



10 April 2017

(17-1922)

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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): ICS Code(s): 13, 65 Pesticides
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 Technical Resolution N° 313, 23 February 2017. Language(s): Portuguese. Number of pages: 6 http://portal.anvisa.gov.br/documents/10181/2859776/CONSULTA+PUBLICA+N+313+GGTOX.pdf/673e9056-2963-4a57-961a-bfab6f07a5cb
6. Description of content: This Draft Resolution provides the criteria and procedures for toxicological reassessment of active ingredients of pesticides within the scope of the Brazilian Health Regulatory Agency (ANVISA). The active ingredients of pesticides that show signs of altering risks to human health can be re-evaluated at any time. The toxicological re-evaluation process of active pesticide ingredients includes: indication of the active ingredients of pesticides for toxicological re-evaluation; selection and definition of the scope of the reevaluation; disclosure of the beginning of the reevaluation; public consultation; publication of the regulatory decision; elaboration of the final technical note. ANVISA will select the active ingredients of pesticides that will be submitted to the re-evaluation based on the risk of to human health and the list of the active ingredients selected to re-evaluation will be shared on Anvisa website. The toxicological re-evaluation of active ingredients shall follow the criteria for toxicological evaluation of technical and formulated products established by the technical regulation. A public consultation will be published with the proposed regulatory decision on the active ingredient. The Brazilian Health Regulatory Agency will publish the final decision about the reevaluation process. This Resolution revokes Resolution RDC N° 48 of 7 July 2008, published on 8 July 2008 on Brazilian Official Journal n° 129, section 1, pages 43 and 44.
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.	<p>Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <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>
9.	<p>Other relevant documents and language(s) in which these are available:</p>
10.	<p>Proposed date of adoption (dd/mm/yy): To be determined after the end of the consultation period.</p> <p>Proposed date of publication (dd/mm/yy): To be determined after the end of the consultation period.</p>
11.	<p>Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): To be determined after the end of the consultation period.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
12.	<p>Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 3 May 2017</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Patrícia Oliveira Pereira Tagliari Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p>
13.	<p>Text(s) available from: <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Patrícia Oliveira Pereira Tagliari Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p>