

MINISTRY OF HEALTH AND CONSUMER AFFAIRS

20273 ROYAL DECREE 1079/2002 of October 18, regulating maximum nicotine, tar and carbon monoxide content of cigarettes, labeling of tobacco products, and measures relating to ingredients and denominations of tobacco products.

Tobacco consumption is the main risk factor for disease and mortality in developed countries; therefore, the regulation and control of such consumption is a public health priority.

Under the framework of the measures developed by the European Union, various community Directives have been approved in this regard: Directive 89/622/CEE, of November 13, 1989, regarding the approximation of the laws, regulations and administrative provisions of the member States concerning the labeling of tobacco products; Directive 90/239/CEE, of May 17, 1990, regarding the approximation of the laws, regulations and administrative provisions of the member States in respect of the maximum tar content of cigarettes, and Directive 92/41/CEE, of May 15, 1992, regarding the approximation of the laws, regulations and administrative provisions of the member States concerning the labeling of tobacco products. These norms are contained in Royal Decrees 192/1988, of March 4, regarding limitations on the sale and use of tobacco for the protection of the health of the people; 510/1992, of May 14, regulating the labeling of tobacco products and establishing certain limitations in commercial aircraft, and 1185/1994, of June 3, regarding the labeling of tobacco products other than cigarettes and prohibiting certain tobacco for oral use, and updating the penalization system for tobacco matters.

The most recent regulations in this matter are embodied in Directive 2001/37/CE, which substantially amends and enhances existing regulations on tobacco products.

The purpose of this Royal Decree is to incorporate into our legal framework the content of Directive 2001/37/CE by the European Parliament and Council, of June 5, 2001, regarding the approximation of the laws, regulations and administrative provisions of the member States concerning the manufacture, presentation and sale of tobacco products, and the affected entities have been heard in its preparation.

This Royal Decree, which has the nature of a basic norm, is issued based on the provisions of Article 149.1.16.a of the Spanish Constitution and in development of Articles 24, 25.2, 32 to 37, 40.5 and 40.6 of Law 14/1986, of April 25, on General Health.

Therefore, at the proposal of the Ministry of Health and Consumer Affairs, in accordance with the State Council and upon deliberation by the Council of Ministers in its meeting of October 18, 2002,

I DO HEREBY DECREE:

Article 1. Definitions.

For the purposes of this Royal Decree, the following definitions are provided:

a) Tobacco products: means products for the purposes of smoking, sniffing, sucking or chewing, inasmuch as they are, from their inception, even partly made of tobacco products, whether or not genetically modified.

b) Tar: raw anhydrous, nicotine-free condensate of smoke.

c) Nicotine: means nicotinic alkaloids.

d) Oral tobacco: means all products for oral use, except those intended to be smoked or chewed, made wholly or partly of tobacco, in powder or in particulate form or in any combination of these forms - particularly those presented in sachet portions or porous sachets - or in a form resembling a food product.

e) Ingredient: means any substance or component, except for natural tobacco leaf or other natural or untransformed parts of the tobacco plant, 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, ink and glue.

Article 2. Oral tobacco. The marketing of oral tobacco, understood to be as defined in paragraph d) of Article 1.

Article 3. Maximum tar, nicotine and carbon monoxide content of cigarettes.

1. As of January 1, 2004, cigarettes released for free circulation, sold or made in Spain, cannot have contents exceeding:

a) 10 milligrams of tar per cigarette,

b) 1 milligram of nicotine per cigarette,

c) 10 milligrams of carbon monoxide per cigarette.

2. For cigarettes made in Spain, but exported outside of the European Community, the limits set out in this Article shall apply as of January 1, 2007.

Article 4. Measurement methods.

1. The tar, nicotine and carbon monoxide yields of the cigarettes shall be measured in accordance with the standards of the International Organization for Standardization (ISO) 4387, 10315 and 8454, respectively. The accuracy of the indications on the packets regarding tar and nicotine shall be verified in accordance with standard ISO 8243.

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Such tests shall be performed by such laboratories as determined by the Ministry of Health and Consumer Affairs. The Ministry of Health and Consumer Affairs shall inform the European Commission of the list of approved laboratories and of their modification, as applicable, establishing the criteria used for the approval and the means of supervision applicable.

2. The Ministry of Health and Consumer Affairs may demand that tobacco manufacturers and importers perform tests to evaluate the content, specified by their brands and individual types, of other substances produced by their tobacco products, and their effects on health, considering, among other things, the addiction hazard that they entail. It may also be required that such tests be conducted by the laboratories determined by the Ministry of Health and Consumer Affairs.

3. The results of the tests performed in accordance with the provisions of section 2 shall be presented annually to the Ministry of Health and Consumer Affairs, and more frequently as determined by the Ministry of Health and Consumer Affairs, when there have been no variations in product specifications. The Ministry of Health and Consumer Affairs must be informed when product specifications change. The Ministry of Health and Consumer Affairs shall disseminate, by such means as deemed appropriate, the information presented in accordance with the requirements of this Article, to inform the consumers, considering where applicable any information deemed a commercial secret.

4. The Ministry of Health and Consumer Affairs shall annually inform the European Commission of all data and information referenced in this Article.

Article 5. Labeling.

1. The tar, nicotine and carbon monoxide yields of cigarettes sold in Spain, 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 at least 10% of the corresponding surface is covered.

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

a) A general warning:

1. «Smoking kills» or «Smoking can kill».
2. «Smoking is a serious hazard to your health and others around you ».

The above general warnings shall be rotated in such a manner as to guarantee the successive appearance of each warning in an equal amount of unit packets, with an annual tolerance of more or less 5 percent. These warnings shall be printed on the most visible surface of the unit packet, and on all external packaging used in the retail sale of the product, with the exception of the transparent packaging used in the retail sale of the product; and

b) An additional warning from among those set out in the annex.

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The additional warnings mentioned earlier shall be rotated in such a manner as to guarantee the successive appearance of each warning in an equal amount of unit packets, with an annual tolerance or more or less 5 percent.

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

3. The unit packets of smoke-free tobacco products shall carry the following specific warning:

«This tobacco product can be hazardous to your health and create addiction.»

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

4. The general warnings referenced in paragraph a) of section 2, and the specific warning for the smoke-free tobacco products mentioned in section 3, shall cover at least 30 percent of the external surface of the relevant side of the tobacco unit packet in which they are to be printed. The additional warning referenced in paragraph b) of section 2 shall cover at least 40 percent of the outside surface of the relevant side of the tobacco unit packet on which it is to be printed. Nonetheless, in the unit packets for products other than cigarettes, the most visible side of which exceeds 75 square centimeters, the surface of the warnings mentioned in sections 2, a), and 2, b), shall be at least 22.5 square centimeters.

5. The text of the warnings and the indications pertaining to tar, nicotine and carbon monoxide contents required in this Article must be printed:

a) In black Helvetica bold type on a white background, using a font type such that they occupy the largest space possible on the surface reserved to such effect.

b) In lower case.

c) Centered in the area in which the text is required to be printed, parallel to the upper edge of the package.

d) On tobacco products other than those mentioned in section 3, surrounded by a black border not less than 3mm in width and not more than 4mm in width, which does not in any way interfere with the text of the warning or information given.

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

6. All warnings referenced in sections 2 and 3 shall be preceded by the notice: «Health authorities warn». This notice shall be placed outside of the box referenced in paragraph d) of section 5; shall occupy an additional surface of 4 mm high, at least, on cigarette unit packets, and must bear the same proportion when regarding unit packets of other tobacco products; shall be positioned contiguously and immediately above the health warnings; shall have the same length as that of the

space provided for health warnings and the text shall have the characteristics set out in paragraphs a), b), c) and e) of section 5.

7. The tar, nicotine and carbon monoxide content, and the warnings required under this Article, must be printed by the manufacturers at origin or by a third-party authorized by the manufacturers. The texts required under this Article cannot be printed on the tax stamps of unit packets. They must be irremovably fixed, indelible and shall not in any way be hidden, obscured or interrupted by other written or pictorial matter, nor by the opening of the packet. In the case of other tobacco products, aside from cigarettes, the texts may be fixed by adhesives, provided they cannot be detached.

8. To guarantee the identification and traceability of the product, tobacco products shall be marked, through lot number or equivalent on the unit packet, so as it is possible to determine the place and time of manufacture.

9. The sale or delivery of cigarettes that are not packaged or have no external packing is 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 to them a list of all ingredients, and quantities thereof, used in the manufacture of their tobacco products, specified by brand name and individual types.

This list shall be accompanied by a statement setting out the reasons for the inclusion of such ingredients in their tobacco products, indicating their function and category. The list shall further be accompanied by the toxicological data at the disposal of the manufacturer or importer as regards such ingredients, with or without combustion, as the case may be, specifically mentioning their effects on health and indicating, among other things, their possible addictive effects. The list shall present all the ingredients making up the product by weight, in decreasing order.

The information set out in this section shall be presented annually and for the first time before December 31, 2002.

2. The Ministry of Health and Consumer Affairs shall disseminate, by any means deemed appropriate, the information provided in accordance with the requirements of this Article, to inform the consumers. Nonetheless, all information pertaining to the formula of specific products constituting a commercial secret shall be considered accordingly.

3. The Ministry of Health and Consumer Affairs shall publish the list of ingredients per product, indicating tar, nicotine and carbon monoxide content.

4. The Ministry of Health and Consumer Affairs shall annually report to the European Commission all data and all information referenced in this Article.

Article 7. Product descriptions.

As of September 30, 2003, and notwithstanding the provisions of section 1 of Article 5, the use of texts, names, brands and images or other marks conveying the impression that a particular tobacco product is less harmful than others on the unit packets of tobacco products sold in Spain is strictly prohibited.

Article 8. Infractions and penalties.

Breach of the provisions of this Royal Decree shall constitute an administrative infraction of health regulations, as provided by Chapter VI of Title I of Law 14/1986, of April 25, General Health, and other applicable provisions and shall be subject to the relevant administrative penalties, following the instruction of the respective docket in accordance with the provisions of Title IX of Law 30/1992, of November 26, Legal System of Public Administrations and Common Administrative Procedure. All of this notwithstanding any civil, criminal or other such liabilities as may apply.

Specifically, the following are considered very serious, serious and mild infractions, in accordance with the provisions of Article 35 of Law 14/1986, of April 25, General Health, to wit:

a) Mild infractions:

1.a The incorrect compliance of the rule of rotating the warnings referenced in section 2 of Article 5, considered as an element of those set out in Article 35.A.1.a of the General Health Law.

2.a In general, breach of the provisions of this Royal Decree, provided the infraction is not considered very serious or serious, as provided by Article 35.A.3.a of the General Health Law.

b) Serious infractions:

1.a Breach of the specific requirements presented by the health authorities, provided it is a first offense, considered as an element of those set out in Article 35.B.4.a of the General Health Law.

2.a Reluctance to supply data, furnish information or provide collaboration to the health authorities or their agents, as provided by Article 35.B.5.a of the General Health Law.

3.a Repeated mild infractions over the last three months, as provided by Article 35.B.7.a of the General Health Law.

c) Very serious infractions:

1.a The introduction on the market of oral tobacco products, with oral tobacco being defined as provided in paragraph d) of Article 1, considered among the elements of those established in Article 35.C.1.a of the General Health Law.

2.a A failure to register, or the incorrect registration of the general, additional or specific warnings, tar, nicotine and carbon monoxide content, and the mention to the health authorities on the

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unit packets of tobacco products, as provided by Article 5, considered as an element of those set out in Article 35.C.1.a of the General Health Law.

3.a The commercialization, manufacture and delivery of cigarettes for free circulation with higher tar, nicotine and carbon monoxide contents than those established in Article 3, considered as an element of those set out in Article 35.C.1.a of the General Health Law.

4.a Lack of a lot number or equivalent on the unit packet of the tobacco products, as indicated in section 8 of Article 5, considered as an element of those set out in Article 35.C.1.a of the General Health Law.

5.a Refusal or reluctance by the manufacturers, importers and brand owners of tobacco products to provide the Ministry of Health and Consumer Affairs a list of all tobacco ingredients, as stated by Article 6, considered as an element of those set out in Article 35.C.1.a of the General Health Law.

6.a The use in the unit packets of tobacco products, of texts, names, brands or images or other marks conveying the impression that a given tobacco product is less toxic than another, considered as an element of those set out in Article 35.C.1.a of the General Health Law.

7.a The repeated commission of serious offenses over the last five years, as established by Article 35.C.8.a of the General Health Law.

The above penalties shall be punishable in accordance with their respective levels of severity, as provided by Article 36 of Law 14/1986, of April 25, General Health.

Sole transitory provision. Extension on sales.

Notwithstanding the sole abrogating provision, cigarettes that do not meet the provisions of this Royal Decree may continue to be sold until September 30, 2003, and other tobacco products may be sold until September 30, 2004. As necessary, until then, the provisions of Royal Decrees 510/1992, of May 14, regulating the labeling of tobacco products and establishing certain limitations on commercial aircraft, and 1185/1994, of June 3, on the labeling of tobacco products other than cigarettes and prohibiting certain oral tobacco and updating the penalty system for tobacco matters, shall continue to apply.

Sole abrogating provision. Regulatory repeal.

Royal Decrees 510/1992, of May 14, regulating the labeling of tobacco products and establishing certain limitations on commercial aircraft, and 1185/1994, of June 3, on the labeling of tobacco products other than cigarettes and prohibiting certain oral tobacco and updating the penalty system for tobacco matters are hereby abrogated, notwithstanding the content of the sole transitory provision; and any provisions of the same or lesser status opposing the provisions of this Royal Decree.

First final provision. Source of authority.

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This Royal Decree is fundamental, issued on the basis of Article 149.1.16.a of the Constitution and in development of Articles 24, 25.2, 32 a 37, 40.5 and 40.6 of Law 14/1986, of April 25, General Health.

Second final provision. Development powers.

The Minister of Health and Consumer Affairs is authorized to issue the necessary provisions for the development of this Royal Decree.

Third final provision. Entry into force.

This Royal Decree shall be effective as of the date of its publication in the «Official State Bulletin».

Given in Madrid on October 18, 2002.

JUAN CARLOS R.

ANNEX

List of additional health warnings

1. Smoking shortens your life.
2. Smoking clogs arteries and causes heart conditions and cerebrovascular accidents.
3. Smoking causes deadly lung cancer.
4. Smoking when pregnant harms your baby.
5. Protect children: do not make them breathe tobacco smoke.
6. Your doctor and pharmacist can help you quit smoking.
7. Tobacco is highly addictive: do not start smoking.
8. Quitting smoking reduces the risk of deadly heart and lung diseases.
9. Smoking may cause a slow and painful death.
10. There is help to quit smoking: consult your doctor or pharmacist.
11. Smoking can reduce blood flow and cause impotence.
12. Smoking causes skin aging.
13. Smoking can harm sperm and reduce fertility.
14. Smoke contains benzene, nitrosamines, formaldehyde and hydrogen cyanide.

MINISTRY OF ECONOMY

20274 RESOLUTION of October 16, 2002, by the Commissioner for the Tobacco Market, publishing public sales prices of certain tobacco products at tobacco and stamp outlet networks of the monopoly area.

By reason of the provisions of Article 4 of Law 13/1998, Ordering of Tobacco Market, publishing the public sales prices of certain tobacco products at tobacco and stamp outlet networks of the monopoly area, proposed by the relevant manufactures and importers.

One.—Public sales prices of the following tobacco products, including the various taxes, at the tobacco and stamp outlet networks of the Peninsula and the Balearic Islands, are as follows:

	Total public sales price — Euros/pack
A) Cigars	
B52	1.55
Che	2.25
Madison	2.00
Windsor Blue	2.00