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):** HS Code(s): 38220090 (nutritional formulas); 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:** Resolution - RDC number 401, 21 July 2020.**Language(s):** Portuguese. **Number of pages:** 2  Resolution: <http://portal.anvisa.gov.br/documents/10181/5963498/RDC_401_2020_.pdf/19672219-83e2-4326-8ee9-6a74d0619d5d> |
| **6.** | **Description of content:** This resolution changes the Resolution - RDC number 22, 13 May 2015 in order to update the specification references for nutrient sources and other substances for use in formulas of enteral nutrition. |
| **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)*:** Food Chemicals Codex - FCC  **[ ]****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?**  **[****X]** **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:** Resolution - RDC number 22, 13 May 2015 |
| **10.** | **Proposed date of adoption *(dd/mm/yy)*:** In the date of its publication.  **Proposed date of publication *(dd/mm/yy)*:** In the date of its publication. |
| **11.** | **Proposed date of entry into force: [ ]****Six months from date of publication**, **and/or** ***(dd/mm/yy)*:** In the date of 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)*:**  **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) |