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Agency: Ministry of Health / Brazilian Health Regulatory Agency (ANVISA) / Collegiate Board

ANVISA COLLEGIATE BOARD RESOLUTION NO. 1,047, OF NOVEMBER 5, 2026

Revokes Collegiate Board Resolution (RDC) No. 184, of October 17, 2017, and establishes transitional rules.

The COLLEGIATE BOARD OF THE BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA), in exercise of the powers conferred upon it by Article 15, items III and IV, in conjunction with Article 7, items III and IV, of Law No. 9,782, of January 26, 1999, and Article 187, item VI, paragraphs 1 and 3, of the Internal Rules approved by Collegiate Board Resolution (RDC) No. 585, of December 10, 2021, hereby resolves to adopt the following Collegiate Board Resolution, as decided at the meeting held on October 29, 2026, and I, the Director-President, order its publication.

Article 1. Collegiate Board Resolution (RDC) No. 184, of October 17, 2017, published in the Official Gazette of Brazil No. 201, of October 19, 2017, Section 1, page 29, which provides for the simplified procedure for toxicological evaluation for registration and post-registration amendments concerning technical products, premixes, pesticides, related products and wood preservatives, is hereby revoked.

Sole paragraph. Consequently, the Toxicology Petitioning System (SIPTOX) is discontinued.

Article 2. Applications submitted under the simplified procedure provided for in Collegiate Board Resolution (RDC) No. 184, of October 17, 2017, that are awaiting evaluation by ANVISA shall be evaluated in accordance with the legislation in force applicable to the type of product.

Sole paragraph. As from the publication of this Resolution, companies shall arrange for and submit the studies required under the applicable legislation, without awaiting prior notification and without prejudice to any additional requirements imposed by ANVISA during the evaluation.

Article 3. Companies whose applications have already been evaluated and approved by ANVISA under Collegiate Board Resolution (RDC) No. 184, of October 17, 2017, shall submit the Letter of Authorization for the Use of Technical Data from Toxicological Studies, in accordance with the template in the Annex to this Resolution, upon migration of the applications to the Unified Information, Petitioning and Electronic Evaluation System (SISPA), or upon the first application for a post-registration amendment, whichever occurs first.

Paragraph 1. Applications submitted under the simplified procedure shall be migrated to SISPA in accordance with the guidelines, responsibilities and procedures governing the implementation and operation of that System.

Paragraph 2. If a post-registration amendment requiring ANVISA evaluation is requested before authorization for migration to SISPA, the Letter of Authorization shall be submitted to ANVISA together with the documents required by the other regulations applicable to the

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specific product.

Paragraph 3. Toxicological evaluations approved under the simplified procedure shall remain valid and effective under the terms approved at the time they were granted, with submission of the Letter of Authorization being the only additional requirement.

Article 4. Companies that do not wish to maintain a registration following the termination of the simplified procedure shall request voluntary withdrawal through the Solicita system, using subject code “5075 - Voluntary withdrawal of petition/application”, and shall provide a copy of the filing receipt for the registration cancellation request submitted to the registering authority.

Article 5. Failure to comply with the requirements established in this Resolution shall result in rejection of the application or cancellation of the approval of the respective toxicological evaluation.

Article 6. This Resolution enters into force on the date of its publication.

LEANDRO PINHEIRO SAFATLE

Director-President

ANNEX

LETTER OF AUTHORIZATION FOR THE USE OF TECHNICAL DATA FROM TOXICOLOGICAL STUDIES FOR APPLICATIONS WITH TOXICOLOGICAL EVALUATIONS APPROVED UNDER THE SIMPLIFIED PROCEDURE

To

Brazilian Health Regulatory Agency - ANVISA

The companies identified below:

Company holding the original primary application

Corporate Name: _____

CNPJ (Brazilian Corporate Taxpayer ID): _____

and

Company holding the application evaluated under the simplified procedure for toxicological evaluation of technical products, premixes, pesticides, related products and wood preservatives

Corporate Name: _____

CNPJ (Brazilian Corporate Taxpayer ID): _____

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Hereby declare, for all due purposes, that the application evaluated under the simplified procedure, ANVISA case number: _____, MAPA/IBAMA registration: _____, previously linked to the original primary application, ANVISA case number: _____, MAPA/IBAMA registration: _____, has been formally unlinked.

The company holding the original primary application, in its capacity as the owner of the studies and technical data, declares that it authorizes the company holding the application evaluated under the simplified procedure to use and reference, in its regulatory proceedings before ANVISA, MAPA and IBAMA, the studies and technical data owned by it relating to the following product:

Product / Active Ingredient: _____

This authorization entails the granting of rights to use the data and access to the information by the company holding the application evaluated under the simplified procedure.

This authorization is intended exclusively for the regulatory use of the aforementioned studies and technical data for the purpose of supporting the relevant registration application, post-registration amendments or technical evaluations before the competent regulatory authorities in Brazil.

The signatory companies acknowledge that, as of this date, there is no longer any technical, documentary or regulatory dependency between the aforementioned applications, without prejudice to the provisions of this authorization for the use of data.

Place and Date: _____

Company Holding the Original Primary Application

Legal Representative: _____

Position: _____

CPF (Brazilian Individual Taxpayer ID) No.: _____

Signature (digital): _____

Company Holding the Application Evaluated Under the Simplified Procedure

Legal Representative: _____

Position: _____

CPF (Brazilian Individual Taxpayer ID) No.: _____

Signature (digital): _____

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