



18 December 2014

(14-7344)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. | <b>Notifying Member:</b> <u>BRAZIL</u><br><b>If applicable, name of local government involved:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2. | <b>Agency responsible:</b> ANVISA - The Brazilian Health Surveillance Agency                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3. | <b>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):</b> Food additives to enteral nutrition.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 4. | <b>Regions or countries likely to be affected, to the extent relevant or practicable:</b><br><input checked="" type="checkbox"/> All trading partners<br><input type="checkbox"/> Specific regions or countries:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 5. | <b>Title of the notified document:</b> Draft Technical Resolution nº 108, 8 December 2014, regarding the authorized food additives to use in formulas to enteral nutrition.<br><b>Language(s):</b> Portuguese <b>Number of pages:</b> 9<br><a href="http://portal.anvisa.gov.br/wps/wcm/connect/12bd6b004683e18a8cdc9c99223cd76e/Consulta+publica+n%C2%B0+108+GPESP.pdf?MOD=AJPERES">http://portal.anvisa.gov.br/wps/wcm/connect/12bd6b004683e18a8cdc9c99223cd76e/Consulta+publica+n%C2%B0+108+GPESP.pdf?MOD=AJPERES</a>                                                                                                                                                                                                                                                                                                                  |
| 6. | <b>Description of content:</b> Draft Technical Resolution nº 108, 8 December 2014, regarding the authorized food additives to use in formulas to enteral nutrition.<br><br>This draft Technical Resolution establishes the approved lists of food additives with its respective functions, which are authorized to use in formulas to enteral nutrition.<br><br>According to this draft technical resolution, the formulas to enteral nutrition are classified as: ready-to-feed formulas to enteral nutrition; and powder to preparation of formulas to enteral nutrition.<br><br>The companies will have a period of 12 (twelve) months from the date of publication of this resolution to make the necessary adjustments to comply therewith. The products manufactured until this deadline can be marketed until its expiration date. |
| 7. | <b>Objective and rationale:</b> <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. | <b>Is there a relevant international standard? If so, identify the standard:</b><br><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text)<br><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number)<br><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number)<br><input checked="" type="checkbox"/> None                                                                                                                                                                                                                                                                                                                                                   |

|                                                                                                                                                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Does this proposed regulation conform to the relevant international standard?</b><br/> <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| 9.                                                                                                                                                                                                                                                                   | <p><b>Other relevant documents and language(s) in which these are available:</b><br/>         Brazilian Official Journal (Diário Oficial da União), 10 December 2014; Section 1, p. 99, Draft Resolution (Consulta Pública) number 108, 8 December 2014, issued by Brazilian Health Surveillance Agency ANVISA. When adopted, it will be published at the Brazilian Official Journal (available in Portuguese).</p>                                                                                                                                |
| 10.                                                                                                                                                                                                                                                                  | <p><b>Proposed date of adoption (dd/mm/yy):</b> To be determined after the end of the consultation period.</p> <p><b>Proposed date of publication (dd/mm/yy):</b> To be determined after the end of the consultation period.</p>                                                                                                                                                                                                                                                                                                                   |
| 11.                                                                                                                                                                                                                                                                  | <p><b>Proposed date of entry into force:</b> <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>                                                                                                                                                                                                                                                                                            |
| 12.                                                                                                                                                                                                                                                                  | <p><b>Final date for comments:</b> <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 16 February 2015</p> <p><b>Agency or authority designated to handle comments:</b> <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Patricia Oliveira Pereira<br/>         Tel: +(55 61) 3462 5402/5404/5406<br/>         E-mail: rel@anvisa.gov.br</p> |
| 13.                                                                                                                                                                                                                                                                  | <p><b>Text(s) available from:</b> <input type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Patricia Oliveira Pereira<br/>         Tel: +(55 61) 3462 5402/5404/5406<br/>         E-mail: rel@anvisa.gov.br</p>                                                                                                                                                                                            |