



Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

<b>1. Notifying Member:</b> BRAZIL <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Brazilian Health Regulatory Agency (Anvisa) <b>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:</b>  National Institute of Metrology, Quality and Technology (INMETRO) Telephone: +(55) 21 2563.2765 Telefax: +(55) 21 2563.5637 Email: <a href="mailto:barreirastecnicas@inmetro.gov.br">barreirastecnicas@inmetro.gov.br</a> Web-site: <a href="http://www.inmetro.gov.br/barreirastecnicas">www.inmetro.gov.br/barreirastecnicas</a>  <b>The comments to this Draft Regulation shall be sent to</b> <a href="http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=32938">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=32938</a>
<b>3. Notified under Article 2.9.2 [ X ], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> HS 33
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Resolution RDC n. 366, 13 July 2017. 4 pages in Portuguese.
<b>6. Description of content:</b> This Draft Resolution provides for amendment and inclusion of labelling for personal hygiene products, cosmetics and perfumes, and establishes the rules for coexistence of more than one final art (label) for the same product.  The coexistence of more than one final approved labelling art is permitted in a single product registration or registration-free product notification, provided that the requirements of this Resolution are met. All final arts (labels) that the company intends to market must be in the product registration petition or registration-free product notification.  The labelling elements that may differ in more than one final art for the same product or which may be changed with immediate implementation are:  I - colours;  II - figures and images that do not have technical purpose, suggestion of way of use or suggestion of properties of the product;  III - references to commemorative dates;  IV - other names that do not change the name of the product;  V - promotional statements;

<p>VI - manufacturer information and the technical responsible; and</p> <p>VII - final arts that specifically meet the programs of the Ministry of Health.</p> <p>This draft resolution also establishes other provisions about procedures regarding labelling changes for cosmetics, perfumes and personal hygiene products.</p> <p>This Resolution revokes the Resolution RDC nº 131, December 5th 2016.</p>
<p><b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Health</p>
<p><b>8. Relevant documents:</b> 1) Brazilian Official Journal (Diário Oficial da União), 134, 14 July 2017; Section 1, p. 48; 2) Resolution RDC 16, 1 April 2014 (Resolução RDC Nº 16, de 1 de Abril de 2014); Law 6437, 20 august 1977; 3) Brazilian Official Journal; 4) Not stated.</p>
<p><b>9. Proposed date of adoption:</b> to be determined after the end of the consultation period.</p> <p><b>Proposed date of entry into force:</b> on the date of publication.</p>
<p><b>10. Final date for comments:</b> August 19, 2017</p>
<p><b>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:</b></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: <a href="http://www.anvisa.gov.br">www.anvisa.gov.br</a></p> <p><a href="http://portal.anvisa.gov.br/documents/10181/3178095/Corpo+-+CP+366+-+Atera%C3%A7%C3%A3o+de+rotulagem+de+cosm%C3%A9ticos.pdf/4f92a7d9-8f07-4bf2-bee9-259309ce2350">http://portal.anvisa.gov.br/documents/10181/3178095/Corpo+-+CP+366+-+Atera%C3%A7%C3%A3o+de+rotulagem+de+cosm%C3%A9ticos.pdf/4f92a7d9-8f07-4bf2-bee9-259309ce2350</a></p>