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PUBLIC HEALTH

MINISTERIAL DECISION No. 275/2003

WHEREAS: ARTICLE 66 of Law No. 41 on Public Health, of 13 July 1983, states that the Ministry of Public Health shall issue provisions relating to the nutritional status of the population and the sanitary control of foodstuffs and beverages of human consumption, and shall establish the dietary regulations required by specific population groups subject to certain risks.

It also establishes provisions relating to health controls on articles of personal use, domestic items, toys, cosmetics and other items with potential health effects.

WHEREAS: Agreement No. 2840 of 28 November 1994, adopted by the Executive Committee of the Council of Ministers, pursuant to the Final Sixth and Seventh Provisions of Decree Law No. 147 “Reorganization of Central Government Bodies”, of 21 April 1994, authorizes the Ministry of Public Health to direct, execute and oversee the application of State and government policy on public health, the development of medical sciences and the medical-pharmaceutical industry; for this purpose giving it responsibility for the control and epidemiological surveillance on diseases and their risk factors, among other functions.

WHEREAS: Agreement No. 3790, adopted by the Executive Committee of the Council of Ministers on 30 October 2000, called for the establishment of the National Commission on Health and the Quality of Life, to coordinate and control all activities relating to the promotion of a better quality of life, with the aim of stimulating healthier lifestyle practices.

WHEREAS: Decision No. 3 of 27 January 1994, of the former State Committee on Prices, now the Ministry of Finance and Prices, authorizes units of the national economy to set technical productive fees for the services provided to national or foreign mixed-ownership or private enterprises, non-State associations or institutions, domestic entities that trade in foreign currency, and domestic, foreign, or mixed entities that provide tourism services and engage in tourist operations.

WHEREAS: Section 2 of Decision No. 64 of 28 April 1997, of the Ministry of Public Health, establishes that the sanitary registration of foodstuffs, additives, cosmetics and articles of personal or domestic use, is an essential requirement for their circulation and sale throughout national territory; as a result of which, products manufactured from tobacco were excluded from the scope and purpose of the aforementioned legal instrument.

WHEREAS: The consumption of tobacco products today constitutes one of the most serious health problems worldwide, and is one of the etiological factors underlying numerous complaints, including, in particular, cardiopathies, malignant tumours and cerebro-vascular diseases causing some 4 million deaths per year throughout the world— a situation from which our country is not immune, since 30% of the causes of death are associated with tobacco, the prevalence rate of which is currently 31.6%, according to data

provided by the Second Annual Risk Factors Survey. The fact that Cuba is a producer country of multiple tobacco products has a special influence on the above.

WHEREAS: It has been proven that the level of advertising of tobacco products influences their level of consumption, both among the population at large and in specific target groups, and that the packet or box containing such products is an ideal vehicle for this; for which reason this form of publicity has grown in importance while other forms have been restricted, offering manufacturers the possibility of manipulating their ingredients and design characteristics, to make their products more attractive.

WHEREAS: One of the overriding objectives of Cuban State and government policy is to constantly raise in the level of health of our people and their quality of life, it is necessary to approve and implement a regulation establishing the procedures for sanitary registration of tobacco products, which, notwithstanding the right of each person to autonomously choose whether or not to consume such products, ensures that they reach consumers with the necessary safety and free from advertising devices that encourage their addiction.

WHEREAS: Exercising the prerogatives granted to me,

I hereby resolve as follows:

- I. To approve and implement the Regulation for the Sanitary Registration of Products Manufactured from Tobacco, as described in the attached Annex No.1, and which forms an integral part of this Decision.
- II. The Vice Minister responsible for hygiene-epidemiological programmes and the Vice Minister responsible for the economic area, shall be responsible for enforcing the provisions of this Ministerial Decision in their respective jurisdictions, and are also authorized to issue the instructions and other complementary provisions needed to enforce it.

13 March 2004, Official Gazette 220

To be communicated to the bodies, organizations, directors and officials to whom it may concern, and the original to be filed in the Legal Department of the Organization.

To be published in the Official Gazette of the Republic.

Done in the City of Havana, Ministry of Public Health, 26 December 2003.

Dr. Damodar Peña Pentón
Minister of Public Health

ANNEX No.1
REGULATION FOR THE SANITARY REGULATION OF PRODUCTS
MANUFACTURED FROM TOBACCO

CHAPTER I
GENERAL PROVISIONS

ARTICLE 1. The present regulation aims to establish, for national territory, the procedures and basic requirements for sanitary registration of products manufactured from tobacco.

ARTICLE 2. For the purposes of this Regulation, the following definitions shall apply:

- **Products manufactured from tobacco**, hereinafter, “tobacco products”, means products that are wholly or partially produced using tobacco leaves and their derivatives as raw material, together with a paper wrapping and additives in their manufacture, to be smoked, sucked, chewed, ingested, smeared, used as snuff, or any type of human consumption for non-therapeutic purposes; generally presented the form of cigars [*cigarros* and *puros*], cigarettes [*cigarillos*] or other forms including snuff and pipe tobacco.
- **Ingredient** means any substance or component of the leaves and other natural or processed parts of the tobacco plant, used in the manufacture or preparation of a product therefrom, which remains present in the manufactured product either directly or modified, including the paper, filter, inks and glue.
- **Sanitary registration** means the evaluation and control procedure to approve, or otherwise, a product as suitable for human consumption, based on verification of the physical, chemical, biological, or toxicological characteristics, using laboratory analyses in conjunction with current health standards, for which an essential requirement is the presentation of health or other certificates issued by the competent authorities. This is done in the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics, attached to the Nutrition and Food Hygiene Institute of the Ministry of Public Health.
- **Health certificate** means the document issued by the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics, accrediting authorization for the production, importation, exportation, processing, packaging and marketing of the product in question, throughout national territory.
- **Tar** means raw anhydride smoke condensate.
- **Nicotine** means nicotine alkaloids.
- **Tobacco for oral use** means all tobacco products intended for oral use, except for products intended to be smoked or chewed, consisting partly or wholly of tobacco in the form of powder or fine particles or any combination thereof, in particular when presented in single-dose sachets or porous bags, or in a form that suggests an edible product.
- **Packaging and external labelling** means any package and label used in the retail sale of the product.
- **Commercial brand “Vitola”** means the name used to identify the various formats, such as sizes and shapes, in which a twisted-leaf tobacco brand can be marketed.

ARTICLE 3. The Institute of Nutrition and Food Hygiene of the Ministry of Public Health, acting through the Department of Registration, Oversight and Health Quality of Food and Cosmetics, is the only entity in the country authorized to perform activities leading to the sanitary registration of tobacco products.

ARTICLE 4. The registration of tobacco products in the Department of Registration, Oversight and Health Quality of Food and Cosmetics will be an essential requirement for their marketing throughout national territory.

CHAPTER II SANITARY ASSESSMENT

ARTICLE 5. The Department of Registration, Oversight and Health Quality of Foods and Cosmetics will evaluate all tobacco products prior to issuing the corresponding Sanitary Certificate.

ARTICLE 6. The sanitary assessment of tobacco products will require presentation of:

- (a) Five representative samples of each product, preferably from five different batches or production dates; in the case of twisted-leaf tobacco products, a sample will be presented containing 25 units of the commercial brand vitola, together with sample all types of packaging in which they will be sold.
- (b) Technical specifications to evaluate the product, according to the model contained in Annex No.2 of this Decision.
- (c) The Sanitary Permit held by the producer establishment, issued by the Provincial Hygiene and Epidemiological Centre.
- (d) In the case of imported tobacco products, a health certificate or a commercialization permit issued in the country of origin.

ARTICLE 7. The owners of the brand, or the importers and traders authorized thereby, shall send the results of tests conducted pursuant to the foregoing article to the Department for the Sanitary Registration of Food and Cosmetics, at the time of the request and thereafter annually. A longer periodicity may be established to coincide with the renewal of the health certificate, if no changes in the product specifications have occurred.

ARTICLE 8. The owners of the brand, or else the importers, traders, or other competent bodies authorized thereby, shall notify the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics of any changes in specifications regarding the composition of their products; the Department may also require these test results to be verified by its own selected laboratories.

ARTICLE 9. The information contained in the specifications established in Annex No. 2 shall be strictly confidential and for the exclusive use of the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics, insofar as the corresponding formulas represent a commercial secret.

CHAPTER III
PACKAGING AND LABELLING

SECTION I
PACKAGING AND LABELLING OF CIGARETTES

ARTICLE 10. In relation to activities corresponding to sanitary registration, the packets and external packaging of tobacco products known as “cigarettes” to be sold in the retail market shall:

1. Contain appropriate information to identify the origin of the product, the name of the manufacturer, the batch number and date of production, to allow for product traceability.
2. Not contain descriptive terms or elements, or figurative or other signs, providing false or misleading information, intended to create an erroneous impression in the consumer about characteristics or health effects of the product, such as: “Low Tar”, “Light”, “Ultralight”, “Mild”, or others.
3. Not contain publicity messages in any form, including those intended to make the product more attractive or induce its consumption; brand images are excluded from this prohibition.
4. Contain a rotating series of health warnings, which, in particular, will:
 - (a) Provide complementary information from the National Health Authorities, concerning the harmful effects of tobacco consumption on human health;
 - (b) Be written in Spanish, in clear, legible, visible, capital letters in the Arial type font, positioned centrally, in a colour that contrasts strongly with the background, for ease of reading;
 - (c) May or may not be accompanied by pictograms, images, or both, and will occupy either 30% of each of the main faces or 60% of one of them; one of these alternatives may be chosen, but the presence of the health warning on the cigarette packet is obligatory and indispensable;
 - (d) Number at last four rotating annually, except for cigarettes manufactured by Cuban industry for sale in national currency, for which there will be a single health warning also rotating annually. Excluded from the above requirements are cigarettes of the CRIOLLOS brand, or other similar brands, manufactured from the modernization of Cuban factories, which will be required to display the four health warnings, with an annual rotation.
 - (e) Variations on health warnings resulting from their annual rotation will constitute an amendment of the Sanitary Certificate.
5. Apart from the health warnings specified in paragraph 4, the tar, nicotine and carbon monoxide content of the cigarettes shall be printed on the sides of the packets.
6. The texts used to fulfil the provisions of the foregoing paragraphs may not be printed in official premises of the packaging units; they will be printed in an immovable, indelible form and will in no circumstances be disguised, masked, or separated by other information or images. They will not be printed in places that could be damaged when the product is opened.

ARTICLE 11. The authorized national health authorities shall indicate the content of the health warnings and update them annually, to ensure their rotation; updatings shall be

announced at least six months in advance, at the start of the following year. Annex No.3 of this Decision contains the first health warnings for the purpose of facilitating and initiating application and interpretation of the provisions contained therein.

SECTION II PACKAGING AND LABELLING OF PRODUCTS OTHER THAN CIGARETTES

ARTICLE 12. In relation to activities leading to sanitary registration, the packets and packages of tobacco products known as *cigarritos*, *tabaquitos* and *picadura*, destined for retail sale, shall fulfil the provisions established for cigarettes in Articles 11 and 12 of this Decision; other non-cigarette tobacco products, also for retail sale, shall:

1. Contain appropriate information to identify the origin of the product, the name of the producer, the batch number or date of production, to allow for product traceability; except for tobacco packages with special characteristics that make it unnecessary to indicate the batch number.
2. Not contain descriptive terms or elements, or figurative or others signs, providing false or misleading information intended to create an erroneous impression in the consumer about characteristics or health effects of the product.
3. Contain a rotating series of health warnings, which in particular will:
 - (a) Provide complementary information from the National Health Authorities, concerning the harmful effects of tobacco consumption on human health;
 - (b) Be written in Spanish, in clear, legible, visible, capital letters in the Arial type font, positioned centrally, in a colour that contrasts strongly with the background, for ease of reading;
 - (c) May or may not be accompanied by pictograms, images or both, and as a whole will occupy at least 30% of the principal outside faces; in the case of packaging units whose most visible face is larger than 75 cm², such as boxes of cigars or tobacco, the health warnings will be printed on the upper face of the package, occupying an area of at least 22 cm².
 - (d) Number at least four, rotating annually; in the case of boxes and other tobacco packages, their will be a single health warning, without annual rotation, stating: "This product may be harmful to your health and create addiction. Ministry of Health".
 - (e) Variations in the health warnings as a result of their annual rotation will constitute a modification of the Sanitary Certificate, except in relation to cigars [*puros*] or tobaccos.
 - (f) The texts used to fulfil the provisions of the foregoing paragraphs may not be printed in official premises of the packaging units; they will be printed in an immovable, indelible form and will in no circumstances be disguised, masked, or separated by other information or images. They will not be printed in places that could be damaged when the product is opened.
 - (g) In the case of other non-cigarette tobacco products, the texts in question may be affixed with adhesives, provided they cannot become detached.

ARTICLE 13. The authorized national health authorities shall indicate the content of the health warnings and update them annually, to ensure their rotation. Annex No.3 of this

Decision contains the first health warnings for the purpose of facilitating and initiating application and interpretation of the provisions contained therein

CHAPTER IV REGISTRATION

ARTICLE 14. Registrations of tobacco products made at the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics, attached to the Institute of Nutrition and Food Hygiene of the Ministry of Public Health, will be valid for three years. Registration may be renewed for each product within 90 days before the expiry date, in which case the fee payable will be half of that set for the original registration.

ARTICLE 15. The registration of a product in the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics will result in the granting of the Sanitary Certificate.

ARTICLE 16. The brand owners, or else the importers, traders, or other competent bodies authorized by them, shall be the only persons authorized to register their products in the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics; following the registration of their products in the aforementioned institution, they shall be considered the registration holders.

ARTICLE 17. The registration holder shall report any updates or alterations made to its product, which differ from the information provided for its registration, during the period of validity of the sanitary certificate granted, and shall pay an additional sum equal to one quarter of the fee established for product registration.

ARTICLE 18. The registration of a product in the Department of Registration, Oversight and Sanitary Quality of Foods and Cosmetics, shall not exempt it from controls on samples or other types of hygiene-epidemiological actions specified by the Regulation on State Sanitary Inspection, implemented by Ministerial Decision No. 215, of 27 August 1987, including the application of measures against persons who violate its rules.

CHAPTER V FEES

ARTICLE 19. The fees payable will be as established by the Ministry of Finance and Prices in complementary provisions to this Regulation.

ARTICLE 20. The fees payable for services provided by the Department of Registration, Oversight and Health Quality of Foods and Cosmetics will be subject to market fluctuations related to the procurement of reactive agents and raw materials.

SPECIAL PROVISIONS

- I. The Vice Minister responsible for Hygiene-Epidemiological Programmes may authorize, on an exceptional basis, the non-commercial importation and exportation

of small quantities of tobacco products, exempt from the registration requirements established in this regulation; this exception shall not exclude the actions of State Sanitary Inspection.

- II. The decision as to the final destination of the products will be made by the authority expressly appointed for the purpose, the Director of the Provincial Hygiene and Epidemiology Centre, once the products have been removed from circulation.
- III. The provisions of this Regulation shall not be applicable to the duty-free market.

SOLE TRANSITORY PROVISION

Brand holders, or else the importers, traders, or other competent bodies authorized thereby, who are currently selling their products in our country, registered or otherwise, in the Department of Registration, Oversight and Health Quality of Foods and Cosmetics attached to the Institute of Nutrition and food hygiene of the Ministry Public Health, shall have 180 days from the date of publication of this legal instrument in the Official Gazette of the Republic, to take the steps needed to fulfil the provisions contained herein, and register their products in conformity therewith.

FINAL PROVISIONS

- I. Following the expiry of the period established in the Transitory Provision, it will be prohibited, throughout national territory, to market tobacco products that do not have the corresponding registration in the Department of Registration, Control, and Health Quality of Foods and Cosmetics, attached to the Institute of Nutrition and Food Hygiene, of the Ministry Public Health, which will be subject to retention and confiscation as authorized by Decree Law No. 54, on Basic Health Provisions, of 23 April 1982.
- II. The provisions of the foregoing paragraph shall be applicable to the registration holders, who, having registered their products and obtained the Sanitary Certificate, fail to comply with the provisions of this Regulation.
- III. The Institute of Nutrition and Food Hygiene shall keep the State Sanitary Inspection and national health system authorities informed on the tobacco products and specifications approved by the Department of Registration, Oversight and Health Quality of Foods and Cosmetics, attached thereto.

City of Havana, 26 December 2003.

ANNEX No.2

SPECIFICATIONS FOR PRODUCTS MANUFACTURED FROM TOBACCO

- 1. Product: (in the case of tobacco specify whether twisted by hand or using machines)
- 2. Commercial Brand: _____
- 3. Producing factory and address: _____
- 4. Producer or marketing enterprise: _____
- 5. Food ingredients. (Dose per 100 g of product, details of the name and function, or declaration only of function and number. Consult in case of doubt) .

6. Glue (specifications): _____
7. Filters (specifications): _____ ***
8. Type of wrapping and packaging (description): _____
9. Labelling of wrappers and packaging information: (including ring and/or seals of the tobaccos): _____
10. Date of production: _____
11. Attach results of analyses performed.
12. Date of expiry or period of guarantee: _____
13. Decipher key, if any: _____
14. Number of packages per container, by height: _____
15. Conditions of storage and/or conservation: _____
16. Brief description of technological process: _____
17. Physical-chemical specifications:
 - (a) Humidity
 - (b) Net weight
 - (c) Length
 - (d) Circumference
 - (e) Nicotine content of smoke *****
 - (f) Tar content in the smoke *****
 - (g) Carbon monoxide (CO) *****
 - (h) Burning time *****
 - (i) Pesticide residues
 - (j) Other

Legend:

*****: Applicable to cigarettes only.

City of Havana, 26 December 2003.

ANNEX No.3

1. First four health warnings:

“HELP YOUR KIDS NOT TO SMOKE” Ministry of Health
 “SMOKING WHEN PREGNANT HARMS YOUR BABY” Ministry of Health
 “PROTECT YOUR FAMILY FROM TOBACCO” Ministry of Health
 “WE’RE ENTITLED TO BREATHE CLEAN AIR” Ministry of Health

2. Format for health warnings on cigarette packets:

- (a) They shall be written in Spanish, in clear, visible, and legible letters.
- (b) They shall be written in capital letters, using the Arial type font, positioned located in a colour that contrasts strongly with the background for ease of reading.
- (c) They shall occupy no less than 30% of the total of the principal outer faces.
- (d) They shall be displayed on one of the principal outer faces.
- (e) In the cases of cigarettes sold in box-type packets or filter cigarettes in soft packs, the text of the message will be printed in 16 point size, with 20-point line spacing. In

the case of non-filter cigarettes sold in soft packs, the message will be printed in 14-point type with line spacing of 17 points

- (f) In the cases of cigarettes sold in box-type packets or filter cigarettes in soft packs, the acronym MINSAP (Ministry of Health) will be printed with the same characteristics but in 10 point type; and soft-type packets with filter; in the case of non-filter cigarettes sold in soft packs, the acronym will be printed in 8-point type.
- (g) The predominant colour of the ink used on the packet must not affect the eligibility of the message.
- (h) The circle and diagonal of the pictogram representing the international No-Smoking symbol will be shown in red, with the outline of the cigarette in white.

March 30, Official Gazette.