

OFFICIAL STATE GAZETTE

No. 128

Wednesday 26 May 2010

Sec. I. Page 45931

I. GENERAL PROVISIONS

MINISTRY OF HEALTH AND SOCIAL POLICY

8388 *Royal Decree 639/2010 of 14 May, which amends Royal Decree 1079/2002 of 18 October, which defines the maximum yields for nicotine, tar, and carbon monoxide in cigarettes, the labelling of tobacco products, as well as measures relating to tobacco ingredients and product names.*

The labelling of tobacco products is governed by Royal Decree 1079/2002 of 18 October, which defines the maximum yields for nicotine, tar, and carbon monoxide in cigarettes, the labelling of tobacco products, as well as measures relating to tobacco ingredients and product names.

The said Royal Decree transposed into Spanish Law 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, which provides at article 5.3 that Member States may decide whether or not to include health warnings in the form of colour photographs or other illustrations on unit packets of tobacco products, with the exception of tobacco for oral use and other smokeless tobacco products, and that these warnings must conform to the rules to be laid down by the Commission.

In this regard, initially Commission Decision 2003/641/EC of 5 September 2003 was approved, on the use of colour photographs or other illustrations as health warnings on tobacco packaging, and subsequently Commission Decision, C (2005) 1452 of 26 May 2005 was approved, on the library of source documents selected, which contains photographs or other illustrations for each one of the additional warnings set forth at annex I of Directive 2001/37/EC of the European Parliament and of the Council, subsequently amended by Decision C (2006) 1502 of 12 April 2006.

Likewise, the WHO Framework Convention on Tobacco Control, ratified by Spain on 30 December 2004, envisages at article 11.1 the use of health warnings on the labelling of tobacco products, in the form of images or pictograms, as a suitable instrument for reducing the demand for tobacco.

The purpose of this Royal Decree is to implement certain aspects in respect of the labelling of tobacco products envisaged at Law 28/2005 of 28 December, on health measures to counter tobacco abuse and to regulate the sale, supply, consumption, and advertising of tobacco products, and to amend the health warnings on the labelling of tobacco products to feature photographs or images, which experience and research in other countries have shown to be an effective means of reducing tobacco consumption amongst the population and to inform them of the health risks that smoking poses.

The enactment of this provision has included the submission of reports from the autonomous regions and the participation of business associations, trades-union organizations, scientific societies, and social bodies, which have likewise been consulted through hearings.

This Royal Decree has the status of a basic norm, and is given pursuant to the provisions of article 149.1.16. of the Spanish Constitution and in implementation of articles 24, 25.3, and 40.5 and 6 of the General Health Act 14/1986 of 25 April.

Thus, following the proposal of the Minister of Health and Social Policy, in accordance with the State Council, and following the deliberations of the Cabinet at the meeting held on 14 May 2010,

I HEREBY ORDER:

Sole Article. *Amendment of Royal Decree 1079/2002 of 18 October, which defines the maximum yields for nicotine, tar, and carbon monoxide in cigarettes, the labelling of tobacco products, as well as measures relating to tobacco ingredients and product names.*

Royal Decree 1079/2002 of 18 October is hereby amended as follows:

One. Article 5 shall have the following wording:

“Article 5. *Labelling.*

1. Tar, nicotine, and carbon monoxide yields in cigarettes on sale in Spain and measured pursuant to article 4 shall be printed on one of the sides of cigarette packets, at least in Spanish, the official language of the State, occupying a minimum of 10% of the corresponding surface.

2. All unit packets of tobacco products, with the exception of smokeless tobacco, must carry the following warnings:

a) One general warning:

1. Smoking kills.

2. Smoking seriously damages your health and the health of those around you.

The above general warnings shall be alternated in such a way as to ensure the regular appearance of each warning in a similar quantity of unit packets with an annual tolerance threshold of around 5%. These warnings shall be printed on the most visible surface of the unit packets, as well as on any exterior packaging used in the retail sale of the product, with the exception of the transparent wrappers used in the retail sale of the product, and

b) One additional warning taken from the list set forth at annex II, composed of photographs or illustrations and a text (combined warnings).

The additional warnings referred to above shall be alternated in such a way as to ensure the regular appearance of each warning in a similar quantity of unit packets with an annual tolerance threshold of around 5%.

This warning shall be printed on the other most visible surface of the unit packet and on any external packaging used in the retail sale of the product, with the exception of the transparent wrappers used in the retail sale of the product, preserving the format and proportions of the source document (electronic file containing the additional warnings, supplied by the Ministry of Health and Social Policy, and available on its website), and the graphic integrity of the image, text, and colours, in compliance with the technical printing specifications set forth at annex III.

They shall occupy the total space reserved for the additional health warning and shall be in a parallel position to the upper part of the unit packet and in the same direction as all other information on the unit packet.

They shall be surrounded by a black border with a minimum width of 3 millimetres and a maximum width of 4 millimetres, which in no way interferes with the text or the visual element of the additional warning. The black border shall not be included in the calculation of the surface area to be occupied by the said warning.

3. Unit packages of smokeless tobacco products shall carry the following specific warning:

‘This tobacco product may be harmful to your health and creates addiction.’

This warning shall be printed on the most visible surface of the unit packet and on any exterior packaging used in the retail sale of the product, with the exception of any transparent wrappers used in the retail sale of the product.

4. The general warnings envisaged at paragraph (a) of section 2 and the specific warning for smokeless tobacco products referred to in section 3 shall cover not less than 30% of the external area of the corresponding surface of the unit packet of tobacco on which they must be printed. The additional warning envisaged at paragraph b) of section 2 shall cover not less than 40% of the external area of the corresponding surface of the unit packet of tobacco on which it must be printed. However, in the case of unit packets intended for products other than cigarettes where the most visible surface exceeds 75 square centimetres, the warnings referred to in sections 2.a) and 2.b) shall cover an area of at least 22.5 square centimetres.

5. The text of the general and specific warnings and of the statements of tar, nicotine and carbon monoxide yields required pursuant to this article shall be printed:

a) In black Helvetica bold type on a white background with a font size such 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 each warning, which shall be in upper case.

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

d) For tobacco products other than those referred to in section 3, surrounded by a black border with a minimum width of 3 millimetres and a maximum width of 4 millimetres which in no way interferes with the text of the warning or the information given.

The black border shall not be included in the calculation of the surface area to be occupied by the said warnings and the statements of tar, nicotine and carbon monoxide yields.

e) In Spanish, the official language of the State.

6. All of the warnings referred to in sections 2 and 3 shall be preceded by the words: ‘Warning from the Health Authorities:’ This text shall be placed outside the box provided for under paragraph b) of section 2 and paragraph d) of section 5; it shall occupy an additional area of at least 4 millimetres in height on unit packets of cigarettes, and it should maintain the same

proportion when applied to the unit packets of other tobacco products; it shall be located adjacent to and immediately above the health warnings; it shall have the same length as the space defined for the health warnings, and the text shall have the characteristics set out at paragraphs a), b), c), and e) of section 5.

The statement 'NOT FOR SALE TO PERSONS AGED UNDER 18' shall also be included. This statement shall be located on one of the sides of the cigarette unit packets, occupying a minimum of 13% of the corresponding area. The text shall be printed in two lines in upper-case type and shall comply with the characteristics described at paragraphs a), c), and e) of section 5. On the unit packets for all other tobacco products, the said statement shall be located adjacent to and immediately above one of the texts stating 'Warning from the Health Authorities'; it shall occupy an additional area of at least 4 millimetres in height, it shall have the same length as the space defined for the said statement, and it shall comply with all the requirements and characteristics laid down at paragraphs a), b), and e) of section 5.

7. The tar, nicotine and carbon monoxide yields, the health warnings, and the texts required pursuant to this article shall be printed by the manufacturers at the place of manufacture or by a third party authorised by the manufacturers. They shall be printed so as to be irremovable and indelible and shall in no way be hidden, obscured or interrupted by other texts or images. They shall not be located anywhere that may be damaged by the opening of the product, and they may not be printed on the tax stamps. In the case of tobacco products other than cigarettes, the warnings and the texts may be affixed by means of stickers, provided that such stickers are irremovable.

The unit packets, as well as all exterior wrapping used in retail sale, may not come with any kind of covering, bag, flap, box, or any other item that hides, obscures, or covers, whether in whole or in part, the warnings, texts, and contents envisaged in this article.

8. To ensure product identification and traceability, tobacco products shall be marked with a batch number or equivalent on the unit packet enabling the place and time of manufacture to be determined.

9. The sale or supply of cigarettes which are not packaged and which do not have exterior wrapping is hereby prohibited."

Two. Section 2 of sub-section c) of article 8 shall have the following wording:

"2. Any failure to include or any incorrect inclusion of the general, additional, or specific warnings for the tar, nicotine and carbon monoxide yields, or the references to the health authorities, or the prohibition of sale to persons aged under 18, on unit packets of tobacco products, as provided for at article 5, as well as the retail sale of tobacco products with any kind of covering, bag, flap, box, or any other item that hides, obscures, or covers, whether in whole or in part, the warnings, texts, and contents envisaged at article 5, considered as one of the cases provided for at Article 35.C.1 of the General Health Act."

Three. This annex containing the list of additional health warnings becomes annex I, with the same title and content.

Four. Two new annexes are added, numbered II and III, with the contents set forth in parts A and B, respectively, of the annex to this Royal Decree.

Sole temporary provision. *Marketing extension.*

As from the entry into force of this Royal Decree, and for twelve months in the case of cigarette packets, or twenty-four months in the case of all other tobacco products, said products may continue to be sold despite not complying with the requirements introduced by this Royal Decree, provided that they comply with the provisions of Royal Decree 1079/2002 of 18 October, and Law 28/2005 of 26 December, on health measures to combat tobacco abuse and to regulate the sale, supply, consumption, and advertising of tobacco products.

First final provision. *Nature of competency.*

This Royal Decree, which has the status of a basic norm, is promulgated under the provisions of Article 149.1.16 of the Spanish Constitution, which attributes powers to the State with regard to health bases and general co-ordination.

Second final provision. *Entry into force.*

This Royal Decree shall enter into force on the day after it is published in the 'Official State Gazette'.

Given in Barcelona, 14 May 2010.

JUAN CARLOS R.

The Minister of Health and Social Policy,
TRINIDAD JIMÉNEZ GARCÍA-HERRERA

ANNEX

PART A

Annex II

Additional warnings

In order to facilitate the printing of these warnings on the packaging of tobacco products, they shall be supplied by the Ministry of Health and Social Policy in the form of an electronic file. They shall also be available on the Department's website.

1.



[image with the text: Smokers die younger]

2.



[image with the text: Smoking clogs the arteries and causes heart disease and strokes]

3.



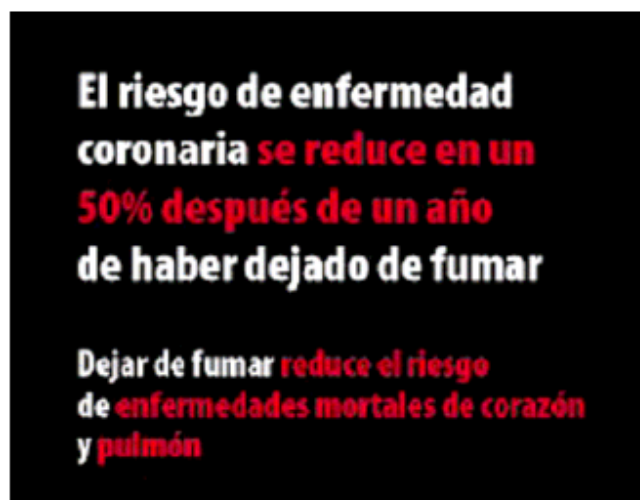
[image with the text: Smoking causes fatal lung cancer]

4.



[image with the text: Tobacco is highly addictive: don't start]

5.



[text: The risk of coronary disease is reduced by 50% one year after giving up. Stopping smoking reduces the risk of fatal heart and lung diseases]

6.



[image with the text: Smoking can cause a slow and painful death]

7.



[image with the text: Smoking causes ageing of the skin]

8.



[image with the text: Smoking can damage the sperm and decreases fertility]

9.



[image with the text: Smoking may reduce the blood flow and causes impotence]

10.



[image with the text: Smoking can damage the sperm and decreases fertility]

11.



[image with the text: Smoking when pregnant harms your baby]

12.



[image with the text: Protect children: don't make them breathe your smoke]

13.



[text: You can do it, we can help you. Your doctor or your pharmacist can help you stop smoking]

14.



[text: 0803 00 00 00. Choose freedom, we will help you. Help to stop smoking]

In this last warning, the telephone number must be replaced (given that in Spain there is no single telephone number to provide assistance to smokers) by the web address of the Ministry of Health and Social Policy, www.msps.es.

PART B

Annex III

Technical specifications for the printing of the additional warnings

1. General technical specifications:

- a) The warnings shall be reproduced with no alterations to their proportions or colours.
- b) The warnings have been created as one single image and should not be altered.
- c) The warnings shall be printed in the four colours of the CMYK scale (cyan, magenta, yellow, and black), at 133 lines per inch.

2. Technical specifications for the printing of the additional warnings on some unit packets of tobacco products in order to avoid the distortion of the said warnings: Where required by the size of the packet, the warnings may be altered in accordance with the following rules:

- a) The text shall be graphically edited, altering the size of the characters and the line breaks in order to make them easier to read.
- b) For those warnings where the illustration is a text, the said text shall be graphically edited, altering the size of the characters and the line breaks. The relative areas occupied by the illustration text and the additional-warning text shall be respected.
- c) For those warnings where the illustration is a photograph or other image, the graphic editing shall be performed by way of altering the size of the photograph or other image and altering the relative areas occupied by the said photograph or other image and the additional-warning text.
- d) Where the proportion between the height and the width of the warning is less than 0.8 and the additional-warning text is below the photograph or other illustration, said text may be moved to appear on the right of the said photograph or other illustration.
- e) Where the proportion between the height and the width of the warning is more than 1.2 and the additional-warning text is beside the photograph or other illustration, said text may be moved to appear below the said photograph or other illustration.