NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Brazil  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Brazilian Health Regulatory Agency (Anvisa)  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  National Institute of Metrology, Quality and Technology (INMETRO)  Telephone: +(55) 21 2563.2840  Telefax: +(55) 21 2563.5637  Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Web-site: [www.inmetro.gov.br/barreirastecnicas](http://www.inmetro.gov.br/barreirastecnicas)  The comments to this Draft Regulation shall be sent to  http://formsus.datasus.gov.br/site/formulario.php?id\_aplicacao=32938 |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [****], 5.6.2 [****], 5.7.1 [****], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Pesticides, components, related products and wooden preservatives. |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft resolution number 484, 16 March 2018. - criteria for the evaluation and toxicological classification of pesticides, components, related products and wooden preservatives. (29 page(s), in Portuguese) |
| **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 January 4, 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.  It revokes item "l", "m", 1.3 and 1.4 of "Guidelines and Requirements Ministry of Health, Regarding the Authorization of Registration and Extension of Use of Agrochemicals and Related ", approved by the Divisions of Human Ecology and Health Environment and Risk Assessment as "Guidelines and Requirements of the Ministry of Safety,  Regarding the Authorization to Register and Extend Use of Agrotóxicos and Afins N°. 01, of 09 December 1991", published in the Official Gazette of the Union on 13 December 1991 and ratified by Administrative Rule 03, of 16 January 1992, of the Technical-Normative Department of the Health Surveillance Secretariat of the Ministry of Health. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:** (1) Brazilian Official Journal, 19 March 2018 (Diário Oficial da União de 19 de Março de 2018); (2) Guidelines and requirements of the Ministry of Health, Regarding the Authorization of Registration and Extension of Use of Agrochemicals and Related; (3) Brazilian Official Journal (Diário Oficial da União); (4) Not stated. |
| **9.** | **Proposed date of adoption:** date of its publication  **Proposed date of entry into force:** 90 (ninety) days after its publication |
| **10.** | **Final date for comments:** 24 April 2018 |
| **11.** | **Texts available from: National enquiry point [ ]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF/Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: [www.anvisa.gov.br](http://www.anvisa.gov.br)  <http://portal.anvisa.gov.br/documents/10181/2858730/CONSULTA+P%C3%9ABLICA+N%C2%BA+484+-+GGTOX/18d3d6d5-0623-4daf-871b-f6825f92fd32> |