



4 January 2019

(19-0026)

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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: 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 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: Brazilian Health Regulatory Agency (Anvisa) http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=28757
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): Plants, medical products containing controlled substances
5. Title, number of pages and language(s) of the notified document: Draft Resolution 587, 27 December 2018, published by Brazilian Official Gazette (15 page(s), in Portuguese)
6. Description of content: This draft resolution establishes the import and export controls, of plants and medical products containing controlled substances subject to special control for any purpose, among other measures. The lists of substances subject to special control and prohibited plants are included in Annex I of Portaria SVS/MS 344, 12 May 1998, and its updates. Any legal entity which imports or exports, for any purpose, controlled substances, plants and medicinal products, and Teaching and Research Institutions that realize any activity with this products are covered by this Resolution. Exceptions for the controls provided on this Resolution are: <ul style="list-style-type: none">• The isotope and radioisotope patterns;• Isotopically labelled organic substances patterns;• Kits for in vitro diagnostics and for the detection of controlled substances in the environment;• Non-medicamental formulation containing substances in List D1 (does not apply to analytical standards on the list); and

<ul style="list-style-type: none"> • Substances on list D2, which are subjected to the control and supervision of the Justice Ministry. <p>This resolution establishes the places for entry and exit of specific substances listed on the annex of Portaria SVS/MS 344.</p> <p>RDC 99, 30 September 2008, RDC No.11, 11 March 2013, RSC 201, 18 July 2002 and RDC 62, 11 February 2016 are hereby revoked.</p> <p>Also articles from Portaria SVS/MS 344, 12 May 1988 and Portaria SVS/MS 6, 29 January 1999 are hereby revoked.</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety</p>
<p>8. Relevant documents:</p> <ul style="list-style-type: none"> • Ordinance (Portaria) SVS/MS 344 • Ordinance (Portaria) SVS/MS 6
<p>9. Proposed date of adoption: On the date of its publication</p> <p>Proposed date of entry into force: 30 days from the date of its publication</p>
<p>10. Final date for comments: 30 days from notification</p>
<p>11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <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/consultas-publicas#/visualizar/388482</p>