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 2563.2765 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):**
5.	**Title, number of pages and language(s) of the notified document:** Draft Resolution nº 534 of 12 June 2018. 12 pages , Portuguese.
6.	**Description of content:** THE SECRETARY OF AGRICULTURAL DEFENSE OF THE MINISTRY OF AGRICULTURE, LIVESTOCK AND FOOD SUPPLY, THE DIRECTOR-PRESIDENT OF THE BRAZILIAN HEALTH REGULATORY AGENCY- ANVISA and the PRESIDENT OF THE BRAZILIAN INSTITUTE OF THE ENVIRONMENT AND RENEWABLE NATURAL RESOURCES - IBAMA, in the use of their legal and in view of the provisions of Law n. 7,802 of July 11, 1989, and in items II and X of art. 2, as well as in art. 68 and 69 of Decree n. 4,074 dated January 4, 2002 and considering the need to establish acceptable maximum limits for toxicological and environmentally relevant impurities present in agrochemicals, their components and the like, RESOLVE: Article 1 To approve the regulation that establishes the maximum limits of the relevant impurities to be investigated in the studies of five batch and controlled after registration, and gives other measures. Article 2 This Normative Instruction applies to applicants and holders of registration of technical products, premixtures and formulated products. §1 Technical products under registration must demonstrate compliance with the maximum limits established in the Annex of this Normative Instruction.

§2 The holders of registration of technical products, premixtures or formulated products must guarantee the maximum limits of relevant impurities stipulated in the Annex of this Normative Instruction.

Article 3 For the purpose of this Normative Instruction, any impurities that, in comparison to the active ingredient, may produce a significant toxic adverse effect on health or the environment are considered relevant impurity.

§ 1 An impurity that occurs in two different active ingredients may be considered as relevant to one and non-relevant to the other, or have different acceptable maximum limits for different active ingredients.

§2 The effects of acute oral toxicity, skin or ocular corrosion / irritation, skin sensitization, mutagenicity, carcinogenicity, reproductive toxicity or other toxicological or ecotoxicologically significant effects are considered to be toxic adverse effects of the relevant impurities.

§ 3 Impurities of toxicological or ecotoxicological concern are those impurities structurally similar to the substances or classes of substances listed in the Annex, requiring a technical evaluation, based on additional data, to consider them as relevant impurities.

Article 4 The holders of registration of technical products produced in the country or imported and of premixes and formulated products imported, based on active ingredients listed in the Annex, shall guarantee:

I - that the sampling is carried out lot by lot and is statistically representative of the quantities produced or imported, not being accepted the sampling methodology composed of more than one batch or batch; and

II - that the analyzes for the control of the relevant impurities are conducted with traceability and making use of appropriate parameters and methods.

Single paragraph. The collection and sampling methodologies will be subject to specific regulation.

Article 5 The analyzes for the control of the relevant impurities must be carried out with the technical product.

Paragraph 1 By means of justified justification, the analyzes may be carried out in the premix or in the formulated product, when imported or when it is an integrated production, and the results must be expressed according to the quantity of technical product.

Paragraph 2 When the analyzes are carried out outside the quality control unit of the manufacturer of the product, they must be carried out by an accredited laboratory in the ABNT NBR / IEC 17025, ISO 17025 or in Good Laboratory Practices - GLP, by the National Institute of Metrology, Quality and Technology - INMETRO, with valid certificate, considering the tests carried out.

Article 6 Certificates of analysis shall contain the following items:

I - batch or batch identification, date of manufacture, validity;

II - name and address of the manufacturer;

III - content of active ingredient and the relevant impurity (s), with their respective limits established in the Annex of this Normative Instruction;

IV - identification of the analytical method (s) used, with their respective quantification limits, for both active ingredient and impurity (s);

V- name and address of the laboratory where the analyzes were carried out;

VI - dates of receipt of the sample by the laboratory and date of the analysis and

VII - names, functions and signatures of the persons responsible for issuing the certificate.

Single paragraph. All analysis certificate information shall be readily identifiable and traceable, including data imputed directly to computer systems.

Article 7 The certificates of analysis must be kept vernacular under the custody of the holders of registration of the products.

Paragraph 1 When requested, registrants must present the raw data of the analyzes.

Paragraph 2 Certificates of analysis and their raw data must be finalized and available for inspection within 30 (thirty) days of the date of production in the country or importation (clearance), remaining under the custody and control of the holders of the registration for the minimum period of five (5) years.

Article 8 The registration holder shall maintain control over the destination of each lot or batch of the technical product or formulated, produced or imported, including the identification of the companies for which the product has been supplied, and this data shall remain at the disposal of the authorities for a period of at least five (5) years, counted from the date of local manufacture or importation (clearance).

Article 9 It is the responsibility of the owner of the registration to guarantee the quality of the control of impurities in the product, even when the manufacture, production, manipulation or importation of the product is performed by third parties.

Paragraph 1 The batch or batch of technical product, premix or formulated product based on active ingredient listed in the Annex to this INC may only be used or marketed after confirmation that the relevant impurity is within the limit established in this standard.

Paragraph 2 If the results of the analyzes of the imported lots indicate any relevant impurity above the maximum permitted limit, it is the responsibility of the registration holder to proceed with the appropriate measures for the return of the product.

Paragraph 3 In case the results of the analyzes of the batches produced in the country indicate any relevant impurity above the maximum permitted limit, the holder of the registration must:

I - promote preliminary investigation, including the evaluation of the need for the application of precautionary measures and corrective actions;

II - adopt measures, according to its own procedure, for the treatment of non-compliance or disposal, as the case may be; and

III - to keep all the documents related to the procedure used, for a period of five years, from the date of execution of the procedure.

Article 10 The Annex of this Normative Instruction will be updated whenever other impurities relevant to the establishment of their respective maximum limits are identified.

Paragraph 1 Relevant impurities identified in products based on new active ingredients shall have their maximum limits defined in the registration process until their forecast is expressed in an update of the Annex of this Normative Instruction.

Paragraph 2 In the case of identification of new impurities relevant to products based on active ingredients already registered, these should be controlled according to the maximum limit already established by recognized national or international organisms,

	until updating of the Annex of this Normative Instruction. Article 11 Non-compliance with the provisions contained in this Normative Instruction constitutes an infraction, without prejudice to the applicable civil, administrative and penal liabilities. Article 12 This Normative Instruction shall enter into force within thirty (30) days after the date of its publication and revokes Normative Instructions No. 2 of June 20, 2008 and No. 2 of August 15 2014.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** Protection of Human Health
8.	**Relevant documents:** Brazilian Official Journal, 14 June 2018 (Diário Oficial da União de 14 de Junho de 2018); (3) Brazilian Official Journal (Diário Oficial da União); (4) Not stated
9.	**Proposed date of adoption:** On the date of its publication **Proposed date of entry into force:** 30 days after its publication
10.	**Final date for comments:** 20TH July 2018
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:** 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://portal.anvisa.gov.br/documents/10181/4537751/Minuta+da+Consulta+P%C3%BAblica+534-2018.pdf/86d05e06-d33c-4860-bbdf-fdd25252d1e1