



18 April 2017

(17-2103)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>BRAZIL</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: Brazilian Health Regulatory Agency (Anvisa) Name and address (including telephone and fax numbers, email and website 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=30795
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): Dental products
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution n. 324, 21 March 2017 (2 pages, in Portuguese)
6. Description of content: This Draft Resolution establishes the prohibition of the mercury and amalgam non-encapsulated indicated for use in dentistry (odontology). The manufacture, importation and marketing, as well as the use in health services, of mercury and amalgam in its non-encapsulated form indicated for use in odontology are prohibited throughout the national territory. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, pursuant to Law No. 6.437, of 20 August 1977, without prejudice to the applicable civil, administrative and criminal responsibilities. This Resolution shall enter into force on 1 January 2019.
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), 22 March 2017; Section 1 page 72. Draft Resolution (Consulta Pública) number 324, 21 March 2017, issued by the Brazilian Health Regulatory Agency – Anvisa; When adopted, it will be published at Brazilian Official Journal. Available in Portuguese

9. Proposed date of adoption: To be determined after the end of the consultation period.
Proposed date of entry into force: 1 January 2019

10. Final date for comments: 29 May 2017

11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of 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/10181/3113092/CONSULTA+P%C3%9ABLICA+N+324+GGTPS.pdf/b720b65c-cda5-4a36-8e2c-5aacd43c8b7b>