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) Telephone: +(55) 21 2145.3817 Telefax: +(55) 21 2563.5637 Email: [barreirastecnicas@inmetro.gov.br](mailto:barreirastecnicas@inmetro.gov.br)  Web-site: [www.inmetro.gov.br/barreirastecnicas](http://www.inmetro.gov.br/barreirastecnicas) |
| **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 Code(s): Products subject to public health surveillance. |
| **5.** | **Title, number of pages and language(s) of the notified document:**  Draft Resolution number 1039, 8 April 2021. (6 page(s), in Portuguese). Draft: <http://antigo.anvisa.gov.br/documents/10181/6253937/Minuta+1039.pdf/c8c9ff4d-3438-4b3c-be0e-5a4d8fe09d8c>  Comment form: <https://pesquisa.anvisa.gov.br/index.php/929469?lang=pt-BR> |
| **6.** | **Description of content:** Public Consultation proposal to establish criteria for the utilization of impact assessment undertaken by Equivalent Foreign Regulatory Agency for the purpose of regularization of products subject to public health surveillance in Anvisa through an optimized analysis procedure. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health; Protection of human health or safety  Regulatory Justification:  <http://antigo.anvisa.gov.br/documents/10181/6253937/Justificativa+Regulat%C3%B3ria.pdf/a2c361d4-5e95-4833-89da-e9bca5683a09> |
| **8.** | **Relevant documents:** 01) Brazilian Official Gazette 65-A on 08 April 2021, section 1, page 3; 02) Regulatory Impact Analysis (RIA) Report  <https://www.in.gov.br/web/dou/-/consulta-publica-n-1.039-de-8-de-abril-de-2021-312833681>  <http://antigo.anvisa.gov.br/documents/10181/6253937/REMAI.pdf/07e2940f-3532-4efc-87f7-065a9b380265> |
| **9.** | **Proposed date of adoption:** Not applicable  **Proposed date of entry into force:** Not applicable |
| **10.** | **Final date for comments:** 15 June 2021 |
| **11.** | **Texts available from: National enquiry point [** **]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  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.anvisa.gov.br)  <http://antigo.anvisa.gov.br/documents/10181/6253937/Minuta+1039.pdf/c8c9ff4d-3438-4b3c-be0e-5a4d8fe09d8c> |