



21 August 2025

(25-5235)

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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: CHILE If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: <i>Ministerio de Salud, MINSAL (Ministry of Health)</i>
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
4.	Products covered (HS codes or national tariff lines. ICS numbers may be provided in addition, where applicable): <i>In vitro</i> diagnostic reagents for the microbiological qualification of blood donations, as indicated
5.	Details of notified document(s) (title, number of pages and languages, means of access): <i>PROYECTO REGULATORIO, INCORPORA A LOS REACTIVOS DE DIAGNÓSTICO IN VITRO PARA CALIFICACIÓN MICROBIOLÓGICA DE DONACIONES EN SERVICIOS DE SANGRE QUE SE INDICAN, AL RÉGIMEN DE CONTROL SANITARIO ESTABLECIDO EN EL ARTÍCULO 111 DEL CÓDIGO SANITARIO</i> (Draft regulation incorporating the indicated <i>in vitro</i> diagnostic reagents for the microbiological qualification of blood donations into the health control system established in Article 111 of the Health Code); (3 pages, in Spanish) Link to notified document(s) and/or contact details for agency or authority which can provide copies upon request: https://members.wto.org/crnattachments/2025/TBT/CHL/25_05535_00_s.pdf https://www.minsal.cl/wp-content/uploads/2021/11/Propuesta-Decreto-Dm-Calificacion-Microbiologica-en-Servicios-de-Sangre-V-08082025-para-CP.pdf <i>Departamento de Aspectos Regulatorios del Comercio (Trade Regulations Department)</i> <i>Subsecretaría de Relaciones Económicas Internacionales, SUBREI (Under-Secretariat for International Economic Relations)</i> tbt_chile@subrei.gob.cl
6.	Description of content: The notified draft regulation establishes that the <i>in vitro</i> diagnostic reagents for the microbiological qualification of blood donations associated with Chagas disease, syphilis, hepatitis B/hepatitis C and HTLV I/II shall be subject to sanitary control.
7.	Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8.	Relevant documents: <i>Código Sanitario Decreto 725 Ministerio de Salud – Art 111</i> (https://bcn.cl/24us4).

• <i>Decreto Supremo N°825/1999 Ministerio de Salud, que aprobó reglamento de control de productos y elementos de uso médico</i> (https://bcn.cl/2krkj).	
9.	Proposed date of adoption: To be determined Proposed date of entry into force: To be determined
10.	Provision of comments: Final date for comments: 20 October 2025 [X] 60 days from notification Contact details of agency or authority designated to handle comments regarding the notification: <i>Departamento de Aspectos Regulatorios del Comercio</i> (Trade Regulations Department) <i>Subsecretaría de Relaciones Económicas Internacionales, SUBREI</i> (Under-Secretariat for International Economic Relations) Email: tbt_chile@subrei.gob.cl