REPUBLIC OF PANAMA

MINISTRY OF HEALTH

GENERAL DIRECTORATE OF PUBLIC HEALTH

RESOLUTION No. 660

(of <u>August</u> 11th, 2009)

THE DIRECTOR-GENERAL OF PUBLIC HEALTH,

in use of its legal powers,

TAKING INTO CONSIDERATION:

That, Law 13 of January 24th, 2008, adopts measures for the control of tobacco and its harmful effects on health. In accordance with Article 18 of the aforementioned Law, the State, through regulation, adopts in all special economic areas, open or free-trade zones, the measures to specifically monitor, document, and control, the storage and distribution of tobacco products that are located or move in suspension of taxes or duties.

That, the Executive Decree 230 of May 6th, 2008 regulated Law 13 of January 24th, 2008, which adopted measures for the control of tobacco and its harmful effects on health. The Article 23 of the Executive Decree 230 establishes that the agents of the marketing chain of all tobacco products and their derivatives have the obligation to have the license that allows the commercialization of tobacco products and their derivatives and to be registered in the corresponding import register.

That, on the other hand, the FDA notified health professionals and patients that in laboratory analysis of samples of electronic cigarettes, it has been found that they contain toxic and carcinogenic chemicals such as diethylene glycol, an ingredient used in antifreeze. Battery-operated electronic cigarettes, also called "e-cigarettes", are devices that contain nicotine, flavor, and other chemicals. The electronic cigarette converts nicotine, which is highly addictive, and other chemicals into a vapor that is inhaled by the user. These products are commercialized and sold to young people and are available online and in shopping malls. They are also available in different flavors, such as chocolate and mint, which can appeal to youth.

That, the FDA's Pharmaceutical Analysis Division analyzed the ingredients in a small sample of the cartridges of two leading brands of electronic cigarettes. In one sample, the FDA analysis detected diethylene glycol, a chemical used in antifreeze that is toxic to humans, and in several other samples, the FDA's analysis detected carcinogens, including nitrosamines. These products do not contain health warnings comparable to those approved by the FDA, nor do they represent nicotine replacement products or conventional cigarettes. It is important to note that these products have not been submitted to the FDA for evaluation or approval. At this time, the agency has no way of knowing (except for the limitation of the performed tests) the nicotine levels nor the quantities or types of other chemicals that the various brands of these products offer for sale to the consumer.

That, Article 25 of Executive Decree 230 of May 6th, 2008 establishes that the competent authority, namely the Ministry of Health, shall empower the National Customs Authority to inspect, stop, confiscate, and suspend goods in process, subject to any customs destination that may be inflicting health regulations on tobacco products and their derivatives, and that do not have the corresponding authorizations.

That, by Decree-Law 1 of February 13th, 2008, the National Customs Authority was created and provisions concerning the Customs Regime were issued, related to the exercise of customs authority, legal relations between the entity responsible for customs activity, natural or legal persons involved in the entry, stay, departure of goods, persons and means of transport in the national territory, as well as the customs regimes applicable to goods and customs operations.

That, Article 6 of Decree-Law 1 of February 13th, 2008, establishes that the customs territory is the national territory and comprises the geographic space of the State between borders, including the terrestrial and aquatic areas within which the customs authority exercises its full competence in the exercise of its powers.

That, Article 98 of Decree-Law 1 of February 13th, 2008 establishes that the National Customs Authority exercises control, supervision, and surveillance in open or free-trade zones.

That, it is necessary to develop articles 15, 23 and 25 of Executive Decree 230 of May 6th, 2008, so that the National Customs Authority can perform its functions effectively and adopt the necessary provisions to comply with the legal provisions contemplated in Law 13 of January 24th, 2008 and in the aforementioned Executive Decree 230 of May 6th, 2008. In view of the aforementioned,

RESOLVES:

- **ARTICLE 1**: To warn that the Ministry of Health, as the competent authority, declares the commercialization of ELECTRONIC AND SIMILAR CIGARS in the Panamanian market to be inappropriate because they are harmful and detrimental to the health of the Panamanian population.
- **ARTICLE 2**: To authorize the National Customs Authority to adopt the applicable provisions not to allow the entry into the country and corresponding confiscation of ELECTRONIC AND SIMILAR CIGARS, which will restrict the commercialization of tobacco products and their derivatives to the agents of the commercialization chain of these products.
- **ARTICLE 3**: To authorize the National Customs Authority to inspect, detain, confiscate, and suspend the sale and commercialization of ELECTRONIC AND SIMILAR CIGARETTES, subject to any customs destination.
- **ARTICLE 4**: To order all the health authorities of the country, upon withdrawal from the national market, of the ELECTRONIC AND SIMILAR CIGARETTES, which are for sale in the different stores in the country.
- **ARTICLE 5**: To instruct all the Regional Directors of the country, in order to faithfully comply with the provisions of this Resolution.
- **ARTICLE 6**: This Resolution shall take effect as of its promulgation in the Official Gazette.

LEGAL GROUND: Law 13 of January 24th, 2008; Executive Decree 230 of May 6th, 2008; and Decree Law 1 of February 13th, 2008.

TO BE PUBLISHED AND ENFORCED,

EDUARDO LUCAS MORA DIRECTOR-GENERAL OF PUBLIC HEALTH