any addictive effects; and
 - (g) 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.
- (2) The reference in paragraph (1)(f) to the appropriate forms of an ingredient is a reference—
- (a) in the case of a product intended to be burnt, to the burnt and unburnt forms of the ingredient;
 - (b) in the case of products designed to be heated, to the heated and cold forms of the ingredient;
 - (c) in any other case, to the form in which the product is intended to be used and the form in which it is intended to be sold.

Emissions information

19. The emissions information referred to in regulation 17(1) is—

- (a) in the case of cigarettes—
 - (i) the tar, nicotine and carbon monoxide emission levels (“TNCO emissions”) by brand and variant name, measured in compliance with regulation 13(1) and (2) (measurement of emission levels);
 - (ii) the emission levels of substances other than TNCO (“non-TNCO emissions”), insofar as the information is available to the producer, by brand and variant name.

^(a) OJ No L 396, 30.12.2006, p.1.

- (b) in the case of tobacco products other than cigarettes, and insofar as the information is available to the producer, the TNCO and non-TNCO emissions by brand and variant name; and
- (c) for the levels referred to in paragraphs (a)(ii) and (b), the methods of measurement used.

Sales data and market research information

20.—(1) A producer of a tobacco product must submit the following information to the Secretary of State in accordance with paragraphs (2) to (5)—

- (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 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) is to be made on or before 20 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) Insofar as the information is available to the producer—

- (a) sales volume data relating to sales conducted during the calendar year 2015, and any market research data and market surveys relating to the same period, must be submitted on or before 19th November 2016; and
- (b) sales volume data relating to sales conducted during the period beginning with 1st January 2016 and ending with 19th May 2016, and any market research data and market surveys relating to the same period, must be submitted on or before 20th May 2017.

Enhanced reporting obligation for priority additives

21.—(1) A producer of cigarettes or hand rolling tobacco which contain an additive listed in [reference to priority list to be adopted under article 6.1 of the Directive to be inserted] ("the priority list") must—

- (a) carry out the study specified in regulation 22 in respect of that additive; and
- (b) on or before the relevant deadline, submit a report on the result of the study to the Secretary of State and to the European Commission.

(2) The report must include—

- (a) an executive summary;
- (b) a comprehensive overview—
 - (i) compiling the available scientific literature on the additive concerned, and
 - (ii) summarising the data, whether published or not, which is available to the producer on the effects of that additive; and
- (c) such supplementary information regarding the additive as the European Commission or the Secretary of State may request.

(3) The relevant deadline is—

- (a) 20th November 2017 where paragraph (1) applies to a producer on the day these Regulations come into force; or
 - (b) in any other case, the end of the day 18 months after the day paragraph (1) first applies to a producer.
- (4) This regulation does not apply to a person who produces cigarettes or hand rolling tobacco containing an additive which is included in the priority list where—
- (a) the person is a small or medium sized enterprise as defined in the Annex to Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises^(a); and
 - (b) the additive concerned is the subject of a report which has been submitted to the Secretary of State by another producer.

Research study into priority additives

22.—(1) The study referred to in regulation 21(1)(a) is a comprehensive study which examines whether an additive—

- (a) contributes to the toxicity or addictiveness of the product concerned, and whether this has the effect of increasing the toxicity or addictiveness of the product to a significant or measurable degree;
 - (b) results in a characterising flavour;
 - (c) facilitates inhalation or nicotine uptake;
 - (d) leads to the formation of substances that meet the criteria for classification as a category 1A, 1B or 2 carcinogen, mutagen or reprotoxin in accordance with the criteria in Annex 1 to the Classification, Labelling and Packaging Regulation, and if so—
 - (i) in what quantities, and
 - (ii) whether this has the effect of increasing the carcinogenic, mutagenic or reprotoxic properties of the product concerned to a significant or measurable degree.
- (2) The study must also—
- (a) take into account the intended use of the product concerned;
 - (b) examine in particular the emissions resulting from the combustion process involving the additive concerned; and
 - (c) examine the interaction of that additive with other ingredients contained in the product concerned.
- (3) Two or more producers who use the same additive in their products, in a comparable product composition, may carry out a joint study.

Publication and trade secrets

23.—(1) A person who submits information under regulations 17 (Ingredients and emissions information), 20 (Sales data etc) or 21 (Enhanced reporting obligation) must specify the information which that person considers to constitute a trade secret.

(2) The Secretary of State must ensure that the information submitted in accordance with regulations 17, 20 or 21 is made publicly available on a website, except where this would be incompatible with the duty in paragraph (3).

(3) The Secretary of State when exercising functions under this regulation and regulation 24(2) must take the need to protect trade secrets duly into account.

(a) OJ L 124, 20.5.2003, p.36 (in which enterprise categories are determined by staff headcount and financial ceilings).

Electronic Format

24.—(1) Information submitted to the Secretary of State under regulations 17, 20 or 21 must be submitted—

- (a) in electronic form; and
- (b) in accordance with [implement technical specifications to be defined by instrument to be adopted under article 5.5 of the Directive].

(2) The Secretary of State must—

- (a) store the information electronically; and
- (b) ensure that the Commission and the competent authorities of other EEA States have access to that information for the purposes of applying the Tobacco Products Directive, but not in a case which would be incompatible with the duty in regulation 23(3).

Notification of novel tobacco products

25.—(1) A producer who intends to supply a novel tobacco product must comply with paragraphs (2) to (10).

(2) A producer must notify the Secretary of State of the producer's intention to supply a novel tobacco product.

(3) 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 18;
- (d) the emissions information specified in regulation 19;
- (e) studies or research on the matters specified in paragraph (5);
- (f) any available studies or research on—
 - (i) the preferences of consumer groups, including young people and current smokers, in respect of the product, and
 - (ii) the risks and benefits of the product; and
- (g) any other available information relating to the product that is relevant to an understanding of its use and effects.

(4) The detailed description required by paragraph (3)(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.

(5) For the purpose of paragraph (3)(e) studies or research on the following matters are specified—

- (a) the toxicity of the product, its ingredients and emissions;
- (b) the addictiveness of the product, its ingredients and emissions;
- (c) the expected effects of the product on the cessation of tobacco consumption by existing users of tobacco products; and
- (d) the perception of the product by consumers or potential consumers (or predictions as to how the product will be perceived), including the attractiveness of the product.

(6) Notification under paragraph (2) must be given at least six months before the date on which a producer intends to supply the product concerned, unless paragraph (7) applies.

(7) This paragraph applies where the intended supply is to commence during the period beginning with 20th May 2016 and ending with 19 November 2016.

(8) Where paragraph (7) applies, notification under paragraph (2) must be given on 20th May 2016.

(9) 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 paragraphs (3)(f) and (5).

(10) Information provided to the Secretary of State under this regulation must be provided in electronic form.

No supply of tobacco product where reporting obligation not complied with

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

PART 5

Herbal products for smoking

Labelling and presentation of herbal products for smoking

27.—(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 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 others,
 - (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

28.—(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, set out in descending order by weight, on or before the relevant deadline.

(2) Paragraph (1) also applies where the composition of a herbal product for smoking is modified in a way that would affect the information required by that paragraph (“a modified herbal product for smoking”).

(3) The relevant deadline—

- (a) in the case of a herbal product for smoking which a producer supplies on the day these Regulations come into force, is 19th November 2016;
- (b) in any other case, is at least one day before the day a producer first supplies a herbal product for smoking, or first supplies a modified herbal product for smoking.

Herbal products for smoking - supplementary

29.—(1) Regulations 23 (publication and trade secrets) and 24 (electronic format) apply in relation to information provided in accordance with regulation 28 (ingredients information for herbal products for smoking) as they apply in relation to information provided in accordance with regulations 17, 20 or 21.

(2) A producer who fails to submit the information required by regulation 28 by the relevant deadline in respect of a herbal product for smoking, may not supply the product concerned until the producer submits the required information.

PART 6

Electronic cigarettes

Notification of new products

30.—(1) A producer must notify the Secretary of State in accordance with paragraphs (2) and (3) if the producer intends to supply electronic cigarettes or refill containers.

(2) The notification must be submitted—

- (a) at least 6 months before the intended supply commences, unless paragraph (4) applies; and
- (b) in electronic form;
- (c) [Implement reporting format for e-cigarettes under article 20.13 of the Directive.]

(3) The notification must contain the following information (insofar as relevant to the product being notified)—

- (a) the name and contact details of the person who manufactures the product, the importer (if applicable) and, if neither is based in the EEA, a responsible person within the EEA;
- (b) a list of all ingredients contained in, and emissions resulting from the use of, the product by brand name and variant, 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) This paragraph applies where the intended supply is to commence during the period beginning with 20th May 2016 and ending with 19th November 2016.

(5) Where paragraph (4) applies, notification under paragraph (1) must be given on 20th May 2016.

Notification of existing products

31.—(1) A producer must notify the Secretary of State in accordance with paragraphs (2) and (3) of any electronic cigarettes or refill containers that the producer has supplied before 20th May 2016 and continues to supply on or after that date.

(2) The notification must be submitted—

- (a) on or before 20th November 2016; and
- (b) in electronic form.

(3) The notification must contain the information set out in regulation 30(3).

Notification of substantial modification of a product

32.—(1) The producer of a product that has been notified under regulation 30 or 31 must notify the Secretary of State in accordance with paragraph (2) of any substantial modification made to that product.

(2) The notification must be submitted—

- (a) before the modified product is supplied; and
- (b) in electronic form.

Secretary of State power to request completion of information in notification

33.—(1) This regulation applies where the Secretary of State considers that the information submitted in a notification made under regulation 30, 31 or 32 is incomplete.

(2) The Secretary of State may request the producer who submitted the notification to provide the complete information.

(3) A producer must comply immediately with a request made of it under paragraph (2).

No supply of product where notification not complied with

34. A producer who fails to submit the information required by any provision of regulation 30, 31 or 32 by the relevant deadline in respect of any electronic cigarettes or refill containers may not supply those electronic cigarettes or refill containers until the producer submits the required information.

Secretary of State duty to publish notifications

35.—(1) The Secretary of State must make information submitted in accordance with regulations 30 to 33 publicly available on a website, except where to do so would be incompatible with paragraph (2).

- (2) The Secretary of State must take the need to protect trade secrets duly into account.

Product requirements

36.—(1) No person may produce or supply an electronic cigarette or a refill container which contains a nicotine-containing liquid unless it complies with paragraphs (2) to (11).

(2) The nicotine-containing liquid must be in—

- (a) a dedicated refill container not exceeding a volume of 10 millilitres;
- (b) a disposable electronic cigarette; or
- (c) a single use cartridge where the cartridge or tank does not exceed a volume of 2 millilitres.

(3) The nicotine-containing liquid may not contain nicotine in excess of 20 milligrams per millilitre.

(4) The nicotine-containing liquid may not contain additives listed in regulation 15 (no vitamins, colourings or certain other additives in tobacco products).

(5) The nicotine-containing liquid must be manufactured using only ingredients of high purity.

(6) Substances other than the ingredients notified under regulation 30, 31 or 32 (as applicable) may not be present in the nicotine-containing liquid unless present in trace levels, where such trace levels are technically unavoidable during manufacture.

(7) With the exception of nicotine, the ingredients used in the nicotine-containing liquid may not pose a risk to human health in heated or unheated form.

(8) In the case of e-cigarettes, the dose of nicotine must be delivered at consistent levels under normal conditions of use.

(9) The product packaging must be child-resistant and tamper-evident.

(10) The product must be protected against breakage and leakage.

(11) With the exception of disposable e-cigarettes, the product must have a mechanism for ensuring re-filling without leakage.

(12) For the purposes of this regulation, product packaging 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 packaging has been opened.

Information 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 the EEA, a contact person within the EEA.

(3) Each unit packet and any container pack of the electronic cigarette or refill container 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 of the electronic cigarette or refill container must carry a health warning consisting of the text: “This product contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers”, in a manner which conforms with paragraph (5).

(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) Where other text appears on the surface concerned, the health warning must be parallel to that text, or if there is more than one piece of text, the most prominent text.

Product presentation requirement

38.—(1) No person may produce or supply an electronic cigarette or refill container unless it complies with paragraph (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 e-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 e-cigarette or refill container—
 - (i) is less harmful than others,
 - (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 e-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.

Annual reporting requirement

39.—(1) A producer of electronic cigarettes or refill containers must submit to the Secretary of State in accordance with paragraph (2) to (4)—

- (a) comprehensive data on the producer’s sales volumes in the United Kingdom, by brand and variant name;

- (b) information available to the producer on the preferences of consumer groups in the United Kingdom, including young people, non-smokers and the main types of current users;
- (c) the mode of sale of the producer's products in the United Kingdom; and
- (d) executive summaries of any market surveys carried out by the producer in respect of paragraphs (a) to (c).

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

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

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

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

Vigilance requirements

40.—(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 EEA 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 EEA 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 immediately with a request made of it under paragraph (5).

Action to protect human health

41.—(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; and
- (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) Any producer or supplier of a product that is the subject of a provisional measure must comply with the measure insofar as it applies to that producer or supplier.

PART 7

Distance sales to consumers

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

42.—(1) In this regulation a “relevant product” is a tobacco product, an electronic cigarette or a refill container.

(2) 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 EEA State; and
- (b) a retailer who is established other 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.

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

- (a) the information specified in paragraph (4);
- (b) the additional information specified in paragraph (5) or (6), as appropriate; and
- (c) such other information as the Secretary of State may reasonably require.

(4) The information referred to in paragraph (3) is—

- (a) the retailer’s name or company name;
- (b) the retailer’s trading name, if different;
- (c) the address of the retailer’s principal place of business;
- (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;
- (f) a description of the details and functioning of the age verification system operated by the retailer in accordance with paragraph (8)(c);

(5) A retailer who falls within paragraph (2)(a) must also submit—

- (a) confirmation of registration provided by the competent authority of any EEA State in which the retailer is registered to supply products via a cross border distance sale to a consumer located in that EEA State; and
- (b) the name of any other EEA state to which the retailer has applied, or is in the course of applying, for registration.

(6) A retailer who falls within paragraph (2)(b) must also provide the name of an individual who is responsible for verifying (before the product is supplied to the consumer) that a relevant product complies with the provisions of these Regulations that are relevant to that product.

(7) The Secretary of State must—

- (a) provide confirmation of registration to a retailer who complies with paragraph (3);
 - (b) publish a list of retailers registered with the Secretary of State.
- (8) 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 EEA 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 EEA State in which the consumer is located.
- (9) A retailer must not supply a relevant product via a cross-border distance sale to a consumer located in an EEA State in which cross border distances sales are prohibited in accordance with Article 18(1) of the Tobacco Products Directive.
- (10) In this regulation—
- “age verification system” means a computing system that unambiguously confirms the consumer’s age electronically; and
- “confirmation of registration” means written confirmation provided by the competent authority of any EEA State in accordance with the requirements in that EEA State which implement Article 18 of the Tobacco Products Directive.

PART 8

Penalties and enforcement

Offences

43. A person is guilty of an offence if that person—
- (a) publishes an image in breach of regulation 11 (labelling on images of tobacco products);
 - (b) fails to provide samples in accordance with regulation 13(4) (measurement and verification of emission levels);
 - (c) produces or supplies a tobacco product, or manufactures a tobacco product for export, in breach of a provision of Part 2 (labelling), Part 3 (emissions and ingredients) or regulation 26 (no supply of products where reporting obligations not complied with);
 - (d) fails to submit information to the Secretary of State in accordance with a provision of Part 4 (reporting about tobacco products) or regulation 28 (ingredients information for herbal products for smoking);
 - (e) produces or supplies a herbal product for smoking in breach of regulation 27 (labelling and presentation of herbal products for smoking) or regulation 29(2)(no supply where reporting obligation not complied with);
 - (f) breaches any provision of Part 6 (electronic cigarettes) with the exception of regulations 35 (Secretary of State duty to publish notifications) and 39(5) (annual reporting requirement); or
 - (g) supplies a product in breach of regulation 42 (cross border distance sales of tobacco products and electronic cigarettes etc).

False and misleading information

44.—(1) Any person who provides a relevant person with information pursuant to an obligation in these Regulations which is false or misleading in a material particular is guilty of an offence.

- (2) For the purpose of this regulation, a “relevant person” means—

- (a) the Secretary of State; or
- (b) the competent authority of any EEA State.

Defences

45.—(1) In any proceedings for an offence under these Regulations brought against a person who supplies any tobacco 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 under regulation 44 against an importer, it is a defence that the importer exercised all due diligence to avoid committing the offence.

(3) A defendant may not, without permission of the court, rely on the defence provided by paragraph (1) or (2) by reason 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 (4).

(4) That notice is notice 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.

(5) 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

46. 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 or 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

47.—(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

48.—(1) For the purpose of enforcement, the provisions of the Consumer Protection Act 1987(a) (“the 1987 Act”), except for sections 12 and 13, are to apply to these Regulations as if these Regulations were safety regulations within the meaning of that Act.

(2) 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 as a reference to three months.

(3) The enforcement duty 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 13(4) (measurements and verifications of emission levels);
- (b) Part 4 (Reporting), except for regulation 24;
- (c) regulation 28 (ingredients information for herbal products for smoking);
- (d) regulations 30 to 33 (notification provisions for electronic cigarettes); and
- (e) regulation 39 (annual reporting for electronic cigarettes).

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

- (a) regulation 26 (no supply of products where reporting obligations not complied with);
- (b) regulation 29(2) (herbal products for smoking);
- (c) regulation 34 (no supply of product where notification not complied with); and
- (d) regulation 41(4) (action to protect public health).

(5) The Secretary of State may direct, in relation to cases of a particular description or a particular case, that the enforcement duty imposed on a local weights and measures authority in Great Britain or a district council in Northern Ireland is to be discharged instead by the Secretary of State or by the appropriate Minister.

(6) 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; and

“enforcement duty” means the duty imposed by section 27(1) of the 1987 Act, as that duty has effect by virtue of paragraph (1) in relation to these Regulations.

PART 9

Miscellaneous provisions

Revocation

49. The following regulations are revoked (although see regulation 50(2)(savings and transitional provisions))—

- (a) The Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002(a); and

(a) 1987 c.43.

- (b) The Tobacco Products (Manufacture, Presentation and Sale) (Safety) (Amendment) Regulations 2007^(b).

Savings and transitional provisions

50.—(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;
- (b) the supply takes place before 20th May 2017; and
- (c) the product complies with the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 at the time of supply.

(2) For the purposes of paragraph (1)(c) the Regulations referred to in regulation 49 continue to apply as if they had not been revoked.

(3) The provisions of regulation 14 (flavourings etc) do not apply to menthol cigarettes until 20th May 2020.

(4) The provisions of regulation 27 (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; 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 supply of an electronic cigarette or a refill container where—

- (a) the product was produced before 20th November 2016; and
- (b) the supply takes place before 20th May 2017.

Review

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

- (a) carry out a review of these Regulations;
- (b) set out the conclusions of the review in a report; and
- (c) publish the report.

(2) In carrying out the review, the Secretary of State must, so far as is reasonable, have regard to how the Tobacco Products Directive (which is implemented in part by these Regulations) is implemented in other states.

(3) The report must in particular—

- (a) set out the objectives intended to be achieved by the regulatory system established by these Regulations;
- (b) assess the extent to which those objectives are achieved; and
- (c) assess whether those objectives remain appropriate and, if so, the extent to which they could be achieved with a system that imposes less regulation.

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

(5) Reports under this regulation are afterwards to be published at intervals not exceeding five years.

(a) S.I. 2002/3041.

(b) S.I. 2007/2473.

PART 10

Amendment of other legislation

Tobacco for oral use - Amendment of the Tobacco for Oral Use (Safety) Regulations 1992

52. In regulation 1(2)(a) of the Tobacco for Oral Use (Safety) Regulations 1992(a) for “smoked” substitute “inhaled”.

Signed by authority of the Secretary of State for Health

[Date]

Name
Parliamentary Secretary
Department of Health

SCHEDULE

regulation 5 and 6

Graphical health warning library

PART 1



(a) S.I. 1992/3134.



PART 2





PART 3



