



22 September 2022

(22-7119)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>BRAZIL</u> 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): Food technology (ICS code(s): 67)
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Draft Resolution number 1114, 6 September 2022. Language(s): Portuguese. Number of pages: 11 Draft: http://antigo.anvisa.gov.br/documents/10181/6485886/consulta_publica_1114_2022+GE.REG.pdf/a2f4a70c-5925-4245-9542-c467fea19008 Comment form: https://pesquisa.anvisa.gov.br/index.php/926683?lang=pt-BR
6. Description of content: This draft resolution is regarded to a proposal for a Normative Instruction - In that "Establishes the form of regularization of the different categories of food and packaging, and the respective documentation that must be presented". 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. This regulation will be also notified to the TBT Committee.
7. Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.
8. Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):

<p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
<p>9. Other relevant documents and language(s) in which these are available:</p>
<p>10. Proposed date of adoption (dd/mm/yy): To be determined after the end of the consultation period.</p> <p>Proposed date of publication (dd/mm/yy): To be determined after the end of the consultation period.</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): To be determined after the end of the consultation period.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 13 December 2022</p> <p>Agency or authority designated to handle comments: <input type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Assessoria de Assuntos Internacionais – AINTE International Affairs Office Agência Nacional de Vigilância Sanitária – Anvisa Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p>
<p>13. Text(s) available from: <input type="checkbox"/> National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Assessoria de Assuntos Internacionais – AINTE International Affairs Office Agência Nacional de Vigilância Sanitária – Anvisa Brazilian Health Regulatory Agency Tel: +(55 61) 3462 5402/5404/5406 E-mail: rel@anvisa.gov.br</p>