NOTIFICATION

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| **1.** | **Notifying Member:** Brazil  **If applicable, name of local government involved:** |
| **2.** | **Agency responsible:** The 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: Food; 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 (Consulta Publica) number 456, 28 December 2017. **Language(s):** Portuguese. **Number of pages:** 11  <http://portal.anvisa.gov.br/documents/10181/3898888/CONSULTA+PUBLICA+N+456+GGALI.pdf/cee6ec99-1319-44f6-a482-476793982d80> |
| **6.** | **Description of content:** This Resolution sets out the requirements for composition, quality, safety and labeling of food supplements and for updating lists of nutrients, bioactive substances, enzymes and probiotics, limits on use, claims and supplementary labeling of these products. This Resolution does not apply to food for special purposes and to conventional foods, including those added with nutrients, bioactive substances, enzymes or probiotics. Other ingredients with a technological or sensorial purpose can be used in the elaboration of food supplements, provided that they meet the following requirements:  I - do not misrepresent the purpose of use or the presentation of the product as a food supplement;  II - are not classified as novel foods or novel ingredients according to Resolution 16 of 30 April 1999, which approves the technical regulation of procedures for registration of food and / or new ingredients. The minimum and maximum limits must be met in the daily consumption recommendation of the product for the respective population groups for which the product is indicated by the manufacturer. Food supplements must be developed and produced in such a way as to ensure the maintenance of their characteristics until the expiration date, taking into account the storage instructions and the method of preparation indicated by the manufacturer. The products must be designated as "Food Supplement", with at least one of the following indications and the presentation of the product:  I - individual names of nutrients, bioactive substances or enzymes;  II - names of categories of nutrients, bioactive substances or enzymes.  Food supplements may not be labeled with tagging and labeling with medicines, cosmetics or other products subject to health surveillance. |
| **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:**  **[ ]** **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)*:** On the date of its publication.  **Proposed date of publication *(dd/mm/yy)*:** On the date of its publication. |
| **11.** | **Proposed date of entry into force: [ ]****Six months from date of publication**, **and/or** ***(dd/mm/yy)*:** On 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)*:** 9 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 Tagliari  Tel: +(55 61) 3462 5402/5404/5406  E-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 Tagliari  Tel: +(55 61) 3462 5402/5404/5406  E-mail: rel@anvisa.gov.br |