ASSESSMENT OF EXPOSURE OF OPERATORS, WORKERS, RESIDENTS AND BYSTANDERS IN RISK ASSESSMENT OF PESTICIDES-

GUIDANCE NO. 84/2025 – VERSION 1

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ASSESSMENT OF EXPOSURE OF OPERATORS, WORKERS, RESIDENTS AND BYSTANDERS IN RISK ASSESSMENT OF PESTICIDES - GUIDANCE No. 84/2025 – VERSION 1[1]

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This Guidance expresses Anvisa's understanding of best practices in relation to procedures, routines and methods considered appropriate for compliance with technical or administrative requirements required by the legislative and regulatory frameworks of the Agency.[1]

It is a non-normative regulatory instrument, of a recommendable and non-binding nature, therefore possible to use alternative approaches to the propositions set out here in, provided that compatible with the requirements relating to the specific case. The failure to comply with the content of this document does not characterize a sanitary infraction, nor is it grounds for rejection of petitions, provided that the requirements required by the legislation are met.

The recommendations contained in this Guidance take effect from the date of its publication on the Anvisa Portal and are subject to receipt of suggestions from the society through an electronic form, available at https://pesquisa.anvisa.gov.br/index.php/934994?lang=pt-BR

The contributions[2] received will be evaluated and may support the revision of the Guidance and the consequent publication of a new version of the document. Regardless of the decision of the area, a general analysis of contributions and rational will be published that justifies the revision or not of the Guidance.

[1]Ordinance No. 162, of March 12, 2021, which establishes guidelines and procedures for improving regulatory quality at Brazilian Health Regulatory Agency (Anvisa).

[2] In order to ensure greater transparency to the process of drafting regulatory instruments edited by Anvisa, clarify that the names of those responsible for contributions (individuals and legal entities) are considered public information and will be made available unrestricted in the reports and other documents generated from the results of this Guidance. The e-mail and CPF of the participants, considered confidential information, will have their access restricted to legally authorized public agents and the persons to which such information refers, as recommended in article 31, Paragraph 1, item I of Law No. 12,527, of November 18, 2011. Other information that may be considered confidential by the participants may be attached in a specific field on the electronic form.

[1] Note from ProHuma: abbreviations used in equations have been kept in their original form (Portuguese). When an abbreviation for the same parameter in English is available, it was included in this document.

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1. SCOPE

This Guidance provides technical guidance on the process of assessing the exposure of operators, workers, residents, and bystanders to the active ingredients (a.i.) of pesticides, environmental control products, and related products. The objective of this Guidance is to indicate the fundamental principles of this assessment so that the methods, models, criteria and general parameters to be used and the information necessary for a more refined exposure assessment are clear, so that the risk assessment (RA) conducted for products registered in Brazil is representative of the Brazilian reality.

The publication of this Guidance ensures the transparency of the procedures established by Anvisa, in order to allow for greater alignment between the RA adopted by the Agency and that presented by the registering companies. The information presented in this Guidance reflects the most representative scenario of the Brazilian reality at this moment. Therefore, it is recommended that a justification containing scientifically based arguments be presented for the use of methods, models, criteria, or parameters different from those recommended.

It is important to explain that this Guidance aims to include the general procedure for non-dietary exposure assessment to pesticides, looking to approach the most important operator, workers, residents and bystanders exposure scenarios. Based on this assessment, mitigation measures can be adopted to protect the health of exposed individuals, such as the use of PPE in addition to those recommended based on the assessment of the hazard of the products.

However, specific characteristics of each product can lead to very specific assessments, that require special approaches. So, situations not included in this Guidance will be analysed on a case-by-case and the exposure assessment will be carried out based on the available technical and scientific justifications, always cherishing for alignment with internationally accepted guidelines and guidances and for the peculiarities of the scenarios for the use of pesticides in the country.

Due to the specificities that are expected to be found for some scenarios, of the Constant international updates on this topic and the expectation of progress in obtaining specific data for the Brazilian scenarios for the use of pesticide, this Guidance will be periodically revised as part of a continuous improvement process to enhance the representativeness of the national reality in the AR.

2. INTRODUCTION

In relation to human health, the approval of a pesticide registration in Brazil must be based on its intrinsic properties of damage to the organism and the risk to the exposed population associated with its use. To characterize the risk, it is necessary to know the toxicological characteristics of the a.i. and the exposure of people in real conditions of use. The knowledge about these conditions includes the type of equipment used, the crop or group of crops, the dose of application, the personal protective equipment, the size of the treated area and the type of activity performed by people exposed to the product. These conditions are grouped as exposure scenarios. In addition to occupational scenarios, it is important to be more comprehensive and also approach risk to residents and bystanders resulting from the application of pesticides.

The risk assessment of a pesticide begins with the identification of the hazard, by observing outcomes of toxicological relevance during the toxicological evaluation of AI. From the analysis of these studies, it is possible to determine the dose-response relationship of the relevant toxicological outcome and establish the reference doses that will be used to characterize the risk. The guidance lines for establishing reference doses are contained in a specific guidance on the subject. For risk characterization, the exposure value predicted for a certain population is compared to the derived reference doses.

The exposure prediction is based on generic exposure data obtained from observational studies conducted with formulated pesticide products in the field following Good Agricultural Practices (GAP) and internationally accepted guidance lines. The results of these studies compose an important database for exposure prediction of other pesticides without exposure studies available. The exposure prediction also depends on other parameters related to the exposure scenario, such as cutaneous absorption[2] of the product, population weight, crop characteristics, among others. These parameters are usually assigned default values for a more comprehensive risk assessment. However, specific data about the product used and the scenarios evaluated ensure a more representative assessment and can be used to refine the RA, provided that such refinement represents a more realistic and reliable version for the exposure estimate than the generic method.

When characterizing the risk, by comparing the reference doses with the predicted exposure, it is possible to manage it with the adoption of mitigation measures that ensure the protection of the populations health, such as: restrictions on the use of the product, the type and volume of packaging, the quantity sold, the types of application equipment recommended and the approved crops; recommendation for the use of specific PPE, adoption of closed systems or mandatory drift reduction technology, certification requirement for application, establishment of re-entry intervals, among others.

AR is conducted for all application equipment, modalities, and indications of product use. Within the same scenario, exposure assessment can only be performed for scenarios with higher exposure (higher dose and number of applications, and shorter intervals between applications), which encompasses the other scenarios with lower exposure, being considered the worst-case scenario.

Although RA was included in Brazilian legislation starting in 2002, occupational RA and RA for residents and bystanders began to be implemented at Anvisa in 2017, using the a.i. under revaluation as a starting point, to attend a demand arising from Public Consultations regarding the quantification of the risks of pesticides maintained in Brazil after toxicological reassessment. Initially, it was decided to carry out an overview of the RA for the a.i., using the worst scenarios for each crop among all registered products. American and European exposure prediction models were used, according to the adequacy of the database for scenarios in Brazil. These assessments were made by a.i. and, therefore, general risk mitigation measures were adopted for all products. Subsequently, the RA by product formulated was implemented, which made it possible to indicate specific mitigation measures for each of them.

The conduction of these first RA allowed the identification of data gaps, like absence of information on the treated areas, exposure values for specific scenarios in Brazil, cutaneous absorption studies and data to refine exposure, among others. Still, there was a need for improvement in the information included in the leaflet and the need to improve the indication of mitigation measures. Some of these limitations have been remedied and this Guidance already contemplates these advances. However, there are many challenges for the improving RA, such as obtaining exposure data for scenarios with

[2] Note from ProHuma: ANVISA has adopted the word 'cutaneous' instead of dermal.

great relevance for the country and the reformulation of the leaflet, to improve the communication of the risk to the exposed population.

Until the approval of the Resolution of the Collegiate Board - RDC nº 998, November 21, 2025, RA due to exposure to pesticides, in order to guarantee a low exposure, Anvisa opted for the recommendation of all PPE, even after conducting product RA reassessed. However, this practice of recommending PPE contributes to a mistaken perception of risk by product users and/or can cause extreme discomfort for operators, leading to discouragement of PPE use. The ideal is the recommendation of PPE in the product leaflet according to the results of the RA and hazard classification of each formulated product (Lichtenberg et al., 2015) and, therefore, that determination was established by the RDC nº 998/2025.

Nowadays, countries use different methods to assess non-dietary exposure to pesticides, the (i) American model being more widespread, based on average exposure units or medians of a sample, normalized by the amount of a.i. handled, and the (ii) European model, based on the statistical estimate of the 75th or 95th percentile of the theoretical or sample population.

Through Technical Cooperation Agreement No. 02/2020 between Anvisa and the Prohuma Institute (https://www.gov.br/anvisa/pt-br/acessoainformacao/convenios-etransferencias/2020/arquivos/1791json-file-1/view), a study was conducted on the methods, models, and parameters used in non-dietary risk assessments, and a calculator was developed that unifies the exposure data used in the American and European models until Brazilian data are generated, which will also be incorporated into the models used in the calculator. The calculator allows for the standardization and uniformity of risk assessments presented for registration or post-registration evaluations in Brazil, incorporating the recommendations of this Guidance.

The calculator and its manual, as well as the documents that supported its development, are available for download at the following link: https://www.gov.br/anvisa/pt-br/assuntos/agrotoxicos/avaliacao-dorisco-da-exposicao-ocupacional-residentes-e-transeuntes-aos-agrotoxicos.

The use of the calculator for the available scenarios is mandatory for registration, post-registration, and reanalysis assessments, as determined by RDC No. 998/2025. In cases where scenarios are unavailable in the calculator, this guidance presents the exposure assessment calculation methods, as well as the default values assumed for the calculations and exposure prediction. As stipulated in paragraph 1 of article 7 of RDC No. 998/2025, for scenarios not covered by the available models, specific exposure studies may be presented or exposure estimates obtained from similar scenarios may be adopted, at the discretion of Anvisa.

Furthermore, as defined in RDC No. 998/2025, a report must be filed with the RAs conducted by the registering companies or the registration holder for their product, according to the specifications of this Guidance, including the digital files of the calculators used with the exposure prediction simulations. It is important that this report describes and technically justifies all parameters used and deviations from this Guidance, including references and studies used as a basis.

When applicable, risk mitigation measures established through occupational, resident, and bystanders RA should be included in the product information leaflets, along with the recommended measures resulting from the hazard assessment. When it is not reasonable to adopt risk mitigation measures or when they are insufficient, the necessary usage restrictions should be adopted to ensure a safe level of exposure for the population of interest.

3. LEGAL BASIS

The regulatory standard that supports the considerations presented in this guidance is Law No. 14,785, of December 27, 2023 (Brazil, 2023); Decree 4,074, of January 4, 2022; RDC No. 998 of November 21, 2025 (ARO), RDC No. 294, of July 29, 2019 and RDC No. 295, of July 29, 2019 (Brazil, 2019ab), or other regulations that may replace them.

Law No. 14,785 of 2023, in paragraph 10 of its article 3, stipulates that a risk analysis will be carried out for the granting of registrations for new products, as well as for modifications in uses that imply an increase in dose, inclusion of a crop, application equipment, or in cases of re-analysis. In Chapter II, where the registration information is laid out, § 4º of article 4º reinforces the mandatory nature of risk analysis for granting registrations, which will support the risk management decision-making process (§ 10), as well as § 3º of article 4º establishes the prohibition of registering products with unacceptable risk, even with the implementation of risk management measures.

Occupational RA for residents and bystanders is one of the phases of risk assessment that includes non-dietary risk and is regulated by RDC No. 998 of November 21, 2025 (ARO), which provides guidance lines for the Assessment of Exposure and Risk of Operators, Workers, Residents and Bystanders to Pesticides. Article 7 of the aforementioned resolution - RDC states that the assessment procedures related to the Resolution must comply with the provisions of the specific Guidance.

4. EXPOSURE SCENARIOS FOR RISK ESTIMATION

For RA, an exposure scenario is a detailed and contextualized characterization of the conditions under which individuals from different population subgroups may be exposed to pesticides during or after the application of these products. This representation considers a number of factors, such as the characteristics of the exposed population (age, sex, body weight, height, body surface area, respiratory rate), the conditions of individual exposure, the type of pesticide used, the application equipment, and the agricultural practices employed.

By understanding the different scenarios, it is possible to estimate the dose of a.i. to which an individual will potentially be exposed; identify vulnerable groups; verify whether the mitigation measures to be implemented – for example, PPE recommendations – are sufficient to reduce exposure; and direct exposure prevention efforts to the highest-risk scenarios.

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

4.1 Exposed Population

For RA purposes, exposed populations are separated into four groups according to the context in which pesticide exposure occurs, namely: operators, re-entry workers, residents, and bystanders. Specific methodologies are used for each of these groups to estimate exposure, a topic that will be discussed later.

4.1.1 Operators

Operators are individuals involved in activities related to the application of pesticides, including mixing and loading equipment and application, or activities related to cleaning and maintaining the equipment used in these activities. For the purpose of defining scenarios, the activities of operators are divided into:

i. **Mixing and loading (M/L):** the stage in which the operator handles the concentrated product packaging to prepare the spraying mixture to be applied to the crop and fills the tank of the application equipment. For this activity, the main routes of exposure are: cutaneous (direct contact with the skin), respiratory (inhalation of particles and vapours), and ocular.

ii. **Application (A):** the stage in which the operator uses the application equipment to spread the mixture containing the pesticide on the crop to be treated. In this activity, the main routes of exposure are: cutaneous (contact with the spraying mixture during application), respiratory (inhalation of particles and vapours), ocular, and oral (accidental ingestion).

In evaluation operator exposure, it is necessary to consider that the same individual may perform mixing, loading, and application (M/L/A) activities. Therefore, the exposures resulting from each of these activities are added together so that the exposure estimate represents the real-world scenario. When relevant, the exposure estimate for these activities may be calculated individually.

4.1.2 Re-entry Workers

Re-entry workers are individuals who, as part of their work, enter areas previously treated with pesticides or who handle treated crops to perform activities related to crop management (harvesting, pruning, irrigation maintenance) and, consequently, come into contact with pesticide residues that have settled on surfaces. To understand the exposure of re-entry workers, it is important to consider:

i. Activity time: The duration of exposure is directly proportional to the amount of pesticide to which the worker will be exposed. The longer the worker remains in the treated area, the greater their exposure will be.

ii. Type of activity: Different agricultural activities require varying levels of contact with treated plants, contaminated soil, and equipment, which consequently alters the intensity and duration of exposure.

iii. Crop-related variables: The type of crop (size, density, and leaf characteristics), the plant's development stage, the density, and the planting method influence the distribution of pesticide residues on the plant and in the environment, consequently affecting how the residues are transferred from the crop surface to the worker.

iv. Variables related to the a.i.: A variety of physical, chemical, and biological factors determine the nature of the transformation, displacement, and dissipation of the residue in the treated field. These factors include volatilization, evaporation, hydrolysis, oxidation, photolysis, and biodegradation. The importance of each of these mechanisms depends on the structure of the a.i. and other factors related to the study site, such as the climatic conditions of the treated area.

v. Re-entry interval (RI): This is the time that must elapse between the application of the pesticide and the worker's entry into the treated area without the need to use PPE. This interval is directly related to the pesticide dissipation time, that is, the time required for the product to degrade until the remaining quantity in the environment is no longer relevant.

These variables are related and will be described in the section on calculating worker exposure.

4.1.3 Residents

Residents are individuals who live in or are regularly present near areas treated with pesticides, environmental control products, or similar substances, without the intention of working in the treated area or with the treated crop. Unlike the nature of the exposure of operators and workers, which stems from their work activity, residents are exposed to pesticides due to drift and surface deposits of the spray mixture.

Drift is the improper displacement of the application mixture outside the area to be treated. This drift can directly affect the population residing near the treated area, but it can also indirectly expose residents by settling on surfaces that may later come into contact with this population. Thus, the main routes of exposure for residents are inhalation, cutaneous contact, and oral contact. In this scenario, it is important to consider age, body weight, and behavior, which can reflect an increased exposure for children (hand-to-mouth or object-to-mouth contact).

4.1.4 Bystanders

Bystanders are individuals who occasionally pass through the vicinity of treated areas, without the intention of working in those areas or with the treated crop. The nature of exposure for bystanders is very similar to that of residents. However, because they remain near the treated areas for less time, acute exposure is more relevant for these individuals.

4.2 Formulated Product

The FP is the commercial product, that is, what can be purchased by rural producers from retailers and is the result of mixing one or more a.i. with other ingredients, such as adjuvants, solvents, and preservatives. This mixture or formulation, in most cases, needs to be diluted on the farm before application.

To estimate exposure and characterize occupational risk for residents and bystanders, it is necessary to know some of the physical-chemical characteristics of the FP and its a.i., namely: formulation type, physical state of the formulation, agronomic class, and a.i. of the formulation. This information must be submitted by the registering companies to DAROC and delivered completed in the file of the avaliAR calculator. The recommended model for DAROC is presented in Annex II.

The type of formulation and its physical state are relevant for cutaneous absorption, and its use is described in detail in item 5.2.4 regarding cutaneous absorption values of the FP.

Occupational RA for residents and bystanders of pesticides, requires the definition of a set of physicochemical and toxicological parameters relating to the FP and the a.i. for the prediction of exposure. Regarding the FP, it is necessary to know:

i. Composition: the FP may contain one or more a.i. in its composition at different concentrations. Each of these a.i. has its own physicochemical and toxicological characteristics, which are considered in the RA.
ii. Formulation type: the terminology used for pesticide formulation types is determined by NBR 12697:2004. The formulation type determines the form (powder, liquid, granules) and the precautions related to handling, application, and possible mitigation measures, consequently affecting the level of exposure and risk. Additionally, the formulation type influences the amount of active ingredient (a.i.) that can be absorbed by the individual's body through oral, inhalation, and cutaneous routes.

4.2.1 Active ingredient

The a.i. is the physical, chemical, or biological agent that confers effectiveness to pesticides. This guidance will only address chemical agents, i.e., chemical substances, considering that physical and biological risks are managed within the scope of other labor standards. The information on the a.i. necessary for the RA is:

i. Toxicity:

It is an intrinsic characteristic of the substance that determines its ability to cause harm to health, that is, it is the potential danger of the substance. The greater the toxicity of the a.i., the lower the individual's exposure must be for its use to be safe. To characterize the danger of the a.i., it is necessary to evaluate the dose-response from toxicological studies, which will allow describing the relationship between the amount of a.i. administered (the dose) and the intensity of the observed response (the effect) in an organism. In other words, it is the relationship between the amount of a.i. to which an individual is exposed and the effects that this exposure can cause.

Based on dose-response assessment, reference doses are defined for use in RA of operators, re-entry workers, residents, and bystanders: Acceptable Operator Exposure Level (AOEL), Acute Acceptable Occupational Exposure Level (AAOEL), and Acute Reference Dose (ARfD) in the specific case of assessing oral intake in children. The derivation of these reference doses is detailed in a specific guidance.

ii. Physicochemical Characteristics:

The estimation of exposure and characterization of occupational, resident and bystanders risks depends on knowledge of certain physicochemical information regarding the a.i. in the formulation, such as vapour pressure (Pa), molecular weight (g/mol), dissipation rate (DT50) in air (days), and the chemical form used in the studies from which the AOEL/AAOEL was derived. Recognized sources of information for this search include: https://commonchemistry.cas.org/, https://pubchem.ncbi.nlm.nih.gov/, or https://sitem.herts.ac.uk/aeru/ppdb/en/index.htm

Vapour pressure is important for estimating the average 24-hour vapour concentration that can be inhaled during application. According to the vapour pressure (at 20 or 25°C), the following default values for average inhaled vapour concentration are used (EFSA, 2022):

• For substances with low volatility, with vapour pressure < 0.005 Pa, the value of 1 $\mu g/m^3$ is used;

• For substances with moderate volatility, with vapour pressure between 0.005 Pa and 0.01 Pa, the value of 15 $\mu g/m^3$ is used;

• For substances with very low volatility (< 10^{-5} Pa) or very high volatility (>10^{-2} Pa), it is assumed as the worst case that the average inhaled vapour concentration can be calculated from the maximum vapour pressure (MVP), using the following calculation:

$$PMV = \frac{MM \ x \ PV}{(R \ x \ T)}$$

Where:

PMV = maximum vapour pressure (mg/m^3) (MVP)
MM = molecular mass of a.i. (g/mol)
PV = vapour pressure (Pa) (VP)
R = gas constant = 8.31451 J/mol x K
T = temperature = 293K (corresponding to 20°C)
Thus, we have:

$$PMV = 0,41 \ x \ MM \ x \ PV$$

The correct indication of the chemical form used in the toxicological studies that gave rise to the reference doses, for example, whether it was a salt or an acid equivalent, is relevant information for the correct calculation of exposure. The DT50 corresponds to the time required for the concentration of the a.i. to reduce to half its initial value. This value is obtained from experimental studies carried out in accordance with OPPTS guideline 875.2100 (USEPA, 2006), as well as other documents cited in the European Food Safety Authority (EFSA, 2022) guidance on occupational, resident and bystanders exposure assessment. Alternatively, default values can be used.

The default value for DT50 was set at 20 days, which corresponds to the 90th percentile of the EPA (2012), EFSA (2014, 2022), and Lewis and Tzilivakis (2017) datasets. The choice of the 90th percentile considered the non-normal distribution of the data, the high variability, and the uncertainties of the data.

4.3 Recommendation for Pesticides Use

All recommendations for the use of pesticides must be carried out in accordance with the Good Agricultural Practices (GAP) stated on the product leaflet and label insert. GAP is understood as the recommended safe use of pesticides and related products, regarding dose, concentration, number of applications, interval between applications, and safety interval for obtaining the desired effect, registered under legally established conditions for use in any phase of the production, transport, storage, processing, and distribution of food.

Therefore, occupational RA, for residents and bystanders considers not only the specific characteristics of the product, but also the procedures and context of handling and applying pesticides, which are also determinants of individual exposure.

One of the main factors influencing exposure to pesticides is the amount of product handled (mixing and loading) and applied. Thus, for RA it is necessary to consider the dose of the product, the number of applications and the mixture volume.

Additionally, the target application, the type of equipment used in the application, the environment (open or closed), and the expected surface coverage of the application significantly influence exposure.

4.3.1 Application Target

The ultimate target of a phytosanitary treatment is the pest that one wishes to control. However, not all applications of the spray mixture are carried out directly on the part of the plant where the pest is present, as this depends, among other factors, on the product's mode of action. Furthermore, treatment may be carried out only on parts of plants used for propagation, on stored products, or even for treating the soil or planting substrate. The case of herbicides for weed control must also be considered, where application occurs on plant species other than the cultivated one.

The following describes the variables related to the application target that directly or indirectly affect the level of exposure to pesticides.

4.3.1.1 Crop

Plant height and foliage density are relevant crop characteristics in exposure assessment.

i. Plant height: as well as the trellising method, plant height can determine whether the spray jet will be directed upwards (>50 cm) or downwards. It can also influence drift and the transfer coefficient (TC) of dislodgeable foliar residue (DFR) to the worker.

ii. Foliage density: for exposure estimation, foliage is considered dense when the applicator cannot avoid contact with the leaves or the crop where spraying occurs. Therefore, it is also necessary to consider the spacing between plants in the crop.

4.3.1.2 Soil

Soil applications can occur with or without the presence of the plant in the area. It can be carried out in the entire area or in directed applications.

4.3.1.3 Propagative Material

Applications to propagative material, seed or vegetative propagation occur in specific exposure scenarios and models. For seeds, local scenarios are defined, i.e., seed treatment carried out on the farm and the industrial scenario.

Considering the diversity of scenarios for vegetative propagation treatment – tray, soil, immersion – in the absence of specific models or studies, exposure will be estimated based on an analogous scenario.

4.3.1.4 Application Equipment

RA takes into account that the equipment used in the application will be calibrated and in operating condition within the technical specifications recommended for each situation. There is a wide variety of application equipment on the market with different levels of technology employed. They vary according to the mode of transport (ground or air), tank characteristics, size, engine, type of traction, cabin pressurization, air assistance in spraying, number and type of applicator nozzles, among others.

These characteristics, in addition to directly influencing exposure, define the area treated per day (COC[3]), which is the area (ha) potentially treated by a given piece of equipment in the use scenario in question in a working day (8 hours). The larger the area that can be treated, the more product will be handled, which may lead to greater exposure. However, to make the RA feasible, it is necessary to group these spraying equipment according to common characteristics.

It should be noted that for equipment not included in the calculator, the RA must consider equipment considered analogous in terms of application type, and the technical rationale must be submitted to DAROC.

Thus, equipment can be divided into ground-based and aerial.

Among the ground-based equipment are manual-knapsack equipment, stationary/semi-stationary manual equipment, tractor-mounted equipment, towed tractor-mounted

[3] Translator Note: from the Portuguese *Capacidade Operacional de Campo*

equipment, self-propelled tractor-mounted equipment, tractor-mounted turbo sprayer equipment, and irrigation equipment, whose definitions are described in the glossary.

Regarding aerial equipment, according to Gandolfo et al. (2020), considering the technical details involved in aerial spraying equipment that can influence the level of exposure to pesticides, the Brazilian market can be divided into two large groups: small-scale and large-scale. To make this distinction, the authors used the Ipanema EMB 202 (piston engine) as the most suitable representative for the small-scale group and the Air Tractor 502 F (turboprop) as the representative of large-scale aerial sprayers.

According to research on Brazilian agricultural scenarios (PROHUMA, 2024), there is no significant use of helicopters in the aerial application modality. However, there is significant indication of the use of drones, in addition to regulations from the National Civil Aviation Agency (ANAC) and the Ministry of Agriculture, Livestock and Supply (MAPA) that regulate this type of application.

4.3.2 Environment

Individual exposure to pesticides also depends on the application environment (open or closed). For the purposes of calculating exposure according to the method used and described in this Guidance and in the avaliAR calculator, a closed environment will be considered to be the treated area that has protective structures installed to alter the characteristics of the growing environment, even if the structure covers only one side of the environment and regardless of the material of the structure (type, color, transparency, etc.). This does not apply to windbreaks and hedges.

4.3.3 Application Coverage

It is also necessary to differentiate applications according to the type of coverage expected from the spraying. The application can be in total area or with a directed jet. In total area application, the pesticide is applied uniformly throughout the growing area, reaching both the area of the rows and the area between the rows. In directed jet application, the area coverage is partial, with the jet directed to a specific area (part of the plant, weeds between the rows) to increase the efficiency of the application. Thus, in directed application, it is possible to apply a smaller amount of product per area, while a larger amount of product is applied to the total area. Therefore, in each of these situations, the amount of pesticides to be handled and applied varies, which affects exposure.

5. EXPOSURE ASSESSMENT

5.1 Exposure Models

This step aims to estimate the amounts of a.i. to which different population groups may be exposed and, based on this data, compare it with reference doses to characterize the health risk to the exposed population.

Exposure prediction is performed using statistical models that allow predicting the potential amount of pesticide absorbed by the body based on the amount of pesticide that comes into direct or indirect contact with individuals. These models are based on data from observational studies conducted in accordance with the Guidance of

Organisation for Economic Co-operation and Development (OECD) for conducting occupational exposure studies (OECD, 1997).

The United States Environmental Protection Agency (USEPA) uses the Pesticide Handler Exposure Database – PHED/ Agricultural Handler Exposure Task Force – AHETF to assess operator exposure, which includes exposure data via inhalation and cutaneous routes, during pesticide mixing, loading, and application activities. In the PHED/AHEFT model, it is assumed that occupational exposure depends more on the application method, equipment, and formulation type than on the physicochemical properties of the a.i. In this model, exposure is considered proportional to the total a.i. handled, and exposure units are generated from sample central tendency values.

The model used by EFSA is based on 34 studies conducted between 1994 and 2009, including some from the PHED database (pesticides applied as granules). The exposure data obtained from these studies were used in statistical modelling through quantile regression to predict exposure for a theoretical population, resulting in six validated models for typical outdoor mixing/loading and application scenarios, using mounted tractor vehicles and manual equipment, with applications directed upwards or downwards. In this model, the 75th percentile of the theoretical population obtained from the statistical modelling is generally used.

Through Technical Cooperation Agreement No. 02/2020 between Anvisa and the Prohuma Institute, exposure data from studies used in American and European models were combined and statistically evaluated for use as generic data for predicting non-dietary exposure in Brazil. Furthermore, a calculator was developed which, in the future, may incorporate Brazilian data that are generated to complement the existing data.

Initially, aiming to support the assessment of occupational risk to residents and bystanders exposed to pesticides in Brazil, a Compatibility/Representativeness Assessment Study of International Agricultural Scenarios (North American – AHED and European – EFSA) with Brazilian Agricultural Scenarios of Occupational Exposure of Rural Workers (operators) was carried out within the scope of the aforementioned Cooperation, as well as the acquisition and permission to access international data/studies on Occupational Exposure of Operators to Pesticides.

Based on this initial study, priority was given to evaluating data from the scenarios of handling, loading and manual application of knapsack sprayers. Therefore, for these scenarios, the statistical modelling from the Anvisa and Prohuma Institute Cooperation (Brazil, 2025) was adopted. For the other scenarios, the European model was adopted, as it is considered the most appropriate, and, subsidiarily, the American model for scenarios not covered by the European model (Table 1).

Table 1 presents the models that should be used to assess operator exposure, according to scenarios commonly used for different types of pesticides. For scenarios not covered by the available models, specific studies necessary for conducting the exposure assessment must be presented. If there are no specific studies, the scenarios may be evaluated by adopting calculations from analogous and more restrictive scenarios, subject to technical justification to be assessed by Anvisa.

Table 1: Models used to predict exposure by type of spraying equipment and exposed population group.

Types of sprayers		Application	Mixing and Loading	Residents	Bystanders
Manual	Knapsack	Brasil (2025)		EFSA (2022)	
	Stationary/ Semistationary			EFSA (2022)	
Tractor	Mounted bar	AHETF (2020)[4]		EFSA (2022)	
	Turbo sprayer	EFSA (2022)		EFSA (2022)	
	Self-propelled	EFSA (2022)		EFSA (2022)	
Manned aircraft	Small size	AHETF (2020)		Unrealized*	
	Large size	AHETF (2020)		Unrealized*	
Unmanned aircraft	Drone	AHETF (2020)#		Unrealized*	

* Until exposure data is available, mitigation measures for residents and bystanders will be adopted in accordance with Normative Instruction No. 2, of January 3, 2008, and MAPA Ordinance No. 298, of September 22, 2021 (MAPA, 2008, 2021).

Until specific exposure data for drone application is not available, the assessment will be carried out considering analogous and more restrictive mixing and loading scenarios (liquid, dispersible granules or wettable powder) and application with an open-cab tractor boom, according to the exposure units for these scenarios obtained from AHETF (2020) and considering a FOC of 48ha/day.

Table 2: Models used for predicting exposure according to the type of application.

Application Type	Model
Immersion	Need for exposure study
Seed treatment	ExpoSAC SOP 14 (UESPA, 2022a), ExpoSAC SOP 15.2 (USEPA, 2022b)
Seed planting	
Application of solid formulations	EFSA, 2022

5.1.1 Calculations for predicting operator exposure

For calculating the daily subchronic or acute exposure of operators during mixing, loading and application, the following equation is used for each scenario:

$$EDT_{Mist.\ e\ Abast.\ ou\ Aplicação} = EDC + EDI$$

Where:

EDT = Total daily exposure (μg/kg bw/day).
EDC = Daily cutaneous exposure (μg/kg bw/day).
EDI = Daily inhalation exposure (μg/kg bw/day).

[4] Note from ProHuma: it will be requested to ANVISA to correct this and all similar entries to 'USEPA (2020)'

$$EDC\ ou\ EDI = \frac{UEC\ ou\ UEI_{Subcrônica\ ou\ Aguda}\ x\ TMA\ x\ COC\ x\ AC\ ou\ AI}{PC}$$

Where:

UEC = Cutaneous Exposure Unit (subchronic or acute), in µg/kg a.i.
UEI = Inhalation Exposure Unit (subchronic or acute), in µg/kg a.i.
TMA = Maximum Application Rate (kg a.i. /ha).
COC = Area treated per day (ha/day).
AC = Cutaneous Absorption (%).
AI = Inhalation Absorption (%).
PC = Body weight (BW) in kg (Adults combined: 72kg; Women: 69kg; Men: 75kg).

For the purpose of verifying the need to define risk mitigation, the total exposures of the mixing/loading and application scenarios are calculated individually and added together.

The exposure units used for the calculation and their references are available in the avaliAR calculator spreadsheet.

To calculate the daily exposure of operators during seed treatment and of workers during the planting of treated seeds, the COC/ Area treated per day value is replaced by the quantities of treated/planted seeds per day for each crop, as shown in Tables 13 and 15.

5.1.2 Calculations for predicting exposure of re-entry workers

RA of workers is not necessary for scenarios where significant exposure of this population is not expected, for example, after planting seeds, in the application of pesticides in the planting furrow and in the pre-emergence of crops (Table 6). For other cases not specified in Table 6, a technical justification must be presented.

The following equation is used to calculate the exposure of re-entry workers:

$$ECR = \frac{CT\ x\ RFD\ x\ TE\ x\ TAC\ x\ 0,001}{PC}$$

Where:

ECR: Daily Cutaneous Re-entry Exposure (mg a.i./kg b.w./day).
CT: Activity Transfer Coefficient (cm^2/h). (TC)
RFD: Dislodgeable Foliar Residue ($\mu g/cm^2$). (DFR)
TE: Activity Exposure Time (h/day).
TAC: Cutaneous Absorption Rate (% expressed as an absolute value) Example: 10% = 0.1.
PC: Body Weight in kg (Adults combined – 72kg; Women – 69kg; Men 75kg).
0.001: Conversion of µg (from DFR) to mg, making the final unit mg a.i./kg b.w./day.

Thus, to calculate worker re-entry exposure, it is necessary to use specific product values or generic data.

TC is the term used to describe the ratio between post-application exposure, exposure time, and the DFR of the contact surface for the worker. Conceptually, TC can be thought of as a “contact factor” that determines worker re-entry exposure and depends on how long they work and the activity being performed (Exposac, 2021).

To obtain the TC (Transfer DFR) of the activity, it is necessary to conduct observational or monitoring studies of the activities performed after application. Within ACT/Prohuma, data generated by the *Agricultural Re-entry Task Force* (ARTF), used by USEPA and EFSA, were acquired[5]. This data generated a publication proposing TC values for adoption in the assessment of exposure of re-entry workers, these values being generic for representative Brazilian activities and crops (PROHUMA, 2023).

These TC values have been incorporated into the evaluate calculator. Specific TC values based on studies can be presented when there is a need for refinement or lack of TC for the evaluated crop or activity. Furthermore, it is possible to present a proposal for a new grouping based on the similarity of activities and crop architecture in which greater exposure is expected (worst-case scenario).

The worker exposure data included in the avaliAR calculator were obtained using only workwear, and risk mitigation with the use of PPE is not possible. Therefore, as a mitigation measure, only an increase in the IR can be established. However, refinements to other parameters of the equation can also be used for more accurate RA.

When the need to establish an IR is not identified using the avaliAR calculator, it should be indicated in the product leaflet that the re-entry activity can be performed after the applied/sprayed mixture has dried.

A variety of physical, chemical, and biological factors determine the nature of the transformation, displacement and dissipation of the residue in the treated field. These factors include volatilization, evaporation, hydrolysis, oxidation, photolysis, and biodegradation. The importance of each of these mechanisms depends on the physicochemical characteristics of the a.i. and other factors related to the study environment, such as climate. Dissipation can be influenced by leaf size or plant growth stage.

The DFR study is conducted to determine the levels of pesticides that can be transferred to the worker as a result of contact with surfaces during the work routine after application. When the expected contact is with grass, this parameter is called Turf Transferable Residue (TTR), and when the contact is with cotton bolls, it is called Boll Transferrable Residue (BTR).

In the absence of specific experimental data, a default value for the initial DFR of 2.2 (µg/cm^2)/ (kg a.i. applied/ha) can be used, obtained from exploratory analysis of DFR data from ARTF studies and corresponding to the upper limit of the 95% CI.

The calculations used for DFR refinement and for IR determination are:

[5] Note from ProHuma: it will be requested to ANVISA to correct this paragraph, as no studies regarding reentry activities monitoring were acquired or accessed; the reference used in the publication from ProHuma, 2023, was USEPA ExpoSAC Policy 3 (dated March 2021).

$$\mathbf{RFD} = \boldsymbol{RFD_0 \, x \, e^{-k \, x \, d}}$$

Where:

RFD: Dislodgeable foliar residue (µg/cm^2).
RFD0=Dislodgeable foliar residue on day 0 (µg/cm^2), where
$RFD0 = TA \; x \; 2.5$
TA : Application Rate.
k: dissipation constant = In(2)/DT50.
DT50: 50% dissipation rate (days).
d: re-entry interval in days.

DFR0 can be obtained by multiplying the indicated application rate in kg a.i./ha by 2.5, which is an estimated value that considers that approximately 25% of the first applied rate may be dislodged from the leaf.

In the case of multiple applications of PF, the evaluation should consider the potential for DFR accumulation after successive treatments. Thus, a Multiple Application Factor (MAF) must be determined and included in the calculation of the nth application DFR.

$$\boldsymbol{RFD \; n_{ésima} = RFD_0 \; x \; FAM}$$

Where:

$RFD_{enésima}$ = Dislodgeable Foliar Residue after ‘n’ applications (µg/cm^2).
RFD0 = Initial Dislodgeable Foliar Residue or in the first application (µg/cm^2).
FAM = Multiple Application Factor. (MAF)
For the calculation of FAM:

$$\boldsymbol{FAM = \frac{1 - e^{-nki}}{1 - e^{-ki}}}$$

Where:

e = Euler's number (2.71828182845905...).
n = number of applications.
k = dissipation constant (In(2)/DT50).
i = shortest interval between applications (days).

When there is no specific experimental data for DT50 for the a.i., the default half-life value of 20 days is used.

The number of applications and the minimum interval, in days, between applications is relevant for assessing worker exposure. Therefore, if there is no mention of the minimum application interval, a one-day interval should be considered, which corresponds to the worst-case scenario.

The assessment should be conducted to cover re-entry activities of 8 (eight) hours of work. The risk found can be mitigated by calculating the number of days necessary to reduce exposure to levels below the appropriate reference value, thus determining the IR.

5.1.3 Calculations for predicting the exposure of residents and bystanders

Risk assessment is not required for residents and bystanders in scenarios where significant exposure of this population is not expected, for example, after planting treated seeds or applying pesticides in planting furrows. For other unspecified cases, a technical justification must be provided.

Total exposure for residents and bystanders is calculated by summing cutaneous and inhalation exposures, i.e., those originating from direct drift (cutaneous contact or inhalation), vapour, and surface deposits. For children, the latter includes, in addition to cutaneous contact, oral contact via hand-to-mouth and object-to-mouth.

The European model is adopted for estimating the exposure of residents and bystanders, using the parameters and calculations presented in the EFSA Guidance on Exposure Assessment for Operators, Workers, Residents and Bystanders (2022).

Although the European model includes exposure resulting from entering the treated area in the total exposures, this practice is not adopted by Anvisa (Brazilian Health Regulatory Agency), since agricultural properties are private (including the use of fences in some cases). Therefore, residents and bystanders should not have access to the treated areas. Given this, calculations for residents and bystanders are performed by summing the exposures, but without considering the exposure factor related to entering the treated area.

5.1.3.1 Drift Exposure

Subchronic or acute drift exposure according to the EFSA model is defined as:

$$\boldsymbol{Exposição}_{\boldsymbol{Residente\ ou\ Transeunte}} = \frac{[(\boldsymbol{ECP\ x\ TAC\ x\ (1 - FARL) + EIP\ x\ TAI)\ x\ (1 - EBRD) x\ CPD}]}{\boldsymbol{PC}}$$

Where:

ECP = Default Cutaneous Exposure (mL).
TAC = Cutaneous Absorption Rate (%).
FARL = Light Clothing Fit Factor (Adults: 18%; Children: 18%).
EIP = Default Inhalation Exposure (mL).
TAI = Inhalation Absorption Rate (%).
EBRD = Efficiency of Drift Reducing Nozzle, if applicable (50%).
CPD = Concentration of Diluted Product (g/L).
PC = Body Weight (in kg; Combined Adults: 70kg; Children: 12kg).

Default cutaneous exposure is calculated based on values obtained from the BREAM (Bystander and Resident Exposure Assessment Model), which is a model for estimating drift from agricultural sprayers (KENNEDY et al., 2012).

For cutaneous exposure, it is assumed that 1 mL of the drifting solution contains 1 mg of the active ingredient. When necessary, exposure values were adjusted considering respiratory rate and body surface area. The tables below show the default cutaneous and inhalation exposure values for subchronic (Table 3) and acute (Table 4) exposures.

Table 3: Default cutaneous and subchronic inhalation exposure in mL/person (75th percentile of potential cutaneous and inhalation exposure data corrected for respiratory rate)

Application method (distance from the sprayer)	Cutaneous		Inhalation	
	Adult	Child	Adult	Child
Tractor-mounted boom sprayer – Temporary crops (downward application)[1]				
2 m	0,47	0.33	0.00012	0.00016
5 m	0,24	0.22	0.00011	0.00012
10 m	0,20	0.18	0.00010	0.00010
Turbo sprayer – Perennial crops (upward application)[2]				
2-3 m	ND	NA	ND	ND
5 m	5,63	1.717	0.0021	0.00105
10 m	5,63	1.717	0.0021	0.00105
Based on the rationale for calculating default exposures, the values in gray are not influenced by body weight and respiratory rate and come directly from references 1. Kennedy et al., 2012; and 2. Lloyd et al., 1987. The other values were recalculated. ND= Data not available. *Source: Adapted from EFSA, 2022.*				

Table 4: Default acute cutaneous and inhalation exposure in mL/person (95th percentile of cutaneous and inhalation exposure data corrected for respiratory rate)

Application method (distance from the sprayer)	Cutaneous		Inhalation	
	Adult	Child	Adult	Child
Tractor-mounted boom sprayer – Temporary crops (downward application)[1]				
2 m	1.21	0.74	0.00060	0.00135
5 m	0.57	0.48	0.00058	0.00100
10 m	0.48	0.39	0.00062	0.00091
Turbo sprayer – Perennial crops (upward application)[2]				
2-3 m	ND	ND	ND	ND
5 m	12.9	3.93	0.0044	0.0035
10 m	12.9	3.93	0.0044	0.0035
Based on the rationale for calculating default exposures, the values in gray are not influenced by body weight and respiratory rate and come directly from references 1. Kennedy et al., 2012; and 2. Lloyd et al., 1987. The other values were recalculated. ND= Data not available. *Source: Adapted from EFSA, 2022.*				

For exposure calculations, the default values for diluted product obtained from the EFSA Cutaneous Absorption Guidance (2017) are used as the cutaneous absorption value or, in the case of refinement, the specific value from a cutaneous absorption study referring to the highest dilution of spray solution to be used.

In estimating the exposure of residents and bystanders, EFSA applies a light clothing adjustment factor, taking into account the protection provided by the minimal use of ordinary clothing. It is assumed that the torso represents 36% of the body surface area and that clothing provides 50% protection, with an 18% reduction for adults and children. This adjustment can only be applied to estimate the potential for cutaneous exposure from drift.

The use of a drift-reducing nozzle or other certified drift-reducing technology may be considered a risk mitigation measure to be included in the product leaflet. The use of a drift adjustment factor of 50% based on drift reduction is adopted by EFSA and Anvisa. The use of values higher than 50% depends on the presentation of additional studies.

This Guidance does not address a methodology for evaluating the exposure of residents and bystanders in the aerial application scenario, as Anvisa understands that it is still necessary to verify the representativeness of existing studies in relation to the Brazilian reality.

Until Anvisa adopts a risk assessment model for aerial application for residents, at a minimum, the measures determined by Normative Instruction No. 02, of January 3, 2008, from MAPA, must be followed, which determines that the aerial application of pesticides may only occur at a minimum distance of: (a) five hundred (500) meters from populated areas, cities, towns, neighbourhoods and water sources for supplying the population; (b) two hundred and fifty (250) meters from water sources, isolated dwellings and animal groups. The use of signal lights during the aerial application of pesticides is not permitted.

Furthermore, regarding drones, according to ANAC Ordinance No. 11,121/SAR, of April 24, 2023, operations must be carried out at a maximum distance of 1,000 (one thousand) meters from the remote pilot or observer. Also, according to MAPA Ordinance No. According to Decree 298 of 2021, aerial application by Remotely Piloted Aircraft (RPA) of pesticides and related products, adjuvants, fertilizers, inoculants, soil amendments and seeds with RPA is not permitted in areas located at a minimum distance of 20 (twenty) meters from settlements, cities, towns, neighbourhoods, isolated dwellings, animal groups, water catchment sources for population supply, including legal reserves and permanent preservation areas, as well as other environmental areas with minimum protection widths established in specific legislation, if they are not target areas of the application, and the distance restrictions contained in the recommendation of the product to be applied must also be respected, when applicable.

5.1.3.2 Vapour Exposure

According to the EFSA model, vapour exposure should be estimated using the method developed in the United Kingdom (CRD, 2008) and Germany (Martin et al, 2008), based on the highest time-weighted average exposure over a 24-hour period, according to the volatility of the a.i.:

$$\boldsymbol{EISR/T = (CV\ x\ TR\ x\ AI\ )/PC}$$

Where:

EISR/T = Systemic Inhalation Exposure of Residents/Bystanders (mg/kg b.w. day). (SERI)
CV or SVC = Vapour concentration (mg/m^3). (VC)
TR = Respiratory Rate (m^3/day). (IR)
AI = Inhalation Absorption (%) = 100% or 1. (IA)
PC = Body weight (kg; Combined adults: 70 kg; Children: 12 kg).

For moderately volatile compounds (vapour pressure ≥0.005 Pa or <0.01 Pa), exposure should be calculated assuming a default air concentration of 15 μg/m^3. For slightly volatile compounds (vapour pressure <0.0005 Pa), a default concentration of 1 μg/m^3 is assumed, resulting in the EISR/T values in Table 5.

Table 5: Default vapour exposure values to be used in calculations for assessing resident and bystanders exposure.

Vapour concentration (mg/m^3)	Residents			Bystanders		
	Population	Chronic inhalation rate (m^3/day)*	EISR (mg/kg bw/day)	Population	Acute inhalation rate (m^3/day)	EISR (mg/kg bw/day)
Moderately volatile						
0.015	Adult	16	0.00343	Adult	68.44	0.01466
0.015	Child	8	0.01	Child	54.72	0.06840
Low volatility						
0.001	Adult	16	0.00023	Adult	68.44	0.00098
0.001	Child	8	0.00067	Child	54.72	0.00456

* The value expressed in the table for the chronic inhalation rate (m^3/day) corresponds to the multiplication of the vapour concentration (0.23 mg/m^3 for adults; 0.67 mg/m^3 for children) by the corresponding default body weight (Adults combined: 70 kg; Children: 12 kg).
Source: *EFSA, 2022.*

5.1.3.3 Exposure from surface deposits

According to the EFSA model (EFSA Panel, 2010), cutaneous exposure from surface deposits resulting from spray drift is based on the following equation:

$$ESC_{(R\ ou\ T)} = \frac{RD\ x\ D\ x\ \ x\ CT_{R/T}\ x\ H\ x\ AC\ x\ (100\% - EBRD)\ x\ 0,001}{PC}$$

Where:

$ESC_{(R\ or\ T)}$ = Systemic exposure via the cutaneous route of residents or bystanders (mg/kg bw/day). (SERD)
RD = Dislodgeable residue (μg/cm^2), calculated by Application Rate x TTR0.
D = Drift (%), if multiple applications have been taken into consideration, a smaller percentage may be considered in risk refinement. Default drift values (%) for different scenarios can be found in Table 6.
TTR0 = Default value for TTR calculation ((μg/cm^2)/(kg a.i. applied/ha)), for products applied as liquids, use the value of 0.1 and for products applied as solids, granules 0.02.
$CT_{R/T}$ = Transfer coefficient for residents and bystanders (cm^2/h), default value of 7,300 cm^2/h referring to minimum clothing protection when the assessment is for residents and default value of 14,500 cm^2/h for adult bystander (EFSA PPR Panel, 2010). The values for children used the same approach, correcting the values by Brazilian estimates of body surface area for adults and children (5370 cm^2/ 17611 cm^2 = 0.304923059), resulting in 2,226 cm^2/h for resident children and 4,421 cm^2/h for bystander children.
H = duration of exposure (h), a value of 2h is assumed, as recommended by the USEPA.

AC = Cutaneous absorption (%), use the higher value observed between the concentrated and diluted product.
PC = body weight (kg; Combined adults: 70 kg; Children: 12 kg).

For calculations of estimated exposure from surface deposits for residents and bystanders, adults or children, according to the formula presented, the following values should be considered for drift (%).

Table 6: Default drift values (%) for calculating systemic exposure via the cutaneous route in residents or bystanders.

Drift (%)	75th Percentile	Mean	95th Percentile
Arable crops - 2-3m	5.6%	4.1%	8.5%
Arable crops – 5m	2.3%	1.8%	3.5%
Arable crops - 10m	1.3%	1.0%	1.9%
-	77th Percentile	Mean	90th Percentile
Fruit crops, no leaves - 2-3m	23.96%	18.96%	29.20%
Fruit crops, no leaves - 5m	15.79%	11.69%	19.89%
Fruit crops, no leaves - 10m	8.96%	6.07%	11.81%
Fruit crops, dense foliage - 2-3m	11.01%	6.96%	15.73%
Fruit crops, dense foliage - 5m	6.04%	3.73%	8.41%
Fruit crops, dense foliage - 10m	2.67%	1.6%	3.60%
Grapes - 2-3m	6.90%	5.25%	8.02%
Grapes - 5m	3.07%	2.32%	3.62%
Grapes - 10m	1.02%	0.77%	1.23%
Hops - 2-3m	15.93%	9.95%	19.33%
Hops - 5m	8.57%	5.91%	11.57%
Hops - 10m	3.70%	2.91%	5.77%

Source: *Adapted from EFSA, 2022*

The drift values (%) are derived from BREAM (Kennedy et al., 2012) and Ganzelmeir and Rautmann (1995) and Rautman et al. (2001) and are used in the downward and upward terrestrial application scenarios, respectively. While the 75th and 77th percentiles are used in the calculation of exposure from Surface Deposits in isolation, the mean and median measures of central tendency are used in the calculation of "Combined Exposure Pathways," that is, together with exposure from Drift and Vapour, since for these cases the sum of high percentiles would not be realistic (EFSA 2010; EFSA 2022). The 90th and 95th percentiles are used in the calculation of acute exposure.

Ganzelmeir and Rautmann (1995) and Rautman et al. (2001) do not have published data for mean, 75th and 95th percentiles, but they do have median, 77th and 90th percentiles. The latter are used analogously to the former, without any detriment to the applicability of the calculations explained above.

For resident and bystander children, in addition to cutaneous exposure, oral exposure from hand-to-mouth transfer should be considered, which is calculated using the equation:

$$ESOMB_{R\ ou\ T} = \frac{RD\ x\ D\ \ x\ ES\ x\ AS_{mão}\ x\ F\ x\ H\ x\ AO\ x\ 0,001}{PC}$$

Where:

$ESOMB_{R\ or\ T}$ = Oral Hand-Mouth Systemic Exposure of residents or bystanders (mg/kg bw/day). (SOEH)
RD = Dislodgeable Residue (µg/cm^2), calculated by Application Rate x TTR0.
D = Drift (%), if multiple applications have been considered, a smaller percentage may be considered in risk refinement. Default drift values (%) for different scenarios can be found in Table 6.
TTR0 = Default value for TTR calculation ((µg/cm^2)/(kg a.i. applied/ha)). For products applied as liquids, the value of 0.1 is used, and for products applied as solids, granules, the value of 0.02 is used.
ES = Saliva extraction factor (%), which refers to the fraction of pesticide extracted from the hand via saliva. The value of 50% is recommended by the USEPA (2001).
$AS_{mão}$ = Hand Surface Area (cm^2); It is assumed that 20 cm^2 of cutaneous area is in contact each time the child puts their hand in their mouth (USEPA, 2011).
F = Frequency with which the child puts their hand in their mouth (events per hour); for short-term exposure, a value of 9.5 events per hour is recommended for residents (arithmetic mean of the intervals from 0 to 70 events per hour) and 20 events per hour for bystanders (95th percentile of the intervals from 0 to 70 events per hour) (USEPA, 2011).
H = duration of exposure (h); a value of 2h is assumed, as recommended by the USEPA.
AO = Oral Absorption (%); the value must be corrected when oral absorption is less than 80% (the calculator performs the correction automatically).
PC = body weight (kg; children: 12 kg).

For oral exposure resulting from object-to-mouth transfer, we have:

$$ESOOB_{R\,ou\,T} = \frac{RD\ x\ D\ x\ PRD\ x\ ES\ x\ AS_{mão}\ x\ F\ x\ H\ x\ AO}{PC}$$

Where:

$ESOOB_{R\ or\ T}$ = Systemic Oral Exposure Object to Mouth of residents or bystanders (mg/kg b.w./day). (SOEO)
RD = Dislodgeable Residue (mg/cm^2), calculated by Application Rate x Initial DFR (consider MAF, if necessary).
D = Drift (%); if multiple applications have been considered, a smaller percentage may be considered in risk refinement. Default drift (%) values for different scenarios can be found in Table 6.
PRD = Percentage of Dislodgeable Residue (%); refers to the fraction of pesticide transferred from the object to the mouth. A value of 20% is recommended (USEPA, 2011).
$AS_{mão}$ = Hand Surface Area (cm^2); it is assumed that 20 cm^2 of skin area is in contact each time the child puts his/her hand in their mouth (USEPA, 2011).
IG = gram/day intake rate (cm^2); A default value of 25 cm^2 of grass/day is recommended (USEPA, 2011).
AO = Oral Absorption (%); the value should be corrected when oral absorption is less than 80% (the calculator performs the correction automatically).
PC = body weight (kg; children: 12kg).

5.2 Parameters related to exposed populations

5.2.1 Body weight and height

The body weight values to be used in the risk assessment for operators and re-entry workers were selected from the National Health Survey (PNS, 2020) based on data collected from the population aged 18-65 years residing in rural areas. To obtain the body weight and height to be used in the risk assessment for residents and bystanders, data collected from the population over 15 years of age (youngest age available) residing in rural areas were selected, also from the PNS (BRAZIL, 2020), which is considered the most representative range for this population.

The PNS has national coverage and collects information on the performance of the National Health System with regard to access to and use of available services and continuity of care, population health conditions, surveillance of chronic non-communicable diseases and the risk factors associated with them (Brazil, 2020a).

For the selection of children's body weight, data from the National Survey of Infant Feeding and Nutrition (ENANI, 2019) were used. The lower limit of the 95% CI for the 12-35 month age range was selected, as this is the most vulnerable population. ENANI (2019) is a national household-based survey of children up to five years old (59 months) that assessed 14,558 children in 12,524 households distributed across 123 municipalities in the 26 states of the Federation and the Federal District. As a representative body weight value for the adult population, the population arithmetic mean of the measured weights was used, considering the distribution and sampling variability

(PNS, 2019). Table 7 presents the body weight values, in kg, adopted in the AR of operators, workers, residents and bystanders by Anvisa.

Table 7: Body weight and height values to be used in estimating the exposure of operators, workers, residents, and bystanders

Population	Activity	Weight (kg)	Height (cm)
Men and women	Operator/worker	72	-
Men	Operator/worker	75	-
Women	Operator/worker	69	-
Men and women	Resident/bystander	70	163.74
Children	Child Resident/ Bystander	12	84.9

A reference dose (RD) is generally conducted using the average body weight of men and women.

If there is a specific dose for the female subpopulation, for example, in the case of a reference dose derived from reproduction or development studies, the RD can be performed separately for operators and workers to indicate differentiated mitigation measures in the package insert:

a. An RD for women of childbearing age, with the specific reference dose for this population group and average body weight of women; and

1. An RD for the rest of the population with the reference dose derived for the general population and the average body weight of men and women.

It should be noted that it is not appropriate to conduct separate RD for women and men in the case of residents and bystanders, as no differentiated mitigation measures will be adopted for these populations.

5.2.2 Body surface area of residents and bystanders

To assess the exposure of residents and bystanders, it is necessary to establish body surface area *(superficie corporal)* data. For this purpose, height *(altura)* and weight *(peso)* data from the population over 15 years of age (PNS, 2020) were used to estimate body surface area based on the Dubois Formula:

$$\boldsymbol{Superfície\ corporal = 0,007184\ x\ peso^{0,425}\ x\ altura^{0,725}}$$

For children, height and body weight data from ENANI (2019) were used. The Haycock formula was used to calculate body surface area:

$$\boldsymbol{Superfície\ corporal = 0,024265 \times peso^{0,5378} \times altura^{0,3964}}$$

Based on the Lund-Browder Table for estimating the percentage of total body part areas related to patient age, the following values were defined for the default surface area of the different body parts (cm^2) (Table 8).

Table 8: Default Surface Area of Different Body Parts (cm^2).

	Children (12 months)		Adult	
	% Area according to Lund-Browder	Estimated surface area (cm^2)	% Area according to Lund-Browder	Estimated surface area (cm^2)
Total	100.00%	5370.001	100.00%	17611.002
Hands	5.00%	268.50	5.00%	880.55
Upper Arms	8.00%	429.60	8.00%	1408.88
Lower Arms	6.00%	322.20	6.00%	1056.66
Head	17.00%	912.90	9.00%	1584.99
Neck	2.00%	107.40	2.00%	1352.22
Trunk	32.00%	1718.40	32.00%	5635.52
Upper Legs	13.00%	698.10	19.00%	3169.98
Lower Legs	10.00%	537.00	14.00%	2289.43
Feet	7.00%	375.90	7.00%	1232.77

[1]According to the Haycock formula result.
[2]According to the Dubois formula result.
Source: *Adapted from Lund and Browder, 1944; PHTLS, 2017*

5.2.3 Respiratory Rate

For the calculation of chronic and acute respiratory rates for resident and bystander children and chronic rates for resident adults, the values for average daily respiratory rate described in the Exposure Factors Handbook (USEPA, 2011) were considered, as detailed in Table 9.

Table 9: Average chronic and acute respiratory rate for resident and bystander adults and children.

Frequency of exposure - scenario	Inhalation rate	Inhalation rate adjusted for body weight (b.w.)	Observations
Chronicle – resident child	8.0 m^3/day or 0.334 m^3/hour	0.67 m^3/day/kg bw	The worst-case scenario was selected from the available data for children up to 14 years old (12 kg).
Chronicle – resident adult	16.0 m^3/day ou 0.667 m^3/hour	0.23 m^3/day/ kg bw	The worst-case scenario was selected from the available data for adults and includes individuals older

			than 15 years (70 kg).
Acute – bystander child	2.280 m^3/hour	0.190 m^3/hora/kg bw	The worst-case scenario was selected from the available data for children up to 14 years old (12 kg).
Acute – bystander adult	2.852 m^3/hour	0.041 m^3/hora/kg bw	The respiratory rate value from NR15 was selected for an individual running on a flat surface at 15km (47.53 L air/min).
Source: *USEPA, 2011.*			

5.2.4 Parameters related to the formulated product

For RA, it is necessary to know characteristics related to the formulation of the commercial product, but also the characteristics of the active ingredients that compose it. In addition, when there are components in the formulation with relevant toxicological characteristics, these characteristics will also be necessary.

Information regarding PF is described in Section 4.2.

i- PF cutaneous absorption values: In the absence of specific cutaneous absorption values for PF, default values should be used, as recommended by the EFSA Cutaneous Absorption Guidance (2017). These default values are presented in Table 10.

Table 10: Default values for cutaneous absorption to be used in predicting exposure in the absence of specific values for the formulated product.

Formulation type	Product dilution	Default value
Formulations based on organic solvents[1] or other types of formulation[2].	Concentrate	25%
	Diluted	70%
	Concentrate	10%
Water-based formulations/dispersions[3] or solid[4]	Diluted	50%
[1.] Emulsifiable concentrate (EC), oil-in-water emulsion (EW), suspoemulsion (SE), dispersible concentrate (DC), oil-miscible liquid (OL), dispersible or oil-miscible concentrated suspension (OF), oil dispersion (OD), seed treatment emulsion (ES), microemulsion (ME). [2.] Bait (RB), capsule suspension (CS), water-soluble gel (GW), CS and SC mixture (ZC), pesticide-coated seed (PS), active ingredient (a.i.). [3.] Soluble concentrate (SL), concentrated suspension (SC), concentrated seed treatment suspension (FS). [4.] Wettable powder (WP), water-dispersible granules (WG), water-soluble granule (SG), water-soluble powder (SP), dry seed treatment powder (DS). ***Source:*** *EFSA (2017).*		

Specific absorption values for PF can be obtained by conducting in vitro studies with human skin, in vitro studies with rat skin, or in vivo studies with rats, according to OECD Guidance lines 427 and 428 (OECD, 2004a, b). These guidance lines, as well as the recommendations of the EFSA Guidance on Dermal Absorption (2017), serve as a basis for evaluating studies and obtaining cutaneous absorption percentages.

These studies are conducted with the concentrated product and with the dilutions recommended for field use. It is important to present, in addition to the study report, the file used for calculating the percentages of cutaneous absorption.

In the absence of cutaneous absorption studies for PF, it is possible to derive values different from the default values, for example, by using cutaneous absorption rates of similar products both qualitatively and quantitatively. For this, a technical justification must be presented, based on the requirements of the EFSA Guidance on Dermal Absorption (2017).

5.2.5 Reference Doses

Reference doses are derived according to the scenarios of interest for assessing the risk to exposed human populations. In general, the duration of exposure can be acute (up to 24 hours), short-term (up to 30 days), subchronic or intermediate term (from 30 to 90 days), and chronic (lifetime exposure).

Brazilian Regulatory Decree No. 998/2025 establishes that hazard identification and dose-response assessment must include the AOEL (Acceptable Operator Exposure Level) and, when appropriate, the AAOEL (Acute Acceptable Occupational Exposure Level), for the risk assessment of operators, workers, residents, and bystanders. It also establishes that appropriate conversion factors must be used when these doses are derived from studies conducted via the oral route.

Occupational, resident, and bystanders risk assessment is performed considering subchronic exposure via cutaneous and inhalation routes, for which the AOEL is derived. There is also the possibility of AR for the acute scenario when a pesticide has relevant systemic cutaneous or inhalation toxicity after acute exposure, for which an AAOEL is derived.

The AOEL is defined by Resolution - RDC No. 998/2025 as the estimated amount of a substance to which an individual may be exposed daily without experiencing adverse health effects, expressed in milligrams of substance per kilogram of body weight per day (mg/kg bw/day).

The AAOEL (Acute Acceptable Occupational Exposure Level) is defined by resolution - RDC No. 998/2025 as the estimated amount of a substance to which an individual may be exposed in a single day without experiencing adverse health effects, expressed in milligrams of substance per kilogram of body weight (mg/kg bw).

As can be seen in Table 11, in the case of pesticides with the potential for acute systemic toxicity, it is considered that the AR (Acute Exposure Assessment) for acute exposure of bystanders already includes the AR for residents. Similarly, the subchronic AR for residents includes that of bystanders. Therefore, it is necessary to perform the AR for subchronic exposure of residents and acute exposure of bystanders. When AAOEL is not derived due to the absence of significant systemic toxicity, the AR for bystanders is not necessary.

Table 11: Risk assessments required according to the type of expected exposure to pesticides.

Exposed Group	Acute Risk Assessment*	Short-Term Risk Assessment
Operators	X	X
Workers	X**	X
Residents	- (covered by bystanders)	X
Bystanders	X	- (covered by residents)
X: assessment performed; -: assessment not performed. * Performed when an AAOEL is derived. ** Risk assessment is, in principle, necessary, but the data is insufficient to perform it. *Source: Adapted from EFSA, 2022.*		

For substances that can produce local effects on the skin or respiratory tract, deriving a systemic reference dose may not be appropriate, as the systemic dose would not be the determinant of the response. In these cases, it may be necessary to derive a specific reference value in mg/m^3 of air or mg/cm^2 of skin. A specific value for the route of exposure is also necessary when available data show that toxicity by a specific route (e.g., inhalation) is critically different from data by the oral route (ECHA, 2017). Furthermore, reference doses may be established for more sensitive subpopulations, such as women of childbearing age and children.

The AR for exposure scenarios involving residents and bystanders also depends on the derivation of a subchronic systemic reference dose. Furthermore, the derivation of an AAOEL is necessary when there is relevance to acute or short-term systemic toxicity, which includes, in addition to cutaneous and inhalation exposure, incidental oral exposure of children due to them putting their hands in their mouths after contact with pesticide residues (EFSA, 2022). Generally, the derivation of the AAOEL is necessary when a ARfD has been chosen based on developmental toxicity studies.

One problem related to respiratory exposure (RA) is the need to assess cutaneous and inhalation exposures, and the lack of specific studies for these routes to derive reference doses for occupational RA and for residents and bystanders. When using oral exposure studies to derive AOEL/AAOEL, it is necessary to calculate the internal dose and convert it to cutaneous and inhalation doses using appropriate conversion factors (USEPA, 2002; OECD, 2010; ECHA, 2017). This conversion is done in the dose-response assessment and reference dose derivation step. Thus, the doses established by toxicologists are already converted and can be readily used in occupational RA, for residents and bystanders. It should be noted that, in the avaliAR calculator, there is the possibility of entering the reference dose without conversion, as well as the possibility of using the already converted dose. Additionally, for doses obtained from route-specific studies, it is possible to include the cutaneous/inhalation AOEL/AAOEL, for which there are specific fields in the calculator.

The reference doses of pesticide active ingredients (a.i.s) to be used in occupational and resident/bystander risk assessments are established during the toxicological evaluation of technical products and presented in the reference dose derivation report. The risk assessor bases their assessment on these doses, as well as on other relevant toxicological information addressed in said report. Furthermore, in the case of AIs already registered or reanalysed, the reference doses can be consulted in the monographs. The guidance lines for the DAROC protocol for new and registered products, according to the availability of the AOEL/AAOEL in monograph, are set forth in resolution - RDC No. 998/2025.

Given the above, the first step in conducting occupational risk assessments of residents and bystanders is to establish which risk assessments will be necessary, identifying:

a) Who is expected to be exposed as a result of the use of pesticides (operators, workers, residents and/or bystanders);

b) If there are potentially more sensitive subpopulations (such as women of childbearing age and children); and

c) The respective reference doses for the exposed populations (AOEL and AAOEL, if any).

5.2.6. Parameters related to usage recommendations

The data used to estimate exposure should, whenever relevant, be the same as those defined in the product label and represent the Good Agricultural Practices (GAP) that is to be authorized. The following information should be detailed in the label for each crop or group of crops, method of application or use:

i. **Target of the application:** Crop (crop name or crop type), soil, or propagation material. For AR, the development stage and crop management method should be indicated when relevant. For crops with multiple variations in use (use characteristics), the procedure is to list each variation on a separate line in the calculator, thus showing all possibilities. This classification follows the "TC Proposition" reference, as exemplified with corn (grain corn, sweet corn, green corn).
ii. **Maximum doses of PF:** Per biological target per application, if necessary: Dose units can be in liters per hectare (L/ha), kilograms per hectare (kg/ha), milliliters per 100 liters of spray solution (mL/100L) or grams per 100 liters of spray solution (g/100L).
iii. **Maximum number of applications and minimum interval between applications (days):** Per crop cycle. For calculation purposes, when the number of applications is equal to one (1), the interval between applications should be considered equal to 365 days.
iv. **Minimum and maximum spray solution volumes in liters per hectare (L/ha):** for each type of application equipment.
v. **Application environment:** indicate whether application can occur in an open and/or closed environment.
vi. **Direction of application:** whether the spray jet is directed upwards, downwards, or in both directions.

vii. **Type of coverage:** specify whether the application will be to the entire area or by directed spray.

viii. **Type of application equipment:** RA will be conducted for all equipment covered by the available models and whose use is technically feasible considering the application context.

ix. **Field Operational Capacity (COC) / Area treated per day (ha):** COC is the area (ha) potentially treated by a given piece of equipment in the scenario in question during a working day (8 hours). The pesticide application areas defined by Anvisa (Table 7) should be used. The area values were established based on the evaluation of COC data presented in the study developed by the ProHuma Institute in partnership with the State University of Northern Paraná (Gandolfo et al., 2020), the values obtained by the study of the Biological Institute (Ramos et al., 2013), and the areas determined by the EFSA Guidance on Exposure Assessment of Operators, Workers, Residents and Bystanders (2014). It is possible to refine the exposure assessment by using more realistic areas for specific crops and types of pesticide application, provided that adequate data and technical justification are presented.

Table 12: Areas used in exposure assessment calculations according to the type of equipment used for product application.

Types of sprayers		Application environment	Type of coverage	COC - Area treated per day (ha) Reference	Reference
Manual	Knapsack	Open	n.a.	1.45	Biological Institute (2013)
	Knapsack	Closed	n.a.	1	Biological Institute (2013)
	Stationary/Semi-stationary	Open	n.a.	4	EFSA (2014)
	Stationary/Semi-stationary lawns*	Open	n.a.	2	
	Stationary/Semi-stationary	Closed	n.a.	1	Biological Institute (2013)
Tractor-mounted	Tracked	Open	Total area	65	Gandolfo et al. (2020)
	Mounted	Open	Total area	34	Gandolfo et al. (2020)

	Tracked	Open	Directed jet	15	Gandolfo et al. (2020)
	Mounted	Open	Directed jet	15	Gandolfo et al. (2020)
	Turbo sprayer	Open	n.a.	16.8	Gandolfo et al. (2020)
	Self-propelled	Open	n.a.	161	Gandolfo et al. (2020)
Manned aircraft	Small size	n.a.	n.a.	395	Gandolfo et al. (2020)
	Large size	n.a.	n.a.	656	Gandolfo et al. (2020)

*Applicable only to grass production fields.

x. Seed treatment or vegetative propagation rate and planting rate of treated seeds: Anvisa's assessment of occupational exposure resulting from seed treatment with pesticides is carried out for treatment on agricultural and industrial properties, based on data used by the USEPA, mainly from AHEFT. In industrial seed treatment facilities, the seeds are professionally treated and packaged for later delivery to producers. In the case of treatment on the agricultural property, the assessment covers the application of products to the seeds, with subsequent loading of equipment and planting, as well as the direct application of products to the planting equipment. For industrial seed treatment, subchronic exposure (30 to 180 days) and short-term exposure (<30 days) are considered relevant. For on-farm seed treatment, only short-term exposure is anticipated. Exposure estimation is based on: (a) the application rate, i.e., the amount of a.i. applied to the seed; (b) generic exposure unit data based on the seed treatment scenario (tasks performed, formulation types, level of PPE used); and (c) the quantities of seeds treated, the quantity of seeds planted, and equipment cleaning time. The USEPA presents its seed treatment assessment approach in two documents prepared by the Agency's Exposure Scientific Advisory Council (ExpoSAC): ExpoSAC SOP 14 (USEPA, 2022a), which contains exposure unit values, and ExpoSAC SOP 15.2 (USEPA, 2022b), with default values for the quantity of seed treated and planted. These two documents have been incorporated by Anvisa for estimating occupational exposure from local (on the farm) and industrial seed treatment, as well as the USEPA exposure calculator, available at https://www.epa.gov/pesticidescience-and-assessing-pesticide-risks/occupational-pesticide-exposure-seed-treatment. The values converted to hectares and kilograms for the quantity of seeds treated per day on the farm and by industrial treatment are presented in Tables 13 and 14, respectively, based on data from the ExpoSAC SOP 15.2 document (USEPA, 2022b). The number of treated seeds planted per day is presented in Table 15. It is possible to refine the assessment of exposure by using rates more representative of the Brazilian reality, provided that adequate data and technical justification are presented.

Table 13: Recommended values, in kilograms (kg), of the quantity of seeds treated per day on the farm, based on the Exposac SOP 15.2 document.

Seed Type	Hectares planted/day	Maximum Seeding Rate (kg/hectare)	Treated seeds/day (kg)
Barley	81	108.7	8800
Corn	81	33.6	2720
Cotton	81	21.2	1720
Flaxseed	32	56.1	1816
Oats	81	100.9	8160
Peanuts	32	255.6	8272
Potatoes	25	7811.5	192928
Rice	81	174.9	14160
Rye	81	100.9	8160
Safflower	32	39.3	1272
Sorghum	32	13.3	432
Soybeans	81	187.2	15160
Tomatoes	32	1.2	40
Triticale	81	122.1	9880
Wheat	81	175.9	14240

The list of crops included in this table is not exhaustive. When a product indicates seed treatment for a crop not listed, the amount of seeds treated per day for that crop is estimated. A value for planted area/day can be chosen from the ExpoSAC 9 document (USEPA, 2009), and a value for the maximum seeding rate from Becker (2011). These two values are multiplied to estimate the amount of seeds treated/day.
Source: *Adapted from ExpoSAC SOP 15.2 (USEPA, 2022b).*

Table 14: Recommended values, in kilograms (kg), of the quantity of seeds treated per day, for industrial treatment, based on the Exposac SOP 15.2 document.

	Seeds treated per day / 8 hours of work	
Seed Type	Short-term exposure (<30 days)	Subchronic exposure (30 to 180 days)
Alfalfa	56699	56699
Beetroot (sugar)	1361	1361
Canola	56699	56699
Corn (field)	153995	108862
Cotton	56699	49895
Vegetables with large seeds	153995	108862
Peanut	57153	47627
Potato	362874	181437
Rice	137212	81647

Vegetables with small seeds – film covering	1361	1361
Vegetables with small seeds – pellet covering	102	102
Soybean	127573	90718
Sunflower	36287	17463
Wheat	163293	81647

Small seed vegetables: asparagus, beetroot (garden), beetroot (sugar), broccoli, Brussels sprouts, cabbage, Chinese cabbage, melon, carrot, cauliflower, celery, chicory, chives, kale, cucumber, eggplant, endive, Tuscan kale, kohlrabi, leek, lentil, lettuce, mustard greens, okra, onion, parsley, parsnip, pepper, radish, rutabaga, Swiss chard, tomato, turnip.

Large seed vegetables: beans, peas, pumpkin, zucchini, watermelon. Due to the limited data from AHETF, it is necessary to assume values for crops without specific data, for example: for flaxseed, mint, mustard seed, sesame, lespedeza, canola data can be used; for corn (popcorn and sweet), field corn data can be used; for dry beans, soybean data can be used; For barley, oats, millet, sorghum, triticale, saffron, and rye, wheat data can be used.

Source: *Adapted from ExpoSAC SOP 15.2 (USEPA, 2022b).*

Table 15: Recommended values, in kilograms (kg), of the quantity of seeds planted per day, based on the Exposac SOP 15.2 document.

Crop	Number of seeds/kg	Number of seeds/hectare	Sowing rate (kg/hectare)	Hectares planted/day	Seeds planted/day (kg)
Alfafa	500	8408184	16.8	81	1361
Aspargus	34567	387416	11.2	32	363
Barley	20723	2274451	109	81	8892
Beans, dry	1763	322894	73.9	81	14828
Beans, lime	2000	234828	47.6	81	9525
Sea Beans	3998	1032454	104.8	81	20914
Beans, pod	3998	1032454	104.8	32	8347
Beetroot, garden	55905	1565042	11.3	32	907
Broccoli	48501	1077882	9.1	81	1797
Cabbage brussels	176369	520982	5.7	32	96
Cabbage	141094	68849	0.2	32	16
China Cabbage	99207	241986	4.9	32	79
Canola	99207	128347	1.7	32	42
Melon	198417	1828012	3.6	81	748
Carrot	35273	33098	0.4	32	30
Cauliflower	176369	53814	0.1	32	10
Celery	2204623	171734	0	32	3
Chicory	825090	5558339	2.7	32	218
Chives	200994	901717	1.8	32	145
Kile	295743	1326456	1.8	32	145
Corn Field	3000	99464	13.6	81	2682

Corn, popcorn	3000	74132	10	81	2000
Corn, sweet	3969	147700	15	32	1207
Cotton	9921	210043	8.6	81	1715
Cowpea	7055	344295	20	32	1577
Cucumber	26455	344295	5.4	32	421
Eggplant	31945	35880	0.5	32	36
Endive	28819	128347	1.8	32	145
Flaxseed	134519	7533007	22.7	32	1814
Kale	220462	1421197	2.7	32	209
kale-radish	220462	143495	0.3	32	21
Leeks	352739	369096	0.5	32	34
Lentils	16470	1293469	31.8	32	2540
Lespedeza	528344	20738463	15.9	32	1270
Lettuce, head	880792	773992	0.4	32	29
Lettuce, leaves	880792	386100	0.4	32	14
Millet, Japanese	341717	9571895	11.3	32	907
Millet, pearl	187393	4197479	9.1	32	726
Millet, proso	102932	3459465	13.6	32	1089
Mint	14706	194118	0	81	1
Melon	35273	95981	0.9	32	88
Mustard	399035	3128259	3.2	32	255
Oatmeal	28660	2890616	40.8	81	8165
Okra	6405	107606	6.8	32	544
Onion, dry bulb	220462	988421	1.8	32	145
Onion, green	220462	6176820	11.3	32	907
Sauce	330693	14820365	18.1	32	1451
Parsnip	192	1077882	2.3	32	181
Pea, garden	3000	1384540	187	32	14920
Peanut	1014	259470	103.4	32	8301
Pepper	110231	515241	1.8	32	152
Potato	11	85495	3161.7	25	192776
Pumpkin	3529	17945	2.3	32	165
Radish	70548	2582230	15	32	1184
Rice	34393	6023621	70.8	81	14793
Turnip	330693	741316	4.4	32	147
Rye	39683	3998551	40.8	81	8165
Safflower	29997	1175906	15.9	32	1270
Sesame	58206	782243	5.4	32	436
Sorghum	18387	246042	5.4	32	436
Soybeans	3306	617761	75.8	81	15118
Spinach	88184	2471054	11.3	32	907
Pumpkin, Summer	4235	28684	2.7	32	220
Pumpkin, Winter	4235	17945	1.8	32	138
Sunflower	4409	19768	1.8	32	145
Swiss chard	56435	506040	8.2	32	290
Tomato	264555	322894	0.5	81	40
Triticale	33068	4041163	49.4	32	8940
Turnip	367235	2582230	2.7	32	227
Watermelon	10582	107606	4.1	32	329
Wheat	21053	3706744	71.7	81	14247

For the assessment of product exposure with doses presented in mL of product/plant, the maximum number of plants per hectare should be used, as per Table 16. If the maximum number of plants/ha for the indicated crop is not specified in this Guide, a technical justification with adequate reference is required to prove the adopted value.

Table 16: Maximum number of plants per hectare according to the crop.

Crop			Number of plants per hectare	
			Minimum	Maximum
Avocado[1]			100	200
Pineapple[2]			34000	50000
Acerola[1]			500	600
Plum[1]	Conventional		-	330
	Dense		666	1250
Anonaceas[2]	Atemoya		158	400
	Sugar apple		129	400
	Soursop		148	416
	Cherimoya		117	416
Banana[2]	Small or medium size		2000	2500
	Tall size		1111	1667
Cacau[2]			1000	2000
Coffee[2]			4500	5000
Cashew[1]	Dwarf		-	204
	Commom		-	125
Persimmon[2]			238	419
Coconut[2]	Dwarf		-	205
	Giant		-	143
Fig[2]	Green		-	2667
	Ripe		1660	1667
Raspberry[1]			-	16600
Guava[2]			179	358
Kiwi[1]			400	500
Lychee[1]			-	134
Apple[2]	Vigorous Cups		1667	2667
	Semi-vigorous Cups		2500	3333
Macadamia[2]			156	500
Papaya[1]			1000	1700
Mango[1]			100	125
Passion fruit[2]			650	1250
Quince[2]			500	833
Strawberry[2]			50000	60000
Nectarine[2]	In Vase		285	417
	In Y		1000	2500
Loquat[2]	Conventional		200	310
	Dense		666	1250
Olive[2]			-	300
Pecan[1]			60	123
Pear[2]			417	834
Peach[2]	In Vase		285	417
	In Y		1000	1250
Grape[1]	Trellis		2000	5000
	Espalier		500	833
	Seedless grapes	Trellis	2500	3333
		Espalier	500	833

	Grapes for industry (trellis)	2500	5000
Sources *: [1]Fahl et al., 1998 (Boletim IAC, 1998); [2]Aguiar et al., 2014 (Boletim IAC, 2014)*			

6. RISK CHARACTERIZATION

After predicting exposure, the exposure values obtained for each population are compared with appropriate reference doses for characterizing occupational risk and risk to residents and bystanders. That is, the exposure estimate is divided by the reference dose and multiplied by one hundred to obtain a percentage. When the percentage is less than or equal to 100%, the scenario is considered approved without the need for mitigation or refinement measures. If a percentage greater than 100% is obtained, risk mitigation measures or refinement may be adopted. If, even with refinement and the adoption of risk mitigation measures, the predicted exposure exceeds the reference doses, the use of the product should be prohibited for the respective scenario.

6.1 Refinements

In cases requiring refinement, registering companies must include, in the risk assessment report submitted to Anvisa (DAROC), all data, studies, justifications, and references that support this change in the exposure value. It is important to mention that the EFSA Guidance on Exposure Assessment of Operators, Workers, Residents and Bystanders (EFSA, 2022) provides suggestions on how to proceed with the refinement of the exposure assessment.

For refining the assessment of occupational exposure and exposure of residents and bystanders, specific cutaneous absorption data of the evaluated product may be presented, as well as more realistic application areas, planting rates, and seed and plant treatment data for specific crops, provided they are accompanied by technical justifications with theoretical basis or data from studies. Furthermore, exposure can be refined through the presentation of exposure studies of operators, workers, residents, and bystanders, provided they are conducted in accordance with international guidance lines.

The refinement of worker exposure assessment can also occur through the presentation of DFR and CT studies, which must be carried out in accordance with international guidance lines.

6.2 Recommendation of risk mitigation measures

6.2.1 Risk mitigation measures for operators

According to the Food and Agriculture Organization of the United Nations (FAO), the recommendation to use PPE is one of the occupational risk mitigation measures, but it is considered one of the least effective strategies, considering that its effectiveness is related to availability, cost, quality, comfort, correct use and size appropriate to the user (FAO, 2020). Therefore, engineering controls should be prioritized and the use of protective factors should be carefully considered, considering the exposure scenario and the type of formulation involved (RIANDA, et al 2007).

Therefore, risk mitigation for operators can be achieved by adopting engineering control measures, such as the use of water-soluble packaging, the use of a closed mixing and dispensing system, and the indication of application only with tractors with closed cabs (USEPA, 2020; EFSA, 2014).

The engineering measures are applied respecting the options available in the models (American or European) considered to evaluate the scenario in question. For the American model, applied to mixing and dispensing in a closed system (liquid), water-soluble mixing (solid), and application in a cab for a boom tractor, the exposure units used by the USEPA were considered. For the European model, applied to mixing and dispensing using water-soluble packaging, 10% of the exposure is calculated when water-soluble packaging is not used.

Resolution of the Collegiate Board - RDC No. 296, of July 29, 2019, in its article 7, establishes that the indication of the use of PPE must consider (i) the specifics of the product; (ii) its handling; (iii) the crops for which it is intended; (iv) its method of application; (v) the application equipment; and (vi) the types and duration of activities performed after application. These criteria are directly related to the assessment of exposure, with the first item also encompassing the hazard of the product.

Baseline studies for exposure prediction models are generally conducted with at least Level 1 PPE and gloves. However, other PPE may be included during the exposure assessment to mitigate risk. The PPE and their respective protection values adopted by the American and European models are indicated in Table 17 (EFSA, 2014; USEPA, 2020).

Table 17: Protection factors adopted for PPE by EFSA and EPA.

PPE	Description	Protection Factor (EFSA, 2015)	Protection Factor (USEPA, 2020)
PPE level 1	Simple workwear, made of cotton or polyester, which meets the requirements of ISO 27065	90%	50%*
PPE level 2	Simple workwear made of cotton or polyester with water repellent finish, which meets the requirements of ISO 27065	95%	50% for the first layer or 75% for the total exposure **
Mask	FP10 (USEPA, 2020)	-	90%
	FP50 (USEPA, 2020)	-	98%
	FP1 ou P1 (EFSA, 2015)	Inhalation: 75% Dermal: 20%	-
	FP2 ou P2 (EFSA, 2015)	Inhalation: 90% Dermal: 20%	-

Glove	Chemical protection	Workers: 90% FL/FS Operators: 90% FL 95% FS	-
Hood***	Without display	50%	-
	With display	95%	-

FL: liquid formulations; FS: solid formulations.
* Studies conducted with the worker's usual clothing, but which, for the purpose of risk assessment in Brazil, should be considered as exposure units for level 1.
** They refer to a second layer of clothing and not to the level 2 PPE description adopted, however, they should be considered as exposure units for level 2.
*** It is an alternative to the mask and should not be added together.

The standard that regulates the use of PPE in the agricultural environment in Brazil is Regulatory Standard No. 31 - Occupational Safety and Health in Agriculture, Livestock, Forestry, Forest Exploitation and Aquaculture, published by MTE Ordinance No. 86, of March 3, 2005. It establishes the employer's obligation to provide personal protective equipment and PPE.

Personal protective equipment (PPE) refers to protective devices that do not require certification, meaning they are not classified as PPE under Regulatory Standard No. 6 - Personal Protective Equipment (MTE, 2022). By convention, when we use the term "work clothes," we are referring to work clothes provided by the employer, for exclusive use in the workplace, consisting of a long-sleeved shirt or t-shirt and long pants, or a one-piece suit with long sleeves and long legs (overalls), socks, and rubber boots.

For the purpose of defining the protection factors to be applied to exposure data, according to the types of clothing to be indicated for the activity, the suitability of the penetration factors defined in ABNT NBR ISO 27065/2023 - Protective clothing - Performance requirements for protective clothing used by workers in the application of pesticides and during the re-entry period, and the available international publications and references were discussed.

According to this standard, there are three fabric classes: C1, C2, and C3. Level C1 refers to a penetration factor of 40%, derived from the analysis of cotton and cotton/polyester fabrics. Level C2 refers to a 5% penetration factor in the laboratory conformity assessment, as it adds the repellency test, with a minimum repellency factor of 80%. For level C3, a maximum cumulative permeation of 1 µg/cm² is expected, which qualifies penetration over a period of 1 hour for products diluted to 5% active ingredient and 15 minutes for concentrated products. For the indication of level C2, the relationship between the need for protection and comfort should be considered. Level C3 should be indicated for activities involving concentrated products and for short periods. These values, however, should not be directly considered for risk mitigation purposes, given that the laboratory penetration of the fabric differs from the penetration of the garment used in the field.

Observational studies of each work activity related to the use of pesticides result in exposure values with VT. These values were used to estimate potential exposure, which would be exposure without clothing, and to calculate exposure with the addition of other PPE (Personal Protective Equipment).

Based on the definition of fabric used by NBR ISO 27065, namely cotton and cotton/polyester without water-repellent treatment, this first level of protection could be considered as the presumed exposure for VT, although this is not considered PPE. This presumption was also adopted by EFSA.

However, it was observed that for the calculation of exposure without clothing, the use of a 60% factor leads to an underestimation of exposure without clothing and consequently of exposure after applying the protection factors for levels C2 and C3. This is because when applying a protection factor of 60% there is a 2.5 increase in the VT value, while if we use a protection factor of 90% there is a 10-fold increase in the potential exposure value, the latter being a more critical scenario.

The choice of the 90% protection factor, also adopted by EFSA, was based on the values recommended by Thongsinthusak et al (1990) apud TNO (2007), which evaluated different clothing systems, consisting of a long-sleeved shirt or t-shirt and long trousers, made of cotton or cotton/polyester, or a one-piece long-sleeved, long-legged, uncoated garment.

For the indication of PPE use, the protection factors indicated in NBR ISO 27065/2023 were used, with level C2 indicated only for body protection and level C3 indicated only for the use of aprons in the activity of mixing and supplying manual knapsack sprayers, as per Table 18.

Table 18: Cutaneous protection factors of personal protective equipment.

Fabric Class	Protection Factor
Workwear - VT	90%
Class 2 - C2	95%
Class 3 - C3	99%
Source: Adapted from NBR ISO 27065/2023 and EFSA, 2022.	

Other cutaneous protection factors for the indication of head protection devices were adopted considering the reduction of exposure in relation to the proportion of the protected area, as shown in Table 19.

Table 19: Cutaneous protection factors for the head.

Protected area	Protection factor
Respirator - Head	20%
Hood - Head	50%
Hood and face shield - Head	95%
Source: Adapted from EFSA, 2014, 2022.	

In the avaliAR calculator, a hood and face shield were adopted as an alternative to respiratory protection equipment. However, it should be noted that the calculation of head exposure with a hood and face shield using the protection factor only occurs for application purposes. For mixing and loading, there is experimental data for the head protector

Considering the chemical characteristics of pesticides, the use of nitrile gloves or other gloves that meet performance level 2 in the permeability test for three different chemical agents is recommended for handling/supplying and application.

Unlike clothing, the certification of glove protection level is based on permeation time or normalization of the permeation rate (1 μg/min/cm²). Level 2 refers to the permeation normalization period of 30-60 minutes, that is, the average time for the glove structure to break down after exposure to at least three chemical agents, with the result not varying by more than 20% (MTE, 2009). Therefore, it was not possible to establish a protection factor based on this guidance.

Based on the protection factors adopted by other authorities, a protection factor of 90% is considered adequate, given that it is the same factor used for the protection of the VT. It is possible to assume that the glove material has lower permeability than the VT. Additionally, it is important to mention that, for most of the available exposure data, the use of a hand protection factor is not necessary, as the exposure data has already been generated with the use of gloves; therefore, this factor is used to estimate potential exposure, which makes the protection factor used more critical (greater potential exposure).

For the definition of respiratory protection factors, the penetration values defined in ABNT NBR ISO 13698:2022 were used, as shown in Table 20.

Table 20: Respiratory protection factors for Class 3 Respiratory mask (PFF3) and Class 3 P3 filter.

Filter Class	Protection Factor
PFF1/P1	80%
PFF2/P2	94%
PFF3/P3	99%
P3	99.95%
Source: ABNT NBR ISO 13698:2022.	

It is important to emphasize that the primary indicator of the need for PPE is the hazard of the formulation; that is, even if the risk assessment does not indicate the need for PPE, its use must be mandatorily indicated according to the hazard of the formulation, as defined by resolution - RDC No. 296 of 2019. The list of PPE to be included on the label and package insert, according to the hazard classification of the formulation, is contained in ANNEX I.

For re-entry workers, the main risk mitigation measure is the establishment of an IR (Incidence Risk), which may vary according to the exposure data available for each type of activity and for the crop architecture (EFSA, 2014). Since the calculator adopted the

American model until this scenario can be better evaluated by ACT/Prohuma/Anvisa, mitigation with the use of gloves, as occurs in the European model for some application scenarios, is not possible.

6.2.2 Risk Mitigation Measures for Residents and Bystanders

Risk mitigation for residents and bystanders should initially be carried out through the use of drift reduction technology, for which the default value of 50% should be used in the calculations, for both manual and tractor-mounted application. If drift reduction is not sufficient, the mandatory inclusion of a 5 (five) or 10 (ten) meter buffer zone may be added. The buffer zone should start at the outer limit of the plantation and extend towards its interior.

For some scenarios, the European model, adopted in the calculator, does not allow the calculation of exposure for residents and bystanders without the use of a minimum buffer zone of 5 (five) meters. In this situation, a buffer zone of 5 (five) meters should be adopted before drift reduction and, if both are insufficient, a buffer zone of 10 (ten) meters should be adopted. For cases in which the model allows calculation with a minimum buffer zone of 5 meters, this buffer zone distance must be indicated in the product label.

Mitigation measures will only be determined by Anvisa if they are considered plausible for the reality of product use and the availability of the technology is proven and will be recommended to facilitate risk communication to farmers and ensure the identification of less toxic products. Other measures may be adopted provided they are effective and technically justified.

7. FINAL CONSIDERATIONS

The avaliAR calculator includes all exposure data from the scenarios modelled by CTA/Prohuma, as well as data obtained from the American and European models chosen as representative for the different Brazilian scenarios. Furthermore, the calculator incorporates all parameters, default values, and guidelines defined by this Guidance. The calculator, as well as the documents that supported its development and the user manual, are available for download at the following link: https://www.gov.br/anvisa/pt-br/assuntos/agrotoxicos/avaliacao-do-risco-daexposicao-ocupacional-residentes-e-transeuntes-aos-agrotoxicos.

Technical justification must be provided for any discrepancy in the Risk Assessment (RA) in relation to this Guidance. Furthermore, for scenarios not covered by the models available and detailed in this Guidance, specific studies necessary for conducting the RA must be presented, or more conservative scenario calculations may be adopted, subject to technical justification to be evaluated by Anvisa.

All risk mitigation measures determined by Anvisa (Brazilian Health Regulatory Agency) must be included in the package inserts of formulated products, along with the recommended measures resulting from the hazard assessment. Specific information about the scenarios, especially when refinements are involved, must also be mentioned in the package insert so that the user can reproduce the conditions under which the risk assessment was conducted.

When risk mitigation measures are not feasible or are insufficient, the necessary usage restrictions should be adopted to ensure a safe level of exposure for the population concerned.

Anvisa will analyse the RA submitted by the companies. When refinement of a particular RA is necessary, the registering companies are responsible for submitting all supporting documents, studies, and technical justifications for analysis by Anvisa. If the submitted data is incomplete, the most conservative data will be used, and the necessary risk mitigation measures and usage restrictions will be adopted to ensure a safe level of exposure for the population.

8. LIST OF ABBREVIATIONS AND ACRONYMS

A: Application
AAOEL: Acute Acceptable Occupational Exposure Level
AC: Cutaneous Absorption
AI: Inhalation Absorption
AHETF: Agricultural Handler Exposure Task Force
ANAC: National Civil Aviation Agency
AOEL: Acceptable Operator Exposure Level
AR: Risk Assessment
ARTF: Agricultural Re-entry Task Force
ARP: Remotely Piloted Aircraft (RPA)
BPA: Good Agricultural Practices (GAP)
COC: Field Operational Capability / Area treated per day (ha)
TC: Transfer Coefficient
DRfA: Acute Reference Dose (ARfD)
DT50: Dissipation Rate
ECHA: European Chemicals Agency
EFSA: European Food Safety Authority
EPI: Personal Protective Equipment (PPE)
ExpoSAC: Science Advisory Council for Exposure
FAM: Multiple Application Factor (MAF)
FAO: Food and Agriculture Organization of the United Nations
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
CLP Guidance: Guidance for Applying the Classification, Labelling, and Packaging Criteria for Chemical Substances and Mixtures
IA: Active Ingredient (a.i.)
IBGE: Brazilian Institute of Geography and Statistics.
IR: Re-entry Interval
M/A: Mixing and Loading
MAPA: Ministry of Agriculture, Livestock and Supply
NOAEL: No Observed Adverse Effect Level
OECD: Organisation for Economic Co-operation and Development
p.c.: Body weight (bw)
PF: Formulated Product
PHED: Pesticide Handler Exposure Database (for agricultural use).
PMV: Maximum Vapour Pressure
PNS: National Health Survey
PoD: Point of Departure
RCD: Boll Transferrable Residue (BTR)
DFR: Dislodgeable foliar residue

RTT: Turf Transferable Residue (TTR)
USEPA: United States Environmental Protection Agency
VT: Workwear

9. GLOSSARY

For the purposes of this Guidance, the definitions listed below are adopted to improve the understanding of the Guidance and facilitate access to information on definitions related to the topic, in accordance with the provisions of resolution - RDC No. 998/2025.

Good Agricultural Practices (GAP): Recommendations for the use of pesticides and related products considered safe regarding dose, concentration, type of application, number of applications, interval between applications and safety interval for obtaining the desired effect, registered under legally established conditions for use in any phase of the production, transport, storage, processing and distribution of food.

Exposure scenario: Theoretical situation assumed for exposure to pesticides, environmental control products or similar, determined by the crop and size of the treated area, type of formulation, method of application, dose and application equipment and by the activity performed or condition of the individual, such as age, location in relation to the treatment, use of PPE or other variable that may alter the level of exposure.

Field Operational Capacity (COC) / Area treated per day (ha): Area (ha) potentially treated by a given piece of equipment in the intended use scenario in one working day (8 hours).

Transfer Coefficient (TC): Rate at which movable leaf debris can be transferred to a worker during a specific activity (expressed in terms of the area of contaminated foliage or fruit from which the debris is transferred per hour - cm^2/h).

Product Dose: Refers to the amount of product applied to a given area, crop, or plant part. The dose may vary depending on the type of product formulation, crop type, stage of development, damage level, pest biology, among other factors.

Acute Reference Dose (ARfD): Estimated amount of substance present in food that can be ingested over a period of up to 24 hours without posing an appreciable risk to consumer health, expressed in milligrams of substance per kilogram of body weight (mg/kg bw).

Dissipation rate (DT50): Time required, in days, for the concentration of pesticide residues, environmental control products, or similar substances on foliage or fruits to be reduced by half.

Personal Protective Equipment (PPE): Device or product for individual use by the operator or worker, designed and manufactured to offer protection against occupational hazards present in the work environment.

Manual ground equipment - knapsack: Portable equipment whose tank is carried by the applicator on their back. The applicator nozzles are manually directed to the target. The application pressure can be generated manually by the applicator or be motorized.

Manual ground equipment - stationary/semi-stationary: Equipment in which the pump and tank remain fixed or distant from the application site. The applicator nozzles are manually directed to the target.

Tractor-mounted ground sprayer: Equipment designed for the application of liquids using a directed jet spraying system, allowing for mobility and control during application.

Tractor-mounted ground sprayer: Sprayer mounted on the rear of the tractor, with a spray bar that extends laterally. The sprayer is attached to the tractor's 3-point hitch system.

Tractor-mounted ground equipment: Sprayer with a wheel system independent of the tractor, which is coupled to the trailer and towed during application, with a spray bar that extends laterally.

Self-propelled tractor-mounted ground equipment: Sprayer that does not require coupling to tractors to operate, as it has its own propulsion system, with a spray bar that extends laterally.

Ground-mounted tractor-mounted turbo sprayer: This type of equipment has the same basic components as mounted and trailed sprayers (tank and pump to propel the liquid). However, they have a ventilation system that reduces the average size of the application droplets and generates an airflow to transport the droplets to the target. Unlike other types of ground sprayers, it does not have a side spray bar.

FAM - MAF (Multiple Application Factor): Coefficient used to determine the total amount of an active ingredient applied to an area over multiple applications within a production cycle.

Risk mitigation measures: Any measure intended to reduce exposure levels to pesticides during their handling and use, such as: personal protective equipment, water-soluble packaging, tractors with closed cabins, drift reduction technologies, visual warnings, closed mixing and supply systems, among others.

Acute Acceptable Operator Exposure Level (AAOEL): A reference value derived from toxicological studies used to compare with acute non-dietary exposure to pesticides, environmental control products, or similar substances. It is an estimate of the amount of substance to which an individual can be exposed in a single day without experiencing adverse health effects, expressed in milligrams of substance per kilogram of body weight (mg/kg bw).

Acceptable Operator Exposure Level (AOEL): A reference value derived from toxicological studies used to compare with exposure to pesticides, environmental control products, or similar substances. It is an estimate of the amount of substance to which an operator, or individual, can be exposed daily without experiencing adverse health effects, expressed in milligrams of substance per kilogram of body weight per day (mg/kg bw/day).

No Observed Adverse Effect Level (NOAEL): The highest dose of a substance tested at which no adverse effects are observed in experimental animals, expressed in milligrams of substance per kilogram of body weight per day (mg/kg b.w./day).

Number of applications: Number of applications required to complete the phytosanitary treatment cycle.

Operators: Individuals involved in activities related to the application of pesticides, environmental control products or similar products, including mixing and loading equipment and application, or activities related to cleaning and maintaining the equipment used in these activities.

Point of Departure (PoD): A numerical value obtained from a point on a dose-response curve derived from toxicological studies and existing epidemiological data to identify the critical outcome.

Vapour pressure (Pa - Pascal): The pressure exerted by the vapour of a substance in equilibrium with its liquid phase in a closed container.

Concentrated product: Product formulated without any dilution.

Diluted product: Product formulated mixed with the diluent to obtain the application solution.

Vegetative propagation: Also called asexual propagation. It is the process of plant reproduction that occurs from vegetative parts of a mother plant, such as stems, roots, leaves, or buds, without the need for seeds. It results in individuals genetically identical to the original plant (clones).

Residents: Individuals that live in or are regularly present in the vicinity of areas treated with pesticides, environmental control products, or similar substances, without the objective of working in the treated area or with the treated crop.

Boll Transferrable Residue (BTR/DRB): Boll Transferrable Residue refers to the amount of pesticide residue that remains on the surface of the cotton ball after application and that can be transferred by external factors such as harvesting or mechanical handling and direct contact.

Turf Transferable Residue (TTR/RTT): Turf Transferable Residue refers to the amount of pesticide residue present on the surface of the grass (turf) that can be transferred to other environments by direct contact.

Dislodgeable Foliar Residue (DFR): Amount of residue of a pesticide, environmental control product or similar after deposition on foliage or fruit, which can be transferred to a person through contact.

Maximum Application Rate (MAR): Maximum amount of active ingredient applied per area, expressed in kg a.i./ha.

Re-entry workers: Individuals who, as part of their work, enter an area that has been previously treated with pesticides, environmental control products or similar, or who handle the treated crop.

Bystanders: Individuals who occasionally pass through the vicinity of treated areas, without the intention of working in those areas or with the treated crop.

Spray volume: Refers to the total amount of spray solution indicated to treat a given area. This solution is loaded into the sprayer tank and subsequently applied. The spray volume may vary depending on the type of application equipment, product formulation, crop type, stage of development, degree of pest infestation, pest biology, among others.

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MTE. Ministério do Trabalho e Emprego. **Norma Regulamentadora NR - 15 - Atividades e operações insalubres**. Vigente a partir de 3 de janeiro de 2022, em virtude de ajustes no Anexo n° 3 (calor) e n° 8 (vibração), por meio da Portaria MTP n° 426, de 07 de outubro de 2021. Portaria MTb n.º 3.214, de 08 de junho de 1978.

MTE. Ministério do Trabalho e Emprego. **Norma Regulamentadora NR - 31 Segurança e Saúde noTrabalho na Agricultura, Pecuária, Silvicultura, Exploração Florestal e Aquicultura.** Última modificação: Portaria MTE n.º 342, de 21 de março de 2024

MTE. Ministério do Trabalho e Emprego. **F.1.8. Riscos de origem química EN 420:2003 + EM 374:2003, ou alterações posteriores.** Portaria DSST/SIT n.º 127, de 02/12/2009.

ANNEX I - INDICATION OF PPE ACCORDING TO THE FORMULATION'S HAZARD ASSESSMENT, ACCORDING TO GHS.

	Category	PPE indication for mixing/loading (concentrate)						Indication of PPE for application (diluted)					
								High cultures	All Cultures				
		All Products				Powders and granules	Liquid		All Products				
		Gloves	C2 PPE + Footwear	Face shield (V) or glasses (O)	Full face respiratory mask if vapour pressure ≥ 0.02Pa	Respiratory mask	C3 Apron	Protective head and neck coveror hood	Gloves	C2 PPE + Footwear	Face shield (V) or glasses (O)	Respiratory mask, if vapour pressure[2] <0.02Pa	Full face respiratory mask, if vapour pressure[2] ≥ 0.02Pa
Acute oral toxicity	1, 2 and 3	X	X	V[3]				X	X	X	V		
	4 and 5												
Aspiration hazard	1												
Acute cutaneous toxicity	1, 2 and 3	X	X	V[3]			X	X	X	X	V		
	4 and 5	X	X					X	X	X			
Skin Corrosion	1	X	X	V[3] o O[3,4]	X	X	X	X	X	X	O	X	X
Skin Irritation	2 and 3	X	X					X	X	X			
Skin sensitization	1	X	X	V[3] o O[3,4]	X	X	X	X	X	X	V		
Eye corrosion	1			O							O		
Eye irritation	2			O							O		
Acute inhalation toxicity	1, 2 and 3	X	X	V[3] o O[3,4]		X	X	X	X	X	O	X	X
	4 and 5												
Inhalation sensitization	1					X	X					X	X
Specific Target Organ Toxicity Single Exposure, Inhalation	3												
Mutagenesis, carcinogenesis and reproductive toxicity	1A, 1B	X	X		X	X	X	X	X	X		X	X
	2	X	X		X	X	X	X					
Reproductive toxicity	Effects on lactation[5]	X	X		X	X	X	X					
Toxicity to specific target organs Single exposure	1	X	X		X	X	X	X					
	2	X	X		X	X	X	X		X	X		
Toxicity to specific target organs Repeated exposure	1	X	X		X	X	X	X	X	X	X		
	2	X	X		X	X	X	X		X	X		

Source: Adapted from Lichtenberg, B., Mischke, U., Scherf, S. et al, 2015

1- If the application is tractor-driven with a closed cabin, the indication of a gas-tight mask or respiratory mask may be omitted

2- Vapor pressure of the active ingredient or other ingredient deemed relevant for classification

3- For WG formulations, with water-soluble packaging or others with the impossibility of splashes or dust reaching the eyes, the need for indication of a face shield or glasses may not be necessary.

4- In case of the need to use a respiratory mask, the use of glasses should be indicated, due to the impossibility of using a face shield

5-Protective equipment indicated only for women

ANNEX II – MODEL OF OCCUPATIONAL RISK ASSESSMENT DOSSIER FOR RESIDENTS AND BYSTANDERS EXPOSED TO PESTICIDES - DAROC.

Company Name	
Registering Company	
CNPJ (Brazilian Taxpayer Identification Number)	
Process Number	
File Number	
Trademarks	
Monograph Codes	
Active Ingredients (a.i.)	

1. EXPOSURE SCENARIOS FOR RISK ESTIMATION

A- Physicochemical characteristics of the active ingredient and formulated product

Include information on the chemical identity and physicochemical properties and reference doses adopted for the active ingredient, formulation type, physical state of the formulation, agronomic class and active ingredient of the formulation. This information must be consistent with that entered in the AvaliAR calculator file. In the case of new active ingredients whose monographs have not yet been published, justify the choice of reference doses, as presented in the PATE, the registration dossier for the new technical product.

B- Usage Recommendations

Include information about scenarios covered by the calculator, justify scenarios not covered by the calculator, and include, if necessary, inferences about scenarios considered similar. Example: choosing the type of crop "ornamental plants or flowers" in the calculator for carnations, chrysanthemums. Or choosing "table grapes" to represent the scenario instructed in the product label.

Application equipment must be listed and justified according to the feasibility of its use. In the case of less restrictive scenarios, within the same application equipment, the governance measures to be taken to guarantee the exclusive use of the equipment must be presented.

In the case of re-entry intervals calculated with deadlines that make re-entry activity unfeasible, including harvesting within the safety interval, the necessary mitigation measure for maintaining the proposed use must be presented.

The DAROC (Application Data and Authorization Form) must reflect the instructions for use established in the product label.

Crop	Maximum dose (L/ha)	Number of applications	Interval between applications (days)	Application equipment[1]	Minimum spray volume (L)	Maximum spray volume (L)	Re-entry interval (days)	Application method	Drift reduction (%)	Border spacing (m)

1. Insert one application equipment per row. Consider one row for each operational field capacity of the specific equipment (large, small, trailed, mounted, directed spray, etc.).

2. EXPOSURE ASSESSMENT

Present which exposed populations were evaluated: operator, worker, resident, and bystanders. Justify if any scenario for the exposed population is not possible. Example: risk assessment for workers re-entering for herbicide application in pre-emergence of crops.

Justify the use of the calculator in relation to the recommended uses, as well as the indicated scenarios that are not covered by the calculator. In this case, indicate the models and calculations performed.

All scenarios indicated in the label must present a proposed exposure data, which must be referenced and justified. The absence of the scenario in the calculator is not a justification for not assessing the risk of the scenario. The use of the calculator is mandatory when the scenarios are available.

3. RISK CHARACTERIZATION

A- Justification for the need for refinement and risk mitigation

In cases requiring refinement, registering companies must include, in the risk assessment report submitted to Anvisa (DAROC), all data, studies, justifications, and references that support the alteration of the default values or the generic exposure data adopted.

It must be verified whether the PPE indicated in the risk assessment is sufficient to protect the user against the product's hazard, as per Annex I of this guidance. The PPE that provides greater protection to the worker must be indicated in the product label.

B- Additional studies presented (if necessary)

In cases where new studies are needed to support the risk assessment or refinement, the studies must be presented and attached in full.

4. CONCLUSION

Present the conclusions regarding the scenarios and safety of use, as well as the risk mitigation measures that should be adopted in the product label.

5. REFERENCES

List and attach the bibliographic references found, according to the guidelines established by ABNT standards.

<u>Appendix</u>

Present the report generated by the avaliAR calculator and the generated Excel file.

Include the studies that supported risk assessment or refinement.

>>>>>>>>>>>>>>>>> end >>>>>>>>>>>>>>>>>>>>