
LEGISLATIVE DECREE of June 24, 2003, no. 184

Implementation of Directive 2001/37/EC regarding the processing, presentation and sale of tobacco products.

In effect on: 08/21/2015

THE PRESIDENT OF THE REPUBLIC

Whereas Articles 76 and 87 of the Constitution;

Whereas Articles 117 and 120 of the Constitution;

Whereas Directive 2001/37/EC of the European Parliament and the Council of the Harmonization of Legislative, Regulatory and Administrative Provisions of Member States regarding the processing, presentation and sale of tobacco products;

Whereas the Law of 1 March 2002, no. 39 and, in particular, Article 1 and Annex A;

Whereas Law no. 400 of August 23, 1988 and, in particular, Article 14;

Whereas the preliminary resolution of the Council of the Prime Minister, adopted in the meeting of November 29, 2002;

Having heard the opinions of the competent commissions of the Lower House and the Senate of the Republic;

Having heard the opinion of the Permanent Conference for relations between the State, the regions and the autonomous provinces of Trento and Bolzano, handed down at the hearing on February 27, 2003;

Whereas the resolution of the Office of the Prime Minister, adopted at the meeting on June 19, 2003;

At the proposal of the Minister for EU policies and the Minister of Health in concert with the Ministries of Foreign Affairs, Justice, Economics and Finance and for Regional Affairs;

Enacts

the following legislative decree:

Art. 1

Field of Application

1. This decree establishes the regulations on the maximum tar, nicotine and carbon monoxide content in cigarettes, the health hazard warnings, the other information that must be included on the tobacco product packages as well as the provisions on the ingredients for these products and the information on their hazardous effects.

Art. 2

Definitions

1. For the purposes of this decree, the following definitions apply:

a) tobacco products, its products, listed below:

“products” to be smoked, inhaled, sucked on or chewed that are, even partially, made from tobacco, whether genetically modified;

b) tar, raw anhydrous smoke concentrate and nicotine-free;

c) nicotine, nicotine alkaloids;

d) tobacco for oral use, all tobacco products for oral use, except for those that are intended to be smoked or chewed, composed of tobacco in whole or in part, in the form of powder, fine particles or any other combination of these forms, specifically those present

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in individual pouches or porous pouches or a similar form for a food product;

e) ingredients, any substances or any component other than leaves or other natural or unprocessed parts of tobacco plants used to produce or prepare a tobacco product or present in the finished product, even if under a modified form, including papers, filters, ink and gluing agents.

Art. 3.

Maximum Tar, Nicotine and Carbon Monoxide Content of Cigarettes

1. Starting on January 1, 2004, the tar, nicotine and carbon monoxide cigarette content sold in free circulation, sold or produced in Italy cannot exceed, respectively:

- a) 10 mg/cigarette for tar;
- b) 1 mg/cigarette for nicotine;
- c) 10 mg/cigarette for carbon monoxide.

2) For cigarettes produced in Italy and intended for export outside of the European Union, the limitations on the substances set forth in section 1 apply as of January 1, 2007.

3. With the resolution of the general director of the autonomous Administration of State Monopolies, the content of the substances set forth in section 1 are published for each calendar year in the Official Gazette of the Italian Republic for the individual types of cigarettes.

Art. 4

Measuring Methods

1. The cigarette tar, nicotine and carbon monoxide contents are measure, respectively, based on the ISO 4387 regulation for tar, ISO 10315 for nicotine and ISO 8454 for carbon monoxide. The accuracy of the information regarding the tar and nicotine contents included on the packs is verified based on ISO 8243. The measurements are performed in qualified analysis laboratories, authorized for this purpose, at the expense of the manufacturers or importers.

2. With the Decree of the Ministry of Health, adopted pursuant to Article 17 of Law no. 400 of August 23, 1988 in concert with the Ministry of Economics and Finance, the following are set forth:

- a) the structural, technological and functional requirements of the laboratories authorized to conduct the analyses as per section 1 or verifying their accuracy as part of a control by the competent authorities;
- b) further evidence requested from the tobacco manufacturers or importers in order to determine the content of other substances contained or derived from their tobacco product, divided based on the brand and type and to verify their health effects, considering their toxicity.

3. The results of the tests conducted based on section 2 are sent by the manufacturers or importers to the Ministry of Health and the Ministry of Economics and Finance once a year and every time the product specifications are changed. With the annual publication of the Official Gazette of the Italian Republic, with publication on the websites of the Ministry of Health and the Ministry of Economics and Finance or through other appropriate means, the information available pursuant to this article is shared, notwithstanding any information that is covered by commercial secrecy.

4. The Ministry of Health shares the list of authorized laboratories with the Ministry of Economics and Finance and the European Commission within six months from the date this decree goes into effect and when there is any change, specifying the criteria used for authorization and the surveillance means implemented. The Ministry of Health also informs the European Commission annually about any other data and information available pursuant to this article.

Art. 5

Authorization Procedure for Analysis Laboratories

1. The Higher Institute of Health is the delegated organization, pending technical assessment, to issue the authorizations and handle the subsequent oversight for the laboratories set forth in Article 4, sections 1 and 2, which measure the tar, nicotine and carbon monoxide content in cigarettes and any other tests to determine the content of other harmful substances, excluding laboratories conducting this test as part of the contract activities performed by the competent authorities.

2. The laboratories set forth in the Decree of the Ministry of Finance have jurisdiction until 31 August 1994 regarding the final controls on the accuracy of the information on the content of the substances set forth in Article 3, section 1 regarding the sale and marketing of the product.

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3. For the authorizations set forth in section 1, the laboratory managers involved will present the appropriate files to the Higher Health Institute with a statement certifying compliance with the structural, technological and functional requirements set forth by the Decree in Article 4, section 2.

4. The Higher Health Institute, having conducted the technical assessment regarding the fitness requirements, authorizes the laboratories set forth in section 1 to measure the contents as per the same section and may handle the oversight that is periodically deemed appropriate.

5. The costs involving the preliminary proceedings before the authorizations indicated in section 1 are issued and the subsequent oversight are at the expense of the laboratories involved. With the decree of the Ministry of Health, to be adopted within sixty days from the date this decree goes into effect, the changes deemed necessary by this article to the decree of the Ministry of Health on March 6, 2000, published in the Official Gazette no. 70 of March 24, 2000, as amended, regarding the rates for the services provided by the Higher Health Institute are implemented.

Art. 6

Labeling

1. The tar, nicotine and carbon monoxide content in the cigarettes measured pursuant to Art. 4 are printed in Italian on the side of each pack of cigarettes so that it covers at least 20% of the corresponding surface area.

2. Each unit pack of products, except for non-smoking tobacco products, must including the following warnings:

a) general warnings:

1) Smoking kills; or:

2) Smoking serious harms you and those around you.

The general warnings indicated above are varied so that each appears regularly. These warnings are printed on the most visible surface of the pack as well as on each external pack, including transparent wrappers used for the retail sale of the product;

b) one of the following supplemental warning appears;

1) Smoking clogs your arteries and causes strokes and heart attacks;

2) Smoking causes lung cancer;

3) Smoking during pregnancy harms the fetus;

4) Protect your children: don't let them breath your smoke;

5) Your doctor or pharmacist can help you quit smoking;

6) Smoking is addictive; don't start;

7) Quitting smoking reduces your risk of fatal cardiovascular and pulmonary disease;

8) Smoking ages your skin.

The supplemental warnings set forth in section 2, letter b) are varied so that they appear regularly. The supplemental warning is printed on the second most visible area of the pack as well as on all external packaging used for the retail sale of the product, including additional transparent wrappers.

3. Non-smoking tobacco products, on the most visible part of the pack and on all external wrappers used for retail sale, excluding additional wrappers, must include the warning: "This tobacco product can harm your health and is addictive."

4. Any measures following the European Commission's adoption of guidelines on the use of color photographs or pictograms that illustrate and explain the repercussions of smoking on the health are defined with the decree of the Ministry of Health in concert with the Ministry of Economics and Finance, to be adopted pursuant to Art. 17 of the Law of August 23, 1988, no. 400.

5. The general warning set forth in section 2, letter a) and the warning for non-smoking tobacco products set forth in section 3 cover at least 30% of the external surface of the package corresponding to the tobacco pack on which they are printed.

The supplemental warning set forth in section 2, letter b) covers at least 40% of the external surface area corresponding to the tobacco pack on which it is printed; nevertheless, for packages for products other than cigarettes, the most visible area of which is greater than 75 cm², the warning surface set forth in section 3 is at least 22.5 cm² for each part.

6. The warnings and the information on the contents set forth in this article is printed:

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- a) in bold Helvetica font on a white background so that the text body takes up as much room as possible on the dedicated surface area;
 - b) in lower case except for the first letter of the message and as required according to the rules of grammar;
 - c) centered in the area where the text is printed, parallel to the super edge of the pack;
 - d) for products other than those set forth in section 3, surrounded by a black border with a minimum thickness of 3 mm and a maximum thickness of 4 mm, included in the surface area indicated in sections 1 and 5, which does not in any way interfere with the warnings and information provided.
7. The warnings and information set forth in this article cannot be included on the tax stamps on the packs; it must be printed in a permanent and non-transferrable manner that cannot in any way be hidden, covered up or partially covered up by other information or images, even after the pack is opened. For tobacco products other than cigarettes, these warnings and information may be placed on stickers so long as they cannot be removed.
8. The information and warnings set forth in this decree are affixed to all products for use in Italy, including the areas set forth in Article 128 of the consolidated text of the legislative provisions on customs issue, approved with the decree of the President of the Republic of January 23, 1973, no. 43.
9. To ensure the identification and traceability of products at all times, in any appropriate form that allows for its provenance and production date to be identified, the batch number or equivalent identifier must be placed on the pack. The provisions set forth in Article 7, section 1 of the Law of March 19, 2011, no. 92 remain in effect.

Art. 7

Other Product Information

- 1. The manufacturers and importers of tobacco products as per Article 2, section 1, letter a) send the Ministry of Health and the Ministry of Economics and Finance the list of all the ingredients used in their production with the relative amounts, divided by brand and type. A declaration is attached to the list that justifies the use of these ingredients in the products, indicating their function and category. The list is also accompanied by the toxicological data available to the manufacturer or importer for the individual ingredients as a combustible or incombustible with particular attention on their effects on health and considering, among other things, their addictive qualities. The list is filled out with the ingredients based on their percentage in the product. The information set forth in this section is provided annually and for the first time within 30 days from the date this decree goes into effect.
- 2. With the annual publication of the Official Gazette of the Italian Republic, with publication on the websites of the Ministry of Health and the Ministry of Economics and Finance or through other appropriate means, the information available pursuant to this article is shared, notwithstanding any information that is covered by commercial secrecy.
- 3. The Ministry of Health informs the European Commission annually about all data and information set forth in this article.

Art. 8

Name of the Product

- 1. Starting on September 30, 2003, notwithstanding that set forth in Article 66, section 1, the use of phrases such as "low tar content," "light," "ultra light," "mild" and names, brands, images and other figurative elements or symbols that suggest that one tobacco product is less harmful than another are prohibited on tobacco packs.

Art. 9

Import, Sale and Consumption of Tobacco Products

- 1. The import, sale and consumption of tobacco products pursuant to this decree is allowed so long as every provision is adopted in order to verify the elements set forth in Article 4.

Art. 10

Temporary Provisions

- 1. Cigarettes that do not comply with the provisions of this decree may still be sold until September 30 2003.
- 2. Tobacco products other than cigarettes that do not comply with the provisions of this decree may be sold until September 30, 2004.

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3. The provisions set forth in sections 1 and 2 apply only to products that are already included in the sales rates on the date the provisions of this decree goes into effect.

Art. 11

Abrogation

1. Article 46 of Law no. 428 of December 29, 1990, Article 37, sections 3, 4 and 5, Law no. 142 of February 19, 1992, the decree of the Ministry of Finance on July 31, 1990, published in the Official Gazette no. 198 of August 25, 1990, the Decree of the Ministry of Finance on July 16, 1991, published in the Official Gazette no. 201 of August 28, 1991, the decree of the Ministry of Finance on November 11, 1991, published in the Official Gazette no. 294 of December 16, 1991, the Decree of the Ministry of Finance on July 26, 1993, published in the Official Gazette no. 230 of September 30, 1993 as well as Article 23, sections 2, 3, 4 and 5 of Law no. 146 of February 22, 1994 are abrogated.

2. The provision of article 3 of the Law no. 76 of March 7, 1985 remains in effect.

Art. 12

Sanctions

1. Without prejudice to this constituting a crime, anyone who produces, sells, imports or exports products that do not comply with that set forth in this decree may be punished by an administrative fine of between ten thousand Euros and fifty thousand Euros.

2. In very serious cases or in case of recidivism, the minimum and maximum fines set forth in section 1 are doubled.

3. The sanctions are applied pursuant to Law no. 689 of November 24, 1981. The judicial police agents and official may conduct controls as per Art. 13 of the cited law and the administrative police may investigate violations, whether discovered or reported. The report required as per Article 17 of Law no. 689 of 1981 is submitted to the Prefecture.

Art. 13

Application

1. The provisions of this decree go into effect on the day after their publication in the Official Gazette of the Italian Republic.

This decree, along with the State seal, will be entered in the Official Registry of regulatory acts for the Italian Republic. All parties must be observed it and ensure that it is observed.

Done in Rome on June 24, 2003

CIAMPI

Berlusconi, Prime Minister

Buttiglione, Secretary for EU Policies

Sirchia, Surgeon General

Frattini, Secretary of State

Castelli, Attorney General

Tremonti, Secretary of the Economy and Finance

La Loggia, Secretary of Regional Affairs

Whereas, the Official Seal: Castelli