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):** 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 483, 16 March 2018 - Toxicological information for labels and leaflets of pesticides, related products and wooden preservatives. **Language(s):** Portuguese. **Number of pages:** 17  <http://portal.anvisa.gov.br/documents/10181/2858730/CONSULTA+P%C3%9ABLICA+N%C2%BA+483+-+GGTOX/57e9a676-19ce-41ea-8c9c-556003533375> |
| **6.** | **Description of content:** This Draft Resolution provides for toxicological information for labels and leaflets of pesticides, related products and wooden preservatives, within ANVISA.  The guidelines for the preparation of toxicological information for labels and leaflets of pesticides, related products and wooden preservatives are approved within ANVISA.  The purpose of this Resolution is to establish:   1. the obligatory information related to the protection of human health that must be included in pesticide labels and leaflets, similar products and wooden preservatives; and 2. the adoption of the labeling guidelines of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).   The company is responsible for all labeling and package leaflet information, and must present it clearly and ensure that it is adequate and sufficient for health protection purposes.  ANVISA may, at its discretion and with a reasoned technical justification, require the company that holds the record to change the texts of labels and package leaflets.  The labels and package inserts of biological products and wooden preservatives must follow the provisions of this Resolution and the determinations provided in other specific devices and norms, and the necessary adaptations must be made to the peculiarities of the product.  For information on appropriate poisoning prevention or risk minimization measures, the pictograms recommended by the Food and Agriculture Organization of the United Nations (FAO) should be used on pesticide labels and leaflets, as well as on wood preservatives.  ANVISA may make available on the ANVISA website the latest version of the package leaflets and approved labels in relation to health information.  Companies with already registered models of labels and pesticides, wood preservatives and preservatives must comply with this Resolution by means of a notification, with protocol under a specific subject code, and submit electronically to ANVISA all relevant documentation, up to 360 days after the validity of this Resolution, and may implement the labels and package inserts, without prior authorization from ANVISA. |
| **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:** Food and Agriculture Organization of the United Nations (FAO) pictograms recommendation on labelling and leaflets of pesticides; Globally Harmonized System (GHS) labelling guidelines |
| **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)*:** 24 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 Tagliari  Tel: +(55 61) 3462 5402/5404/5406  E-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 Tagliari  Tel: +(55 61) 3462 5402/5404/5406  E-mail: rel@anvisa.gov.br |