



2 November 2022

(22-8202)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved:
2. Agency responsible: The Brazilian Health Regulatory Agency (ANVISA)
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): Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of two or more constituents which have been mixed together for therapeutic or prophylactic uses, not put up in measured doses or in forms or packings for retail sale (HS code: 3003); Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale (HS code: 3004)
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: Resolution - RDC number 730, 1 July 2022. Language(s): Portuguese. Number of pages: 10 http://antigo.anvisa.gov.br/documents/10181/2718376/RDC_730_2022_.pdf/0dfa65ac-4176-414b-a130-564dac564e44
6. Description of content: This resolution contains provisions on the human health risk assessment of veterinary medicinal products, maximum residue limits (MRLs) of veterinary medicinal products in foods of animal origin and methods of analysis for conformity assessment purposes. This resolution is the result of the consolidation of previous regulations, which the content has not been changed. This regulation will also be notified in the TBT Committee.
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. Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):

<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>
<p>9. Other relevant documents and language(s) in which these are available:</p>
<p>10. Proposed date of adoption (dd/mm/yy): 1 September 2022</p> <p>Proposed date of publication (dd/mm/yy): 1 September 2022</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): 1 September 2022</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): Not applicable</p> <p>Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Assessoria de Assuntos Internacionais – AINTE International Affairs Office Agência Nacional de Vigilância Sanitária – Anvisa Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p>
<p>13. Text(s) available from: <input type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Assessoria de Assuntos Internacionais – AINTE International Affairs Office Agência Nacional de Vigilância Sanitária – Anvisa Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p>