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 459, 28 December 2017. **Language(s):** Portuguese. **Number of pages:** 4  <http://portal.anvisa.gov.br/documents/10181/3898888/CONSULTA+P%C3%9ABLICA+N+459+GGALI.pdf/7ae4fbd7-f65c-473b-bf18-b696e04029ae> |
| **6.** | **Description of content:** This Resolution establishes the requirements for proving the safety and health benefits of probiotics. This Resolution covers probiotics for use in foods, including food supplements.It does not apply to evidence of the safety and health benefits of probiotics added in infant formulas. Demonstration of the health benefits of probiotics should be performed by proving allegation of general functional property or specific functional property. In the case of a mixture of probiotics, the demonstration of health benefits should be performed by substantiating evidence of specific functional property.  The requirement to prove the claim of functional property does not apply if all lineages of the mixture claim general functional property or if all lineages have the same claim of specific functional property. Requests for registration not yet decided by Anvisa upon the entry into force of this Resolution may be added within 6 (six) months in order to meet the new requirements established by it. |
| **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 |