NOTIFICATION

|  |  |
| --- | --- |
| **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):** HS Code(s): 18, 120750, 081020, 071120, 081040, 081010, 080940, 080820, 080930, 07052, 070970, 080920, 071430, 081190, 0810909002, 12099110, 070990, 12119029, 0709999000; 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 number 924, 18 September 2020, regarding the active ingredient F68 - FLUXAPIROXADE (Fluxapyroxad) of the Monograph List of Active Ingredients for Pesticides, Household Cleaning Products and Wood Preservers, published by Resolution - RE n° 165 of 29 August 2003, on the Brazilian Official Gazette (DOU - Diário Oficial da União) of 2 September 2003.**Language(s):** Portuguese. **Number of pages:** 7  Draft: <http://portal.anvisa.gov.br/documents/10181/2822921/CONSULTA+P%C3%9ABLICA+N+924+GGTOX.pdf/e727090d-50e6-41fa-99d6-21926c487c18>  Comment form:  <http://portal.anvisa.gov.br/documents/111215/0/Formul%C3%A1rio+Padr%C3%A3o+Consulta+P%C3%BAblica+-+GGTOX/5faccd95-356b-4e0e-91d1-9f318e0aa370> |
| **6.** | **Description of content:** This Draft resolution incorporates the following changes for the active ingredient F68 - FLUXAPIROXADE (Fluxapyroxad) from the Relation of Monographies of Active Ingredients of Pesticides, Household Cleaning Products and Wood Preservers, all in the modality of foliar use (application):   * includes the cocoa culture with MRL of 0,7 mg/kg and safety security period of 7 days; * includes acerola, blackberry, raspberry, olive, Brazilian cherry, purple mombin, blueberry, and strawberry cultures with MRL of 1,5 mg/kg and safety security period of 1 day; * includes the plum, loquat, quince, nectarine, peach, and pear cultures with MRL of 1,5 mg/kg and safety security period of 7 days; * includes the chard, watercress, witloof chicory, chicory, spinach, stevia reubadiana, mustard, arugula, and lettuce cultures with MRL of 7,0 mg/kg and safety security period of 5 days; * includes the phrase: "Acute Reference Dose (ARfD): 0,3 mg/kg b.w. (source: JMPR\*, 2012) * includes the following phrase from item "j" to item "m": "for the purpose of residue definition for conformity to MRL and dietary risk assessment, it will be considered the substances Fluxapyroxad and its metabolits 3- (difluoromethyl)-1-methyl-N-(3',4',5'- trifluoro[1,1'-biphenyl]-2-yl)-1H-pyrazole-4-carboxamide (fluxapiroxade), 3-(difluoromethyl)-N-(3',4',5'-trifluorobiphenyl2-yl)-1H‑pyrazole-4-carboxamide (M700F008) and 3-(difluoromethyl)-11(β-D-glucopyranosyl)-N-(3',4',5'-trifluorobiphenyl2-yl)-1Hpyrazole-4-carboxamide (M700F048), expressed as Fluxapyroxad". |
| **7.** | **Objective and rationale: [****X]****food safety, [ ]****animal health, [ ]****plant protection, [ ]****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:**  **[****X]** **Codex Alimentarius Commission *(e.g. title or serial number of Codex standard or related text)*:**   * CAC/MRL 1 Maximum Residue Limits (MRLs) for Pesticides   **[ ]****World Organization for Animal Health (OIE) *(e.g. Terrestrial or Aquatic Animal Health Code, chapter number)*:**  **[ ]****International Plant Protection Convention *(e.g. ISPM number)*:**  **[ ]****None**  **Does this proposed regulation conform to the relevant international standard?**  **[ ]****Yes [****X]** **No**  **If no, describe, whenever possible, how and why it deviates from the international standard:** The scientific methodology used by Brazil to establish MRLs is consistent with international best practice. Countries set MRLs according to the good agricultural practice (GAP) applicable to their region. Agricultural chemical use patterns differ between different production regions and countries as pests, diseases and environmental factors vary. This means that Brazilian MRLs for agricultural chemicals in food may differ from Codex standards. |
| **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)*:** 21 November 2020  **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:**  Assessoria de Assuntos Internacionais - AINTE  International Affairs Office  Agência Nacional de Vigilância Sanitária - Anvisa  Brazilian Health Regulatory Agency  Tel: +(5561) 3462 5402/5404/5406  E-mail: [rel@anvisa.gov.br](mailto: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:**  Assessoria de Assuntos Internacionais - AINTE  International Affairs Office  Agência Nacional de Vigilância Sanitária - Anvisa  Brazilian Health Regulatory Agency  Tel: +(5561) 3462 5402/5404/5406  E-mail: [rel@anvisa.gov.br](mailto:rel@anvisa.gov.br) |