



11 January 2018

(18-0276)

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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=33294
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): Goods and Products
5. Title, number of pages and language(s) of the notified document: Draft Resolution Nº 455, December 28th, 2017. (4 page(s), in Portuguese)
6. Description of content: This Draft Resolution establishes the sanitary risk management applied to control and inspection activities, the importation of goods and products under sanitary surveillance, and other measures. It establishes the application of sanitary risk management to control and inspection activities and incidents in the importation of goods and products under the responsibility of Anvisa. Specific programs and differentiated control and inspection regimes, established by Anvisa, will be taken into account in the application of the health risk management dealt with in this Resolution. This Resolution establishes the sanitary risk management criteria to be applied on the control and inspection activities, in the importation of goods and products under sanitary surveillance. Anvisa will submit procedures for the importation of goods or products under sanitary surveillance into the risk analysis, in accordance with the criteria established in Article 2 of this Resolution, in order to select one of the following inspection channels: I. Green, simplified granting channel applicable to import processes of companies and products regularized at Anvisa by exemption of documentary analysis and inspection of

<p>cargo;</p> <p>II. Yellow, a surveillance channel that performs documentary analysis of the import process with the possibility of approval, by exemption of the inspection of the cargo, in the absence of documentary irregularity;</p> <p>III. Red, surveillance channel that performs documentary analysis, inspection of cargo and other applicable sanitary procedures established in specific norm; and</p> <p>IV. Gray, a surveillance channel that performs special investigation procedure.</p> <p>Regardless of the surveillance channel selected, according to the list above, the identification of evidence of irregularity, by the sanitary authority, may lead to the establishment of a Special Investigation Procedure.</p> <p>This Resolution revokes the Item 8 of Chapter III of the Resolution of the Board of Directors - RDC nº 81, dated 5 November 2008.</p>
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health</p>
<p>8. Relevant documents: Resolution of the Board of Directors - RDC nº 81, dated 5 November 2008.</p>
<p>9. Proposed date of adoption: On the date of its publication. Proposed date of entry into force: On 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 [X] 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/documents/10181/2957335/CONSULTA+PUBLICA+N+455+GG+PAF.pdf/a7bbbe9d-3fd1-4c4b-b6d3-8b72f199c80f</p>