



16 January 2018

(18-0422)

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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 CCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Goods and products subject to Sanitary Surveillance
5. Title, number of pages and language(s) of the notified document: Resolution - RDC N° 208 – Simplification of procedures for the important of goods and products subject to Sanitary Surveillance, January 5th, 2018. (25 page(s), in 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° 46 of 18 May 2000, n° 81 of 5 November 2008, n° 58 of 17 December 2010, n° 68 of 28 March 2003 and n° 204 of 6 July 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 XXI; changes Chapter XXVI; changes Chapter XXVIII; 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 n° 81, of 2008.

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

This Resolution revokes the following provisions of the Resolution of the Collegiate Board of Directors - RDC n ° 81, of 5 November 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 XXX; 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 5 November 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, l 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, g, 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 l 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, l 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 18 May 2000; art. 19, 22 and 23 of the Resolution of the Collegiate Board of Directors - RDC n° 58, of 17 December 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, 28 March 2003.

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| 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 n° 46 of 18 May 2000; n° 81 of November 5, 2008; n° 58 of 17 December 2010; n° 68 of 28 March 2003 and n° 204 of 6 July 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: Not applicable |

11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Agency Responsible
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http://portal.anvisa.gov.br/documents/10181/2957335/RDC_208_2018_.pdf/eccf9152-9aae-43d0-83b4-e2f6b3015425