



STATUTORY INSTRUMENTS.

S.I. No. 252 of 2017



EUROPEAN UNION (MANUFACTURE, PRESENTATION AND SALE
OF TOBACCO AND RELATED PRODUCTS) (AMENDMENT)
REGULATIONS 2017

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I, SIMON HARRIS, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving further effect to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014¹ 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, and giving effect to Commission Implementing Regulation (EU) 2016/779 of 18 May 2016² laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour, Commission Implementing Decision (EU) 2016/786 of 18 May 2016³, laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour, and Commission Implementing Decision (EU) 2016/787 of 18 May 2016⁴ laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations hereby make the following regulations:

1. These Regulations may be cited as the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) (Amendment) Regulations 2017.

2. In these Regulations, “Principal Regulations” means the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016).

3. Regulation 2 of the Principal Regulations is amended, in paragraph (1)—

(a) by the substitution of the following definition for the definition of “Directive”—

“ ‘Directive’ means Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014¹ 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 as amended by Commission Delegated Directive 2014/109/EU of 10 October 2014⁵ amending Annex II

¹OJ No. L 127, 29.04.2014, p. 1 as affected by Corrigendum (OJ No. L 150, 17.6.2015, p. 24)

²OJ No. L 131, 20.05.2016, p. 48

³OJ No. L 131, 20.05.2016, p. 79

⁴OJ No. L 131, 20.05.2016, p. 88

⁵OJ No. L 360, 17.12.2014, p. 22

*Notice of the making of this Statutory Instrument was published in
“Iris Oifigiúil” of 16th June, 2017.*

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 2015⁶ 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 2015⁷ 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 2015⁸ establishing a common format for the notification of electronic cigarettes and refill containers, Commission Implementing Decision (EU) 2015/2186 of 25 November 2015⁹ establishing a format for the submission and making available of information on tobacco products, Commission Implementing Decision (EU) 2016/586 of 14 April 2016¹⁰ on technical standards for the refill mechanism of electronic cigarettes, Commission Implementing Regulation (EU) 2016/779 of 18 May 2016² laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour, Commission Implementing Decision (EU) 2016/786 of 18 May 2016³ laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour and Commission Implementing Decision (EU) 2016/787 of 18 May 2016⁴ laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations;”,

- (b) by the substitution of the following definition for the definition of “retailer”:

“ ‘retailer’ means a person who carries on, in whole or in part, the business of selling a tobacco product, an electronic cigarette or a refill container by retail;”, and

- (c) by the insertion of the following definitions:

“ ‘advisory panel’ means the independent advisory panel established pursuant to Commission Implementing Decision (EU) 2016/786;

‘Commission Implementing Decision (EU) 2016/786’ means Commission Implementing Decision (EU) 2016/786 of 18 May 2016³ laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour;

⁶OJ No. L 252, 29.09.2015, p. 49

⁷OJ No. L 267, 14.10.2015, p. 5

⁸OJ No. L 309, 26.11.2015, p. 15

⁹OJ No. L 312, 27.11.2015, p. 5

¹⁰OJ No. L 101, 16.04.2016, p. 15

‘Commission Implementing Regulation (EU) 2016/779’ means Commission Implementing Regulation (EU) 2016/779 of 18 May 2016² laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour;

‘priority list of additives’ means the priority list of additives laid out in the Annex to Commission Implementing Decision (EU) 2016/787 of 18 May 2016⁴ laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting conditions;

‘same product’ means products with the same ingredients in the same proportions in the tobacco blend composition, irrespective of the brand name or design;”.

4. Regulation 5 of the Principal Regulations is amended—

- (a) in paragraph (7), by the substitution of “and Regulation 6(1)(a), in respect of a new or modified tobacco product, shall be provided not less than one day prior to placing the new or modified tobacco product on the market” for “and Regulation 6, in respect of a new or modified tobacco product, shall be provided not later than 3 months prior to placing the tobacco product on the market”, and
- (b) in paragraph (8), by the substitution of “under this Regulation, a manufacturer or importer shall notify in electronic form the Executive not less than one day prior to placing the new or modified tobacco product on the market” for “under this Regulation or Regulation 6, a manufacturer or importer shall notify in electronic form the Executive within one month of when the modified product was manufactured”.

5. Regulation 7 of the Principal Regulations is amended—

- (a) in paragraph (5), by the substitution of “Subject to paragraph (5A), a manufacturer” for “A manufacturer”, and
- (b) by the insertion of the following paragraph after paragraph (5):

“(5A) Notwithstanding paragraph (5), a manufacturer or importer shall submit the first report referred to in paragraph (4) on or before 1 July 2018.”.

6. The Principal Regulations are amended by the insertion of the following Regulations after Regulation 8:

“Procedure for determining whether a tobacco product has a characterising flavour

8A. (1) Where the Executive considers that a tobacco product may have a characterising flavour:

- (a) it may initiate the procedure for determining whether the tobacco product has a characterising flavour;

(b) it may request the Commission to initiate such a procedure.

(2) Where the Executive initiates the procedure under paragraph (1), it shall inform the manufacturer and the importer in writing that it considers that a tobacco product may have a characterising flavour and request the manufacturer or importer to provide his or her assessment of whether or not the product concerned has a characterising flavour.

(3) A manufacturer or importer of a tobacco product shall reply to and submit his or her written observations to a request under paragraph (2) to the Executive within 4 weeks from the receipt of that request, or such other date as may be agreed by the parties.

(4) In the reply under paragraph (3)—

(a) a manufacturer or importer of the tobacco product shall identify to the extent possible, any other Member States in which the same product has been placed on the market,

(b) a manufacturer of the tobacco product shall, where applicable, set out the views of his or her parent company,

(c) an importer of the tobacco product shall set out the views of the manufacturer, and

(d) a manufacturer or importer of the tobacco product shall indicate if he or she considers that same products placed on the market in other Member States have different flavours in one or more of the Member States concerned and in such cases, the manufacturer or importer shall set out the grounds upon which the claim is based.

Notification of Member States and Commission

8B. (1) Where the procedure referred to in Regulation 8A has been initiated by the Executive, the Executive shall, as soon as practicable, notify the Commission and Member States of the initiation of the procedure.

(2) The Executive shall communicate the information received from the manufacturer or importer under Regulation 8A(3) to Member States and where applicable, the Commission.

(3) Where—

(a) a Member State has initiated a procedure under Article 3 of Commission Implementing Decision (EU) 2016/779, the Executive shall refrain from initiating a parallel procedure concerning the same product, and

(b) procedures concerning the same product have already been initiated in 2 or more Member States, only the Member State in which the procedure was initiated first shall continue the procedure.

(4) The Executive may agree with another Member State that it shall act as an initiating Member State.

(5) The Executive shall suspend any procedures initiated in the State concerning the same product, pending the adoption of a decision by the initiating Member State for that product.

(6) Where the Commission has initiated a procedure, the Executive shall refrain from initiating procedures concerning the same product and, except insofar as provided for in Regulation 8F(6) and (7), all pending national procedures for that product shall cease.

(7) Upon request, the Executive shall exchange information gathered with the Commission and other Member States.

Assessment of the manufacturer or importer

8C. (1) Where a manufacturer or importer does not dispute that the tobacco product has a characterising flavour, he or she shall inform the Executive in his or her reply under Regulation 8A(3).

(2) Where a manufacturer or importer disputes that the tobacco product has a characterising flavour, he or she shall inform the Executive in his or her reply submitted under Regulation 8A(3) and the Executive shall proceed in accordance with Regulations 8D and 8E.

Gathering of further information and consultation of the advisory panel

8D. (1) The Executive may, by notice in writing, request further information from the manufacturer or importer concerned and the manufacturer or importer shall provide the information requested within the time limit specified by the Executive in the notice.

(2) The Executive may also request information from other sources, exchange information with other Member States and the Commission, and where applicable, consult the advisory panel.

(3) Where a manufacturer or importer has not disputed that the tobacco product has a characterising flavour, or where he or she fails to reply in accordance with Regulation 8A(3), the Minister, following consultation with the Executive, may where he or she considers that the information at his or her disposal is sufficient to make a determination, proceed to make a determination in accordance with Regulation 8F.

(4) The Executive may, where it considers it necessary to obtain further information in order to make a conclusive determination on

whether the product has a characterising flavour, gather further information in accordance with this Regulation before the Minister makes a determination in accordance with Regulation 8F.

Right for manufacturers and importers to submit observations

8E. (1) Where the Executive has carried out further investigation under Regulation 8D, and where having regard to information obtained from that investigation, the Executive considers that a tobacco product has a characterising flavour the Executive shall, before the Minister adopts a decision, provide the manufacturer or importer of the tobacco product with an opportunity to submit written observations.

(2) The Executive shall provide the manufacturer or the importer with a summary of the grounds upon which the proposed decision is to be adopted and where the advisory panel was consulted, provide a copy of its opinion.

(3) A manufacturer or importer shall submit his or her observations to the Executive not later than 4 weeks from receipt of the summary under paragraph (2) or by such other date as may be agreed by the parties.

(4) In observations submitted under paragraph (3)—

- (a) a manufacturer of the tobacco product shall indicate, where applicable, whether his or her parent company has been consulted, and
- (b) an importer of the tobacco product shall indicate whether the manufacturer has been consulted.

(5) Where the Executive deems it necessary to gather additional information after receipt of observations submitted by the manufacturer or importer under paragraph (3), it shall provide the manufacturer or importer with the additional information gathered and shall give him or her an opportunity to submit additional written observations within such period as it considers appropriate.

Decision as to whether a tobacco product has a characterising flavour

8F. (1) The Minister, following consultation with the Executive, may prepare a draft decision as to whether or not a tobacco product has a characterising flavour.

(2) A draft decision under paragraph (1) shall be prepared on the basis of the information at the disposal of the Minister and the Executive and shall include any information obtained in accordance with Regulation 8C, 8D or 8E, as appropriate.

(3) The Minister shall submit the draft decision under paragraph (1) to the other Member States and the Commission including—

(a) the opinion of the advisory panel, if consulted, and

(b) details, to the extent possible, of any other Member States in which the same product is placed on the market.

(4) The Minister, following consultation with the Executive, shall consider comments received from the Commission or other Member States.

(5) The Minister, following consultation with the Executive, may provide comments on a draft decision initiated by a Member State under Article 9 of Commission Implementing Regulation (EU) 2016/779 within 3 weeks from the submission of the draft decision, duly justifying any objections to the conclusion reached in the draft decision.

(6) Where no objections have been submitted by Member States or the Commission under Article 9 of Commission Implementing Regulation (EU) 2016/779, the Minister shall adopt the decision and notify the manufacturer or importer.

(7) Where there is divergence as to whether or not a product has a characterising flavour, the Minister shall proceed in accordance with Article 9(3) of Commission Implementing Regulation (EU) 2016/779 and may adopt a decision and notify the manufacturer or importer of same.

(8) The Executive shall notify a manufacturer or importer of an adopted decision under paragraphs (6) or (7) and shall submit a copy of the decision to the Member States and the Commission, as appropriate, highlighting to the extent possible, the Member States in which the same product is placed on the market.

Parallel procedures

8G. (1) As soon as the initiating Member State has adopted a decision under Article 9 of Commission Implementing Regulation (EU) 2016/779, any procedures concerning the same product suspended in accordance with Regulation 8B may resume.

(2) Where the Minister does not agree with the decision of a Member State under Article 11 of the Commission Implementing Regulation (EU) 2016/779, he or she shall communicate his or her position to the Commission and proceed in accordance with that Article.

Confidential information

8H. (1) When submitting information pursuant to Regulations 8A to 8G, a manufacturer or importer of the tobacco product may request that certain information be kept confidential on the grounds that it constitutes a trade secret or is otherwise commercially sensitive.

(2) Where a manufacturer or importer makes a request under paragraph (1), he or she shall clearly identify the information concerned and set out the reasons justifying his or her request.

(3) Where the request is considered justified, the Executive and the Minister, as appropriate, shall ensure that the information received under this Regulation is adequately protected.

Publication of decisions

8I. The Minister shall publish a decision adopted pursuant to Regulation 8F in *Iris Oifigiúil*.”.

7. Regulation 14 of the Principal Regulations is amended, in paragraph (5)(b), by the substitution of “set 2” for “set 3”.

8. Regulation 23 of the Principal Regulations is amended—

(a) by the deletion of paragraph (7),

(b) in paragraph (9), by the deletion of “or the person nominated under paragraph (7)(a)”, and

(c) by the insertion of the following paragraphs after paragraph (11):

“(11A) A retailer registered with the Executive pursuant to this Regulation shall inform the Executive in writing as soon as practicable if a particular entered in the register in relation to him or her ceases to be correct.

(11B) The Executive shall make such alterations to the register as it considers necessary—

(a) upon receiving information under paragraph (11A), or

(b) upon becoming aware that any particular entered in the register is incorrect or has ceased to be correct.

(11C) A retailer shall not supply tobacco products by means of cross-border distance sales to consumers located in a Member State where such sales are prohibited in accordance with Article 18 of the Directive.”.

9. Regulation 26 of the Principal Regulations is amended—

(a) in paragraph (2)(g), by the substitution of “Regulations 25 to 30 in so far as they relate to electronic cigarettes and refill containers” for “this Regulation and Regulation 27”,

(b) in paragraph (6), by the substitution of “Subject to paragraph (6A), a manufacturer or importer of electronic cigarettes or refill containers shall, not later than 30 June each year, submit in electronic form a report for the immediately preceding year to the Executive containing

—” for “A manufacturer or importer of electronic cigarettes or refill containers shall submit in electronic form a report, annually to the Executive containing —”,

(c) by the insertion of the following paragraph after paragraph (6):

“(6A) Notwithstanding paragraph (6), the first report submitted under that paragraph shall cover the period from 20 May 2016 up to and including 31 December 2016 and shall be submitted not later than 30 September 2017.”, and

(d) in paragraph (8), by the substitution of “Commission Implementing Decision (EU) 2015/2183 of 24 November 2015⁸ establishing a common format for the notification of electronic cigarettes and refill containers” for “Commission Implementing Decision (EU) 2015/2186 of 25 November 2015⁶ establishing a format for the submission and making available of information on tobacco products”.

10. Regulation 29 of the Principal Regulations is amended by the substitution of the following paragraph for paragraph (4):

“(4) The health warning referred to in paragraph (3) shall:

- (a) appear on the 2 largest surfaces of the unit packet and any outside packaging,
- (b) cover 32% of the surfaces of the unit packet and any outside packaging,
- (c) be printed in black Helvetica bold type on a white background at such a font size as to occupy the greatest possible proportion of the surface reserved for the health warning,
- (d) be at the centre of the surface reserved for the health warning, and
- (e) be parallel to the main text on the surface reserved for the health warning.”.

11. Regulation 30 of the Principal Regulations is amended, in paragraph (1)(b), by the deletion of “or that it aims to reduce the effect of some of the harmful components of smoke”.

12. Regulation 42 of the Principal Regulations is amended by the substitution of the following paragraph for paragraph (1):

“(1) Where an authorised officer is of the opinion that a manufacturer, importer, distributor or retailer of a relevant product has contravened Regulation 4(1), 8, 22, 27, 28, 33(2) or 33(3), the authorised officer may, with the approval of the Director General of the Executive, or another officer of the Executive designated for that purpose, serve, or arrange to have served, on

the manufacturer, importer, distributor or retailer concerned, an order (in this Regulation referred to as a ‘prohibition order’) in accordance with paragraph (2).”.

13. Regulation 43 of the Principal Regulations is amended—

- (a) in paragraph (1), by the substitution of “Regulation 4(1), 6, 7, 8A(3), 8C, 8D(1), 8E(3), 10, 11, 23, 23(11A), 24, 29, 30, 31, 34, 35 or 36” for “Regulation 4(1), 6, 7, 10, 11, 23, 24, 29, 30, 31, 34, 35 or 36”, and
- (b) in paragraph (3), by the substitution of “Regulation 5, 8, 20, 21, 22, 23(11C), 25, 26, 27, 28 or 33” for “Regulation 5, 8, 20, 21, 22, 25, 26, 27, 28 or 33.”.



GIVEN under my Official Seal,
13 June 2017.

SIMON HARRIS,
Minister for Health.

EXPLANATORY NOTE

(This note is not part of the Instrument and does not purport to be a legal interpretation.)

These Regulations amend the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 (S.I. No. 271 of 2016) and give effect to the following European Commission Implementing Acts:

- (a) Commission Implementing Regulation (EU) 2016/779 of 18 May 2016 laying down uniform rules as regards the procedures for determining whether a tobacco product has a characterising flavour;
- (b) Commission Implementing Decision (EU) 2016/786 of 18 May 2016 laying down the procedure for the establishment and operation of an independent advisory panel assisting Member States and the Commission in determining whether tobacco products have a characterising flavour; and
- (c) Commission Implementing Decision (EU) 2016/787 of 18 May 2016 laying down a priority list of additives contained in cigarettes and roll-your-own tobacco subject to enhanced reporting obligations.

BAILE ÁTHA CLIATH
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR
Le ceannach díreach ó
FOILSEACHÁIN RIALTAIS,
52 FAICHE STIABHNA, BAILE ÁTHA CLIATH 2
(Teil: 01 - 6476834 nó 1890 213434; Fax: 01 - 6476843)
nó trí aon díoltóir leabhar.

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