NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** BRAZIL  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:**  Brazilian Health Regulatory Agency (ANVISA)  **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**  National Institute of Metrology, Quality and Technology (INMETRO)  Telephone: +(55) 21 2145.3817  Telefax: +(55) 21 2563.5637  Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Web-site: www.inmetro.gov.br/barreirastecnicas |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [****],** **5.6.2 [****],** **5.7.1 [****], 3.2 [****], 7.2 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** FOOD TECHNOLOGY (ICS code(s): 67) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft resolution number 1114, 06 September 2022;; (11 page(s), in Portuguese) |
| **6.** | **Description of content:** This Draft Resolution contains provisions on a proposed Normative Instruction that "Establishes the form of regularization of the different categories of food and packaging, and the respective documentation that must be presented"  This regulation will be also notified to the SPS Committee. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** In workshops held with health surveillance, the low effectiveness of current regulatory procedures for food regularization was identified, with the following consequences: lack of access to information about regularized products; lack of clarity of regulation; difficulties with food categorization; lack of definition of how this risk is understood; insufficient technical information resulting in inadequate controls, especially for higher risk products; insufficient operational capacity of analytical laboratories; forms of regularization in insufficient quantity (market authorization or exemption from market authorization), considering the variability of existing foods and their different levels of risk; regulatory gaps, among others. Thus, given the whole scenario found in the analysis of the problem, among other measures, the need for regulatory changes to solve the main problem is pointed out.; Protection of human health or safety |
| **8.** | **Relevant documents:**  - |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 13 December 2022 |
| **11.** | **Texts available from: National enquiry point [****]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Brazilian Health Regulatory Agency (Anvisa)  SIA, Trecho 5, Área Especial 57  Brasília – DF / Brazil  CEP: 71.205-050  Phone.: +(55) 61 3462.5402  Website: www.anvisa.gov.br  The final text is available only in Portuguese and can be downloaded at:  Draft: <http://antigo.anvisa.gov.br/documents/10181/6485886/consulta_publica_1114_2022+GEREG.pdf/a2f4a70c-5925-4245-9542-c467fea19008> Comment form: https://pesquisa.anvisa.gov.br/index.php/926683?lang=pt-BR |