

RESOLUTION RDC No. 46, OF 28 MARCH 2001
(Updated)

With the authority invested by Article 11, section IV, of the ANVISA Regulation approved by Decree No. 3.029 of 16 April 1999, c/c §1 of Article 111, section I, subparagraph "b", of the Internal Regulation (*Regimento Interno*) approved by Ruling No. 593 of 25 August 2000, and republished in the Official Gazette (D.O.U.) of 22 December 2000,

considering the terms of Law No. 9.294 of 15 July 1996;

considering the terms of Federal Law No. 10.167 of 27 December 2000;

considering the terms of Law No. 9.782 of 26 January 1999, establishing the regulation, oversight and inspection of products and services that represent a public health hazard;

considering the substantial increase in tobacco consumption, which led to the loss of at least 3.5 million lives worldwide in 1998, and a predicted 10 million per year until 2030, with 70% of these occurring in developing countries;

considering the worldwide recognition of the need to establish and control maximum levels of tar, nicotine and carbon monoxide in cigarettes; and

considering that cigarette consumers do not differentiate the risks associated with exposure to high, medium and low levels of tar, nicotine and carbon monoxide, thus making it essential to abandon the terminology used to characterize the products in question, since they do not enlighten consumers and also allow for dubious messages to be included in the advertising of these products;

At a meeting held on 27 March 2001, the Collegiate Board of the National Health Surveillance Agency has adopted the following Collegiate Board Resolution, applicable to tobacco products produced, transported, marketed and/or stored in national territory or imported; and I, the Chairman, hereby order its publication:

Article 1. Establish the maximum tar, nicotine and carbon monoxide levels allowed in the primary smoke current for cigarettes marketed in Brazil.

§ 1 Tar, nicotine and carbon monoxide levels shall be reduced gradually, adhering to the time limits indicated below, as from the date of the publication of this Resolution:

I - Nine (9) months for a maximum of 12 milligrams, 1.0 milligram and 12 milligrams in each cigarette, for tar, nicotine and carbon monoxide levels, respectively;

II - Eighteen (18) months for a maximum of 10 milligrams, 1.0 milligram and 10 milligrams in each cigarette, for tar, nicotine and carbon monoxide levels, respectively.

§ 2 The methods defined by the International Standards Organization (ISO) and recognized by the Brazilian Technical Standards Association (ABNT) shall be used to measure the corresponding levels.

Article 2. It is forbidden to make any reference, in packaging or advertising material, to characteristics such as: class(es), ultra low level(s), low level(s), light, soft, mild, moderate level(s), high level(s), or any other term that could mislead consumers as to the levels contained in the cigarettes in question.

Sole paragraph. Cigarette manufacturers and importers shall have nine (9) months, from the date of publication of this Resolution, to fulfil the provisions of this Article.

Article 3. Cigarette packaging may optionally display the respective levels of tar, nicotine and carbon monoxide present in the primary smoke current. *(Wording indicated in Resolution RDC No. 335/03)*

§ 1 The said information must be printed legibly and in full, on any part of the packaging apart from that used for additional phrases or to display the brand image. The respective levels per cigarette, shall be indicated with to accuracy of one tenth of a milligram in the case of nicotine, and in whole milligrams for tar and carbon monoxide. *(Wording indicated in Resolution RDC No 335/03)*

§ 2 The term "packaging" shall include "packets", "pouches", "packs" and any another form of container used to hold the product as sold to consumers. *(Wording indicated in Resolution RDC No 335/03)*

Article 4. Failure to observe the terms of this Resolution constitutes violation of a health regulation, for which the offender shall be liable to the penalties listed in Law No. 6.437 of 20 August 1977 and Federal Law No. 9.294 of 15 July 1996.

Article 5. This Collegiate Board Resolution shall enter into force on the date of its publication.

GONZALO VECINA NETO