



19 September 2019

(19-6019)

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Committee on Sanitary and Phytosanitary Measures

Original: Spanish

NOTIFICATION

1. Notifying Member: <u>ECUADOR</u> If applicable, name of local government involved:
2. Agency responsible: <i>Agencia Nacional de Regulacion, Control y Vigilancia Sanitaria, ARCSA</i> (National Agency for Sanitary Regulation, Control and Surveillance)
3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Natural processed products for medicinal use
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: <i>Proyecto de Normativa técnica sanitaria sustitutiva de registro sanitario de productos naturales procesados de uso medicinal, y de buenas prácticas de manufactura para laboratorios farmacéuticos de productos naturales procesados de uso medicinal</i> (Draft Substitute Sanitary Technical Regulation on the sanitary registration of natural processed products for medicinal use, and good manufacturing practices for pharmaceutical laboratories working with natural processed products for medicinal use) Language(s): Spanish Number of pages: 41 Text available at: https://members.wto.org/crnattachments/2019/SPS/ECU/19_5034_00_s.pdf
6. Description of content: Purpose: The notified Sanitary Technical Regulation seeks to establish quality, safety and efficacy parameters for the sanitary registration of natural processed products for medicinal use, and criteria for the promotion, control and monitoring of such products and the penalties relating to them. It establishes the parameters for the operation, control and monitoring of, and penalties for, establishments that manufacture, store, distribute or market natural processed products for medicinal use. It also seeks to establish requirements and guidelines for delivery of certificates of good manufacturing practices to domestic pharmaceutical laboratories that manufacture, process, package, store, distribute and transport natural processed products for medicinal use. Scope of application: The notified Regulation is binding on all natural or legal persons, whether domestic or foreign, who are required to register natural processed products for medicinal use for marketing in Ecuador, as well as natural or legal persons, whether domestic or foreign, who are responsible for manufacturing, importing, packaging or packing, transporting, storing, distributing or marketing natural processed products for medicinal use throughout the national territory.

7.	Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8.	<p>Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organisation for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM No.):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
9.	Other relevant documents and language(s) in which these are available:
10.	<p>Proposed date of adoption (dd/mm/yy): 13 November 2019</p> <p>Proposed date of publication (dd/mm/yy): 13 November 2019</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): Upon publication in the Official Journal</p> <p><input type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 18 November 2019</p> <p>Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and email address (if available) of other body:</p> <p><i>Agencia Nacional de Regulacion, Control y Vigilancia Sanitaria, ARCSA (National Agency for Sanitary Regulation, Control and Surveillance)</i> Ciudadela Samanes, Av. Francisco de Orellana y Av. Paseo del Parque, Bloque 5 Guayaquil - Ecuador Tel.: (+593 04) 3727 440 Website: https://www.controlsanitario.gob.ec/</p>
13.	<p>Text(s) available from: <input type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and email address (if available) of other body:</p> <p><i>Subsecretaría de Calidad (Under-Secretariat for Quality)</i> Ministerio de Producción, Comercio Exterior, Inversiones y Pesca, MPCEIP (Ministry of Production, Foreign Trade, Investment and Fisheries) Address: Av. Amazonas entre Unión Nacional de Periodistas y Alfonso Pereira, Piso 8, Bloque amarillo Tel.: (+593 2) 3948 760, Ext. 2254 - 2272 Email: puntocontactoOTCECU@produccion.gob.ec puntocontactoOTCECU@gmail.com aramon@produccion.gob.ec cyepez@produccion.gob.ec jsanchez@produccion.gob.ec Website: https://www.controlsanitario.gob.ec</p>