



31 May 2018

(18-3260)

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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 CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Improve knowledge of existing, emerging and innovative technologies, subsidizing the processes of evaluation of technologies and production of regulations in Sanitary Surveillance
5. Title, number of pages and language(s) of the notified document: Public call number 2, 21 May 2018 - Portuguese.
6. Description of content: This Public Call aims to promote a collaborative environment between the Anvisa, industry, academic-scientific community and third sector in the search to increase the safety and effectiveness of products and services to be made available to the Brazilian population; improve knowledge of existing, emerging and innovative technologies, subsidizing the processes of evaluation of technologies and production of regulations in Sanitary Surveillance; Improve critical thinking and problem solving by better understanding difficulties, challenges and regulatory needs in the development cycle of innovative and emerging technologies; establish transparent and universal criteria and procedures for partnerships with the various actors involved and interested in the evaluation of technologies and the production of regulations in Health Surveillance; The main themes are: Regulation and Registration of Health Products; Regulation of Blood, Tissues, Cells and Organs; Regulation and Registration of Food Products; Regulation of Agrochemicals; Regulation of Technologies in Health Services; Monitoring of Products subject to Health Surveillance and Emergency Information Management in Health Surveillance
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health

8.	Relevant documents: Nota Técnica nº 67/2015/CGNOR/DENOP/SEGEP/MP; Resolução ANVISA da Diretoria Colegiada - RDC nº 2, de 15 de janeiro de 2007; Instrução Normativa ANVISA nº 15, de 13 de abril de 2017; Consulta Pública Nº485/2018.
9.	Proposed date of adoption: Not applicable Proposed date of entry into force: Not applicable
10.	Final date for comments: Not stated
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 CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br http://www.imprensa nacional.gov.br/web/guest/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/15358016/do3-2018-05-22-aviso-de-chamamento-publico-n-2-de-21-de-maio-de-2018-15358012