



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: Anvisa – Brazilian Health Surveillance Agency 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 2563.2840 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=19729
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): industrialized allergenic products of biological origin.
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution nº 19, March 10 th 2015, regarding the registration and post-approval changes of industrialized allergenic products of biological origin (17 pages, Portuguese).
6. Description of content: Draft Technical Resolution nº 19, March 10 th 2015, regarding the registration and post-approval changes of industrialized allergenic products of biological origin. This Draft Technical Resolution aims to establish the minimum requirements to the registration and post-approval changes of industrialized allergenic products of biological origin, in order to ensure quality, safety and efficacy of these products. This Resolution applies to industrialized allergenic products of biological origin that will be submitted to the registration analysis and post-approval changes of those products, besides regulating nominal allergenic products and their use by qualified professional. This Resolution revokes the Resolution RDC nº 233/2005.
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), March 11 th 2015; Section 1, p. 78; 2) Resolution RDC nº 55/2010, Resolution RDC nº 47/2009, Resolution RDC nº 71/2009, Resolution RDC nº 49/2011, Law nº 6.437, 20 August 1977; 3) Brazilian Official Journal; 4) Not Stated.
9.	<p>Proposed date of adoption: To be determined after the end of the consultation period.</p> <p>Proposed date of entry into force: 90 days after the publication</p>
10.	Final date for comments: May 15 th , 2015.
11.	<p>Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</p> <p>Agency Responsible Anvisa - Brazilian Health Surveillance Agency SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br</p> <p>http://portal.anvisa.gov.br/wps/wcm/connect/8f190300479abb288ba4ebfe096a5d32/CP+19-2015+-+Minuta.pdf?MOD=AJPERES</p>