



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 2563.2840 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=30775
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): Tobacco Products
5. Title, number of pages and language(s) of the notified document: Draft Technical Resolution n. 314, 17 March 2017. 18 pages, Portuguese.
6. Description of content: This Draft Resolution provides the technical requirements and procedures to be observed in the market authorization of tobacco processed and in the procedures for smoking products derived from tobacco. It applies to all tobacco processed in the country and to all smoking products derived from tobacco, processed, manufactured, stored in the national territory, imported, exported or marketed in the country. It is considered tobacco processed all types of tobacco that have passed through any process step at the national company intended for use as raw material for obtaining smoking products derived from tobacco. Smoking products shall mean any manufactured product containing tobacco in its composition. All tobacco smoke products must be registered in order to: manufacturing and marketing in the national territory; import and marketing in the national territory; and manufacture in the national territory exclusively for export. Different importing companies will be able to obtain from ANVISA the market authorization for the same smoking tobacco product manufactured outside the country. The importing company must request the authorization for the tobacco smoking product to be imported, even if the product has already been registered by another importing company.

Every year, national manufacturing companies and companies importing smoking products derived from tobacco must electronically submit a secondary application for Renewal of Smoking Product Authorization, through the online procedure, available in the ANVISA's Electronic Petition System.

Tobacco companies must petition annually to register all the tobacco they have processed in the previous year through the Electronic Petitioning System of ANVISA. Disclosure and commercialization of the requested authorization for smoking product may only be initiated after the corresponding petition has been granted and published in the Official Gazette.

The registration of smoking product has validity of 1 (one) year, counted from the date of publication in the Official Gazette, and must have its validity annually renewed.

The import, export and marketing in the national territory of any smoking product that is not properly authorized under the terms of this Resolution shall be prohibited. The commercialization, in the Brazilian market, of smoke products authorized exclusively for export is not allowed.

This Resolution revokes Resolution nº 90 of 27 December 2007, Resolution nº 32 of 29 May 2008 and Resolution nº 44 of 18 June 2008.

This resolution comes into force on the date of its publication.

7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health

8. Relevant documents: (1) Brazilian Official Journal (Diário Oficial da União), 20 March 2017; Section 1 page 63; (2) Technical Resolution RDC nº 90, de 27 December 2007; (3) Brazilian Official Journal; (4) Not stated.

9. Proposed date of adoption: to be determined after the end of the consultation period.
Proposed date of entry into force: to be determined after the end of the consultation period.

10. Final date for comments: 27/04/2017

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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