NOTIFICATION

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| **1.** | **Notifying Member:** Brazil**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):** Pesticides, components, related products and wooden preservatives; ICS Code(s): 13, 65 |
| **4.** | **Regions or countries likely to be affected, to the extent relevant or practicable:****[****X] All trading partners** **[ ]** **Specific regions or countries:**  |
| **5.** | **Title of the notified document:** Draft Resolution Nº 484, 16 March 2018 - Criteria for the evaluation and toxicological classification of pesticides, components, related products and wooden preservatives. **Language(s):** Portuguese. **Number of pages:** 29[http://portal.anvisa.gov.br/documents/10181/2858730/CONSULTA+P%C3%9ABLICA+N%C2%BA+484+-+GGTOX/18d3d6d5-0623-4daf-871b-f6825f92fd32](http://portal.anvisa.gov.br/documents/10181/2858730/CONSULTA%2BP%C3%9ABLICA%2BN%C2%BA%2B484%2B-%2BGGTOX/18d3d6d5-0623-4daf-871b-f6825f92fd32) |
| **6.** | **Description of content:** This Draft Resolution establishes the criteria for the evaluation and toxicological classification of pesticides, components, related products and wooden preservatives, within ANVISA.The process of toxicological evaluation of products must be instructed with all the documentation established in Decree No. 4,074 of 4 January 2002, its updates or other specific legislation.The documentation required for the toxicological evaluation for product registration and post-registration shall be in accordance with specific legislation and standards.In order to instruct or justify the granting of registration to third parties, ANVISA may use data or information related to the results of studies submitted by another company.All toxicological studies submitted to comply with this Resolution shall be carried out in accordance with current protocols published by the Organization for Economic Co‑operation and Development (OECD) or other authorities having similarity of requirements and validation.Without prejudice to the provisions of Decree No. 4,074 of 4 January 2002, for the studies of corrosion/skin irritation and ocular corrosion/irritation, the toxicological profile of a technical product is considered equivalent to the profile of the technical reference product, when does not fall into a category of greater danger, in accordance with specific legislation and in accordance with the equivalence criteria of the Food and Agriculture Organization of the United Nations (FAO).For purposes of toxicological classification, the criteria based on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are adopted in this Resolution.For pesticides, related and preservatives of wood already registered, the company must evaluate its toxicological dossier and verify the need for toxicological reclassification, considering the provisions of this Resolution.The company is responsible for evaluating the composition/formulation of its registered products and checking for the presence of unauthorized components. |
| **7.** | **Objective and rationale: [ ]****food safety, [ ]****animal health, [ ]****plant protection, [****X] protect humans from animal/plant pest or disease, [ ]****protect territory from other damage from pests.**  |
| **8.** | **Is there a relevant international standard? If so, identify the standard:****[ ]** **Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:****[ ]** **World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:** **[ ]** **International Plant Protection Convention *(e.g. ISPM number)*:** **[****X] None****Does this proposed regulation conform to the relevant international standard?** **[ ]** **Yes [ ]** **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:** Organization for Economic Co-operation and Development (OECD) applicable standards; Food and Agriculture Organization of the United Nations (FAO) equivalence criteria; Globally Harmonized System of Classification and Labelling of Chemicals (GHS) criteria  |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** On the date of its publication.**Proposed date of publication *(dd/mm/yy)*:** To be determined after the end of the consultation period. |
| **11.** | **Proposed date of entry into force: [ ]****Six months from date of publication**, **and/or** ***(dd/mm/yy)*:** 90 days after its publication.**[ ]** **Trade facilitating measure**  |
| **12.** | **Final date for comments: [ ]****Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*:** 23 April 2018**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:** Patrícia Oliveira Pereira TagliariTel: +(55 61) 3462 5402/5404/5406E-mail: rel@anvisa.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:** Patrícia Oliveira Pereira TagliariTel: +(55 61) 3462 5402/5404/5406E-mail: rel@anvisa.gov.br |