

UPDATE ON SCIENTIFIC APPROACHES IN EXPOSURE ASSESSMENT DEVELOPMENT OF OPERATORS, REENTRY WORKERS, RESIDENTS AND BYSTANDERS TO PESTICIDE IN BRAZIL

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INTRODUCTION

The implementation of Operators, Re-entry Workers, Residents and Bystanders Risk Assessment in Brazil has been discussed for several years and a new legislation including a Technical Guidance will soon be published by the National Health Agency (ANVISA). In this scenario of technical discussion, a Technical Cooperation Agreement (ACT) was signed in 2020 between ANVISA and the ProHuma Institute for Scientific Studies and will be extended for 5 more years (2025-2030) further expanding collaborative arrangements, scientific projects, data generation and knowledge exchange. To deploy the ACT work plan, a Task Force (FT-ACT) was formed, composed of technical experts in risk assessment from ANVISA and ProHuma along with experts in statistics, application technologies and IT (Information Technology) systems development.

OBJECTIVE

The objective of this update is to present the main actions and results of the Task Force (FT-ACT) since 2020, with a focus on the achievements during intensified discussions over the last two years (2023 and 2024). This includes the development of a Calculator to estimate occupational (operators and reentry workers) along with resident/bystander exposure, as well as other technical-scientific activities performed and still on-going to support the non-dietary risk assessment of pesticides in Brazil.

WORK PLAN

- DEVELOPMENT OF THE BRAZILIAN EXPOSURE DATABASE
- RISK ASSESSMENT FOR OPERATORS
- RISK ASSESSMENT FOR WORKERS (involved in reentry activities)
- RISK ASSESSMENT FOR RESIDENTS/ BYSTANDERS

INITIAL ACTIONS:

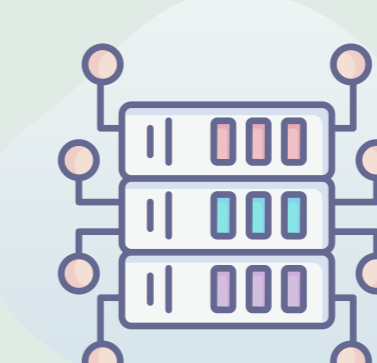
The approach, development and implementation of a non-dietary risk assessment is complex and challenging, which requires continuous scientific growth, data generation, tools development as well as actions to improve education and communication. Therefore, it is a long process and is necessary improvements along the way. The main actions taken includes:

•Detail of the two main actions:

• Development of an Integrated Calculator for estimating the exposure of operators, re-entry workers, residents and bystanders

The development of an integrated calculator, carried out with the support of IT programmers and exposure/statistics experts, was considered fundamental, in this 1st phase of the FT-ACT work, to harmonize the tool for calculating exposure estimates to be used by product applicants and regulators in Brazil, providing users with a publicly available, transparent and as friendly as possible tool, available in Excel.

The 1st version of the tool will be grounded on parameters, references and data which predicts exposure for scenarios already evaluated by the FT-ACT. The exposure scenarios that have not yet been discussed follow the references/approaches recommended and being currently used by ANVISA and will be updated once the discussions and development of the assessment advances in order to obtain exposure estimates most representative of the Brazilian scenario.



•Pilot study in Brazil to obtain GLP accreditation to conduct local OPEX studies

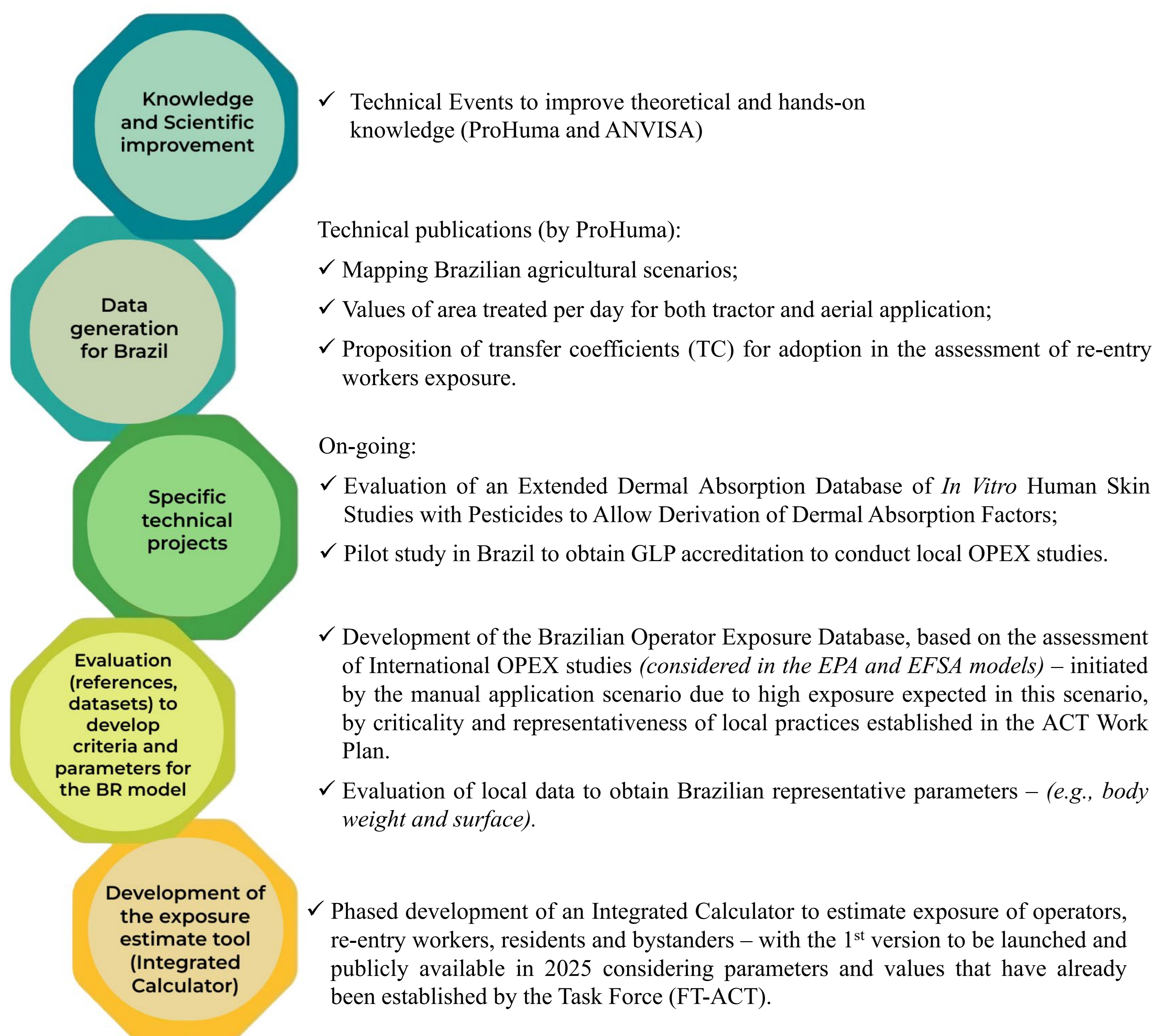
In order to conduct OPEX studies in Brazil – following GLP and all special requirements needed to conduct such a unique and complex study that involves human subjects performing their normal day-to-day work, it was necessary to understand the requirements for conducting an OPEX study, in accordance with the *OCDE/GD(97)148 series n° 9*, and also to issue approval and consent by each of the local Brazilian agencies intrinsic to the process, in order to allow the conduction of a pilot OPEX study, being:

ANVISA: Brazilian Health Regulatory Agency, issued a Technical Note supporting the conduction of a pilot OPEX study, with the appropriate conditions for soil-directed backpack application so that other regulatory bodies such as MAPA (Brazilian Ministry of Agriculture) and IBAMA (Brazilian Institute of the Environment) also consented. The action was completed in June 2022.

CONEP: The National Research Ethics Committee – the body responsible for approving research involving humans – carried out the necessary assessment of the pilot OPEX study project in accordance with Brazilian ethical regulations. Approved in September 2022.

INMETRO: Brazilian Metrology Institute, responsible for GLP accreditation in Brazil. The first step was the creation of a new area of scope – Occupational Exposure Studies with Pesticides for Agricultural Application – to obtain GLP accreditation. For that measure there was a need to conduct two pilot studies (soil-directed backpack application scenario), in 2022 and 2023. GLP Accreditation is expected to be granted in October 2024 to the ProHuma partner laboratory in this project.

A new OPEX study covering a different exposure scenario (still under discussion) is expected to be conducted between the second half of 2025 and early 2026.



CONCLUSION:

The development and implementation of robust scientific regulatory documents and tools to estimate occupational, resident, and bystander exposure to pesticides are essential for ensuring transparency and clarity in risk assessment process. These efforts provide the core principles and recommendations for the general criteria and parameters needed to assess pesticide exposure. The work conducted under the first ACT – Technical Cooperation Agreement – marks a significant step forward. By establishing criteria and certain exposure assessment parameters that account for local specificities, this initiative is grounded in science and technical knowledge. Combined with the development of a tool – calculator – to calculate the exposure estimate, Brazil is increasingly advancing in its objective of implementing risk assessment in the context of exposure to pesticides to ensure protection of operators, rural workers, residents and bystanders. Through conducting a risk assessment that is better suited to Brazil, the outcome is the improvement in human health safety and overall society benefit.