

Transposition Note

Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 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 and repealing Directive 2001/37/EC

1. This transposition note has been prepared by the Department of Health and is intended to explain how Directive 2014/40/EU (“the Directive”) is implemented in the UK.
2. The Directive is transposed by the Tobacco and Related Products Regulations 2016 (“the Tobacco Products Regulations 2016”), other than Articles 6, 13 to 16, one element of article 9.3 and certain elements of article 20.5. Articles 13, 14 and one element of article 9.3 are implemented by the Standardised Packaging of Tobacco Products Regulations (S.I. 2015/829)¹. Certain elements of article 20.5 are implemented by the UK Code of Broadcast Advertising² and the OFCOM Broadcasting Code³. The final indent of article 20.2 is implemented by the Electronic Cigarettes etc. (Fees) Regulations 2016.
3. The Tobacco Products Regulations 2016 also revoke Tobacco for Oral Use (Safety) Regulations 1992 (SI 1992/3134) and the Tobacco Products (Manufacture, Presentation and Sale) (Safety) Regulations 2002 (SI 2002/3041), which implemented Directive 2001/37/EC, the precursor to the Tobacco Products Directive 2014.
4. The delegated and implementing acts which have been adopted under the Directive at the time of writing are implemented as set out at Table 2.

Table 1

Article	Objective of the Article	Implementation
		References are to the Tobacco Products Regulations 2016 unless otherwise stated.
1	Subject matter	No transposition needed.
2	Definitions	Regulations 2, 3 and 4
3	Maximum emission levels from cigarettes	Article 3.1 is transposed by regulation 13. Articles 3.2 to 3.5 do not require transposition.
4	Measurement methods for emissions	Articles 4.1 and 4.2 are transposed by regulation 14. Articles 4.3 to 4.5 do not require transposition. Article 4.6 is optional and is not yet transposed.
5	Reporting of ingredients and emissions	Article 5 is transposed by regulations 18 to 21, 25 and 26, subject to the following:

¹ http://www.legislation.gov.uk/ukxi/2015/829/pdfs/ukxi_20150829_en.pdf

² <https://www.cap.org.uk/Advertising-Codes/Broadcast.aspx>

³ <http://stakeholders.ofcom.org.uk/broadcasting/broadcast-codes/broadcast-code/>

		<p>Article 5.5 does not require transposition.</p> <p>Article 5.8 is optional and is not yet transposed.</p>
6	Priority list of additives and enhanced reporting	Article 6 will be transposed when the Commission adopts the implementing act laying down a list of priority additives under Article 6.1.
7	Regulation of ingredients	<p>Article 7 is transposed by regulations 15 and 16, subject to the following:</p> <p>Articles 7.2 to 7.5, 7.8, 7.10 and 7.11 do not require transposition.</p> <p>Article 7.13 is optional and is not yet transposed.</p> <p>Article 7.14 is transposed by regulation 56(3).</p> <p>Article 7.15 does not require transposition in the UK because such tobacco is prohibited.</p>
8	Labelling – general provisions	<p>Article 8.1 to 8.6 is transposed by regulation 11.</p> <p>Article 8.7 does not require transposition.</p> <p>Article 8.8 is transposed by regulation 12.</p>
9	General warnings and information messages on tobacco products for smoking	<p>Article 9 is transposed by regulations 7 and 8, subject to the following:</p> <p>Article 9.3, third indent (minimum height of shoulder box) is transposed by regulation 4(7) of the Standardised Packaging of Tobacco Products Regulations (S.I. 2015/829)</p> <p>Article 9.5 and 9.6 do not require transposition.</p>
10	Combined health warnings	<p>Article 10 is transposed by regulations 5 and 6, subject to the following.</p> <p>The optional exemption at Article 10.1(e) is not required in the UK.</p> <p>Articles 10.3 and 10.4 do not require transposition.</p>
11	Labelling of other tobacco products	The option is taken up at regulation 9, in relation to certain tobacco products.
12	Labelling of smokeless tobacco products	Regulation 10.
13	Product presentation	Regulation 10 of the Standardised Packaging of Tobacco Products Regulations (S.I. 2015/829).
14	Appearance of packs	Regulations 4 and 8 of the Standardised

		Packaging of Tobacco Products Regulations (S.I. 2015/829).
15	Traceability	Not yet transposed.
16	Security feature	Not yet transposed.
17	Prohibition of tobacco for oral use	Regulation 17.
18	Cross border distance sales	Article 18 is transposed by regulation 47, subject to the following: The UK has not taken up the option at Article 18.1 to prohibit cross border distance sales. Article 18.5 does not require transposition.
19	Notification of novel tobacco products	Article 19.1 and 19.2 are transposed by regulations 22 to 24. The UK has not taken up the option at Article 19.3 to introduce an authorisation system. Article 19.4 does not require specific transposition for it to have effect.
20	Regulation of electronic cigarettes	Article 20.1 is transposed by Part 6 and by the definitions of electronic cigarette and refill container in regulation 2.
20.2	Notifications	Regulation 31 and 33(2)(a). The final indent (fees) is transposed in the Electronic Cigarettes etc. (Fees) Regulations 2016.
20.2	Product requirements	Regulation 36.
20.4	Information leaflet, product labelling and presentation.	Regulations 37 and 38.
20.5	Advertising	Article 20.5(a) (cross border printed media) is transposed by regulation 42, in accordance with case law C-380/03. Article 20.5(a) (information society services) is transposed by regulation 43. Regulation 43(2) to (4), (6) and Schedule 2 implement Article 3 and 12 to 14 of Directive 2000/31/EC (the E-Commerce Directive) in relation to electronic cigarette advertising. Article 20.5(b) and (c) (radio) are transposed by means of amendments UK Code of Broadcast Advertising and the OFCOM Broadcasting Code. OFCOM is required by section 319 of the Communications Act 2003 ("CA2003") to set a standards code for the content of television and radio and to secure that the UK's international

		<p>obligations with respect to advertising on television and radio are complied with. Under section 325 of CA2003, holders of a broadcasting licence are required to comply with the standards codes. If a licence holder breaches a code rule, OFCOM has statutory enforcement powers including a power to impose a fine and to revoke a licence. The Secretary of State has directed OFCOM under section 321(6) of CA2003 to amend the UK Code of Broadcast Advertising to prohibit electronic cigarette advertising on television and radio, by means of a new paragraph inserted at Rule 10.1 (Prohibited Categories), and consequential changes. The Secretary of State has directed OFCOM under section 321(6) of CA2003 to amend the OFCOM Broadcasting Code to prohibit electronic cigarette sponsorship of radio and television programmes, by means of a new rule inserted within sections 9 and 10 and consequential changes.</p> <p>Article 20(5)(d) (sponsorship) is transposed by regulation 44.</p> <p>Article 20(5)(e) (TV) requires the UK to prohibit audiovisual commercial communications for electronic cigarettes and refill containers which are defined by reference to Directive 2010/13/EU and as such include television advertising, sponsorship and product placement, in both on-demand and broadcast television.</p> <p>Article 20(5)(e) is implemented in relation to on-demand television by regulation 46 which amends part 4A of the CA2003.</p> <p>Article 20(5)(e) is implemented in relation to broadcast television product placement by regulation 45, which amends Schedule 11A to the CA2003. Article 20(5)(e) is implemented in relation to broadcast television advertising and sponsorship by amendments to the UK Code of Broadcast Advertising and OFCOM Broadcasting Code. See above re 20.5(b) and (c).</p>
20.6	Cross border distance sales	<p>Regulation 47.</p> <p>The UK has not taken up the option at Article 18.1 to prohibit cross border distance sales.</p>
20.7	Annual report of sales	Regulation 32.
20.8	Publication	Regulation 34.
20.9	Vigilance	Regulation 39.
20.10	Commission report	Does not require transposition.

20.11	Measures to protect human health	Regulation 40.
20.12 20.13	Delegated and implementing powers	Does not require transposition.
21	Herbal products for smoking	Regulation 28.
22	Reporting of ingredients of herbal products for smoking	Regulation 29 and 30.
23	Cooperation and enforcement	Article 23.1 is transposed by regulation 3(1)(“producer”), Part 4, regulation 29 and 31. Article 23.2 (first sentence) is transposed by Part 2, Part 3, Part 5, Part 6. Article 23.3(second sentence) is transposed by regulations 27, 30(2) and 35. Article 23.3 (penalties) is transposed by Part 9.
24	Free movement	Does not require transposition.
25	Committee procedure for implementing acts	Does not require transposition.
26	Designation of competent authorities	Does not require transposition.
27	Procedure for the adoption of delegated acts by the Commission	Does not require transposition.
28	Commission to report on the application of the Directive	Does not require transposition.
29	Transposition	Article 29.1 is transposed by the Regulations as a whole, in particular, regulation 1. The remaining provisions do not require transposition.
30	Transitional provisions	Regulation 56.
31 Repeal	Repeal of Directive 2001/37/EU.	Regulation 54 revokes the UK regulations which transpose Directive 2011/37/EU.
32	Entry into force	Does not require transposition
33	Addressees	Does not require transposition

Table 2

Delegated Act	Powers	Purpose	Implementation
Delegated Directive 2014/109/EU	Article 10.3(b)	Amending Annex II to the Tobacco Products Directive by establishing the library of picture warnings to be used on tobacco products.	Regulation 5(3)(a).
Implementing Decision 2015/1735/EU	Article 9.6	On the precise position of the general warning and the information message on roll-your-own tobacco/Hand-rolling tobacco marketed in pouches.	Regulation 8(5) to (8).

Implementing Decision 2015/1842/EU	Article 10.4	On the technical specifications for the layout, design and shape of the combined health warnings for tobacco products for smoking.	Regulation 5(6) to (7).
Implementing Decision 2015/2183/EU	Article 20.13	Establishing a common format for the notification of electronic cigarettes and refill containers.	Regulation 33(2)(b)to(d)
Implementing Decision 2015/2186/EU	Article 5.5	Establishing a format for the submission and making available of information on tobacco products.	Regulation 25(2)(b) to(d) and (3)
Implementing Decision 2016/586/EU	Article 20.13	On technical standards for the refill mechanism of electronic cigarettes	Regulation 36 (8) and (10) and Regulation 37(8)