



2 October 2020

(20-6690)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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| 1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved: |
| 2. Agency responsible: 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): HS Code(s): 1005; ICS Code(s): 13, 65 |
| 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 resolution number 919, 18 September 2020, regarding the active ingredient T39 - TERBUTILAZINA (terbuthylazine) of the Monograph List of Active Ingredients for Pesticides, Household Cleaning Products and Wood Preservers, published by Resolution - RE nº 165 of 29 August 2003, on the Brazilian Official Gazette (DOU - Diário Oficial da União) of 2 September 2003. Language(s): Portuguese. Number of pages: 4 Draft: http://antigo.anvisa.gov.br/documents/10181/4171896/CONSULTA+P%C3%9ABLICA+N+925+GGTOX.pdf/1a394226-4da0-4690-b040-48775193a588 Comment form: http://portal.anvisa.gov.br/documents/111215/0/Formul%C3%A1rio+Padr%C3%A3o+Consulta+P%C3%BAblica+-+GGTOX/5faccd95-356b-4e0e-91d1-9f318e0aa370 |
| 6. Description of content: This Draft resolution incorporates the following changes for the active ingredient T39 - TERBUTILAZINA (terbuthylazine) from the Relation of Monographies of Active Ingredients of Pesticides, Household Cleaning Products and Wood Preservers, all in the modality of post emergency use (application): <ul style="list-style-type: none">- includes the corn culture with MRL of 0,1 and safety security period "Not determined due to the modality of use (application);- includes the phrase: "K) Acceptable Daily Intake (ADI): 0,004 mg/kg b.w.(source: EFSA*, 2011)";- includes the phrase: "I) Acute Reference Dose (ARfD) : 0,008 mg/kg b.w. (source: EFSA*, 2011)";- includes the phrase: "*European Food Safety Authority";- includes the phrase: "m) for the purpose of residue definition for conformity to MRL and for the dietary risk assessment it will be considered the active ingredient terbuthylazine. |
| 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. |

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| <p>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input checked="" type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <ul style="list-style-type: none"> - CAC/MRL 1 Maximum Residue Limits (MRLs) for Pesticides <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 type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard: The scientific methodology used by Brazil to establish MRLs is consistent with international best practice. Countries set MRLs according to the good agricultural practice (GAP) applicable to their region. Agricultural chemical use patterns differ between different production regions and countries as pests, diseases and environmental factors vary. This means that Brazilian MRLs for agricultural chemicals in food may differ from Codex standards.</p> |
| <p>9. Other relevant documents and language(s) in which these are available:</p> |
| <p>10. 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> |
| <p>11. 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> |
| <p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 21 November 2020</p> <p>Agency or authority designated to handle comments: <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>Assessoria de Assuntos Internacionais - AINTE International Affairs Office Agência Nacional de Vigilância Sanitária - Anvisa Brazilian Health Regulatory Agency Tel: +(5561) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p> |
| <p>13. 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>Assessoria de Assuntos Internacionais - AINTE International Affairs Office Agência Nacional de Vigilância Sanitária - Anvisa Brazilian Health Regulatory Agency Tel: +(5561) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p> |