STATUTORY INSTRUMENTS

# 2016 No. 507

# CONSUMER PROTECTION

## The Tobacco and Related Products Regulations 2016

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| *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 [F1].

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 [F2].

**F1** 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.

**F2** S.I. 2014/2705.

## 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.

**[F3Extent**

**1A.**—(1) Subject to the following paragraphs, these Regulations extend to England and Wales, Scotland and Northern Ireland.

(2) The following provisions do not extend to Northern Ireland—

(a) regulation 5A;

(b) regulation 7(5);

(c) regulation 8(10);

(d) regulation 9(12);

(e) regulation 10(5);

(f) regulation 13(3);

(g) regulation 14(5) and (6);

(h) regulation 15(3);

(i) regulation 16(4);

(j) regulation 16A;

(k) regulation 20A(6) and (7);

(l) regulation 36(11);

(m) regulation 37(10);

(n) Part 9A;

(o) regulations 54ZA and 54ZB.

(3) The following provisions extend only to Northern Ireland—

(a) regulation 41(3) to (5);

(b) regulation 44;

(d) regulation 47.

(4) An amendment made by these Regulations has the same extent as the provision to which it relates**]**

**F3** Reg. 1A inserted by S.I. 2019/41, **reg. 6(1A)** (as inserted by The Tobacco Products and Nicotine Inhaling Products (Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1316), regs. 1(3), **3(3)** (with reg. 5))

## Interpretation

**2.**—(1) In these Regulations—

"the 2002 Regulations" means the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 [F4];

"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;

**[**[F5]"CAS Registry number" means the number assigned to a substance by the Chemical Abstracts Service;**]**

"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;

**[**[F6]"GB related product" means a related product which is produced for supply, or is supplied, for consumption in Great Britain or through the GB travel retail sector;

"GB tobacco product" means a tobacco product which is produced for supply, or is supplied, for consumption in Great Britain or through the GB travel retail sector;

"the GB travel retail sector" means retail outlets in Great Britain at which tobacco products or related products may be purchased only by people travelling on journeys to destinations outside Great Britain;**]**

"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 [F7];

"medicinal product" has the meaning given to it by regulation 2 of the Human Medicines Regulations 2012 [F8];

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

**[**[F9]"NI related product" means a related product which is produced for supply, or is supplied, for consumption in Northern Ireland or through the NI travel retail sector;

"NI tobacco product" means a tobacco product which is produced for supply, or is supplied, for consumption in Northern Ireland or through the NI travel retail sector;

"the NI travel retail sector" means retail outlets in Northern Ireland at which tobacco products or related products may be purchased only by people travelling on journeys to destinations outside Northern Ireland;**]**

"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;

"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;

**[**[F10]"retailer" means a person who sells, or offers or agrees to sell, a tobacco product or related product to a consumer;**]**

"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 [F11];

"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;

**[**[F12]"travel retail sector" means—

(a) the GB travel retail sector, or

(b) the NI travel retail sector.**]**

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