

ROYAL DECREE 1079/2002 dated October 18th, regulating 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.

Tobacco consumption represents the main risk factor for illness and mortality in developed countries. Therefore, regulation and control of its consumption is a public health priority.

Within the framework of measures implemented by the European Union, various Community Directives have been approved concerning this matter: Directive 89/622/EEC dated November 13th 1989, relating to the approximation of legal, regulatory and administrative provisions of the Member States concerning labelling of tobacco products, Directive 90/239/EEC dated May 17th 1990, relating to the approximation of legal, regulatory and administrative provisions of the Member States concerning the maximum tar yield for cigarettes, and Directive 92/41/EEC dated May 15th 1992 relating to the approximation of legal, regulatory and administrative provisions of the Member States in matters concerning the labelling of tobacco products. These provisions are contained in Royal Decrees 192/1988 dated March 4th relating to restrictions on the sale and use of tobacco for the protection of public health, 510/1992 dated May 14th which regulates the labelling of tobacco products and lays down certain restrictions concerning commercial aircraft, and 1185/1994 dated June 3rd concerning the labelling of tobacco products other than cigarettes and which prohibits certain oral tobaccos and updates the provisions laying down penalties in matters relating to tobacco.

The most recent regulations in this matter are contained in Directive 2001/37/EC which amends and substantially widens the existing regulations concerning tobacco products.

The object of this Royal Decree is to incorporate Directive 2001/37/EC dated June 5th, issued by the European Parliament and the Council relating to the approximation of legal, regulatory and administrative provisions of the Member

States concerning the manufacture, presentation and sale of tobacco products, into our legal system, and the affected parties have had an opportunity to be heard whilst it was in the process of being drafted.

This Royal Decree which is a basic law, is promulgated under the provisions of Article 149.1.16.8 of the Spanish Constitution, and in accordance with the provisions contained in Articles 24, 25.2, 32 to 37, 40.5 and 40.6 of the General Health Act **14/1986 dated April 25th**.

Thus, upon a proposal made by the Minister of Health and Consumer Affairs, pursuant to the State Council and following the deliberations made by the Council of Ministers at their meeting held on October 18th 2002,

I HEREBY ORDER

Article 1. Definitions.

For the purposes of this Royal Decree, the following shall have the meaning as stated:

- a) Tobacco products: any products intended to be smoked, sniffed, sucked or chewed that are made in whole or in part from tobacco, whether genetically modified or not.
- b) Tar: the raw anhydrous nicotine-free condensate of smoke.
- c) Nicotine: nicotine alkaloids.
- d) Tobacco for oral use: all products for oral use, except those intended to be smoked or chewed, made wholly or partly from tobacco, in powder or in fine granulate form or in any combination of those forms, particularly those presented in a dosage sachet or porous sachets or in a form resembling a food product.

- e) Ingredient: any substance or any constituent except for tobacco leaf and other natural or unprocessed tobacco plant parts used in the manufacture or preparation of a tobacco product and still present in the finished product, even if in altered form, including paper, filter, inks and adhesives.

Article 2. Tobacco for oral use.

The placing on the market of tobacco for oral use, which shall be understood to mean the product defined at paragraph (d) of Article 1, is hereby banned.

Article 3. Maximum yields for tar, nicotine and carbon monoxide in cigarettes.

1. As from January 1st 2004, cigarettes released for free circulation, marketed or manufactured in Spain, may not have yields in excess of:

- a) 10 milligrams per cigarette for tar.
- b) 1 milligram per cigarette for nicotine.
- c) 10 milligrams per cigarette for carbon monoxide.

2. For cigarettes produced in Spain but exported outside the European Community, the yields provided for in this Article shall be applicable as from January 1st 2007.

Article 4. Measurement methods.

1. The tar, nicotine and carbon monoxide yields for cigarettes shall be measured pursuant to standards 4387, 10315 and 8454 respectively, laid down by the International Organisation for Standardisation (ISO). The accuracy of the tar and nicotine indications printed on the packets shall be verified in accordance with ISO standard 8243.

These tests shall be verified by those laboratories specified by the Ministry of Health and Consumer Affairs.

The Ministry of Health and Consumer Affairs shall notify the list of approved laboratories to the European Commission, and any amendments occurring thereto, stating the criteria used for their approval and the methods of monitoring applied.

2. The Ministry of Health and Consumer Affairs may require tobacco manufacturers and importers to carry out other tests in order to assess the content of other substances produced by their tobacco products, broken down by brands and individual types, as well as their effects on health, and taking into account, inter alia, the risk of addiction inherent in them. The Ministry may also require that such tests be verified by the laboratories as determined by the said Ministry of Health and Consumer Affairs.

3. The results of tests carried out in accordance with section 2, shall be submitted to the Ministry of Health and Consumer Affairs on an annual basis, and on such other longer basis as the Ministry of Health and Consumer Affairs may stipulate whenever said product specifications have not changed. The Ministry of Health and Consumer Affairs must be informed of any changes in the said specifications of the products.

The Ministry of Health and Consumer Affairs shall, by any appropriate means, disseminate the information submitted in accordance with this Article for the purpose of informing consumers and it shall, whenever pertinent, take into consideration any information which constitutes a trade secret.

4. The Ministry of Health and Consumer Affairs shall, on an annual basis, communicate all data and information referred to in this Article to the European Commission.

Article 5. Labelling.

1. The tar, nicotine and carbon monoxide yields for cigarettes sold in Spain and measured in accordance with Article 4 shall be printed on one side of the

cigarette packet, at least in Spanish, the official language of the State, so that a minimum of 10% of the corresponding surface is covered.

2. Each unit packet of tobacco products, except for smokeless tobacco products, must carry the following warnings:

a) A general warning:

- 1) "Smoking kills" or "Smoking can kill".
- 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 packaging units with an annual tolerance threshold of around 5%. These warnings shall be printed on the most visible surface of the packaging unit, 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) An additional warning taken from the list set out in the Annex.

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 packaging units with an annual tolerance threshold of around 5%.

This warning shall be printed on the other most visible surface of the packaging unit 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.

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

5. The text of the 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 point size of font such as to occupy the greatest possible proportion of the area set aside for the text required;
- b) in lower case type;
- 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 paragraph 3, surrounded by a black border not less than 3 mm and not more than 4mm in width which in no way interferes with the text of the warning or information given;
- e) in Spanish, the official language of the State.

6. All of the warnings referred to in paragraphs 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 letter (d) of paragraph 5; it shall occupy an additional area of at least 4 millimetres in height on packaging units of cigarettes, and it should maintain the same proportion when applied to the packaging units of

other tobacco products; it shall be placed adjacent to and immediately above the health warnings; it shall have the same length as the space provided for the health warnings, and the text shall have the characteristics set out at paragraphs (a), (b), (c) and (e) of paragraph 5.

7. The tar, nicotine and carbon monoxide yields, as well as the warnings 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. The texts required pursuant to this Article shall not be printed on the tax stamps of packaging units. The texts shall be irremovably printed, indelible and shall in no way be hidden, obscured or interrupted by other written or pictorial matter and shall not be placed anywhere such that the opening of the product might damage them. In the case of tobacco products other than cigarettes, the texts may be affixed by means of stickers, provided that such stickers are irremovable.

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.

Article 6. Further information on tobacco products.

1. The Ministry of Health and Consumer Affairs shall require all manufacturers, importers and brand-owners of tobacco products to submit a list of all ingredients in tobacco, as well as the quantities of the said ingredients used in the manufacture of the said tobacco products broken down by brands and individual types.

This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in those tobacco products, indicating their function and category. The list shall also be accompanied by the toxicological data

available to the manufacturer or importer regarding these ingredients in burnt or unburnt form, as the case may be, referring in particular to their effects on health and indicating, inter alia, any possible addictive effects. The list shall set out all of the ingredients included in the product in descending order of weight of each ingredient.

The information referred to in this paragraph shall be submitted on an annual basis and for the first time no later than December 31st 2002.

2. The Ministry of Health and Consumer Affairs shall, by such means as it may deem appropriate, disseminate the information provided in accordance with this Article with a view to informing consumers. Due account shall nevertheless be taken concerning the protection of any information on specific product recipes which constitutes a trade secret.

3. The Ministry of Health and Consumer Affairs shall make public the list of ingredients for each product, and which shall include the tar, nicotine and carbon monoxide yields.

4. The Ministry of Health and Consumer Affairs shall communicate all data and information submitted pursuant to this Article to the European Commission on a yearly basis.

Article 7. Product descriptions.

With effect from September 30th 2003, and without prejudice to the provisions of paragraph 1 of Article 5, the use of texts, names, trademarks and figurative or other signs suggesting that a particular tobacco product is less harmful than others is prohibited on the packaging unit of tobacco products sold in Spain.

Article 8. Offences and penalties.

Any failure to comply with the provisions of this Royal Decree shall be deemed to be an administrative offence against the health regulations, pursuant to the

provisions contained in Chapter VI of Title I of the General Health Act **14/1986 dated April 25th** and any other provisions such as may be applicable and the offender shall be subject to the imposition of the corresponding administrative penalties, following upon due process under the provisions of Title IX of the Legal Structure of the Public Administration and Common Administrative Procedure Act 30/1992 dated November 26th, and of the Common Administrative Procedure. The foregoing shall be without prejudice to any civil, criminal or other liability that may be found to exist.

In particular, the following shall be deemed to amount to very serious, serious or minor offences respectively according as provided under Article 35 of the General Health Act **14/1986 dated April 25th**:

a) Minor offences.

1.a. Any failure to perform the warning rotation rule referred to under paragraph 2 of Article 5, considered as a case provided for under Article 35.A.1.a of the General Health Act.

2.a In general, failure to perform the provisions of this Royal Decree, provided that the offence is not deemed to amount to a serious or very serious offence, as provided under Article 35.A.3.a of the General Health Act.

b) Serious offences.

1.a. Any failure to comply with any specific requirements made by the Health Authorities, provided they are made for the first time, considered as one of those cases provided for under Article 35.13.4.8 of the General Health Act.

2.a. Any failure to provide data, information or to co-operate with the Health Authorities or their agents, as provided under Article 35.13.5.8 of the General Health Act.

3.a. The repeated commission of any minor offences, during the last three months, according as provided in Article 35.13.7.8 of the General Health Act.

c) Very serious offences.

1.a. The introduction onto the market of tobacco products for oral use, where tobacco for oral use shall have the meaning as defined at paragraph (d) of Article 1 of the General Health Act, considered as one of the cases provided for at Article 35.C.1 of the General Health Act.

2.a. Any failure to include or any incorrect inclusion of the general, additional or specific warnings, or of the tar, nicotine and carbon monoxide yields, and the reference to the health authorities on packaging units of tobacco products, as provided for at Article 5, considered as one of the cases provided for at Article 35.C.1 of the General Health Act.

3.a. The marketing, manufacture and release for free circulation of cigarettes that have a yield of tar, nicotine and carbon monoxide that exceeds the limits laid down at Article 3, considered as one of the cases provided for in Article 35.C.1 of the General Health Act.

4.a. Any failure to include the batch or equivalent number on the packaging unit of tobacco, as provided for at paragraph 8 of Article 5, considered as one of the cases provided for in Article 35.C.1 of the General Health Act.

5.a. Any refusal or unwillingness by any manufacturer or importer of tobacco products to provide the Health Authorities with a complete list of tobacco product ingredients, as provided under Article 6, considered as one of the cases provided for in Article 35.C.1 of the General Health Act.

6.a. The use on any packaging unit of tobacco of any text, names, trademark and figurative or other signs suggesting that a particular tobacco product is less harmful than others, considered as one of the cases provided for in Article 35.C.1 of the General Health Act.

7.a. The repeated commission of any serious offence during the last five years, according as provided in Article 35.C.8.a of the General Health Act.

The aforementioned offences shall be punishable depending on their respective degree of seriousness, in accordance with the provisions of Article 36 of the General Health Act **14/1986 dated April 25th**.

Sole temporary provision. Marketing extension.

Notwithstanding the provisions of the sole repealing provision, products that do not comply with the provisions of this Royal Decree may continue to be marketed, until September 30th 2003 for cigarettes, and until September 30th 2004 for other tobacco products. In the mean time, the provisions of Royal Decrees 510/1992 dated May 14th which regulates the labelling of tobacco products and lays down certain restrictions concerning commercial aircraft, and 1185/1994 dated June 3rd concerning the labelling of tobacco products other than cigarettes and which prohibits certain oral tobaccos and which updates the provisions laying down penalties in matters relating to tobacco, shall continue to be in force where appropriate.

Sole repealing provision. Repealing provision.

Without prejudice to the provisions of the sole temporary provision, Royal Decrees 510/1992 dated May 14th which regulates the labelling of tobacco products and lays down certain restrictions concerning commercial aircraft, and 1185/1994 dated June 3rd concerning the labelling of tobacco products other than cigarettes and which prohibits certain oral tobaccos and which updates the provisions laying down penalties in matters relating to tobacco, and any other provisions of a similar or inferior standing which contradict the terms of this Royal Decree are hereby repealed.

First final provision. Nature of competency.

This Royal Decree which is a basic law, is promulgated under the provisions of Article 149.1.16.8 of the Spanish Constitution, and in accordance with the provisions contained in Articles 24, 25.2, 32 to 37, 40.5 and 40.6 of the General Health Act **14/1986 dated April 25th**.

Second final provision. Powers to implement.

The Minister for Health and Consumer Affairs is hereby given powers to issue the necessary regulations to implement the provisions of this Royal Decree.

Third final provision. Entry into force.

This Royal Decree shall come into force on the day it is published in the "Official State Gazette".

Given in Madrid on October 18th 2002.

JUAN CARLOS R.

The Minister for Health and Consumer Affairs,
ANA MARÍA PASTOR JULIÁN

ANNEX

List of additional health warnings.

1. Smokers die younger.
2. Smoking obstructs the arteries and causes heart attacks and strokes.
3. Smoking causes deadly lung cancer.
4. Smoking when pregnant harms your baby.
5. Protect children: don't make them breathe tobacco smoke.
6. Your doctor and your pharmacist can help you stop smoking.
7. Smoking is highly addictive: don't start.
8. Stopping smoking reduces the risk of fatal heart and lung diseases.

9. Smoking can cause a slow and painful death.
10. Get help to stop smoking: consult your doctor or pharmacist.
11. Smoking reduces the blood flow and causes impotence.
12. Smoking causes ageing of the skin.
13. Smoking can damage sperm and decreases fertility.
14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.