



STATUTORY INSTRUMENTS.

**S.I. No. 271 of 2016**



EUROPEAN UNION (MANUFACTURE, PRESENTATION AND SALE  
OF TOBACCO AND RELATED PRODUCTS) REGULATIONS 2016

EUROPEAN UNION (MANUFACTURE, PRESENTATION AND SALE  
OF TOBACCO AND RELATED PRODUCTS) REGULATIONS 2016

ARRANGEMENT OF REGULATIONS

*PART 1*

PRELIMINARY AND GENERAL

1. Citation and commencement
2. Interpretation
3. Competent authority

*PART 2*

TOBACCO PRODUCTS — INGREDIENTS AND EMISSIONS

4. Maximum emission levels and measurement methods for tar, nicotine, carbon monoxide and other substances
5. Reporting of ingredients and emissions
6. Studies regarding market research and submitting of information
7. Comprehensive studies
8. Regulation of ingredients
9. Trade secrets

*PART 3*

TOBACCO PRODUCTS — LABELLING AND PACKAGING

10. General provisions
11. Images of unit packets and any outside packaging
12. General warning and information message on tobacco products for smoking
13. General warning, information message and content of a unit packet of roll-your-own tobacco
14. Combined health warnings for tobacco products for smoking
15. Layout, design and shape of the combined health warning
16. Design of the combined health warning
17. Special rules for certain unit packets of tobacco products with a flip-top lid

18. Labelling of single cigars and cigarillos
19. Labelling of smokeless tobacco products
20. Traceability
21. Security feature

*PART 4*

TOBACCO FOR ORAL USE, CROSS-BORDER DISTANCE SALES  
AND NOVEL TOBACCO PRODUCTS

22. Tobacco for oral use
23. Cross-border distance sales of tobacco products
24. Notification of novel tobacco products

*PART 5*

ELECTRONIC CIGARETTES AND HERBAL PRODUCTS FOR  
SMOKING

25. General provisions for electronic cigarettes and refill containers
26. Notification of electronic cigarettes and refill containers
27. Safety and quality requirements for electronic cigarettes and refill containers
28. Refill mechanism of electronic cigarettes
29. Information and labelling on electronic cigarettes and refill containers
30. Product presentation for electronic cigarettes
31. Commercial communications relating to electronic cigarettes and refill containers
32. Market developments concerning electronic cigarettes and refill containers
33. Public health concerns relating to electronic cigarettes and refill containers
34. Herbal products for smoking
35. Reporting of ingredients of herbal products for smoking
36. Product presentation for herbal products

*PART 6*

ENFORCEMENT AND SANCTIONS

- 37. Designated laboratories
- 38. Construction of references (authorised officers)
- 39. Indemnification of authorised officers
- 40. Taking of samples by authorised officers
- 41. Compliance notice
- 42. Prohibition notice
- 43. Offences and penalties
- 44. Forgery of documents
- 45. Evidence in proceedings for an offence
- 46. Service of documents

*PART 7*

TRANSITIONAL PROVISIONS AND REVOCATIONS

- 47. Transitional provisions
- 48. Revocations

SCHEDULE

LIST OF TEXT WARNINGS

S.I. No. 271 of 2016

EUROPEAN UNION (MANUFACTURE, PRESENTATION AND SALE  
OF TOBACCO AND RELATED PRODUCTS) REGULATIONS 2016

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 effect to Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014<sup>1</sup>, 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, hereby make the following regulations:

PART 1

PRELIMINARY AND GENERAL

*Citation and commencement*

1. (1) These Regulations may be cited as the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016.

(2) Subject to Regulations 8(7), 13(7), 20(16), 21(2) and 27(3), these Regulations shall come into operation on 20 May 2016.

*Interpretation*

2. (1) In these Regulations—

“combined health warning” has the meaning assigned to it by Regulation 14;

“Commission” means the European Commission;

“designated laboratory” means a laboratory designated by the Minister pursuant to Regulation 37;

“Directive” means Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014<sup>1</sup> 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 2014<sup>2</sup> 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<sup>3</sup> on the precise position of the general warning and the information message on roll-your-own tobacco marketed in pouches,

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

<sup>2</sup>OJ No. L 360, 17.12.2014, p. 22

<sup>3</sup>OJ No. L 252, 29.09.2015, p. 49

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 24th May, 2016.*

Commission Implementing Decision (EU) 2015/1842 of 9 October 2015<sup>4</sup> 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<sup>5</sup> establishing a common format for the notification of electronic cigarettes and refill containers and Commission Implementing Decision (EU) 2015/2186 of 25 November 2015<sup>6</sup> establishing a format for the submission and making available of information on tobacco products, and Commission Implementing Decision (EU) 2016/586 of 14 April 2016 on technical standards for the refill mechanism of electronic cigarettes<sup>7</sup>;

“Executive” means the Health Service Executive;

“importer” means the owner of, or a person having a right of disposal over, tobacco or related products that have been brought into the State;

“information society services” has the same meaning as it has in Article 1 of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998<sup>8</sup> laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services;

“Minister” means the Minister for Health;

“relevant product” means—

- (a) a tobacco product,
- (b) a herbal product for smoking,
- (c) an electronic cigarette, or
- (d) a refill container;

“retailer” means a person who carries on, in whole or in part, the business of selling a tobacco product by retail;

“trade mark” has the same meaning as it has in the Trade Marks Act 1996 (No. 6 of 1996);

“unique identifier” has the meaning assigned to it by Regulation 20.

(2) A word or expression which is used in these Regulations and which is also used in the Directive has, unless the context otherwise requires, the same meaning in these Regulations as it has in the Directive.

#### *Competent authority*

3. (1) The Executive is designated as the competent authority in the State for the purpose of Articles 5, 6, 18, 19, 20, 22(1) and 23 of the Directive.

<sup>4</sup>OJ No. L 267, 14.10.2015, p. 5

<sup>5</sup>OJ No. L 309, 26.11.2015, p. 15

<sup>6</sup>OJ No. L 312, 27.11.2015, p. 5

<sup>7</sup>OJ No. L101, 16.4.2016, p.15

<sup>8</sup>OJ No. L204, 21.7.1998, p.37

(2) The Executive shall cooperate with competent authorities in other Member States and with the Commission to ensure the correct application and due enforcement of the Directive and shall transmit to them, all necessary information for the application of the Directive in a uniform manner.

## PART 2

### TOBACCO PRODUCTS — INGREDIENTS AND EMISSIONS

*Maximum emission levels and measurement methods for tar, nicotine, carbon monoxide and other substances*

4. (1) A person shall not manufacture, or place on the market, cigarettes with emission levels greater than—

- (a) 10 milligrams of tar per cigarette,
- (b) 1 milligram of nicotine per cigarette, or
- (c) 10 milligrams of carbon monoxide per cigarette.

(2) (a) The tar, nicotine and carbon monoxide emissions from cigarettes shall be measured on the basis of—

- (i) ISO standard 4387 for tar,
- (ii) ISO standard 10315 for nicotine, and
- (iii) ISO standard 8454 for carbon monoxide.

(b) The accuracy of the tar, nicotine and carbon monoxide measurements referred to in subparagraph (a) shall be determined in accordance with ISO standard 8243.

(3) The measurements referred to in paragraph (2) shall be verified by a designated laboratory.

(4) The Minister shall notify the Commission of—

- (a) a list of designated laboratories including—
  - (i) the criteria used for the designation of such laboratories, and
  - (ii) the methods of monitoring applied to such laboratories, and
- (b) any measurement methods which a designated laboratory uses for—
  - (i) emissions from cigarettes, other than tar, nicotine and carbon monoxide emissions, and
  - (ii) emissions from tobacco products other than cigarettes.

(5) The Minister shall—

- (a) update the list referred to in paragraph (4)(a) whenever any change is made to the list, and
- (b) notify the Commission of the updated list.

*Reporting of ingredients and emissions*

5. (1) A manufacturer or importer of a tobacco product shall submit in electronic form to the Executive, the following information by brand name and type:

- (a) a list of all ingredients, and quantities thereof, used in the manufacture of the tobacco products, in descending order of the weight of each ingredient included in the tobacco products;
  - (b) the emissions levels referred to in Regulation 4(1);
  - (c) where available, information on other emissions and their levels.
- (2) The list of ingredients referred to in paragraph (1)(a) shall—
- (a) be accompanied by a statement setting out the reasons for the inclusion of such tobacco ingredients in the product concerned,
  - (b) indicate the status of the ingredients, including—
    - (i) whether they have been registered under Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006<sup>9</sup> concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency, and
    - (ii) the classification of the ingredients under Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008<sup>10</sup> on classification, labelling and packaging of substances and mixtures, and
  - (c) be accompanied by the relevant toxicological data regarding the ingredients in burnt or unburnt form, as appropriate, referring (in particular) to the effects on the health of consumers and taking into account any addictive effects.

(3) A manufacturer or importer of cigarettes or roll-your-own tobacco shall submit in electronic form to the Executive, a technical document setting out a general description of the additives used and their properties.

(4) Subject to paragraph (5), a manufacturer or importer of a tobacco product shall indicate in electronic form to the Executive, the methods of measurement of emissions used.

(5) Paragraph (4) shall not apply to tar, nicotine and carbon monoxide and for emissions referred to in Regulation 4.

<sup>9</sup>OJ No. L 396, 30.12.2006, p. 1

<sup>10</sup>OJ No. L 353, 31.12.2008, p. 1



(6) The information required under this Regulation shall be provided on or before 20 November 2016 in respect of tobacco products placed on the market before 20 May 2016.

(7) The information required under this Regulation 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.

(8) Where the composition of a tobacco product is modified in any way that affects the information provided 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.

*Studies regarding market research and submitting of information*

6. (1) A manufacturer or importer of a tobacco product shall—

(a) submit in electronic form to the Executive, internal and external studies available to the manufacturer or importer on market research and preferences of various consumer groups, including young people and current smokers, relating to ingredients and emissions, as well as executive summaries of any market surveys that a manufacturer or importer carries out when launching new products, and

(b) report in electronic form to the Executive their sales volumes in the State per brand and type, reported in sticks or kilograms, on a yearly basis from 1 January 2015.

(2) The first report under paragraph (1)(b) shall be made on or before 20 November 2016 and the second and each subsequent report shall be made on or before 30 June of each subsequent calendar year.

(3) A manufacturer or importer of a tobacco product shall carry out such studies as the Executive may determine in order to assess the effects of ingredients referred to in Regulation 5(1) on health, taking into account their addictiveness and toxicity of the ingredients.

(4) A manufacturer or importer of a tobacco product shall submit in electronic form to the Executive the information referred to in this Regulation and Regulation 5, including information regarding modifications and withdrawal from the market—

(a) in accordance with the format in the Annex to Commission Implementing Decision (EU) 2015/2186 of 25 November 2015<sup>6</sup> establishing a format for the submission and making available of information on tobacco products, and

(b) by means of the common electronic entry gate for data submission.

(5) Prior to submitting information under this Regulation and Regulation 5 for the first time, a manufacturer or importer of a tobacco product shall apply to the Commission for an identification number in accordance with Article 4

of Commission Implementing Decision (EU) 2015/2186 of 25 November 2015<sup>6</sup> establishing a format for the submission and making available of information on tobacco products.

(6) A manufacturer or importer of a tobacco product shall upon request from the Commission, submit in electronic form a document providing company identification and authentication of activities in accordance with the national legislation where the company is established.

(7) A manufacturer or importer of a tobacco product shall assign a Tobacco Products ID (in this Regulation referred to as a “TP-ID”) based on the identification number referred to in paragraph (5) to each tobacco product for which information is reported.

(8) When submitting information under this Regulation and Regulation 5 on tobacco products with the same composition and design, a manufacturer or importer of a tobacco product shall use the same TP-ID to the extent possible, in particular, where data is submitted by various members of a group of companies.

(9) Paragraph (8) shall apply regardless of the brand, subtype or number of markets on which the tobacco products concerned are placed.

(10) Where a manufacturer or importer of a tobacco product is not able to ensure that the same TP-ID is used for tobacco products with the same composition and design in accordance with paragraph (8), they shall provide, in so far as possible, the different TP-ID that was assigned to each such product.

#### *Comprehensive studies*

7. (1) A manufacturer or importer of cigarettes or roll-your-own tobacco containing an additive that is included in the priority list of additives, shall carry out comprehensive studies, in addition to the reporting requirements under Regulations 5 and 6, which shall examine whether each such additive—

- (a) contributes to the toxicity or addictiveness of the products concerned and whether this has the effect of increasing the toxicity or addictiveness of any of the products concerned to a significant or measurable degree,
- (b) results in a characterising flavour,
- (c) facilitates inhalation or nicotine uptake, or
- (d) leads to the formation of substances that have CMR properties, the quantities thereof, and whether this has the effect of increasing the CMR properties in any of the products concerned to a significant or measurable degree.

(2) The studies referred to in paragraph (1) shall—

- (a) take into account the intended use of the products concerned,

- (b) examine, in particular, the emissions resulting from the combustion process involving the additive concerned, and
- (c) examine the interaction of the additive with other ingredients contained within the products concerned.

(3) Where 2 or more manufacturers or importers use the same additive in their tobacco products, such manufacturers or importers may carry out a joint study when using that additive in a comparable product composition.

(4) Subject to paragraph (7), a manufacturer or importer shall compile a report on the results of the studies carried out under this Regulation which shall include—

- (a) an executive summary, and
- (b) a comprehensive overview compiling the available scientific literature on that additive and summarising internal data on the effects of the additive.

(5) A manufacturer or importer shall submit the report referred to in paragraph (4), in electronic form to the Commission and a copy shall be submitted in electronic form to the Executive where a tobacco product containing this additive is placed on the market not later than 18 months after the additive has been included in the list of priorities.

(6) The Commission or the Executive may request a manufacturer or importer to include supplementary information in the report referred to in paragraph (4) regarding the additive concerned and the manufacturer or importer, as appropriate, shall comply with any such request.

(7) Small and medium-sized enterprises as defined in Commission Recommendation 2003/361/EC of 6 May 2003<sup>11</sup> are exempt from the obligations under this Regulation, if a report on the additive concerned is prepared by another manufacturer or importer.

#### *Regulation of ingredients*

8. (1) Subject to paragraph (2), a person shall not place on the market a tobacco product with a characterising flavour.

(2) Paragraph (1) does not apply to the use of additives that are essential for the manufacture of tobacco products, provided those additives do not result in a product with a characterising flavour and do not increase to a significant or measurable degree the addictiveness, toxicity or the CMR properties of the tobacco product.

(3) A person shall not place on the market a tobacco product containing any of the following additives:

<sup>11</sup>OJ L124, 20.5.2003, p. 36

- (a) vitamins or other additives that create the impression that a tobacco product has a health benefit or presents reduced health risks;
  - (b) caffeine, taurine, other additives or stimulant compounds that are associated with energy and vitality;
  - (c) additives having colouring properties for emissions;
  - (d) for tobacco products for smoking, additives that facilitate inhalation or nicotine uptake;
  - (e) additives that have CMR properties in unburnt form.
- (4) A person shall not place on the market—
- (a) a tobacco product containing flavourings in any of their components such as filters, papers, packages or capsules,
  - (b) a tobacco product containing any technical features allowing modification of the smell or taste of the tobacco product concerned or its smoke intensity, or
  - (c) filters, papers or capsules containing tobacco or nicotine.
- (5) A person shall not place on the market a tobacco product containing additives in quantities that increase the toxic or addictive effect or the CMR properties at the stage of consumption to a significant or measurable degree on the basis of scientific evidence.
- (6) Paragraphs (1), (2) and (4) shall not apply to tobacco products other than cigarettes and roll-your-own tobacco.
- (7) This Regulation shall apply from 20 May 2020 in the case of tobacco products with a characteristic flavour whose sales volumes in the European Union represent 3% or more in a particular product category.

*Trade secrets*

9. (1) A manufacturer or importer shall specify when submitting information under Regulations 5(1), 7, 26 or 35, the information which he or she considers a trade secret or otherwise confidential and, upon request by the Executive, duly justify their claims.

(2) When submitting the information referred to in paragraph (1), the following shall not be considered a trade secret or otherwise confidential:

- (a) in the case of all tobacco products—
  - (i) inclusion and quantity of additives other than flavourings, and
  - (ii) inclusion and quantity of ingredients other than additives used in quantities above 0.5% of the total tobacco product unit weight;

- (b) in the case of cigarettes and roll-your-own tobacco, inclusion and quantity of individual flavourings used in quantities above 0.1% of the total tobacco product unit weight;
  - (c) in the case of pipe tobacco, cigars, cigarillos, smokeless tobacco products and all other tobacco products, inclusion and quantities of individual flavourings used in quantities above 0.5% of the total tobacco unit weight;
  - (d) in the case of electronic cigarettes and refill containers, ingredients used in quantities above 0.1% of the final formulation of the liquid, and
  - (e) studies and data submitted in accordance with paragraphs (2)(c), (3) and (4) of Regulation 5, Regulation 6(3) and Regulation 26(2) in particular on toxicity and addictiveness; and where those studies are linked to specific brands, the explicit and implicit references to the brand shall be removed and the redacted version shall be accessible.
- (3) The Executive shall make available on its website, information received under Regulations 5(1), 7, 26 and 35.
- (4) The Executive shall take the need to protect trade secrets duly into account when making the information in paragraph (3) publicly available.

### PART 3

#### TOBACCO PRODUCTS — LABELLING AND PACKAGING

##### *General provisions*

10. (1) A person shall not—
- (a) place on the market a tobacco product, or
  - (b) manufacture or import a tobacco product that is intended for sale by retail in the State,

unless the requirements of this Part have been complied with.

(2) Each unit packet of a tobacco product and any outside packaging shall carry the health warnings provided for in this Part in the Irish language and in the English language.

(3) The health warnings shall cover the entire surface of the unit packet of a tobacco product or outside packaging that is reserved for them and they shall not be commented on, paraphrased or referred to in any form.

(4) When a tobacco product is placed on the market, the health warnings on the unit packet of a tobacco product and any outside packaging shall be irremovably printed, indelible and fully visible, including not being partially or totally

hidden or interrupted by tax stamps, price marks, security features, wrappers, jackets, boxes, or other items.

(5) The health warnings on a unit packet of a tobacco product, other than cigarettes and roll-your-own tobacco in pouches, may be affixed by means of stickers, provided that such stickers are irremovable.

(6) The health warnings on a unit packet of a tobacco product shall remain intact when opening the unit packet of a tobacco product other than packets with a flip-top lid, where the health warnings may be split when opening the packet, but only in a manner that ensures the graphical integrity and visibility of the text, photographs and cessation information.

(7) The health warnings on a unit packet of a tobacco product shall not hide or interrupt the tax stamps, price marks, tracking and tracing marks, or security features on the unit packet.

(8) The dimensions of the health warnings provided for in Regulations 12 to 19 shall be calculated in relation to the surface concerned when the packet is closed.

(9) Subject to paragraph (10), the health warnings on a unit packet of a tobacco product shall be surrounded by a black border of a width of 1 mm inside the surface area that is reserved for these warnings.

(10) Paragraph (9) shall not apply to health warnings referred to in Regulation 18.

*Images of unit packets and any outside packaging*

11. A person shall ensure that images of a unit packet of tobacco product and any outside packaging targeting consumers in the European Union shall comply with the provisions of this Part.

*General warning and information message on tobacco products for smoking*

12. (1) Subject to paragraph (6), each unit packet and any outside packaging of tobacco products for smoking shall carry—

(a) the following general warning—

“Toradh caithimh tobac — bás

Smoking Kills”, and

(b) the following information message—

“Cuimsíonn deatach tobac breis agus 70 substaint arb eol dúinn gur cúiseanna ailse iad

Tobacco smoke contains over 70 substances known to cause cancer”.

(2) The general warning referred to in paragraph (1)(a) and the information message referred to in paragraph (1)(b) shall each cover 50% of the surfaces on which they are printed.

(3) For cigarette packets and roll-your-own tobacco in cuboid packets—

(a) the general warning referred to in paragraph (1)(a) shall appear on the bottom part of one of the lateral surfaces of the unit packets, and

(b) the information message referred to in paragraph (1)(b) shall appear on the bottom part of the other lateral surface.

(4) The warnings referred to in paragraph (3) shall have a width of not less than 20 mm.

(5) For packets in the form of a shoulder box with a hinged lid that result in the lateral surfaces being split into 2 when the packet is open—

(a) the general warning referred to in paragraph (1)(a) and the information message referred to in paragraph (1)(b) shall appear in their entirety on the larger parts of those split surfaces,

(b) the general warning referred to in paragraph (1)(a) shall also appear on the inside of the top surface that is visible when the packet is open, and

(c) the lateral surfaces of the packet shall have a height of not less than 16mm.

(6) The general warning referred to in paragraph (1)(a) and the information message referred to in paragraph (1)(b) shall be—

(a) 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 these health warnings, and

(b) at the centre of the surface reserved for such warnings, and on cuboid packets and any outside packaging parallel to the lateral edge of the unit packet or of the outside packaging.

*General warning, information message and content of a unit packet of roll-your-own tobacco*

13. (1) A unit packet of roll-your-own tobacco shall contain tobacco weighing not less than 30g.

(2) In relation to roll-your-own tobacco—

(a) if that tobacco is marketed in pouches, the general warning referred to in Regulation 12(1)(a) and the information message referred to in Regulation 12(1)(b) shall appear on the surfaces that ensure full visibility of those health warnings, and

- (b) if that tobacco is marketed in cylindrical packets, the general warning referred to in Regulation 12 (1)(a) shall appear on the outside surface of the lid and the information message referred to in Regulation 12(1)(b) shall appear on the inside surface of the lid.

(3) Subject to paragraphs (4) and (5), for roll-your-own tobacco in rectangular pockets with a flap that covers the opening (in this Regulation referred to as “rectangular pouches”), the general warning referred to in Regulation 12(1)(a) and the information message referred to in Regulation 12(1)(b) shall be—

- (a) printed on the 2 surfaces which become visible when the unit packet is fully opened as illustrated in sections 1 and 2 of the Annex to Commission Implementing Decision (EU) 2015/1735 of 24 September 2015<sup>4</sup>, and
- (b) positioned at the top edge and shall cover 50% of the respective surfaces on which they are printed, as illustrated in sections 1 and 2 of the Annex to Commission Implementing Decision (EU) 2015/1735 of 24 September 2015<sup>4</sup>.

(4) For roll-your-own tobacco in rectangular pouches, the general warning referred to in Regulation 12(1)(a) shall be printed on the top surface.

(5) Without prejudice to the generality of paragraph (3), the following shall apply to roll-your-own tobacco in rectangular wraparound pouches made of polyethylene, polypropylene or laminate material as illustrated in section 3 of the Annex to Commission Implementing Decision (EU) 2015/1735 of 24 September 2015<sup>4</sup>:

- (a) the information message referred to in Regulation 12(1)(b) may be positioned on the surface that becomes visible when the unit packet is partly unwrapped;
- (b) the general warning referred to in Regulation 12(1)(a) may be positioned on the bottom surface, which becomes visible when the unit packet is fully opened;
- (c) the inside of the flap, which becomes visible when the unit packet is fully opened, shall not be printed upon or used in any other way;
- (d) the general warning referred to in Regulation 12(1)(a) and information message referred to in Regulation 12(1)(b) shall be positioned at the top edge of the respective surfaces on which they are printed.

(6) Paragraph (5) shall have effect until 20 May 2018.

(7) Roll-your-own tobacco in pouches manufactured or released for free circulation on or before 20 May 2018 and labelled in accordance with paragraph (5) may be placed on the market on or before 20 May 2019.



(8) For roll-your-own tobacco in standing pouches, the general warning referred to in Regulation 12(1)(a) and information message referred to in Regulation 12(1)(b) shall—

- (a) be positioned on the surfaces on the bottom of the standing pouch that become visible when the pouch is laid on its back, as illustrated in section 4 of the Annex to Commission Implementing Decision (EU) 2015/1735 of 24 September 2015<sup>4</sup>, and
- (b) cover 50% of the respective surfaces on which they are printed, which surfaces shall be calculated using their dimensions after the edges are sealed.

(9) For roll-your-own tobacco in standing pouches—

- (a) the general warning referred to in Regulation 12(1)(a) shall be printed on the surface above the crease on the base of the unit packet, and
- (b) the information message referred to in Regulation 12(1)(b) shall be printed on the surface below the crease.

*Combined health warnings for tobacco products for smoking*

14. (1) Each unit packet and any outside packaging of tobacco products for smoking shall carry one of the combined health warnings (in these Regulations referred to as a “combined health warning”) which shall—

- (a) contain one of the text warnings listed in the Schedule in the Irish language and in the English language and a corresponding colour photograph set out in the picture library in Annex II to the Directive,
- (b) include the smoking cessation information:

“www.Quit.ie, Saorghlao/ Freephone 1800 201 203”,

- (c) cover 65% of—
  - (i) both the external front and back surface of the unit packet and any outside packaging, and
  - (ii) in the case of cylindrical packets which shall display 2 combined health warnings, their respective half of the curved surface,
- (d) show the same combined health warning on both sides of the unit packets and any outside packaging,
- (e) subject to paragraph (2), appear at the top edge of a unit packet and any outside packaging, and be positioned in the same direction as any other information appearing on that surface of the packaging,
- (f) be reproduced in accordance with the format, layout, design and proportions specified by the Commission pursuant to Article 10(3) of the Directive, and

- (g) in the case of unit packets of cigarettes, respect the following dimensions:
  - (i) height of not less than 44 mm;
  - (ii) width of not less than 52 mm.
- (2) Where a tobacco product is placed on the market on or before 20 May 2019—
  - (a) the combined health warning that is to appear on the back surface may be positioned directly below the tax stamp, where a tax stamp is affixed at the top edge of a unit packet made of carton material, or
  - (b) a rectangular area may be reserved for a tax stamp of a height not exceeding 13 mm between the top edge of the packet and the top end of the combined health warnings where a unit packet is made of soft material.
- (3) Where paragraph (2) applies, brand names or logos shall not be positioned above the combined health warnings.
- (4) Each set of combined health warnings set out in Annex II to the Directive—
  - (a) shall be used in a given year and rotated from May to May on an annual basis, and
  - (b) shall be displayed to the extent possible in equal numbers on each brand of tobacco products.
- (5) For the combined health warnings set out in Annex II to the Directive—
  - (a) in set 1, for the health warning with the text “Smoking causes 9 out of 10 lung cancers”, the additional embedded text “lung surgery” shall appear in the Irish language as “Máinliacht scamhóige”, and
  - (b) in set 3, for the health warning with the text “Smoking damages your lungs”, the additional embedded text “open wound after lung surgery” shall appear in the Irish language as “Cneá oscailte tar éis máinliacht scamhóige”.

*Layout, design and shape of the combined health warning*

15. (1) Where the height of the combined health warning is greater than 70% of its width, a manufacturer shall lay out the combined health warnings in a stacked format as illustrated in section 1 of the Annex to Commission Implementing Decision (EU) 2015/1842<sup>5</sup>.

(2) Where the height of the combined health warning is greater than 20% but less than 65% of its width, a manufacturer shall lay out the combined health

warnings in a side-by-side format as illustrated in section 2 of the Annex to Commission Implementing Decision (EU) 2015/1842<sup>5</sup>.

(3) Where the height of the combined health warning is greater than or equal to 65% but less than or equal to 70% of its width, a manufacturer may choose whether to use the stacked or side-by-side format, as long as all the elements of the combined health warning remain fully visible and are not distorted.

(4) (a) Where a stacked format is used in accordance with paragraph (1), the photograph shall be placed at the top of the combined health warning, with the text warning and cessation information printed underneath the combined health warning as illustrated in section 1 of the Annex to Commission Implementing Decision (EU) 2015/1842<sup>5</sup>.

(b) The photograph referred to in subparagraph (a) shall occupy 50% of the surface area of the combined health warning inside the outer black border, the text warning shall occupy 38% of the surface area of the combined health warning inside the outer black border and the cessation information shall occupy 12% of the surface area of the combined health warning inside the outer black border.

(5) (a) Where a side-by-side format is used in accordance with paragraph (2) the photograph shall be placed on the left half of the combined health warning, with the text warning at the top right and the cessation information at the bottom right of the combined health warning as illustrated in section 2 of the Annex to Commission Implementing Decision (EU) 2015/1842<sup>5</sup>.

(b) The photograph referred to in subparagraph (a) shall occupy 50% of the surface area of the combined health warning inside the outer black border, the text warning shall occupy 40% of the surface area of the combined health warning inside the outer black border and the cessation information shall occupy 10% of the surface area of the combined health warning inside the outer black border.

(6) (a) Where, due to the shape of the unit packet of a tobacco product or outside packaging, the height of the combined health warning is less than or equal to 20% of its width, the combined health warning shall be laid out in a side-by-side extra-wide format as illustrated in section 3 of the Annex to Commission Implementing Decision (EU) 2015/1842<sup>5</sup>.

(b) The photograph in the combined health warning shall occupy 35% of the surface area of the combined health warning inside the outer black border, the text warning shall occupy 50% of the surface area of the combined health warning inside the outer black border and the cessation information shall occupy 15% of the surface area of the combined health warning inside the outer black border.

*Design of the combined health warning*

16. (1) A combined health warning shall—

- (a) be printed in four-colour CMYK,
- (b) have all elements in black printed in C0, M0, Y0 and K100,
- (c) have all elements in warm yellow printed in C0, M10, Y100 and K0, and
- (d) be reproduced at a minimum resolution of 300 dpi when printed in actual size.

(2) The text warning in a combined health warning shall be printed—

- (a) in the Irish language in white, and
- (b) in the English language in warm yellow;

on a black background.

(3) The cessation information in a combined health warning shall be printed in black on a warm yellow background, as illustrated in the Annex to Commission Implementing Decision (EU) 2015/1842<sup>5</sup>.

(4) Where a side-by-side, stacked reversed or side-by-side extra-wide format is used, a 1 mm black border shall be printed between the cessation information and the photograph within the cessation information panel.

(5) A manufacturer or importer of a tobacco product shall ensure that the photograph to be used in the combined health warning—

- (a) is reproduced without applying effects, adjusting the colours, retouching, or extending the background,
- (b) is not cropped too close or too far from the focal point of the image, and
- (c) is scaled proportionally without being stretched or condensed.

(6) A manufacturer of a tobacco product shall, in relation to a combined health warning, ensure that—

- (a) the text warning and cessation information are left aligned and centred vertically,
- (b) the text warning and cessation information are printed in *Neue Frutiger Condensed Bold*,
- (c) the text warning is printed in a uniform font size,

- (d) the font size of the text warning and of the cessation information is as large as possible to ensure maximum visibility of the text,
- (e) subject to paragraph (7) and Regulation 17(3), the minimum font size of the text warning is 6 pt and the minimum font size of the cessation information is 5 pt,
- (f) subject to paragraph (7) and Regulation 17(3), the space between lines is 2 pt larger than the font size of the text warning and is 1 to 2 pt larger than the font size of the cessation information, and
- (g) the text warning is reproduced in the Irish language and in the English language as set out in the Schedule, including the use of capital letters, but excluding the numbering.

(7) A manufacturer or importer of a tobacco product for smoking other than cigarettes, roll-your-own tobacco or waterpipe tobacco may reduce the font size or space between the lines of the text warning and cessation information referred to in subparagraphs (e) and (f) of paragraph (6) where unavoidable, provided that all elements of the combined health warning remain fully visible.

(8) Regulation 14(5) shall apply to a combined health warning.

*Special rules for certain unit packets of tobacco products with a flip-top lid*

17. (1) Subject to paragraphs (4) and (5) of Regulation 15, in relation to combined health warnings to be placed on the front of unit packets having a flip-top lid, the following shall apply:

- (a) where the lid is smaller than the surface area foreseen for the photograph in paragraphs (4) and (5) of Regulation 15 and compliance with that provision would result in the photograph being split upon opening—
  - (i) the text warning shall be placed at the top of the combined health warning, with the cessation information and photograph underneath the combined health warning as illustrated in section 4 of the Annex to Commission Implementing Decision (EU) 2015/1842<sup>5</sup>, and
  - (ii) the photograph shall occupy at least 50% of the surface area of the combined health warning, the text warning shall occupy at least 30% of the surface area of the combined health warning and the cessation information shall occupy at least 10% but not more than 12% of the surface area of the combined health warning inside the outer black border;
- (b) where the lid is larger than the surface area foreseen for the photograph in paragraphs (4) and (5) of Regulation 15 and compliance with that provision would result in the text warning or cessation information being split upon opening—

- (i) the photograph shall be placed at the top of the combined health warning, with the text warning and cessation information underneath the combined health warning as illustrated in section 1 of the Annex to Commission Implementing Decision (EU) 2015/1842 of 9 October 2015<sup>5</sup>, and
- (ii) the photograph shall occupy at least 50% of the surface area of the combined health warning, the text warning shall occupy at least 30% of the surface area of the combined health warning and the cessation information shall occupy at least 10% but not more than 12% of the surface area of the combined health warning inside the outer black border.

(2) A manufacturer of a tobacco product shall ensure that none of the 3 elements of the combined health warning are split upon opening of the unit packet.

(3) A manufacturer or importer of cigarettes, roll-your-own tobacco or water-pipe tobacco in unit packets with a flip-top lid may reduce the font size or space between the lines of the text warning and cessation information of the combined health warning on the front of packages referred to in subparagraphs (e) and (f) of Regulation 16(6), provided that all elements of the combined health warning remain fully visible.

*Labelling of single cigars and cigarillos*

18. (1) Each unit packet and any outside packaging of a single cigar or cigarillo shall—

(a) carry the following general warning—

“Toradh caithimh tobac — bás

Smoking Kills”, and

the following cessation message—

“www.Quit.ie, Saorghlao/Freephone 1800 201 203”, and

(b) carry one of the text warnings listed in the Schedule in the Irish language and in the English language.

(2) The general warning referred to in paragraph (1)(a) shall—

(a) appear on the most visible surface of the unit packet and any outside packaging, and

(b) cover 32% of the relevant surface of the unit packet and any outside packaging.

(3) The text warnings referred to in paragraph (1)(b) shall—

- (a) appear on the next most visible surface of the unit packet and any outside packaging,
- (b) be displayed to the extent possible in equal numbers on each brand of these products, and
- (c) cover 45% of the relevant surface of the unit packet and any outside packaging.

(4) For unit packets with a hinged lid, the next most visible surface referred to in paragraph (3)(a) is the surface that becomes visible when the packet is open.

(5) Where the health warnings referred to in paragraph (1) are to appear on a surface exceeding 150cm<sup>2</sup>, the warnings shall cover an area of 48cm<sup>2</sup>.

(6) The health warnings referred to in paragraph (1) shall—

- (a) comply with the requirements specified in Regulation 12(6),
- (b) be surrounded by a black border of a width of not less than 3mm and not more than 4mm which shall appear outside the surface reserved for the health warnings, and
- (c) be parallel to the main text on the surface reserved for these warnings.

#### *Labelling of smokeless tobacco products*

19. (1) Each unit packet and any outside packaging of smokeless tobacco products shall carry the following health warning:

“Déanann an táirge tobac seo dochar do do shláinte agus is táirge andúile é

This tobacco product damages your health and is addictive”.

(2) The health warning referred to in paragraph (1) shall—

- (a) comply with the requirements specified in Regulation 12(6),
- (b) appear on the 2 largest surfaces of the unit packet and any outside packaging, and
- (c) cover 32% of the surfaces of the unit packet and any outside packaging.

(3) The text of the health warnings referred to in paragraph (1) shall be parallel to the main text on the surface reserved for these warnings.

#### *Traceability*

20. (1) A person shall not manufacture or import tobacco products unless each unit packet of the tobacco product is marked with a unique identifier (in these Regulations referred to as the “unique identifier”) which shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form,

including through tax stamps or price marks, or by the opening of the unit packet.

(2) The unique identifier in relation to the tobacco product concerned shall allow the following to be determined:

- (a) the date and place of manufacturing;
- (b) the manufacturing facility;
- (c) the machine used to manufacture the tobacco products;
- (d) the production shift or time of manufacture;
- (e) the product description;
- (f) the intended market of retail sale;
- (g) the intended shipment route;
- (h) where applicable, the importer into the European Union;
- (i) the actual shipment route from manufacturing to the first retail outlet, including all warehouses used as well as the shipment date, shipment destination, point of departure and consignee;
- (j) the identity of all purchasers from manufacturing to the first retail outlet;
- (k) the invoice, order number and payment records of all purchasers from manufacturing to the first retail outlet.

(3) The information referred to in subparagraphs (a) to (g) of paragraph (2) and, where applicable, subparagraph (h) of paragraph (2) shall form part of the unique identifier.

(4) The information referred to in subparagraphs (i), (j) and (k) of paragraph (2) shall be electronically accessible by means of a link to the unique identifier.

(5) An economic operator involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, shall record the entry of all unit packets into their possession, all intermediate movements and the final exit of the unit packets from their possession.

(6) The economic operator may comply with paragraph (5) by marking and recording aggregated packaging such as cartons, mastercases or pallets, provided that the tracking and tracing of all unit packets remains possible.

(7) A person engaged in the supply chain of tobacco products shall maintain complete and accurate records of all relevant transactions.



(8) A manufacturer of a tobacco product shall provide all economic operators involved in the trade of tobacco products, from the manufacturer to the last economic operator before the first retail outlet, including importers, warehouses and transporting companies, with the equipment that is necessary for the recording of the tobacco products purchased, sold, stored, transported or otherwise handled.

(9) The equipment referred to in paragraph (8) shall be able to read and transmit the recorded data electronically to a data storage facility pursuant to paragraph (10).

(10) A manufacturer or importer of a tobacco product shall conclude data storage contracts with an independent third party approved by the Commission, for the purpose of hosting the data storage facility for all relevant data.

(11) The third party's activities referred to in paragraph (10) shall be monitored by an external auditor, who has been approved by the Commission and has been proposed and paid for by the tobacco manufacturer.

(12) The external auditor referred to in paragraph (11) shall submit an annual report to the competent authority and to the Commission, assessing in particular any irregularities in relation to access.

(13) The manufacturer and third party referred to in paragraph (10) shall ensure that the Commission, the competent authorities and the external auditor shall have full access to the data storage facilities.

(14) An economic operator involved in the trade of tobacco products shall not modify or delete recorded data.

(15) Personal data obtained under this Regulation shall only be processed in accordance with the Data Protection Acts 1988 and 2003.

(16) This Regulation shall apply to—

(a) cigarettes and roll-your-own tobacco placed on the market on or after 20 May 2019, and

(b) tobacco products other than those referred to in paragraph (a) placed on the market on or after 20 May 2024.

#### *Security feature*

21. (1) Subject to paragraph (2), a person shall not place a tobacco product on the market unless each unit packet of the tobacco product carries a tamper proof security feature in addition to the unique identifier, composed of visible and invisible elements which shall be irremovably printed or affixed, indelible and not hidden or interrupted in any form, including through tax stamps and price marks, or other elements imposed by legislation.

(2) Paragraph 1 shall apply to—

- (a) cigarettes and roll-your-own tobacco placed on the market on or after 20 May 2019, and
- (b) tobacco products other than those referred to in paragraph (a) placed on the market on or after 20 May 2024.

#### PART 4

### TOBACCO FOR ORAL USE, CROSS-BORDER DISTANCE SALES AND NOVEL TOBACCO PRODUCTS

#### *Tobacco for oral use*

22. A person shall not place tobacco for oral use on the market in the State.

#### *Cross-border distance sales of tobacco products*

23. (1) A retailer established in the State who engages or intends to engage in cross-border distance sales of tobacco products to consumers located in the European Union shall register with the Executive and with the competent authority in the Member State where the actual or potential consumers are located.

(2) A retailer established outside the State but in another Member State who engages or intends to engage in cross-border distance sales of tobacco products to actual or potential consumers located in the State shall register with the Executive.

(3) A retailer established outside the European Union who engages or intends to engage in cross-border distance sales of tobacco products to actual or potential consumers located in the State shall register with the Executive.

(4) When registering with the Executive under paragraphs (1), (2) or (3), the retailer shall submit the following information:

- (a) the name and address of the retailer;
- (b) the trading name and address of the retailer, if different;
- (c) the permanent address of each place of activity used by the retailer for the supply of tobacco products;
- (d) the date on which the retailer first started, or intends to start the activity of offering tobacco products for cross-border distance sales to consumers by means of information society services;
- (e) the address of the website or websites used for that purpose;
- (f) all relevant information necessary to identify the website;
- (g) any other information the Executive considers necessary.

(5) The Executive shall—

- (a) where a retailer has submitted the information specified in paragraph (4), register the retailer,
- (b) notify a retailer that he or she has been registered pursuant to this Regulation, and
- (c) publish a list of all retailers registered pursuant to this Regulation on its website.

(6) A retailer shall not place a tobacco product on the market via cross-border distance sales until such time as the retailer has received notification from the Executive that he or she has been registered pursuant to this Regulation.

(7) Before a tobacco product reaches a consumer within the State—

- (a) a retailer shall nominate a person to be responsible for verifying, that the product complies with these Regulations, and
- (b) the person nominated under paragraph (a) shall confirm to the Executive that the tobacco product complies with these Regulations.

(8) A retailer shall operate an age verification system, which verifies, at the time of the sale of the tobacco product, that the purchasing consumer has attained the age of 18 years in the case of tobacco products purchased in the State.

(9) A retailer or the person nominated under paragraph (7)(a) shall provide to the Executive, a description of the details and functioning of the age verification system referred to in paragraph (8).

(10) A retailer—

- (a) shall process personal data of a consumer in accordance with the Data Protection Acts 1988 and 2003,
- (b) shall not disclose personal data processed under paragraph (a) to a manufacturer of a tobacco product or a company forming part of the same group of companies or to other third parties, and
- (c) shall not use or transfer personal data of a consumer for purposes other than the actual purchase.

(11) Paragraph (10) shall apply if the retailer forms part of a manufacturer of tobacco products.

(12) This Regulation applies to a retailer that engages or intends to engage in cross-border distance sales of tobacco products to consumers located in the European Union.

*Notification of novel tobacco products*

24. (1) A manufacturer or importer of a novel tobacco product shall submit a notification to the Executive of any such product the manufacturer or importer intends to place on the market in the State.

(2) A notification referred to in paragraph (1) shall be—

- (a) submitted in electronic form not less than 6 months before it is intended to place a novel tobacco product on the market, and
- (b) accompanied by a detailed description of the novel tobacco product concerned as well as instructions for its use and information on ingredients and emissions in accordance with Regulations 5 and 6.

(3) A manufacturer or importer when submitting a notification of a novel tobacco product shall also provide the Executive with the following:

- (a) available scientific studies on toxicity, addictiveness and attractiveness of the novel tobacco product, in particular as regards its ingredients and emissions;
- (b) available studies, executive summaries thereof and market research on the preferences of various consumer groups, including young people and current smokers;
- (c) other available and relevant information, including a risk-benefit analysis of the product, its expected effects on cessation of tobacco consumption, its expected effects on initiation of tobacco consumption and predicted consumer perception.

(4) A manufacturer or importer of a novel tobacco product shall submit in electronic form to the Executive any new or updated information on the studies, research and other information referred to in paragraph (3).

(5) The Executive may request a manufacturer or importer of novel tobacco products to carry out additional tests or submit additional information and the manufacturer or importer, as appropriate, shall comply with any such request.

(6) The Executive shall make information received under this Regulation available to the Commission.

(7) Where—

- (a) a novel tobacco product is a smokeless tobacco product, the provisions of these Regulations that apply to smokeless tobacco products shall apply to the novel tobacco product concerned, and
- (b) a novel tobacco product is a tobacco product for smoking, the provisions of these Regulations that apply to tobacco products for smoking shall apply to the novel tobacco product concerned.

## PART 5

ELECTRONIC CIGARETTES AND HERBAL PRODUCTS FOR  
SMOKING*General provisions for electronic cigarettes and refill containers*

25. (1) Subject to paragraph (2), a person shall not place electronic cigarettes or refill containers on the market unless they comply with the provisions of these Regulations and all other relevant European acts.

(2) These Regulations do not apply to electronic cigarettes and refill containers that are subject to—

- (a) an authorisation requirement under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001<sup>12</sup> on the Community code relating to medicinal products for human use, or
- (b) the requirements under Directive 93/42/EEC of 14 June 1993<sup>13</sup> concerning medical devices.

(3) Regulation 23 (other than paragraphs (8) and (9)) shall apply to cross-border distance sales of electronic cigarette and refill containers and references in that Regulation to tobacco products shall be construed as references to electronic cigarettes and refill containers.

(4) In this Regulation—

“Act of 1972” means the European Communities Act 1972 (No. 27 of 1992);

“European act” means—

- (a) a provision of the treaties governing the European Union, or
- (b) an act adopted by an institution of the European Union, an institution of the European Communities or any other body competent under those treaties;

“European Communities” has the same meaning as it has in the Act of 1972;

“European Union” has the same meaning as it has in the Act of 1972;

“treaties governing the European Union” has the same meaning as it has in the Act of 1972.

*Notification of electronic cigarettes and refill containers*

26. (1) A manufacturer or importer of an electronic cigarette or a refill container shall submit in electronic form a notification to the Executive of any such products which the manufacturer or importer intends to place on the market in the State.

<sup>12</sup>OJ No. L 311, 28.11.2001, p.67

<sup>13</sup>OJ No. L 169, 12.7.1993, p.1

(2) A notification pursuant to paragraph (1) shall, depending on whether the product is an electronic cigarette or a refill container, contain the following information:

- (a) the name and contact details of the manufacturer, a responsible person within the European Union, and, if applicable, the importer into the European Union;
- (b) a list of all ingredients contained in, and emissions resulting from the use of, the product, by brand name and type, including quantities thereof;
- (c) toxicological data regarding the product's ingredients and emissions, including when heated, referring in particular to their effects on the health of consumers when inhaled and taking into account, any addictive effect;
- (d) information on the nicotine doses 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 containers;
- (f) a description of the production process, including whether it involves series production;
- (g) a declaration that the production process ensures conformity with the requirements of this Regulation and Regulation 27;
- (h) a declaration that the manufacturer and importer bear full responsibility for the quality and safety of the product, when placed on the market and used under normal or reasonably foreseeable conditions.

(3) Where the Executive considers that the information submitted pursuant to paragraph (2) is incomplete, it shall request the completion of the information concerned and a manufacturer or importer, as appropriate, shall comply with any such request.

(4) A manufacturer or importer of an electronic cigarette or a refill container shall submit to the Executive a new notification for each substantial modification of the product.

(5) The notification under paragraph (1) shall be provided—

- (a) by 20 November 2016 in respect of electronic cigarettes or refill containers placed on the market before 20 May 2016, and
- (b) in respect of a new product, not less than 6 months prior to placing an electronic cigarette or refill container on the market.

- (6) A manufacturer or importer of electronic cigarettes or refill containers shall submit in electronic form a report, annually to the Executive containing—
- (a) comprehensive data on sales volumes, by brand name and type of the product,
  - (b) information on the preferences of various consumer groups, including young people, non-smokers and the main types of current users,
  - (c) the mode of sale of the products, and
  - (d) executive summaries of any market surveys carried out in respect of the matters referred to in subparagraphs (a), (b) and (c), including an English translation if necessary.
- (7) A manufacturer or importer of an electronic cigarette or refill container shall submit to the Executive the information referred to in this Regulation, including modifications and withdrawal from the market—
- (a) in accordance with the format provided for in the Annex to Commission Implementing Decision (EU) 2015/2183 of 24 November 2015<sup>5</sup>, and
  - (b) by means of the common entry gate for data submission.
- (8) Prior to submitting information under this Regulation for the first time, a manufacturer or importer of an electronic cigarette or refill container shall apply to the Commission for an identification number in accordance with Article 4 of Commission Implementing Decision (EU) 2015/2186 of 25 November 2015<sup>6</sup> establishing a format for the submission and making available of information on tobacco products.
- (9) A manufacturer or importer of an electronic cigarette or refill container shall upon request, submit in electronic form to the Commission, a document providing company identification and authentication of activities in accordance with the national legislation where the company is established.
- (10) A manufacturer or importer of an electronic cigarette or refill container shall assign an E-Cigarettes ID (in this Regulation referred to as an “EC-ID”) for each product for which information is reported based on the identification number referred to in paragraph (8).
- (11) A manufacturer or importer of an electronic cigarette or refill container, when submitting information on electronic cigarettes or refill containers with the same composition and design, shall use the same EC-ID to the extent possible, in particular, where data is submitted by various members of a group of companies.
- (12) Paragraph (11) shall apply irrespective of the brand, subtype or number of markets upon which a product is placed.

(13) Where a manufacturer or importer is not able to ensure that the same EC-ID is used for products with the same composition and design in accordance with paragraph (11), they shall at least provide, in so far as possible, the different EC-ID that was assigned to such products.

*Safety and quality requirements for electronic cigarettes and refill containers*

27. (1) Subject to paragraph (2), a person shall not place on the market electronic cigarettes or refill containers unless they comply with the following:

- (a) nicotine-containing liquid is contained in—
  - (i) dedicated refill containers not exceeding a volume of 10 ml, or
  - (ii) disposable electronic cigarettes or in single use cartridges or tanks and that the cartridges or tanks do not exceed a volume of 2ml;
- (b) nicotine-containing liquid does not contain nicotine in excess of 20 mg/ml;
- (c) nicotine-containing liquid does not contain an additive listed in Regulation 8(3);
- (d) only ingredients of high purity are used in the manufacture of the nicotine-containing liquid;
- (e) with the exception of nicotine, only ingredients that do not pose a risk to human health in heated or unheated form are used in the nicotine-containing liquid;
- (f) electronic cigarettes deliver the nicotine doses at consistent levels under normal conditions of use;
- (g) electronic cigarettes and refill containers are—
  - (i) child and tamper-proof,
  - (ii) protected against breakage and leakage, and
  - (iii) have a mechanism that ensures refilling without leakage.

(2) For the purposes of paragraph (1)(d), substances other than the ingredients referred to in Regulation 26(2)(b) shall be present in the nicotine-containing liquid only in trace levels, if such traces are technically unavoidable during manufacture.

(3) Paragraph (1) shall apply to electronic cigarettes and refill containers manufactured or released for free circulation after 20 November 2016.

*Refill mechanism of electronic cigarettes*

28. (1) A person shall not place on the market refillable electronic cigarettes or refill containers unless the mechanism by which the electronic cigarettes are refilled—



- (a) uses a refill container—
    - (i) which has a securely attached nozzle at least 9mm long, which is narrower than, and slots comfortably into, the opening of the tank of the electronic cigarette with which it is used, and
    - (ii) which has a flow mechanism that emits no more than 20 drops of refill liquid per minute when placed vertically and subjected to an atmospheric pressure alone at  $20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ , or
  - (b) operates by means of a docking system which only releases refill liquids into the tank of the electronic cigarette when the electronic cigarette and refill container are connected.
- (2) (a) A person shall not place on the market refillable electronic cigarettes or refill containers with a refill mechanism referred to in paragraph (1)(a) unless the width of the nozzle or the width of the opening of the tank is indicated in the instructions for use in a manner that enables consumers to identify the compatibility of refill containers and electronic cigarettes.
- (b) A person shall not place on the market refillable electronic cigarettes or refill containers with a refill mechanism referred to in paragraph (1)(b) unless the instructions for use specify the types of docking system with which the electronic cigarette and refill containers are compatible.

*Information and labelling on electronic cigarettes and refill containers*

29. (1) A person shall not place on the market electronic cigarettes or refill containers unless each unit packet includes 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) instructions for refilling, including diagrams,
  - (c) contra-indications,
  - (d) warnings for specific risk groups,
  - (e) possible adverse effects,
  - (f) addictiveness and toxicity, and
  - (g) contact details of the manufacturer or importer and a contact person within the European Union.
- (2) A person shall not place on the market electronic cigarettes or refill containers unless each unit packet and any outside packaging—

- (a) includes a list of all ingredients contained in the product in descending order of the weight,
- (b) includes an indication of the nicotine content of the product and the delivery per dose,
- (c) includes the batch number,
- (d) includes a recommendation to keep the product out of reach of children, and
- (e) subject to paragraphs (a) and (b), does not include elements or features referred to in Regulation 30.

(3) A person shall not place on the market electronic cigarettes or refill containers unless each unit packet and any outside packaging carries the following health warning:

“Cuimsíonn an táirge seo nicitín, ar substaint an-andúile é

This product contains nicotine which is a highly addictive substance.”

(4) The health warning referred to in paragraph (3) shall comply with the requirements in paragraphs (2) and (3) of Regulation 19.

*Product presentation for electronic cigarettes*

30. (1) A person shall not label any unit packet or any outside packaging of an electronic cigarette or refill container or include any element or feature on an electronic cigarette or refill container that—

- (a) promotes an electronic cigarette or refill container or encourages its consumption by containing information or statements that create an erroneous impression in relation to the characteristics, health effects, risks or emissions of an electronic cigarette or refill container,
- (b) suggests that an electronic cigarette or refill container is less harmful than other electronic cigarettes or refill containers or that it aims to reduce the effect of some of the harmful components of smoke,
- (c) suggests that an electronic cigarette or refill container has vitalising, energetic, healing, rejuvenating, natural or organic properties, or that it has health or lifestyle benefits,
- (d) makes any reference to the taste or smell of an electronic cigarette or refill container or other additives contained in the product or the absence thereof,
- (e) resembles a food or a cosmetic product, or
- (f) suggests that the electronic cigarette or refill container has improved biodegradability or other environmental advantages.

(2) The unit packets and any outside packaging of an electronic cigarette or refill container shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.

(3) The elements and features that are prohibited under paragraphs (1) and (2) shall include texts, symbols, names, trade marks, figurative or other signs.

*Commercial communications relating to electronic cigarettes and refill containers*

31. A person shall not use—

- (a) commercial communications in information society services, in the press or other printed publications, with the aim or direct or indirect effect of promoting electronic cigarettes or refill containers other than—
  - (i) publications that are intended exclusively for professionals in the trade of electronic cigarettes or refill containers, and
  - (ii) publications that are not principally intended for the European Union market where such publications are printed and published in third countries;
- (b) commercial communications on the radio, with the aim or direct or indirect effect of promoting electronic cigarettes or refill containers;
- (c) any form of public or private contribution to radio programmes with the aim or direct or indirect effect of promoting electronic cigarettes or refill containers;
- (d) any form of public or private contribution to any event, activity or individual person with the aim or direct or indirect effect of promoting electronic cigarettes or refill containers and involving or taking place in several Member States or otherwise having cross-border effects;
- (e) audiovisual commercial communications to which the Broadcasting Act 2009 (No. 18 of 2009) and the European Communities (Audiovisual Media Services) Regulations 2010 (S.I. 258 of 2010) applies, for electronic cigarettes or refill containers.

*Market developments concerning electronic cigarettes and refill containers*

32. The Executive shall monitor 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 among young people and non-smokers.

*Public health concerns relating to electronic cigarettes and refill containers*

33. (1) A manufacturer, importer or distributor of electronic cigarettes or refill containers shall establish and maintain a system for collecting information

about all of the suspected adverse effects on human health of such electronic cigarettes or refill containers.

(2) A manufacturer, importer or distributor of electronic cigarettes or refill containers who considers, or has reason to believe, that electronic cigarettes or refill containers, which are in his or her possession and are intended to be placed on the market or are placed on the market, are not safe or are not of good quality or are otherwise not in conformity with these Regulations, shall immediately take the corrective action necessary to bring the product concerned into conformity with these Regulations and withdraw or recall it, as appropriate.

(3) Where a manufacturer, importer or distributor of electronic cigarettes or refill containers considers, or has reason to believe, that electronic cigarettes or refill containers are not safe or are not of good quality or in conformity with these Regulations as referred to in paragraph (2), he or she shall immediately inform the Executive in electronic form providing details, in particular, of the risk to human health and safety and of any corrective action taken, and of the results of such corrective action.

(4) The Executive may request additional information from a manufacturer, importer or distributor of electronic cigarettes or refill containers including information on the safety and quality aspects or any adverse effects of electronic cigarettes or refill containers and the manufacturer, importer or distributor, as appropriate, shall comply with any such request.

*Herbal products for smoking*

34. (1) A person shall not manufacture or import a herbal product for smoking unless each unit packet and any outside packaging of the herbal product for smoking carries the following health warning:

“Má chaitheann tú an táirge seo, déantar dochar do do shláinte  
Smoking this product damages your health.”

(2) The health warning referred to in paragraph (1) shall—

- (a) be printed on the front and back external surface of the unit packet and on any outside packaging,
- (b) comply with the requirements set out in Regulation 12(6), and
- (c) cover 32% of the area of the corresponding surface of the unit packet and of any outside packaging.

*Reporting of ingredients of herbal products for smoking*

35. (1) A manufacturer or importer of herbal products for smoking shall in electronic form—

- (a) submit to the Executive a list of all ingredients, and quantities thereof that are used in the manufacture of such products by brand name and type, and

- (b) inform the Executive when the composition of a product is modified in a way that affects the information submitted pursuant to this Regulation.

(2) The Executive shall make available on its website, the information received under paragraph (1).

(3) The information required under this Regulation shall be submitted in electronic form to the Executive not less than 3 months prior to the placing on the market of a new or modified herbal product for smoking.

*Product presentation for herbal products*

36. (1) A person shall not label any unit packet or any outside packaging of a herbal product or include any element or feature on the herbal product that—

- (a) promotes a herbal product or encourages its consumption by containing information or statements that create an erroneous impression in relation to the characteristics, health effects, risks or emissions of a herbal product,
- (b) suggests that a herbal product is less harmful than other herbal products or that it aims to reduce the effect of some of the harmful components of smoke,
- (c) suggests that a herbal product has vitalising, energetic, healing, rejuvenating, natural or organic properties, or that it has health or lifestyle benefits,
- (d) resembles a food or a cosmetic product, or
- (e) states that the product is free of additives or flavours.

(2) The unit packets and any outside packaging of a herbal product shall not suggest economic advantages by including printed vouchers, offering discounts, free distribution, two-for-one or other similar offers.

(3) The elements and features that are prohibited under paragraphs (1) and (2) shall include texts, symbols, names, trade marks, figurative or other signs.

## PART 6

### ENFORCEMENT AND SANCTIONS

*Designated laboratories*

37. (1) The Minister may, for the purposes of these Regulations, designate by notice in writing published in *Iris Oifigiúil*—

- (a) a laboratory (in these Regulations referred to as a “designated laboratory”) as a laboratory at which—
  - (i) samples taken under these Regulations may be analysed, and

- (ii) measurement methods referred to in Regulation 4 may be verified, and
  - (b) a person as being a person who, or a class of persons the members of which, may, at a designated laboratory, analyse samples taken under these Regulations, and verify the measurement methods referred to in Regulation 4, and each such person or member is, in these Regulations, referred to as a “designated analyst”.
- (2) A laboratory designated under paragraph (1) shall not be owned or controlled directly or indirectly by the tobacco industry.
- (3) The Minister may revoke or amend a designation made under paragraph (1).
- (4) As soon as practicable after a sample taken by an authorised officer under these Regulations has been received at a designated laboratory it shall be analysed and the composition, the amount and concentration of its ingredients and any other properties of the sample shall be determined by a designated analyst at that laboratory.
- (5) As soon as practicable after compliance with paragraph (4), a designated analyst engaged in the analysis of samples at the designated laboratory concerned shall forward the results of the analysis carried out on the sample concerned to the Executive.

*Construction of references (authorised officers)*

38. Section 48 of the Public Health (Tobacco) Act 2002 (No. 6 of 2002) (amended by section 23 of the Public Health (Standardised Packaging of Tobacco) Act 2015 (No. 4 of 2015)) shall apply for the purposes of these Regulations subject to the following modifications:

- (a) references to “this Act” shall be construed as references to “these Regulations”;
- (b) references to “this Act and the Act of 2015” shall be construed as references to “these Regulations”;
- (c) references to “this Act or the Act of 2015” shall be construed as references “these Regulations”;
- (d) the reference to “this Act or under the Act of 2015” shall be construed as a reference “these Regulations”;
- (e) references to “tobacco products” shall be construed as references to “relevant products”;
- (f) references to “retail packaging” shall be construed as references to “packaging”;

- (g) subsection (4)(a)(i) shall be construed as including a reference to “commercial communication, promotion” after “labelling,”;
- (h) it shall include the following additional subsection:
- “(4A) An authorised officer may, for the purposes of obtaining any information which may be required in relation to a matter under investigation under these Regulations, at all reasonable times—
- (a) pay or make tender of payment for a relevant product, or
- (b) confirm any other information in relation to a relevant product for the purposes of the investigation.”;
- (i) any other necessary modifications.

*Indemnification of authorised officers*

39. Where the Executive is satisfied that an authorised officer has discharged his or her duties in relation to the enforcement of the provisions of these Regulations in a *bona fide* manner, the Executive shall indemnify the authorised officer against all actions or claims howsoever arising in respect of the discharge by him or her of his or her duties.

*Taking of samples by authorised officers*

40. (1) Where an authorised officer takes a sample of a relevant product or a sample of any substance or article used in the manufacturing, processing or storage of relevant products, he or she shall divide the sample into 3 approximately equal parts, and place each part into separate containers which he or she shall forthwith seal and mark in such a manner as to identify it as part of the sample taken by that authorised officer.

(2) Where an authorised officer has complied with paragraph (1) he or she shall—

- (a) offer one of the sealed containers to the owner or person for the time being in charge or possession of the relevant product, substance or article from which the sample concerned was taken,
- (b) retain one of the sealed containers, and
- (c) forward, or cause to be forwarded, one of the sealed containers to a designated laboratory for the purposes of analysis.

(3) Where a relevant product, or any substance or article used in the manufacturing, processing or storage of a relevant product is contained in a container and its division into parts is (for whatever reason) not practicable, an authorised officer, who wishes to take samples of such relevant product, substance or article for the purposes of analysis, shall take possession of 3 such containers belonging to the same batch, and each such container shall be deemed to be part of a sample for the purposes of paragraph (1), and the provisions of paragraphs (1) and (2) shall apply thereto accordingly.

*Compliance notice*

41. (1) Where an authorised officer is satisfied that a person has contravened Regulation 5, 6, 7, 10, 11, 24, 26, 27, 28, 29, 30, 33(1), 34, 35 or 36, the authorised officer may serve a notice (in this Regulation referred to as a “compliance notice”) on the person.

(2) A compliance notice shall—

- (a) state the grounds for the authorised officer being satisfied that there has been a contravention referred to in paragraph (1),
- (b) for the purpose of ensuring compliance by the person concerned, require the person to do or refrain from doing such act or acts as is or are specified in the notice by such date as is so specified, and
- (c) contain information regarding the bringing of an appeal under paragraph (5) against the notice, including the manner in which an appeal shall be brought.

(3) A compliance notice shall not specify a date in accordance with paragraph (2)(b) that falls on or before the date by which an appeal under paragraph (5) shall be brought.

(4) An authorised officer may—

- (a) withdraw a compliance notice at any time, as he or she considers appropriate, or
- (b) where no appeal is brought under this Regulation, specify a date extending the period specified in the notice for the purposes of paragraph (2)(b), and notify the person in writing accordingly.

(5) A person may appeal a compliance notice served on him or her to the District Court not later than 14 days after the service of the compliance notice concerned.

(6) The authorised officer and the appellant concerned shall be entitled to be heard and to adduce evidence at the hearing of an appeal under this Regulation.

(7) The District Court shall, upon an appeal under this Regulation, do one of the following:

- (a) affirm the compliance notice concerned;
- (b) direct the authorised officer to withdraw the compliance notice concerned.

(8) An authorised officer shall comply with a direction under paragraph (7).

(9) A person who fails to comply with a compliance notice by the specified date shall be guilty of an offence and shall be liable—



(a) on summary conviction—

- (i) in the case of a first offence, to a class B fine or to imprisonment for a term not exceeding 6 months, or to both, and
- (ii) in the case of a second or subsequent offence, to a class A fine or to imprisonment for a term not exceeding 12 months, or to both, or

(b) on conviction on indictment to a fine not exceeding €500,000 or imprisonment for a term not exceeding 3 years or both.

(10) This Regulation shall not operate to prevent or restrict—

- (a) the entitlement of any person to bring proceedings for the purpose of securing compliance with these Regulations by a person, or
- (b) the bringing or prosecuting of any proceedings for an offence under these Regulations.

(11) In this Regulation “specified date” means, in relation to a compliance notice—

- (a) the date specified in the notice in accordance with paragraph (2)(b), where no appeal against the notice is brought under this Regulation, or
- (b) the day falling immediately after the expiration of the period of 7 days from the date on which the District Court so affirms the notice, where an appeal against the notice is brought under paragraph (5) and the District Court affirms the notice in accordance with paragraph (7)(a).

*Prohibition notice*

42. (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 or importer concerned, an order (in this Regulation referred to as a “prohibition order”) in accordance with paragraph (2).

(2) A prohibition order shall—

- (a) be signed by the authorised officer issuing it,
- (b) state that the authorised officer is of the opinion that a particular consignment, class or batch of a relevant product does not comply with these Regulations,

- (c) specify the provision or provisions of these Regulations in relation to which the relevant product is not in compliance and the matters giving rise to the non-compliance, and
  - (d) direct the person on whom the prohibition order is served to ensure that the relevant product—
    - (i) is not to be placed or made available on the market until such time as all appropriate measures, including corrective measures, have been taken to bring the product into compliance with these Regulations,
    - (ii) is prohibited from being placed or made available on the market,
    - (iii) is to be withdrawn or recalled from the market within a specified time-limit, or
    - (iv) is to be destroyed within a specified time limit and in a manner prescribed by the authorised officer or is to be detained for the purposes of destruction by an authorised officer.
- (3) The approval referred to in paragraph (1) may be given orally or in writing and if given orally, shall be recorded in writing as soon as practicable.
- (4) A prohibition order shall take effect—
- (a) where the prohibition order so declares, immediately the order is received by the person on whom it is served, or
  - (b) in any other case—
    - (i) where no appeal is taken against the prohibition order, on the expiration of the period during which such an appeal may be taken or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later, or
    - (ii) where an appeal is taken, on the day next following the day on which the prohibition order is confirmed on appeal or the appeal is withdrawn or the day specified in the prohibition order as the day on which it is to come into effect, whichever is the later.
- (5) The bringing of an appeal against a prohibition order which is to take effect in accordance with paragraph (4)(a) shall not have the effect of suspending the operation of the prohibition order, but the appellant may apply to the District Court to have the operation of the prohibition order suspended until the appeal is disposed of and, on such application, the District Court may, if it thinks it proper to do so, direct that the operation of the prohibition order be suspended until the appeal is disposed of.
- (6) In the event of non-compliance or delay by the person on whom the prohibition order has been served, an authorised officer shall, with the approval of the Director General or other officer designated in that behalf by the Executive,

take whatever steps are considered necessary to ensure compliance with the direction given under this Regulation and this may include the withdrawal, recall, seizure and destruction of the products in question or the making of any arrangements for such withdrawal, recall, seizure or destruction.

(7) (a) A person who is aggrieved by a prohibition order may, within the period of 7 days beginning on the day on which the prohibition order is served on him or her, appeal against the order to a judge of the District Court in the district court district in which the prohibition order was served in the prescribed manner and in determining the appeal the judge may—

(i) if he or she is satisfied that in the circumstances of the case it is reasonable to do so, confirm the prohibition order, with or without modification, or

(ii) cancel the prohibition order.

(b) Where on the hearing of an appeal under this paragraph a prohibition order is confirmed, notwithstanding paragraph (6), the judge of the District Court by whom the appeal is heard may, on the application of the appellant, suspend the operation of the prohibition order for such period as in the circumstances of the case the judge considers appropriate.

(8) A person who appeals against a prohibition order or who applies for a direction suspending the application of the prohibition order under paragraph (5) shall at the same time notify the Executive of the appeal or the application and the grounds for the appeal or the application and the Executive shall be entitled to appear, be heard and adduce evidence on the hearing of the appeal or the application.

(9) The Director General of the Executive, or another officer of the Executive designated for that purpose may for stated reasons, revoke or vary a prohibition order made in accordance with this Regulation and the Executive shall be notified at the next available meeting of the Executive of any such revocation or variation and the reasons therefore.

(10) (a) Where a prohibition order has been served and activities are carried on in contravention of the prohibition order, the High Court may, on the application of the Executive, by order prohibit the continuance of the activities.

(b) An application to the High Court for an order under this paragraph shall be by motion and the Court, when considering the matter, may make such interim or interlocutory order (if any) as it considers appropriate and the order by which an application under this paragraph is determined may contain such terms and conditions (if any) as to the payment of costs as the Court considers appropriate.

*Offences and penalties*

43. (1) A person who contravenes Regulation 4(1), 6, 7, 10, 11, 23, 24, 29, 30, 31, 34, 35 or 36 commits an offence and shall be liable on summary conviction—

- (a) in the case of a first offence, to a class B fine or to imprisonment for a term not exceeding 6 months, or to both, and
- (b) in the case of a second or subsequent offence, to a class A fine or to imprisonment for a term not exceeding 12 months, or to both.

(2) A person guilty of an offence under paragraph (6) of this Regulation or paragraphs (1), (2) or (3) of Regulation 44 shall be liable—

- (a) on summary conviction—
  - (i) in the case of a first offence, to a class B fine or to imprisonment for a term not exceeding 6 months, or to both, and
  - (ii) in the case of a second or subsequent offence, to a class A fine or to imprisonment for a term not exceeding 12 months, or to both, or
- (b) on conviction on indictment to a fine not exceeding €500,000 or imprisonment for a term not exceeding 3 years or both.

(3) A person who contravenes Regulation 5, 8, 20, 21, 22, 25, 26, 27, 28 or 33 commits an offence and shall be liable—

- (a) on summary conviction—
  - (i) in the case of a first offence, to a class B fine or to imprisonment for a term not exceeding 6 months, or to both, and
  - (ii) in the case of a second or subsequent offence, to a class A fine or to imprisonment for a term not exceeding 12 months, or to both, or
- (b) on conviction on indictment to a fine not exceeding €500,000 or imprisonment for a term not exceeding 3 years or both.

(4) Where an offence under these Regulations is committed by a body corporate and is proved to have been so committed with the consent or connivance of, or to be attributable to any wilful neglect on the part of any person, being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person, as well as the body corporate, commits an offence and shall be liable to be proceeded against and punished as if he or she were guilty of the first-mentioned offence.

(5) Where the affairs of a body corporate are managed by its members, paragraph (4) applies in relation to the acts and defaults of a member in connection

with his or her functions of management as if he or she were a director or manager of the body corporate.

(6) A person who provides to the Executive information which the person knows or ought reasonably to know to be false or misleading (whether on the person's own behalf or on behalf of another person) in purported compliance with a requirement imposed by these Regulations commits an offence.

(7) Summary proceedings for an offence under these Regulations may be brought and prosecuted by the Executive.

(8) In proceedings for an offence under these Regulations, it shall be a defence for a person against whom such proceedings are brought to show that he or she made all reasonable efforts to ensure compliance with such provisions of these Regulations as are alleged to have been contravened.

(9) Unless it is satisfied that there are special and substantial reasons for not so doing, the court shall, where a person is convicted of an offence under these Regulations, order the person to pay to the prosecution the costs and expenses, measured by the court, incurred by the prosecution in relation to the prosecution of the offence.

#### *Forgery of documents*

44. (1) It shall be an offence for a person to forge or utter knowing it to be forged a notice, certificate or other document purporting to be issued, granted or given under these Regulations (in this Regulation referred to as "a forged document").

(2) It shall be an offence for a person to alter with intent to defraud or deceive, or to utter knowing it to be so altered a notice, certificate or other document issued, granted or given under these Regulations (in this Regulation referred to as "an altered document").

(3) It shall be an offence for a person to have, without lawful authority, in his or her possession a forged document or an altered document.

#### *Evidence in proceedings for an offence*

45. (1) In proceedings for an offence under these Regulations, a certificate purporting to be signed by a person employed or engaged at a designated laboratory stating the capacity in which that person is so employed or engaged and stating any one or more of the following, namely—

- (a) that the person received a sample submitted to the designated laboratory,
- (b) that, for such period as is specified in the certificate, the person had in his or her custody a sample so submitted, or
- (c) that the person gave to such other person as is specified in the certificate a sample so submitted,

shall unless the contrary is proved be evidence of the matters stated in the certificate.

(2) In proceedings for an offence under these Regulations, a certificate purporting to be signed by a designated analyst stating any one or more of the following, namely—

- (a) that he or she carried out any procedure for the purpose of detecting the presence of any substance in the sample so submitted, or
- (b) that the sample concerned contained such substance or such amount thereof as is specified in the certificate,

shall unless the contrary is proved be evidence of the matters stated in the certificate.

(3) In proceedings for an offence under these Regulations the court may, if it considers that the interests of justice so require, direct that oral evidence of the matters stated in a certificate under this Regulation be given and the court may, for the purpose of receiving oral evidence, adjourn the proceedings to a later date.

(4) A certificate under this Regulation shall be in such form as may be specified by the Minister.

(5) In proceedings for an offence under these Regulations, a relevant product, or a package containing a relevant product, that purports to bear the name of the manufacturer or importer of that product, shall unless the contrary is proved, be evidence that the relevant product was manufactured or imported, as the case may be, by the person concerned.

(6) In proceedings for an offence under these Regulations a relevant product, or a package containing a relevant product, that bears a trade mark shall unless the contrary is proved be evidence that the product was manufactured by the person who at the time of the alleged commission of the offence owned that trade mark.

#### *Service of documents*

46. (1) Subject to paragraph (2), a notice or document that is required to be served on or given to a person under Regulation 41 or 42 shall be addressed to the person concerned by name and may be given to the person in one of the following ways—

- (a) by delivering it to the person,
- (b) by leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address, or

- (c) by sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address.

(2) For the purposes of this Regulation, a company within the meaning of the Companies Act 2014 shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

## PART 7

### TRANSITIONAL PROVISIONS AND REVOCATIONS

#### *Transitional provisions*

47. (1) These Regulations shall not apply to—

- (a) electronic cigarettes or refill containers manufactured or released for free circulation before 20 November 2016 which are placed on the market on or before 20 May 2017, and
- (b) herbal products for smoking manufactured or released for free circulation before 20 May 2016 which are placed on the market on or before 20 May 2017.

#### *Revocations*

48. (1) Subject to paragraph (2), the following Regulations are revoked:

- (a) European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003 (S.I. No. 425 of 2003);
- (b) European Communities (Manufacture, Presentation and Sale of Tobacco Products) (Amendment) Regulations 2008 (S.I. No. 255 of 2008);
- (c) European Communities (Manufacture, Presentation and Sale of Tobacco Products) (Amendment) Regulations 2011 (S.I. No. 655 of 2011);
- (d) Public Health (Tobacco) (General and Combined Warnings) Regulations 2011 (S.I. No. 656 of 2011).

(2) Notwithstanding paragraph (1)—

- (a) the European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003 (S.I. No. 425 of 2003), and
- (b) the Public Health (Tobacco) (General and Combined Warnings) Regulations 2011 (S.I. No. 656 of 2011),

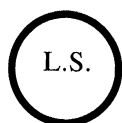
shall continue to apply in respect of tobacco products manufactured or released for free circulation and labelled before 20 May 2016 which are placed on the market before 20 May 2017.

## Schedule

*Regulations 14, 16 and 18*

## LIST OF TEXT WARNINGS

Text Warning in Irish Language	Text Warning in English Language
(1) Caitheamh tobac is cúis le naoi gcinn as gach deich n-ailse scamhóg	(1) Smoking causes 9 out of 10 lung cancers
(2) Caitheamh tobac is cúis le hailse bhéil agus scornaí	(2) Smoking causes mouth and throat cancer
(3) Déanann caitheamh tobac dochar do do scamhóga	(3) Smoking damages your lungs
(4) Caitheamh tobac is cúis le taomanna croí	(4) Smoking causes heart attacks
(5) Caitheamh tobac is cúis le strócanna agus le míchumas	(5) Smoking causes strokes and disability
(6) Nuair a chaitear tobac, tachtar na hartairí	(6) Smoking clogs your arteries
(7) Méadaíonn caitheamh tobac an riosca go dtiocfaidh daille ort	(7) Smoking increases the risk of blindness
(8) Déanann caitheamh tobac dochar do do chuid fiacla agus do do dhrandail	(8) Smoking damages your teeth and gums
(9) Féadann caitheamh tobac do leanbh sa bhroinn a mharú	(9) Smoking can kill your unborn child
(10) Déanann do dheatach tobac díobháil do do leanaí, do do theaghlach agus do do chairde	(10) Your smoke harms your children, family and friends
(11) Is é is dóichí gur caiteoirí tobac a bheidh i leanaí de chuid caiteoirí tobac ná leanaí eile	(11) Smokers' children are more likely to start smoking
(12) Scoir de chaitheamh tobac — coinnigh beo do do mhuintir	(12) Quit smoking — stay alive for those close to you
(13) Laghdaíonn caitheamh tobac torthúlacht	(13) Smoking reduces fertility
(14) Méadaíonn caitheamh tobac an riosca go dtiocfaidh éagumas ort	(14) Smoking increases the risk of impotence



GIVEN under my Official Seal,  
19 May 2016.

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 give effect to 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 provision of the Member States concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC.

These Regulations revoke the following Regulations:

European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003 (S.I. No. 425 of 2003);

European Communities (Manufacture, Presentation and Sale of Tobacco Products) (Amendment) Regulations 2008 (S.I. No. 255 of 2008);

European Communities (Manufacture, Presentation and Sale of Tobacco Products) (Amendment) Regulations 2011 (S.I. No. 655 of 2011);

Public Health (Tobacco) (General and Combined Warnings) Regulations 2011 (S.I. No. 656 of 2011).

The European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003 (S.I. No. 425 of 2003) and the Public Health (Tobacco) (General and Combined Warnings) Regulations 2011 (S.I. No. 656 of 2011) shall continue to apply in respect of tobacco products manufactured or released for free circulation and labelled before 20 May 2016 which are placed on the market before 20 May 2017.

These Regulations may be cited as the European Union (Manufacture, Presentation and Sale of Tobacco and Related Products) Regulations 2016 and come into effect on 20 May 2016.

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.

---

DUBLIN  
PUBLISHED BY THE STATIONERY OFFICE  
To be purchased from  
GOVERNMENT PUBLICATIONS,  
52 ST. STEPHEN'S GREEN, DUBLIN 2.  
(Tel: 01 - 6476834 or 1890 213434; Fax: 01 - 6476843)  
or through any bookseller.

---

€9.65



Wt. (B32107). 285. 5/16. Essentra. Gr 30-15.