

GENERAL ACTS OF ANVISA

Brazilian Health Regulatory Agency Collegiate Board Resolution No. 998, of November 21, 2025

MINISTRY OF HEALTH

BRAZILIAN HEALTH REGULATORY AGENCY

COLLEGIATE BOARD

BRAZILIAN HEALTH REGULATORY AGENCY COLLEGIATE BOARD RESOLUTION No. 998, OF NOVEMBER 21, 2025

Establishes guidelines for the risk assessment of exposure of operators, workers, residents and bystanders to pesticides, environmental control products, related products and bioinputs for phytosanitary use.

Note: This Resolution enters into force on June 1, 2026.

The Collegiate Board of the Brazilian Health Regulatory Agency, in the exercise of the authority conferred upon it by Article 15, items III and IV, together with Article 7, items III and IV, of Law No. 9,782, of January 26, 1999, and Article 53, item VI, paragraphs 1 and 3, of the Internal Rules approved by Collegiate Board Resolution No. 585, of December 10, 2021, resolves to adopt the following Collegiate Board Resolution, as decided at the meeting held on November 19, 2025, and I, the Director-President, order its publication.

CHAPTER I

INITIAL PROVISIONS

Article 1. This Resolution establishes guidelines for the risk assessment arising from exposure to pesticides, environmental control products, related products and bioinputs for phytosanitary use of:

I – operators and workers engaged in occupational activities involving contact with these products; and

II – residents and bystanders in areas treated with these products.

Paragraph 1. Physical process agents and products of biological origin whose active ingredient is a microorganism, biological control agent or semiochemical are excluded from the scope of this Resolution.

Paragraph 2. The provisions of this Resolution shall only apply to products of biological origin whose active ingredient is a biochemical or plant-based product when reference values have been determined, considering their specific characteristics and the provisions of the applicable legislation.

Article 2. For the purposes of this Resolution, where specific legislation or guidelines apply, they shall be observed, and the respective proof of compliance shall be submitted.

Sole paragraph. In cases not covered by this Resolution, or where the requirements established herein are not fully met, Anvisa may, at its discretion and upon technical justification, require the submission of additional tests and documents.

Article 3. For the purposes of this Resolution, the following definitions shall apply:

I – dose-response assessment: analysis of the relationship between the concentrations or doses of the active ingredient administered to an organism, system or population and the incidence of adverse effects resulting from such administration;

II – risk assessment: scientific and systematic characterization of the nature and magnitude of human health risks resulting from exposure to certain substances or products, the process of which includes hazard identification, dose-response assessment, exposure assessment and risk characterization;

III – risk characterization: process of combining hazard, dose-response and exposure assessments to determine the probability of adverse effects of an active ingredient of a pesticide, environmental control product or related product occurring in an individual or population under specific exposure conditions;

IV – exposure scenario: theoretical situation assumed for exposure to pesticides, environmental control products or related products, determined by the crop and size of the treated area, formulation type, use pattern, dose, application equipment and the activity performed or condition of the individual, such as age, location in relation to treatment, use of personal protective equipment or any other variable that may alter the level of exposure;

V – transfer coefficient (TC): rate at which dislodgeable foliar residues may be transferred to a worker during a specific activity, expressed in terms of the area of treated foliage or fruit from which residues are transferred per hour (cm²/h);

VI – dissipation or half-life (DT50): time required, in days, for the concentration of residues of the pesticide, environmental control product or related product on foliage or fruit to be reduced by half;

VII – personal protective equipment (PPE): device or product for individual use by the operator or worker, designed and manufactured to provide protection against occupational risks existing in the work environment;

VIII – hazard identification: stage in which the type and nature of the adverse effects that the pesticide may potentially cause to an organism, system or population are assessed, based on its intrinsic properties;

IX – risk mitigation measures: any measure intended to reduce exposure levels to pesticides, environmental control products or related products during their application, handling and use, such as personal protective equipment, water-soluble packaging, tractors with closed cabins, drift-reduction technologies, visual warnings, closed mixing and loading systems, among others;

X – Acceptable Operator Exposure Level (AOEL): reference value derived from toxicological studies used for comparison with exposure to pesticides, environmental control products or related products, corresponding to the estimated amount of substance to which an individual

may be exposed daily without presenting adverse health effects, expressed in milligrams of substance per kilogram of body weight per day (mg/kg bw/day);

XI – Acute Acceptable Operator Exposure Level (AAOEL): reference value derived from toxicological studies used for comparison with acute non-dietary exposure to pesticides, environmental control products or related products, corresponding to the estimated amount of substance to which an individual may be exposed on a single day without presenting adverse health effects, expressed in milligrams of substance per kilogram of body weight (mg/kg bw);

XII – operators: individuals involved in activities related to the application of pesticides, environmental control products or related products, including mixing and loading of equipment and application, or activities related to cleaning and maintenance of equipment used in such activities;

XIII – Point of Departure (POD): numerical value obtained from a point on a dose-response curve derived from toxicological studies and available epidemiological data for the identification of the critical endpoint;

XIV – residents: individuals who live or are regularly present near areas treated with pesticides, environmental control products or related products, without the purpose of working in the treated area or with the treated crop;

XV – dislodgeable foliar residue (DFR): amount of residue of a pesticide, environmental control product or related product after deposition on foliage or fruit that may be transferred to a person through contact;

XVI – re-entry workers: individuals who, as part of their work, enter an area previously treated with pesticides, environmental control products or related products, or who handle the treated crop; and

XVII – bystanders: individuals who occasionally pass near treated areas, without the purpose of working in such areas or with the treated crop.

CHAPTER II

SUBMISSION OF THE OCCUPATIONAL RISK ASSESSMENT DOSSIER FOR RESIDENTS AND BYSTANDERS EXPOSED TO PESTICIDES (DAROC)

Article 4. Companies holding registrations of pesticides shall submit the Occupational Risk Assessment Dossier for Residents and Bystanders exposed to pesticides, environmental control products or related products (DAROC) for each of their formulated products, in accordance with the model set out in a specific guideline published by Anvisa.

Paragraph 1. The DAROC shall contain detailed information on the risk assessment conducted, allowing Anvisa to verify all exposure scenarios under the proposed conditions of use of the product.

Paragraph 2. Submission of the DAROC is mandatory for each active ingredient with an Acceptable Operator Exposure Level (AOEL) established in the respective monograph.

Paragraph 3. In the case of formulated products containing more than one active ingredient, submission of the DAROC shall become mandatory upon establishment of the first AOEL value in a monograph, and the process shall subsequently be supplemented as AOEL values for the remaining active ingredients are published.

Article 5. For the assessment of occupational risk and risk to residents and bystanders, the calculator made available on Anvisa's website shall be used, as it is indicated as the most representative of Brazilian exposure scenarios.

Paragraph 1. The DAROC submitted to Anvisa shall contain the report generated by the calculator referred to in the main provision of this Article, except for exposure scenarios not covered by the calculator.

Paragraph 2. Where the exposure scenario is not covered by the calculator, the company shall submit the calculation record together with a technical justification for the choice of each parameter used.

CHAPTER III

GUIDELINES FOR RISK ASSESSMENT

Section I

Hazard identification and dose-response assessment

Article 6. Hazard identification and dose-response assessment shall include determination of the Point(s) of Departure (POD) and uncertainty factors for establishment of the Acceptable Operator Exposure Level (AOEL) and, where appropriate, the Acute Acceptable Operator Exposure Level (AAOEL), for the assessment of risk to operators and workers, residents and bystanders, in accordance with a specific guideline published by Anvisa.

Paragraph 1. The values related to the AOEL and, where appropriate, the AAOEL may be reviewed based on updated technical and scientific data.

Paragraph 2. The AOEL and, where appropriate, the AAOEL shall be established in a monograph, following the procedures set out in Collegiate Board Resolution No. 571, of October 15, 2021, or any updates thereto.

Paragraph 3. In the case of an application for registration of a product containing an active ingredient not yet registered or authorized in Brazil, the applicant company shall submit the proposed AOEL values and, where appropriate, AAOEL values, in order to allow submission of the DAROC under the terms of this Resolution.

Section II

Exposure assessment and risk characterization

Subsection I

Assessment of occupational, resident and bystander exposure

Article 7. The estimation of occupational, resident and bystander exposure shall be carried out based on an appropriate calculation method defined by Anvisa, using data representative of Brazilian agricultural practices, allowing assessment of the likely level of individual exposure in the identified exposure scenarios.

Paragraph 1. For scenarios not covered by available models, specific exposure studies may be submitted or exposure estimates obtained from similar scenarios may be adopted, at Anvisa's discretion.

Paragraph 2. Where paragraph 1 of this Article cannot be complied with, or in the absence of technical justification, the proposed scenario shall be excluded from the indications of use of the product under assessment.

Article 8. When the AOEL and AAOEL are established based on an oral-route study, the specific dermal absorption rate for the formulated product under assessment shall be considered for the purpose of estimating dermal exposure.

Sole paragraph. In the absence of specific studies, studies conducted with other formulations, concentrations and dilutions, or default dermal absorption values, may be submitted, provided that an argument is presented to justify the dermal absorption estimate.

Article 9. The average body weight of the operator, worker, residents and bystanders shall be defined based on data that best represent this population.

Sole paragraph. Where there are specific toxicity concerns, duly motivated and technically substantiated, body weight values that ensure protection of the most sensitive population shall be used.

Article 10. The inhalation absorption rate shall be considered as 100%, unless there is a duly substantiated technical justification for adopting another value, to be assessed by Anvisa.

Article 11. The maximum area treated per working day shall be defined by Anvisa, based on data that best represent each scenario.

Sole paragraph. In exceptional situations, the adoption of different values shall be technically justified and submitted to Anvisa for assessment.

Article 12. For assessment of exposure and risk to workers, specific data on Dislodgeable Foliar Residue (DFR), Turf Transferable Residue (TTR), Dislodgeable Boll Residue (DBR), Transfer Coefficient (TC) or dissipation or half-life (DT50) shall be used.

Sole paragraph. In the absence of data from specific studies, corresponding default values shall be used.

Subsection II

Characterization of occupational risk, risk to residents and risk to bystanders

Article 13. For risk characterization in each occupational, resident and bystander exposure scenario, the estimated exposure for each scenario shall be compared with the AOEL and, where appropriate, the AAOEL.

Sole paragraph. Scenarios in which the estimated exposure exceeds the AOEL reference values and, where appropriate, the AAOEL, after considering the possibilities for refinement of the exposure assessment and technically feasible risk mitigation measures, as provided in a specific guideline, shall not be approved.

Section III

Risk mitigation measures

Article 14. The risk mitigation measures most appropriate to the exposure conditions that present an acceptable risk shall be included in the label and package insert.

Paragraph 1. The PPE indicated in the package insert shall consider the results of both the acute and subchronic risk assessment and the hazard assessment, in accordance with a specific guideline published by Anvisa.

Paragraph 2. The indicated mitigation measures shall be consistent with the actual conditions of product use and with the availability and feasibility of engineering measures and PPE for the assessed scenario.

Paragraph 3. Where the adoption of risk mitigation measures is not plausible, or where such measures are deemed insufficient, Anvisa shall define the use restrictions necessary to ensure the protection of the health of exposed individuals.

CHAPTER IV

TRANSITIONAL AND FINAL PROVISIONS

Article 15. The procedures for establishing AOEL and AAOEL and the parameters related to exposure assessment for the risk assessment of the products covered by this Resolution shall be defined in specific guidelines and manuals published by Anvisa.

Article 16. For applications for registration of products containing active ingredients not yet registered or authorized in Brazil, and for applications for registration and amendment of registration of products containing active ingredients authorized in Brazil and with AOEL and AAOEL values established in a monograph by the date this Resolution enters into force, the DAROC shall be filed as of the effective date of this Resolution.

Article 17. For applications for registration and amendment of registration of products containing active ingredients authorized in Brazil and without AOEL and AAOEL values established in a monograph by the effective date of this Resolution, submission of the DAROC shall become mandatory as of the publication date of the Normative Instruction establishing the AOEL and, where appropriate, the AAOEL in a monograph.

Paragraph 1. Submission of the DAROC referred to in the main provision of this Article shall be accompanied by the declaration set out in Annex I to this Resolution.

Paragraph 2. The declaration referred to in paragraph 1 of this Article shall certify that, in the assessment conducted for occupational risk and risk to residents and bystanders, the estimated exposure does not exceed the AOEL reference values and, where appropriate, the AAOEL.

Paragraph 3. The risk assessment submitted shall take into account the possibilities for refinement of the exposure assessment and technically feasible risk mitigation measures, in accordance with a specific guideline published by Anvisa.

Article 18. At the time of technical analysis of the applications provided for in Articles 16 and 17 of this Resolution, failure to submit the DAROC for each active ingredient in the formulation, where mandatory, shall result in suspension of the process until it is duly submitted.

Article 19. For products already registered and based on active ingredients with AOEL and, where appropriate, AAOEL established under the terms of this Resolution, the registrant company shall conduct the risk assessment for all approved scenarios.

Paragraph 1. If scenarios provided for in the sole paragraph of Article 13 of this Resolution are identified, the company shall file the necessary registration amendments for implementation of additional risk mitigation measures, under penalty of revocation of Anvisa's decision.

Paragraph 2. The declaration provided for in Annex I to this Resolution shall be filed as an amendment, together with the respective DAROC, within a maximum period of 12 months, counted from the publication date of the Normative Instruction establishing the AOEL in a monograph.

Paragraph 3. In the case of a registered product containing more than one active ingredient, when more than one AOEL is established within the period referred to in paragraph 2 of this Article, the final deadline for submission of the DAROC shall be counted from the publication date of the most recent Normative Instruction, and the process shall be supplemented as subsequent Normative Instructions are published.

Paragraph 4. The deadline set out in paragraph 3 of this Article shall not apply in the case of identification of scenarios provided for in the sole paragraph of Article 13.

Paragraph 5. For registered products containing active ingredients authorized in Brazil whose AOEL and AAOEL values have been established in a monograph by the effective date of this Resolution, the deadline provided for in paragraph 2 of this Article shall be counted from the effective date of this Resolution.

Paragraph 6. In the case of identification of a scenario provided for in the sole paragraph of Article 13 of this Resolution, the product registration amendment shall be filed within a maximum period of 12 months, counted from the publication of the Normative Instruction establishing the AOEL and AAOEL values in a monograph.

Paragraph 7. Failure to submit the documentation under the terms of this Article may result, at any time, in review of Anvisa's decision.

Paragraph 8. Where the result of the risk assessment indicates the need for a registration amendment, the registration holder shall be required to make the necessary changes to product labels and package inserts within 12 months, counted from the publication date of the authorization of the amendment by the registering authority.

Article 20. The deadlines for submission of the DAROC for products containing active ingredients under re-evaluation shall follow the procedures published under Collegiate Board Resolution No. 221, of March 28, 2018, or any legislation that may replace it.

Article 21. Failure to comply with the provisions of this Resolution constitutes a sanitary infraction, subjecting the offender to proceedings and penalties provided for in the legislation in force, without prejudice to applicable criminal and civil liability.

Article 22. This Resolution enters into force on June 1, 2026.

Rectified, January 2, 2026 – Section 1

LEANDRO
Director-President

PINHEIRO

SAFATLE

ANNEX I

Declaration regarding occupational, resident and bystander exposure to pesticides, environmental control products or related products under Collegiate Board Resolution No. 998, of November 21, 2025

Trade name:

Product registration No. (where applicable):

Corporate name of the registrant company:

Corporate Taxpayer Registry No. (CNPJ):

Process No.:

Case file No.:

Monograph(s):

Active ingredient(s) assessed:

Publication date(s) of the Normative Instruction(s) establishing the AOEL and AAOEL values:

I hereby declare, for all due purposes, that the product _____ does not present scenarios in which the estimated exposure exceeds the AOEL reference values and, where appropriate, the AAOEL, after considering the possibilities for refinement of the exposure assessment and technically feasible risk mitigation measures, in accordance with the specific guideline relating to the active ingredient(s) _____ under the terms of Collegiate Board Resolution No. 998, of November 21, 2025.

I declare that the results of the risk assessment conducted correspond to the data contained in the Occupational Risk Assessment Dossier for Residents and Bystanders (DAROC) attached to this declaration.

I am aware that Anvisa may, at any time, based on technical assessment of the information provided, request additional information or adopt applicable measures in the event of identification of inconsistent information or information not in compliance with the procedures established in Collegiate Board Resolution No. 998, of November 21, 2025.

I declare that I have complied with the sanitary regulations on pesticides with respect to documentation and performance of the required studies, and that I undertake to maintain continuous monitoring to ensure the maintenance of essential safety and quality requirements for human health.

The company, through its legal and technical representatives, assures and assumes responsibility for the truthfulness and reliability of the information provided herein, being aware that it is responsible for the quality and safety of the product registered by it, ensuring that it is suitable for its intended purpose, complies with the requirements established in its registration and in Collegiate Board Resolution No. 998, of 2025; that any inconsistencies between the information provided herein and the pesticide registration process may result in a change to the decision; and that such inconsistencies constitute a sanitary infraction, subjecting the offender to proceedings and penalties provided for in the legislation in force, without prejudice to applicable criminal and civil liability.

Date: // _____

Name: _____

Signature (Technical Representative): _____

Signature (Legal Representative): _____

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This text does not replace the Official Publication.