

5 January 2018

Original: English

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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 (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)

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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): HS 24
- **5. Title, number of pages and language(s) of the notified document:** RDC No 195, 14 December 2017. (16 pages, in Portuguese). Republished on 18 December, 2017, (DOU 241, 142/146) and republished on 19 December 2017 (DOU 242, 154/156).
- **6. Description of content:** This Resolution provides for packaging requirements and health warnings for smoking tobacco products.

This Resolution applies to all smoking products marketed domestically, domestically manufactured and imported. The primary and secondary packaging of all smoking products derived from tobacco should contain health warnings about the harm arising from the use of these products and the message prohibiting the sale for children under the age of eighteen, as provided in this Resolution. All health warnings and the prohibition message for the sale for children younger than eighteen years old must be printed on the outside of the packaging in high resolution, legibly and ostensibly highlighted, according to the models in the Annexes of this Resolution, without changing the proportionality between its elements, as well as its graphic parameters.

The provisions of this Resolution comply with the WHO FCTC, adopted by the Member States of the World Health Organization on May 21, 2003 and signed by Brazil on June 16, 2003, promulgated by Decree 5,658, of January 2, 2006, and follow the guidelines for its implementation, approved by the Conference of the Parties.

This Resolution revokes the Resolutions RDC 335, of November 21, 2003; RDC 168 of July

07, 2004; RDC 10 of February 15, 2007; RDC 30, of May 23, 2013; RDC 43, of September 3, 2013 and RDC 14, April 10, 2015.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety; Protection of Human Health

## 8. Relevant documents:

(1) Brazilian Official Journal (Diário Oficial da União) nº 240, 15 November 2017, section 1, pages 172/181; (2)Law nº 9.782, de 26 January 1999; Law nº 9.294/96; Decree nº 2.018/96 (3) Brazilian Official Journal; (4) Not applicable

**9. Proposed date of adoption:** On the date of its publication.

Proposed date of entry into force: 25 May, 2018

**10. Final date for comments:** No final date for comments

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 Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil

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Phone.: +(55) 61 3462.5402 Website: <u>www.anvisa.gov.br</u>

http://portal.anvisa.gov.br/documents/10181/3119516/RDC 195 2017 .pdf/f165638d-

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