



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> ANVISA – Brazilian Health Regulatory Agency <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  <b>Telephone:</b> +(55) 21 2563.2821 <b>Telefax:</b> +(55) 21 2502.6542 <b>Email:</b> barreirastecnicas@inmetro.gov.br <b>Web-site:</b> <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=11452">http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=11452</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> Traditional Chinese Medicine products (HS:30.00)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Ordinance nº 15, May 14 <sup>th</sup> 2013 – Draft Technical Regulation that establishes requirements to commercialize traditional Chinese medicine products in Brazil. (3 pages, Portuguese)
<b>6. Description of content:</b>  This draft Technical Regulation has the objective to establish requirements to commercialize traditional Chinese medicine products in Brazil.  It is established a period of three years from the date of publication of this Resolution for the monitoring of the use of traditional Chinese medicine products in the country.  For the purposes of this Resolution traditional Chinese medicine products are formulations obtained from vegetable and mineral raw materials in accordance with traditional Chinese medicine techniques and part of the Chinese Pharmacopoeia.  It is forbidden the use of animal origin raw material in the formulations to be

commercialized in Brazil.					
<b>7.</b>	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of Human Health				
<b>8.</b>	<b>Relevant documents:</b> Brazilian Official Journal (Diário Oficial da União), May 15 <sup>th</sup> 2013; Section 1 Draft Resolution (Consulta Pública) number 15, May 14 <sup>th</sup> , 2013, issued by Brazilian Health Regulatory Agency – Anvisa; (2) Not Applicable (3) Brazilian Official Journal (Diário Oficial da União); (4) Not Applicable; When adopted, it will be published at the Brazilian Official Journal. Available in Portuguese.				
<b>9.</b>	<table border="0"> <tr> <td><b>Proposed date of adoption:</b></td> <td rowspan="2">}</td> <td rowspan="2">to be determined after the end of the consultation period. on the date of adoption.</td> </tr> <tr> <td><b>Proposed date of entry into force:</b></td> </tr> </table>	<b>Proposed date of adoption:</b>	}	to be determined after the end of the consultation period. on the date of adoption.	<b>Proposed date of entry into force:</b>
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<b>Proposed date of entry into force:</b>					
<b>10.</b>	<b>Final date for comments:</b> 19 August 2013.				
<b>11.</b>	<p><b>Texts available from: National enquiry point [ ] 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 E-mail: rel@anvisa.gov.br Website: www.anvisa.gov.br</p> <p><a href="http://portal.anvisa.gov.br/wps/wcm/connect/61f704004fa210b897f0f79a71dcc661/Consulta+P%C3%ABblica+n%C2%B0+15+SECOL.pdf?MOD=AJPERES">http://portal.anvisa.gov.br/wps/wcm/connect/61f704004fa210b897f0f79a71dcc661/Consulta+P%C3%ABblica+n%C2%B0+15+SECOL.pdf?MOD=AJPERES</a></p>				