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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:** 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 2563.2765 Telefax: +(55) 21 2563.5637

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

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 subject to Sanitary Surveillance

- **Title, number of pages and language(s) of the notified document:** Resolution RDC Nº 208 Simplification of procedures for the important of goods and products subject to Sanitary Surveillance, January 5th, 2018. 25 pages, Portuguese.
- **6. Description of content:** This Resolution establishes the simplification of procedures for the importation of goods and products subject to Sanitary Surveillance.

This Resolution amends the Resolutions of the Collegiate Board of Directors - RDC  $n^o$  46 of May 18, 2000,  $n^o$  81 of November 5, 2008,  $n^o$  58 of December 17, 2010,  $n^o$  68 of March 28, 2003 and  $n^o$  204 of July 6, 2005, aimed at simplifying procedures for the importation of goods and products subject to sanitary surveillance

This Resolution changes the art. 3; includes in item 1.2 of Chapter II the sub-item 1.2.1.; changes item 3.5 of Subsection II of Section I of Chapter III; changes item 5 of Subsection II of Section I of Chapter III; changes item 7 of Chapter VII; changes item 1 of Chapter IX; changes subitem 1.1 of Chapter IX; changes subitem 3.1 of Chapter IX; changes Chapter XV; changes Chapter XVIII; changes item 1 of Chapter XX; changes subitem 1.3.1 of Chapter XX; changes item 1.4 of Chapter XX; changes Chapter XXII; changes Chapter XXVII; changes item 6 of Section II of Chapter XXX; changes item 10 of Section IV of Chapter XXX; changes Chapter XXXII; changes Chapter XXXIV; changes item 2 of Chapter XXXVII; changes the title of Section I of Chapter XXXIX; changes items 25 and 26 of Section VI of CHAPTER XXXIX; changes the

title of Section VII of CHAPTER XXXIX; changes item 29 of Section VII of CHAPTER XXXIX; changes item 33 of Section VIII of CHAPTER XXXIX; changes section 36 of Section VIII of CHAPTER XXXIX; changes section 57 of Section X of CHAPTER XXXIX of the Resolution of the Collegiate Board of Directors - RDC no 81, of 2008.

This Resolution changes the Paragraph 2 of art. 6 of the Resolution of the Collegiate Board of Directors - RDC  $n^{\circ}$  204, of July 6, 2005; changes the art. 17 of the Resolution of the Collegiate Board of Directors - RDC  $n^{\circ}$  58, of December 17, 2010; changes the caput and paragraph 2 of art. 18 of the Resolution of the Collegiate Board of Directors - RDC  $n^{\circ}$  58, of 2010.

This Resolution revokes the following provisions of the Resolution of the Collegiate Board of Directors - RDC n ° 81, of November 5, 2008: item 3.4 of Subsection II of Section I of Chapter III; item 5.4 of Section IV of Chapter XVIII; subitems 2.1 and 2.1.1 of Chapter XXIV; Chapter XXIX; item 2, subitems 6.2 and 10.2 of Chapter XXXV; Chapter XXXV; item 11, subitems 11.1 and 11.2 of Chapter XXXVII.

This Resolution revokes the following provisions of Chapter XXXIX of the Resolution of the Collegiate Board of Directors - RDC n. 81, of November 5, 2008: item 3, items 4, subparagraphs b, c, h, l, subitems 4.1, 4.2 and item 5, of Section I; subparagraphs b, c, h, j, I of item 10, subitems 10.1, 10.2 and item 11 of Section II; subparagraphs b, c, f, i, j of item 16 of Section III; items 13, subitems 13.1, 13.2, 13.3 and item 14 of Section III; item 17, subparagraphs b, c, f, i, j, l of item 18, subitems 18.1, 18.2, 18.3 and item 19 of Section IV; items b, c, f, h, i of item 22, subitems 22.1, 22.2, 22.3 and item 23 of Section V; subitems 25.1, 25.2, 25.3, 26.1, 26.2, 26.3 and item 27 of Section VI; item 30, subitem 30.1, subparagraphs b, c, d, g, i, j, l of item 31, subitems 31.1, 31.2, 31.3 and item 32 of section VII; item 34, subitem 34.1, item 35, subitems 35.1, 35.2, 35.3, 36.1, 36.2, 36.3 and item 37 of Section VIII; subparagraphs b, c, f, g, h, l, m of item 39, subitems 39.1, 39.2, 39.3 and item 40 of subsection I of Section IX; subparagraphs b, c, f, q, i and j of item 42, subitems 42.1, 42.2, 42.3 and item 43 of subsection II of Section IX; subparagraphs b, c, f, h, j and l of item 45, subitems 45.1, 45.2, 45.3 and item 46 of subsection III of Section IX; subparagraphs b, c, f, g, i, j of item 49; subitems 49.1, 49.2, 49.3, item 50 of Subsection IV of Section IX; subparagraphs b, c, f, g, j and I of item 52, subitems 52.1, 52.2, 52.3 and item 53 of subsection V of section IX; subparagraphs a, b, c, e, f of subitem 54.1, subparagraphs b, c, f, g, h, i of item 55, subitems 55.1, 55.2, item 56 of subsection VI of Section IX; item 58, subitems 58.1 and 58.2, subparagraphs b, c, f, g, h, j, l of item 59, subitems 59.1, 59.2 and 59.3, item 60 of Section X; subparagraphs b, c, f, j, I of item 65, sub items 65.1, 65.2, 65.3 and item 66 of Section XI.

This Resolution revokes the art. 4 and Annex II of the Resolution of the Collegiate Board of Directors - RDC No. 46, of May 18, 2000; art. 19, 22 and 23 of the Resolution of the Collegiate Board of Directors - RDC no 58, of December 17, 2010; the sole paragraph of art. 1, art. 4, art. 5 and art. 6 of the Resolution of the Collegiate Board of Directors - RDC No. 68, March 28, 2003.

- 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
- **8. Relevant documents:** Resolutions of the Collegiate Board of Directors RDC no 46 of May 18, 2000; no 81 of November 5, 2008; no 58 of December 17, 2010; no 68 of March 28, 2003 and no 204 of July 6, 2005.
- 9. Proposed date of adoption:

On the date of its publication.

Proposed date of entry into force:

On the date of its publication.

- **10.** Final date for comments:
- 11. Texts available from: National enquiry point [X] or address, telephone and fax

## numbers, e-mail and web-site addresses, if available of the other body:

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http://portal.anvisa.gov.br/documents/10181/2957335/RDC 208 2018 .pdf/eccf9152-

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