



STATUTORY INSTRUMENTS.

**S.I. No. 656 of 2011**



PUBLIC HEALTH (TOBACCO) (GENERAL AND COMBINED  
WARNINGS) REGULATIONS 2011

**(Prn. A11/2347)**

PUBLIC HEALTH (TOBACCO) (GENERAL AND COMBINED  
WARNINGS) REGULATIONS 2011

I, JAMES REILLY, Minister for Health, in exercise of the powers conferred on me by subsections (4) (as amended by section 9 of the Public Health (Tobacco) (Amendment) Act 2004 (No. 6 of 2004)) and (6) (as amended by section 1 of the Public Health (Tobacco) (Amendment) Act 2011 (No. 15 of 2011)) of section 38 of the Public Health (Tobacco) Act 2002 (No. 6 of 2002) (as adapted by the Health and Children (Alteration of Name of Department and Title of Minister) Order 2011 (S.I. No. 219 of 2011)), for the purpose of giving further effect to Article 5 of Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001<sup>1</sup>, and for the purpose of giving effect to Commission Decision 2003/641/EC of 5 September 2003<sup>2</sup> and Commission Decision C(2005) 1452 final of 26 May 2005 (as amended by Commission Decision C(2006) 1502 final of 12 April 2006), hereby make the following regulations:

1. These Regulations may be cited as the Public Health (Tobacco) (General and Combined Warnings) Regulations 2011.

2. (1) In these Regulations—

“EEA Agreement” has the same meaning as it has in the European Communities (Amendment) Act 1993;

“import” means importation from a country which is not a Member State;

“Member State” means a Member State of the European Communities or of the European Union and shall be construed as including reference to those States that are Contracting Parties to the EEA Agreement;

“nicotine” means nicotinic alkaloids;

“place on the market” means—

(a) import,

(b) sell,

(c) offer or expose for sale,

(d) invite the making by a person of an offer to purchase,

<sup>1</sup>OJ L 194, 18.7.2001, p. 26

<sup>2</sup>OJ No. L226 of 10.09.2003, p.24

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 20th December, 2011.*

(e) distribute free of charge, or

(f) supply for any of those purposes (whether or not for profit);

“tar” means the raw anhydrous nicotine-free condensate of smoke;

“tobacco products” means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, even partly, made of tobacco, whether genetically modified or not.

(2) A word or expression which is used in these Regulations and which is also used in Commission Decision 2003/641/EC of 5 September 2003<sup>2</sup> has, unless the context otherwise requires, the same meaning in these Regulations as it has in Commission Decision 2003/641/EC.

3. (1) The tar, nicotine and carbon monoxide yields of cigarettes measured in accordance with Regulation 4 of the European Communities (Manufacture, Presentation and Sale of Tobacco Products) Regulations 2003 (S.I. No. 425 of 2003) shall be printed on one side of the cigarette packet in both the Irish and English languages, so that at least 12 per cent of the corresponding surface is covered.

(2) (a) One of the general warnings set out in Part 1 of the Schedule shall be printed, in both the Irish and English languages, on—

(i) the most visible surface of each unit packet of tobacco products, except for unit packets containing only smokeless tobacco products, and

(ii) any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

(b) One of the combined warnings set out in Part 2 of the Schedule shall be printed (the textual element of which shall be in both the Irish and English languages) on—

(i) the other most visible surface of each unit packet of tobacco products, except for unit packets containing only smokeless tobacco products, and

(ii) any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

(3) The general warnings referred to at paragraph (2)(a) shall be rotated in such a way as to guarantee their regular appearance.

(4) The combined warnings referred to at paragraph (2)(b) shall be rotated in such a way as to guarantee the regular appearance of all of the additional warnings.

(5) The combined warnings referred to at paragraph (2)(b) shall be printed so that the format and proportions of the source document and the graphical integrity of the picture and the text are respected.

(6) Smokeless tobacco products shall carry the following warning:

“Féadann an táirge tobac seo dochar a dhéanamh do do shláinte agus is táirge andúile é

This tobacco product can damage your health and is addictive”.

(7) The warning referred to at paragraph (6) shall be printed on the most visible surface of the unit packet and on any outside packaging, with the exception of additional transparent wrappers, used in the retail sale of the product.

(8) (a) The general warning referred to at paragraph 2(a) and the warning for smokeless tobacco products referred to at paragraph (6) shall cover not less than 32 per cent of the external area of the corresponding surface of the unit packet of tobacco on which it is printed.

(b) The combined warning referred to at paragraph (2)(b) shall cover not less than 45 per cent of the external area of the other most visible surface of the unit packet of tobacco.

(9) Notwithstanding the generality of paragraph (8), in the case of unit packets intended for products other than cigarettes, the most visible surface of which exceeds 75 cm<sup>2</sup>, the warnings referred to in paragraph (2) shall cover an area of at least 24 cm<sup>2</sup> on each surface.

(10) The text of the warnings referred to at paragraphs (2)(a) and (6) and the information referred to at paragraph (1) 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 area set aside for the text required,

(b) in lower-case type, except for the first letter of the message (in each language version) and where required by grammar usage,

(c) centred in the area in which the text is required to be printed, parallel to the top edge of the packet,

(d) for products other than those referred to in paragraph (6), surrounded by a black border not less than 3 mm and not more than 4 mm in width which in no way interferes with the text of the warning or information given,

(e) in both the Irish and English languages with the Irish text appearing above the English text, using the same font size in each of the two language versions.

(11) The printing of the information referred to at paragraph (1) and the warnings referred to at paragraphs (2) and (6) on the tax stamps of unit packets is prohibited.

(12) The printing of the warnings referred to at paragraph (2)(b) on the price marks of unit packets is prohibited.

(13) The information referred to at paragraph (1) and the warnings referred to at paragraphs (2) and (6) shall be irremovably printed, indelible and shall in no way be hidden, obscured or interrupted by other written or pictorial matter or by the opening of the packet.

(14) In the case of tobacco products other than cigarettes—

(a) the information referred to at paragraph (1) and the warnings referred to at paragraphs (2) and (6) may be affixed by means of stickers, provided that such stickers are irremovable, and

(b) the reproduction of the combined warnings on the stickers shall be in accordance with the technical specifications for printing set out in Part 3 of the Schedule.

(15) Tax stamps or price marks shall not be placed in a way that partially or entirely hides or interrupts the combined warnings or any of their elements.

(16) (a) The combined warnings referred to at paragraph (2)(b) shall be displayed in a manner that ensures that none of the textual or visual elements of the combined warnings will be severed when the tobacco package is opened.

(b) The use of any type of wrapper, pouch, jacket, box, or other device to partially or entirely hide or interrupt the combined warnings or any of their elements is prohibited.

(17) To ensure product identification and traceability, the tobacco product shall be marked in any appropriate manner, by batch numbering or equivalent, on the unit packet enabling the place and time of manufacture to be determined.

(18) The combined warnings referred to at paragraph (2)(b) shall—

(a) be reproduced in accordance with the technical specifications for printing, which are set out in Part 3 of the Schedule,

(b) occupy the entire area reserved for the additional health warning, and be positioned parallel to the top edge of the package and in the same direction as the other information on the package,

(c) be surrounded by a black border not less than 3mm and not more than 4mm in width which in no way interferes with any textual or visual element of the combined warning,

(d) not be commented on, paraphrased or referred to in any form on the tobacco package.

(19) The requirements of paragraphs (1) to (18) shall apply in respect of all tobacco products being placed on the market in the State.

(20) The requirements of paragraphs (1) to (18) shall not apply to products manufactured in the State for the purposes of being placed on the market outside the State.

4. (1) Regulation 3 shall come into effect on 1 February 2013 in respect of tobacco products placed on the market in the State on or after 1 February 2013.

(2) Regulation 3 shall come into effect on 1 February 2014 in respect of tobacco products placed on the market in the State before 1 February 2013.

(3) This Regulation shall not operate to prevent tobacco products which comply with Regulation 3 from being placed on the market in the State before the date on which Regulation 3 comes into effect in respect of those products pursuant to paragraph (1) or (2), as the case may be.

SCHEDULE

Part 1

*Regulation 3(2)(a)*

General Health Warnings

1. Toradh caithimh tobac — bás.

Smoking kills.

2. Déanann caitheamh tobac díobháil thromchúiseach duit agus do na daoine mórthimpeall ort.

Smoking seriously harms you and others around you.

Part 2

*Regulation 3(2)(b)*

Combined Health Warnings

1.



2.



3.



4.



5.



6.





7.



8.



9.



10.



10 [656]

11.



**Má chaitheann tú tobac le linn toirchis, déantar díobháil don leanbán**

**Smoking when pregnant harms your baby**

12.



**Cosain leanaí: ná cuir iallach orthu do chuid deataigh a anáilú**

**Protect children: don't make them breathe your smoke**

13.

**Is andúil thromchúiseach é caitheamh tobac, ná bíodh aon eagla ort iarraidh ar chabhair**

**Smoking is a serious nicotine addiction, don't be afraid to ask for help**

Féadann do dhochtúir nó do chógaiseoir cabhrú leat éirí as caitheamh tobac

**Your doctor or your pharmacist can help you stop smoking**

14.



**Faigh cúnamh chun éirí as caitheamh tobac: Íosghlao Stoptlíne 1850 201203**

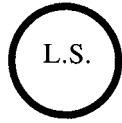
**Get help to stop smoking: Callsave Quitline 1850 201203**

## Part 3

*Regulation 3(14)(b)*

## Technical specifications for printing

- (1) The combined warnings:
  - (a) must be reproduced without any changes to their proportions or colours unless otherwise specified in paragraph (2);
  - (b) are conceived as a whole image and must not be amended unless otherwise specified in paragraph (2);
  - (c) must be printed in four-colour/-CMYK-/ screen 133 lines per inch, as a minimum requirement.
- (2) Where the size of the package so requires, the combined warnings can be modified according to the following rules:
  - (a) the graphical editing of the textual elements shall be done by varying font size and line breaks to ensure high readability;
  - (b) for combined warnings where the illustration is a text, the graphical editing shall be done by varying font size and line breaks; the relative surfaces occupied by text as an illustration and the corresponding text of the additional warning must be respected;
  - (c) for combined warnings where a photograph or other illustration is an image the graphical editing shall be done by proportionate scaling of the photograph or other illustration and varying of the relative surfaces occupied by the photograph or other illustration and the corresponding text of the additional warning;
  - (d) when the proportion between the height and the width of the combined warning is lower than 0.8, the corresponding text of the additional warning, if placed under the photograph or other illustration in the library of selected source documents, may be moved to the right of the photograph or other illustration; and
  - (e) when the proportion between the height and the width of the combined warning exceeds 1.2, the corresponding text of the additional warning, if placed to the side of the photograph or other illustration in the library of selected source documents, may be moved under the photograph or other illustration.



GIVEN under my Official Seal,  
16 December 2011.

JAMES REILLY,  
Minister for Health.

## EXPLANATORY NOTE

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

These Regulations may be cited as the Public Health (Tobacco) (General and Combined Warnings) Regulations 2011 and come into effect on the date of signature.

These Regulations give further effect to Directive 2001/37/EC of the European Parliament and of the Council of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products. They also give effect to Commission Decision 2003/641/EC of 5 September 2003 on the use of colour photographs or other illustrations as health warnings on tobacco packages, Commission Decision C(2005) 1452 final of 26 May 2005 on the library of selected source documents containing colour photographs or other illustrations for each of the additional warnings listed in annex 1 to Directive 2001/37/EC of the European Parliament and of the Council as amended by Commission Decision C(2006) 1502 final of 12 April 2006.

In particular, these Regulations require combined text and photo warnings in addition to existing general health warnings and information notices concerning nicotine, tar and carbon monoxide on all tobacco products.

These Regulations should be read in conjunction with the European Communities (Manufacture, Presentation and Sale of Tobacco Products) (Amendment) Regulations 2011.

BAILE ÁTHA CLIATH  
ARNA FHOILSIÚ AG OIFIG AN tSOLÁTHAIR  
Le ceannach díreach ón  
OIFIG DHÍOLTA FOILSEACHÁN RIALTAIS,  
TEACH SUN ALLIANCE, SRÁID THEACH LAIGHEAN, BAILE ÁTHA CLIATH 2,  
nó tríd an bpost ó  
FOILSEACHÁIN RIALTAIS, AN RANNÓG POST-TRÁCHTA,  
AONAD 20 PÁIRC MIONDÍOLA COIS LOCHA, CLÁR CHLAINNE MHUIRIS,  
CONTAE MHAIGH EO,  
(Teil: 01 - 6476834 nó 1890 213434; Fax: 094 - 9378964 nó 01 - 6476843)  
nó trí aon díoltóir leabhar.

---

DUBLIN  
PUBLISHED BY THE STATIONERY OFFICE  
To be purchased directly from the  
GOVERNMENT PUBLICATIONS SALE OFFICE  
SUN ALLIANCE HOUSE, MOLESWORTH STREET, DUBLIN 2,  
or by mail order from  
GOVERNMENT PUBLICATIONS, POSTAL TRADE SECTION,  
UNIT 20 LAKESIDE RETAIL PARK, CLAREMORRIS, CO. MAYO,  
(Tel: 01 - 6476834 or 1890 213434; Fax: 094 - 9378964 or 01 - 6476843)  
or through any bookseller.

---

€3.81

