

Date

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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: <u>barreirastecnicas@inmetro.gov.br</u>

Website: http://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=19047

- 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): Products subject to health surveillance.

- **Title, number of pages and language(s) of the notified document:** Draft Technical Resolution No 04, January 22nd 2015, concerning the update of register data caused by corporate and commercial restructuration of companies. (9 pages, Portuguese).
- **Description of content:** Draft Technical Resolution No 04, January 22nd 2015, concerning the update of register data caused by corporate and commercial restructuration of companies.

This draft Technical Resolution applies to corporate and commercial transactions between companies that perform the activities mentioned in the federal sanitary law and which result in the need to update register data regarding their operation and the ownership registration transferring of products under sanitary surveillance. It also applies to restructuration performed oversees, including MERCOSUR members.

Once the corporate or commercial transaction is finalized, the successor company has 60 days to deposit the necessary updating documents at Anvisa.

This Draft Technical Resolution revokes Resolution RDC n. 22/2010.

- 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
- **8. Relevant documents:** Brazilian Official Journal (Diário Oficial da União), January 27th 2015; Section 1, p. 34, Draft Resolution (Consulta Pública) Nº 04, January 22nd 2015, issued by Brazilian Health Surveillance Agency Anvisa. When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.
- 9. Proposed date of adoption: Proposed date of entry into force:

To be determined after the end of the consultation period.

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- **10.** Final date for comments: March 04th, 2015.
- 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:

Agency Responsible Brazilian Health Surveillance Agency – ANVISA SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil

CEP: 71.205-050 Phone.: 55 61 3462-5402

Phone.: 55 61 3462-5402 Website: www.anvisa.gov.br

http://portal.anvisa.gov.br/wps/wcm/connect/e18ccc004717045192239341cdd33a01/Co

nsulta+P%C3%BAblica+n%C2%B0+04+GGREG.pdf?MOD=AJPERES