

RESOLUTION WHEREBY THE PARTIAL REFORM OF  
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#### REASON

BOLIVARIAN REPUBLIC OF VENEZUELA  
MINISTRY OF HEALTH AND SOCIAL DEVELOPMENT  
NUMBER 109 OF March 22, 2004  
193 and 145

#### RESOLUTION

Pursuant to what is established in Article 83 of the Constitution of the Bolivarian Republic of Venezuela, in accordance with Article 76, numeral 8 of the Organic Law of Public Administration; Articles 5, 32 and 33 of the Organic Law of Health, and Article 6, numerals 1, 2 and 7 of the Law of Protection of the Consumer and User.

#### WHEREAS

Health is a fundamental right of all persons, and it is incumbent upon the State to guarantee it as part of the right to life.

WHEREAS

All persons have a right to the protection of their health, to participate actively in its promotion and defense, and have a duty to comply with such health measures as the law may establish.

WHEREAS

The progressive increase in tobacco use in the world has brought as a result of the loss of at least 3.5 million lives, as established by the World Health Organization in 1998, estimated at 10 million each year until 2030.

WHEREAS

An average of 16,000 persons die annually in Venezuela due to diseases related to cigarette consumption, such as cancer, cardiovascular disease and respiratory disease, and is one of the main causes of death for adults.

WHEREAS

Many of the toxic components present in cigarettes in their mainstream and sidestream of smoke are producers and accelerators of cancer and other diseases.

WHEREAS

In Venezuela, beginning in 1978, controls over tobacco products were initiated through the Law of Taxation on Cigarettes and Tobacco Products and the reform of the Regulation of the Law of Taxation on Cigarettes and Tobacco Products in 1979.

RESOLVES

Article 1 Regulation and Control of Cigarettes and other Tobacco Derivative Products intended for Human Consumption

The purpose of this Resolution is to establish guidelines for control that companies that process or commercialize

cigarettes and other products derived from tobacco must comply with, whether they are produced in the national territory or imported.

Article 2 For the purposes set forth in this Resolution, the following definitions shall apply:

1. Cigarettes: Any rolled or tubular structure that contains tobacco and is used for smoking.
2. Tobacco: A roll of tobacco leaf pressed for smoking.
3. Cut tobacco: Tobacco cut to be used for smoking.
4. *Chimó*: A paste that is used for chewing which consists of a substance made of bits of natural or reconstituted tobacco leaf.
5. Pack: Package or wrapping that constitutes the smallest container of cigarettes made for consumption.
6. Packaging: Packs, cartons, packets, cans and any other container for packaging products for the consumer market.
7. Mainstream smoke emissions: This corresponds to the smoke that comes out of the orifice of a smoking machine when a tobacco product is inserted into the machine and lit.
8. Sidestream smoke emissions: This corresponds to the smoke that is not mainstream smoke, but emanates from the tobacco product that is inserted into the smoking machine and lit.

Article 3 Companies that sell or manufacture products that are tobacco derivatives, whether or not they produce smoke, and their products, must be registered with the Ministry of Health and Social Development.

Article 4 Any company that sells, or is a national manufacturer, importer or exporter of cigarettes or products derived from tobacco, whether or not they produce smoke, must submit to the General Office of Environmental Hygiene and Health Oversight an application for Company Registration, providing therein the Registration of the company founding, duly certified by the appropriate authority for verification, with indication of the company name, domicile and address clearly stated, and the legal representative thereof, as well as the RIF and NIT numbers.

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Article 5 For the purposes of this Resolution, the following definitions shall apply:

1. National Manufacturing Company: Any company with its domicile in the national territory that processes tobacco, or manufactures any product derived from tobacco, whether or not it produces smoke, whose purpose is to commercialize products in the domestic or external market.
2. Importing Company: A company engaged in the importation of processed tobacco or any manufactured product derived from tobacco, whether or not it produces smoke, for the purpose of distributing or commercializing it in the national territory.
3. Exporting Company: A company engaged in the exportation of processed tobacco or any manufactured product derived from tobacco, whether or not it produces smoke, for the purpose of distributing or commercializing it in the external market.
4. Commercializing Company: Any company with its domicile in the national territory, whose economic activity is directed towards the purchase and/or sale of cigarettes and other products derived from tobacco, for the purpose of the wholesale purchase or sale thereof.

Article 6 The registration of companies established in Article 4 must be carried out once through the General Office of Environmental Hygiene and Health Oversight and for such purpose, certified copies of any modifications thereof are to be filed in the categories of company name, domicile, legal representative or any other amendment that may affect the registration of the company.

Article 7 The company's legal representative must annually renew the company's registration with the General Office of Environmental Hygiene and Health Oversight, giving notification that the company is continuing to operate, and is complying with the requirements of the law to continue to manufacture, distribute or commercialize its products. Once compliance with the conditions for registration has been verified, the respective renewal shall be issued.

Article 8 The companies indicated in Article 4 of this Resolution, must apply to the General Office of Environmental Hygiene and Health

Oversight for a Control Number for each one of the products to be commercialized by brand in their different formulations and presentations, based on the characteristics that differentiate them, such as content levels, composition, flavor and aroma.

SOLE PARAGRAPH: The control number that is the subject of this provision shall be valid for one (1) year as of its issuance to the company, and thereafter, said Number must be annually renewed with the General Office of Environmental Hygiene and Health Oversight of the Ministry of Health and Social Development.

Article 9 The application for a Control Number indicated in the previous Article must be submitted prior to commercialization of the product, accompanied by the following elements:

1. A color photocopy of the whole pack intended for the end consumer.
2. A general list of the types of tobacco and additives used by the company, with specifications of the filter and its wrapping.
3. Data on each product, as well as information regarding the production and composition of the product that each company must provide, specifying:
  - a) Compounds present in the mainstream smoke of the product, as specified in Annex II.
  - b) Compounds present in the sidestream smoke of the product, as specified in Annex III.
  - c) Compounds present in the tobacco overall, as specified in Annex I.
  - d) A witness sample of the product.
  - e) Application for an analysis by the "Rafael Rangel" National Institute of Hygiene, in accordance with the content of Annex 1.

The aforesaid Annexes I, II and III comprise an integral part of this Resolution.

Article 10 The companies referred to in this Resolution must provide information with respect to the sale, production, promotion and advertising data for the products that they commercialize in the market, indicating the following things:

1. Monthly volume of the product sold by State.

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2. Monthly volume exported by country of origin.
3. Monthly volume imported by country of origin.
4. Monthly volume produced.
5. Monthly sale price for the consumer.
6. Monthly expenditure on promotion and advertising of the product by State. Sale data is to be provided by those companies that are selling their products as of the entry into force of this Resolution, as well as for each one of the renewals that they apply for annually.

Article 11 The procedures involving Control Numbers and Company Registration cannot be used by companies as a permit for sale of the product issued by the health authorities, and accordingly any mention of this procedure on packaging and in advertising is prohibited.

Article 12 The General Office of Environmental Hygiene and Health Oversight, acting through the "Rafael Rangel" National Institute of Hygiene, shall establish the appropriate mechanisms for the analysis and verification of tobacco products in order to fulfill what is established in numeral 3 of Article 9 of this Resolution.

Article 13 In the event of any non-compliance or violation of the provisions set forth in this Resolution, the General Office of Environmental Hygiene and Health Oversight shall, pursuant to the terms and conditions established in Articles 65, 66 and 67 of the Organic Law of Health, impose such precautionary measures and/or administrative sanctions provided for therein as may apply, in accordance with the nature and seriousness of the offense.

Article 14 The period of six (06) months is extended to November 23 of 2004, for national companies, importers or exporters of cigarettes and other products derived from tobacco that are commercializing such products, to deliver to the General Office of Environmental Hygiene and Health Oversight the elements required for the assignment of a Control Number for products derived from Tobacco, as well as the respective Company Registration.

Article 15 It is incumbent upon the General Office of Environmental Hygiene and Health Oversight to see to compliance with this Resolution.

Article 16 This Resolution shall enter into force thirty (30) days following its publication in the *Gaceta Oficial* of the Bolivarian Republic of Venezuela.

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Let notification hereof be given, and let this be published,  
ROGER CAPELLA MATEO  
Minister of Health and Social Development

[Annexes Omitted]

(c) JurisMaster