



20 September 2016

(16-4990)

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Committee on Technical Barriers to Trade

Original: Spanish

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

<b>1. Notifying Member:</b> <u>ECUADOR</u> <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> <i>Agencia Nacional de Regulacion, Control y Vigilancia Sanitario, ARCSA (National Agency for Sanitary Regulation, Control and Surveillance)</i> Ciudadela Samanes, Av. Francisco de Orellana y Av. Paseo del Parque, Bloque 5 Guayaquil Fax: (+593-4) 3727 440 Tel.: (+593-4) 3727 440 Email: <a href="mailto:PuntocontactoOTCECU@mipro.gob.ec">PuntocontactoOTCECU@mipro.gob.ec</a> Website: <a href="http://www.controlsanitario.gob.ec/">http://www.controlsanitario.gob.ec/</a>  <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b> <i>Subsecretaría de la Calidad (Under-Secretariat for Quality)</i> <i>Ministerio de Industrias y Productividad, MIPRO (Ministry of Industry and Productivity)</i> Yáñez Pinzón N26-12, entre Av. Colón y La Niña Quito, Ecuador Tel.: (+593-2) 3948 760, Ext. 2358 or 2253 Email: <a href="mailto:PuntocontactoOTCECU@mipro.gob.ec">PuntocontactoOTCECU@mipro.gob.ec</a> , <a href="mailto:mmartinez@mipro.gob.ec">mmartinez@mipro.gob.ec</a> Website: <a href="http://www.industrias.gob.ec/">http://www.industrias.gob.ec/</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> 2106.90.71.00, 2106.90.72.00, 2106.90.73.00, 2106.90.74.00 and 2106.90.79.00.
<b>5. Title, number of pages and language(s) of the notified document:</b> <i>Proyecto de normativa técnica sanitaria para la obtención de la notificación sanitaria y control de suplementos alimenticios y de los establecimientos en donde se fabrican, almacenan, distribuyen, importan y comercializan (Draft Sanitary Technical Regulation on the issuance of sanitary certificates and the control of food supplements and establishments that manufacture, store, distribute, import or market such products) (21 pages, in Spanish)</i>
<b>6. Description of content:</b> The notified draft Technical Regulation covers the following: Purpose and scope; Definitions and abbreviations; Sanitary certificates; Renewal of and changes to sanitary certificates; Certification of good manufacturing practices; Criteria for the formulation of food supplements; Packaging and labelling; Other authorizations; Marketing and advertising; Operating permits for food supplement establishments; Derogations; General provisions; Transitional provisions; Amending provision; and Final provision.

**7. Objective and rationale, including the nature of urgent problems where applicable:**

The aim of the notified Sanitary Technical Regulation is to establish the requirements governing the issuance of sanitary certificates for food supplements.

It also establishes the requirements for the production, processing, formulation, labelling, quality, safety, advertising, control and monitoring of food supplements in establishments that manufacture, store, distribute, import or market such products.

This Sanitary Technical Regulation is binding on natural and legal persons, whether Ecuadorean or foreign, who are responsible for manufacturing, importing, exporting, storing, distributing or marketing food supplements throughout the national territory.

**8. Relevant documents:**

- Publication where notice appears: <http://www.industrias.gob.ec/> and <http://www.controlsanitario.gob.ec/>;
- Proposal and basic document: *Proyecto de Normativa Técnica Sanitaria Ecuatoriana "Obtención de la notificación sanitaria y control de suplementos alimenticios y de los establecimientos en donde se fabrican, almacenan, distribuyen, importan y comercializan"* (Draft Ecuadorian Sanitary Technical Regulation on the issuance of sanitary certificates and the control of food supplements and establishments that manufacture, store, distribute, import or market such products);
- Publication in which Technical Regulation will be published when adopted: *Registro Oficial* (Official Journal).

**9. Proposed date of adoption:** 90 days as from 12 September 2016

**Proposed date of entry into force:** 180 days after adoption

**10. Final date for comments:** 11 December 2016

**11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

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