



G / TBT / N / ECU / 501

March 31, 2021

(21- 2699)

Page: 1 / 1

Committee on Technical Barriers to Trade

Original: Spanish

NOTIFICATION

The following notification is given in accordance with article 10.6.

one.	<p>Notifying Member : <u>ECUADOR</u></p> <p>If applicable, name of the local government in question (articles 3.2 and 7.2) :</p>
two.	<p>Responsible body :</p> <p>Ciudadela Samanes, Av. Francisco de Orellana and Av. Paseo del Parque. Block 5 Guayaquil - Ecuador Telephone: (+ 593-4) 3727 440 WEB Page: www.controlsanitario.gob.ec</p> <p>Name and address (including telephone and fax numbers, as well as email addresses and web sites , if applicable) of the body or authority in charge of processing comments on the notification, in the case of a different body or authority :</p> <p>Undersecretary of Quality Ministry of Production, Trade, Foreign, Investments and Fisheries (MPCEIP) Address: Av. Amazonas between the National Union of Journalists and Alfonso Pereira, 8th Floor, Yellow Block Telephone: (+593 2) 3948760 Ext. 2254 - 2272 Email electronic: puntocontacto-otcecu@produccion.gob.ec puntocontactoecu@gmail.com jmarino@produccion.gob.ec cyeppez@produccion.gob.ec jsanchezc@produccion.gob.ec WEB page: www.produccion.gob.ec</p>
3.	<p>Notification made pursuant to article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], or pursuant to :</p>
Four.	<p>Products covered (HS or NCCA heading when applicable; otherwise, national tariff heading. The ICS heading number may also be indicated when appropriate) : The purpose of this technical health regulation is to regulate and control drugs that contain listed substances subject to control (narcotic drugs, psychotropic drugs, chemical precursors and specific chemical substances). The provisions established in these regulations are applicable to all natural or legal persons, nationals or foreigners, based in Ecuador, who produce, import, export, store, market, distribute and dispense drugs that contain listed substances subject to control (narcotics, psychotropic, chemical precursors and specific chemicals); With the exception of the dispensing, destruction, transfer, donation and notification of claims of these drugs in the pharmacies of the public and private health services. Products for human use and consumption that have non-psychoactive cannabis or hemp or derivatives of non-psychoactive cannabis or hemp in their formulation are excluded from the scope of this regulation, which will be regulated in accordance with the regulations on products for human use and consumption. that contain non-psychoactive cannabis or hemp that the Agency provides for the effect.</p>
5.	<p>Title, number of pages and language (s) of the notified document : PROJECT OF SANITARY TECHNICAL REGULATION FOR THE REGULATION AND CONTROL OF MEDICINES CONTAINING</p>

CATALOGED SUBSTANCES SUBJECT TO CONTROL (48 page (s), in Spanish)

6. Description of content : The purpose of these technical health regulations is to regulate and control drugs that contain listed substances subject to control (narcotics, psychotropic drugs, chemical precursors and specific chemical substances).

The provisions established in these regulations are applicable to all natural or legal persons, nationals or foreigners, based in Ecuador, who produce, import, export, store, market, distribute and dispense drugs containing listed substances subject to control (narcotics, psychotropic, chemical precursors and specific chemicals); With the exception of the dispensing, destruction, transfer, donation and notification of claims of these drugs in the pharmacies of the public and private health services.

Products for human use and consumption that have non-psychoactive cannabis or hemp or derivatives of non-psychoactive cannabis or hemp in their formulation are excluded from the scope of this regulation, which will be regulated in accordance with the regulations on products for human use and consumption. that contain non-psychoactive cannabis or hemp that the Agency provides for the effect.

7. Objective and rationale, including the nature of urgent problems where applicable : Consumer information, Labeling; Prevention of practices that may be misleading and consumer protection; Protection of human health or safety

8. Relevant documents :

-

9. Proposed date of adoption : From 60 days from notification
Proposed effective date : 180 days from the date of adoption

10. Deadline for submission of comments : 60 days from notification

eleven. Texts available from: National inquiry point [X] , or Dirección, telephone and fax numbers and addresses of email and sites web, if any, of other body :

Contact Point and / or National Information Center:

Undersecretary of Quality

Ministry of Production, Trade, Foreign, Investments and Fisheries (MPCEIP)

Address: Av. Amazonas between Unión Nacional de Periodistas and Alfonso Pereira, 8th Floor, Yellow Block

Telephone: (+593 2) 3948760 Ext. 2254 - 2272

Email:

puntocontacto-otcecu@produccion.gob.ec

puntocontactoecu@gmail.com

jmarino@produccion.gob.ec

cyeppez@produccion.gob.ec

jsanchezc@produccion.gob.ec

www.controlsanitario.gob.ec

https://members.wto.org/crnattachments/2021/TBT/ECU/21_2404_00_s.pdf