



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 2563.2840 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=23639
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): analytical methods validation
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution nº 129, February 12 2016, regarding analytical methods validation (28 pages, Portuguese).
6. Description of content: Draft Technical Resolution nº 129, February 12 2016, regarding analytical methods validation. Draft technical resolution regarding the validation of analytical methods on biological, microbiological, immunological, identification, impurity determination quantitative trials; impurity control limit trials, quantitative trials to pharmaceutical ingredients in raw material and medicines in every phase of production. This Resolution revokes the Resolution RE 899/2003 and the Annex I of Resolution RDC 31/2010.
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), February 15 2016; Section 1, p. 44; 2) Not stated; 3) Brazilian Official Journal; 4) Not stated.

9. Proposed date of adoption:	To be determined after the end of the consultation period.
Proposed date of entry into force:	90 days from the publication.
10. Final date for comments:	April 22, 2016.
11. 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>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/wps/wcm/connect/80fde6804bb125c8aaffaebab17fe222/CP+129-2016+-+Minuta.pdf?MOD=AJPERES</p>