



Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Notifying Member: BRAZIL If applicable, name of local government involved (Articles 3.2 and 7.2):
2. Agency responsible: Brazilian Health Regulatory Agency (Anvisa) Name and address (including telephone and fax numbers, e-mail and web-site 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 2563.2765 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas The comments to this Draft Regulation shall be sent to http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=32938
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Food supplements and labeling.
5. Title, number of pages and language(s) of the notified document: Draft resolution (Consulta Publica) number 457, December 28th 2017. 41 pages, Portuguese.
6. Description of content: This Normative Instruction establishes the lists of nutrients, bioactive substances, enzymes and probiotics, limits of use, claims and supplementary labeling of food supplements. Annex I defines the list of probiotics and source ingredients of nutrients, bioactive substances and enzymes authorized for use in food supplements. Annex II sets out the list of minimum levels of nutrients, bioactive substances, enzymes and probiotics to be provided by dietary supplements in the daily recommendation for consumption and by the population group indicated by the manufacturer. Annex III sets out the list of maximum levels of nutrients, bioactive substances, enzymes and probiotics which can not be exceeded by food supplements in the daily recommendation for consumption and by the population group indicated by the manufacturer. Annex IV sets out the list of claims authorized for use on the labeling of food supplements and their composition and labeling requirements. Annex V sets out the list of supplementary labeling requirements for food supplements.

Annex VI defines the list of essential amino acid quantities of the reference protein.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União) Nº. 249, 29 December 2017, section 1, page 119; (2) Law nº 9.782, 26 January 1999; (3) Brazilian Official Journal; (4) Not applicable
9. Proposed date of adoption: On the date of its publication. Proposed date of entry into force: on the date of its publication.
10. Final date for comments: 9 April 2018
11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body: Agency Responsible 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 http://portal.anvisa.gov.br/documents/10181/3898888/CONSULTA+PUBLICA+N+457+G+GALI.pdf/33b58cec-33cd-4295-867c-4ff44e01ca88