



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BRAZIL</u> 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 Web-site: 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=33294
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Pesticides, related products and wooden preservatives
5. Title, number of pages and language(s) of the notified document: Draft Resolution N° 483, 16 March 2018. - toxicological information for labels and leaflets of pesticides, related products and wooden preservatives. (17 page(s), in Portuguese)
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: I - 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 II - 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 (three hundred and sixty) days after the validity of this Resolution, and may implement the labels and package inserts, without prior authorization from ANVISA.

It revokes item 2 of the "Guidelines and Requirements of the Ministry of Health, Registration Authorization, Renewal of Registration and Extension of Use of Agrochemicals and Related", approved by the Product Divisions, Human Ecology and Environmental Health and Risk Assessment as "Guidelines and Requirements Regarding the Authorization of Records, Renewal of Registration and Extension of Use of Agrotóxicos and Afins Products – nº 01, 09 December 1991", published in the Federal Official Gazette on 13 December 1991 and Ratified by Administrative Rule 03, 16 January 1992, of the Technical Department of Normative 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, registration authorization, renewal of registration and extension of use of agrochemicals and related published in the Federal Official Gazette on 13 December 1991 and Ratified by Administrative Rule 03, 16 January 1992, of the Technical Department of Normative of the Health Surveillance Secretariat of the Ministry of Health.; (3) Brazilian Official Journal (Diário Oficial da União); (4) Not stated.

9. Proposed date of adoption: On the date of its publication
Proposed date of entry into force: 90 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:

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