



# Implementation of the risk assessment of operators, workers, residents and bystanders in Brazil by Anvisa

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## Introduction

Since 2017, Anvisa has assessed the exposure risks of pesticides for operators, reentry workers, residents and bystanders. It started with the pesticides 2,4-D<sup>1</sup> and Glyphosate<sup>2</sup> in the scenarios and crops approved, identifying the general risk mitigation measures needed for each active ingredient.

## Methods

- The American and European exposure prediction models of measures from field studies were adapted to the reality of all exposure scenarios of 2,4D and Glyphosate application in Brazil: aerial, tractor application, handheld and backpack
- Worst case scenario: maximum application rate and minimum volume of water among all products
- Dermal absorption rates: determined based on studies with some formulations and, when not available, international standard values were used

Parameters for Exposure Assessment	2,4D	Glyphosate
<b>Body weight</b>		60 kg
<b>Dermal absorption of product</b>	0,08%	1% and 25% (emulsion oil in water-EW)
<b>Dermal absorption of in-use dilution</b>	4,03%	10% and 70% (EW)
<b>Inhalation absorption of active substance</b>		100%
<b>AOEL / Acute dose</b>	0,01 mg/kg/day	0,1 mg/kg/day
<b>Application rate</b>		maximum application rate
<b>Treated area for backpack application</b>		1,38 ha/day
<b>Treated area for hand-held application</b>		4 ha/day
<b>Treated area for tractor application</b>		60 ha/day or 15 ha/day
<b>Treated area for tractor application (self propelled)</b>		121 ha/day
<b>Treated area for aerial application</b>		500 ha/day
<b>Number of applications</b>		1
<b>50% Dissipation Time - DT50</b>	9 days	30 days
<b>Inicial Dislodgeable Foliar Residue (DFR)</b>		3 µg active ingredient/cm <sup>2</sup>
<b>Working hours</b>		2h ou 8h
<b>Dermal transfer coefficient</b>		EFSA, 2014



## Results

For 2,4-D and Glyphosate, general risk mitigation measures were imposed:

- specific reentry intervals for some crops
- buffer zone of 10 meters and drift reduction to protect residents and bystanders
- withdrawal of formulation types and application methods
- limitation of the maximum application rate
- restrictions of performing the activities of mixing/ loading and application by the same individual
- recommendations on Personal Protective Equipment (PPE) usage

## Conclusions

There are still many challenges to improve and implement the pesticides risk assessment in Brazil:

- lack of legal requirements
- data gaps (hectares treated per day, absorption values, DT50 and DFR)
- need of refinement of risk estimates
- need of risk assessment by product
- need of risk assessment of residents/ bystanders on aerial application
- need of a guidance for the recommendation of PPE based on hazard classification
- better risk communication in the labels for safe use of operators

<sup>1</sup> <http://portal.anvisa.gov.br/consultas-publicas#/visualizar/310795>

<sup>2</sup> <http://portal.anvisa.gov.br/consultas-publicas#/visualizar/391760>