



5 June 2019

(19-3856)

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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: Secretariat of Animal and Plant Health and Inspection (SDA) - Ministry of Agriculture, Livestock and Food Supply (MAPA)
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): Biological products for veterinary 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: Draft Normative Instruction that establishes the procedures and conditions for carrying out stability studies for registration or post-registration amendments of biological products for veterinary use. Language(s): Portuguese. Number of pages: 2 http://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=25/04/2019&jornal=515&pagina=4&totalArquivos=60 https://members.wto.org/crnattachments/2019/SPS/BRA/19_3261_00_x.pdf
6.	Description of content: The notified document submits to Public Consultation, a draft of Normative Instruction for the establishment of the procedures and conditions for carrying out stability studies for registration or post-registration amendments of biological products for veterinary use.
7.	Objective and rationale: <input type="checkbox"/> food safety, <input checked="" 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 checked="" type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number): Terrestrial Manual Chapters 1.1.8, 1.1.9, 2.3.4, 2.3.5 <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input type="checkbox"/> None Does this proposed regulation conform to the relevant international standard? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

If no, describe, whenever possible, how and why it deviates from the international standard:	
9.	Other relevant documents and language(s) in which these are available:
10.	Proposed date of adoption (dd/mm/yy): To be defined. Proposed date of publication (dd/mm/yy): To be defined.
11.	Proposed date of entry into force: [] Six months from date of publication, and/or (dd/mm/yy): To be defined. [X] Trade facilitating measure
12.	Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 4 August 2019 Agency or authority designated to handle comments: [] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: Ministry of Agriculture, Livestock and Food Supply Secretariat of Agribusiness International Relations E-mail: sps@agricultura.gov.br
13.	Text(s) available from: [] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: Ministry of Agriculture, Livestock and Food Supply Secretariat of Agribusiness International Relations E-mail: sps@agricultura.gov.br