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## 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

*Status: This is the original version (as it was originally made).*

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](http://www.legislation.gov.uk) website. Copies of the International Standards referred to in this instrument are available for purchase on line from [bsigroup.com](http://bsigroup.com) or by post from BSI Customer Services, 389 Chiswick High Road, London W4 4AL.