



5 October 2021

(21-7485)

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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.

1. Notifying Member: ECUADOR

If applicable, name of local government involved (Articles 3.2 and 7.2):

2. Agency responsible:

Agencia Nacional de Regulacion, Control y Vigilancia Sanitaria, ARCSA (National Agency for Sanitary Regulation, Control and Surveillance)
Ciudadela Samanes, Av. Francisco de Orellana y Av. Paseo del Parque. Bloque 5,
Guayaquil - Ecuador
Tel.: (+593-4) 3727 440

Website: <https://www.controlsanitario.gob.ec>

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:

Subsecretaría de Calidad (Under-Secretariat for Quality)
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) 3948760, Ext. 2254 - 2272
Email:
puntocontacto-OTCECU@produccion.gob.ec
puntocontactoECU@gmail.com
jmarino@produccion.gob.ec
cyepez@produccion.gob.ec
jsanchezc@produccion.gob.ec
Website: www.industrias.gob.ec

3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:

4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Partial Amendment to the Substitute Technical Regulation to authorize the exceptional importation and importation for the purposes of donation of medicines, biological products, medical devices and biochemical and diagnostic reagents

5. Title, number of pages and language(s) of the notified document: *Reforma Parcial a la Normativa Técnica Sustitutiva para autorizar la importación por excepción e importación por donación de Medicamentos, Productos Biológicos, Dispositivos Médicos y Reactivos Bioquímicos y de Diagnóstico* (Partial Amendment to the Substitute Technical Regulation to authorize the exceptional importation and importation for the purposes of donation of medicines, biological products, medical devices and biochemical and diagnostic reagents) (8 pages, in Spanish)

6.	<p>Description of content: Partial Amendment to the Substitute Technical Regulation to authorize the exceptional importation and importation for the purposes of donation of medicines, biological products, medical devices and biochemical and diagnostic reagents.</p> <p>Document for trade facilitation.</p>
7.	<p>Objective and rationale, including the nature of urgent problems where applicable: Prevention of deceptive practices and consumer protection; Protection of human health or safety</p>
8.	<p>Relevant documents:</p> <p>-</p>
9.	<p>Proposed date of adoption: 10 September 2021</p> <p>Proposed date of entry into force: 10 September 2021; The notified Resolution shall enter into force on the date of its signature, without prejudice to its publication in the Official Journal. Resolution ARCSA-DE-2021-013-AKRG was issued and signed on 10 September 2021.</p>
10.	<p>Final date for comments: Not applicable</p>
11.	<p>Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>Contact and/or national enquiry point: Subsecretaría de Calidad Ministerio de Producción, Comercio Exterior, Inversiones y Pesca (MPCEIP) Address: Av. Amazonas entre Unión Nacional de Periodistas y Alfonso Pereira, Piso 8, Bloque amarillo Tel.: (+593 2) 3948760, Ext. 2254 - 2272 Email:</p> <p>puntocontacto-OTCECU@produccion.gob.ec puntocontactoECU@gmail.com jmarino@produccion.gob.ec cyepez@produccion.gob.ec jsanchezc@produccion.gob.ec</p> <p>www.controlsanitario.gob.ec https://members.wto.org/crnattachments/2021/TBT/ECU/21_6334_00_s.pdf</p>