NOTIFICATION

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| **1.** | **Notifying Member:** Brazil**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):** 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 485, 16 March 2018 - Establishes the criteria for the evaluation of the dietary and occupational risk arising from human exposure. **Language(s):** Portuguese. **Number of pages:** 9[http://portal.anvisa.gov.br/documents/10181/2858730/CONSULTA+P%C3%9ABLICA+N%C2%BA+485+-+GGTOX/9da4feb3-19bd-4f19-860f-f8b22d2082c5](http://portal.anvisa.gov.br/documents/10181/2858730/CONSULTA%2BP%C3%9ABLICA%2BN%C2%BA%2B485%2B-%2BGGTOX/9da4feb3-19bd-4f19-860f-f8b22d2082c5) |
| **6.** | **Description of content:** This Draft Resolution establishes the criteria for the evaluation of the dietary and occupational risk arising from human exposure within ANVISA.This Resolution applies, for purposes of registration, post-registration, revaluation, monitoring and inspection, without prejudice to the provisions of Law No. 7.802 of 11 July 1989 and Decree No. 4.074 of 4 January 2002, and its amendments updates to procedures:1. evaluation of acute and chronic dietary risk arising from the presence of residues of pesticides, their metabolites and degradation products in foods; and
2. assessment of the occupational risk arising from the exposure of operators and reentry workers to pesticides, their metabolites and degradation products, in labor activities involving contact with these products.

Residue monitoring data are used to evaluate the dietary risk related to the exposure of pesticide residues present in food and water consumed by the population.To assess the exposure of the population to pesticide residues found in food and water analyzed in monitoring programs, the MRL, MREC or VMP should be replaced by the concentration of agrotoxic residue found in the sample.The Annexes contained in this Resolution are updated by means of publications in the Brazil Official Gazette whenever necessary and at the discretion of 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:**   |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** To be determined after the end of the consultation period.**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)*:** To be determined after the end of the consultation period.**[ ]** **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 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 |