

Development of a Pesticides Occupational Exposure Study following Technical, Regulatory, Ethical and GLP Requirements in Brazil

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Introduction:

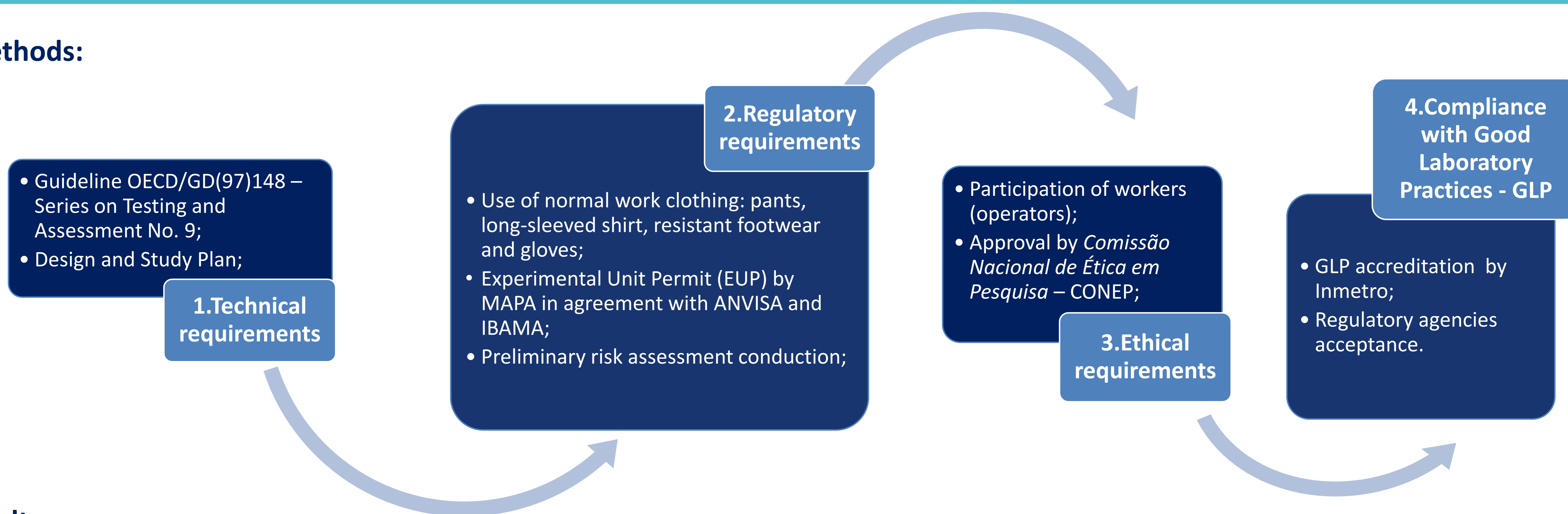
The assessment of occupational risk arising from pesticide use is a regulatory tool implemented in several countries and regions, such as the USA and Europe. It's conducted to determine whether the use presents acceptable risks to worker health. To achieve this, the exposure must be estimated usually from predictive models based on generic data from occupational exposure studies. This type of study shall follow harmonized international guidance to compose databases that estimate exposure in similar scenarios (combining activities, application equipment, crop characteristics, etc.), aiming to reduce the number of studies conducted in human subjects.

Considering the implementation of a Brazilian regulation by *Agência Nacional de Vigilância Sanitária* (ANVISA, Public Consultation 987 of December 15, 2020) and the need to have representative Brazilian agriculture scenarios, a pilot study was conducted.

Objective:

Describe the steps to design, obtain consent and conduct an occupational exposure study with human subjects in Brazil following technical, regulatory, ethical and GLP requirements.

Methods:

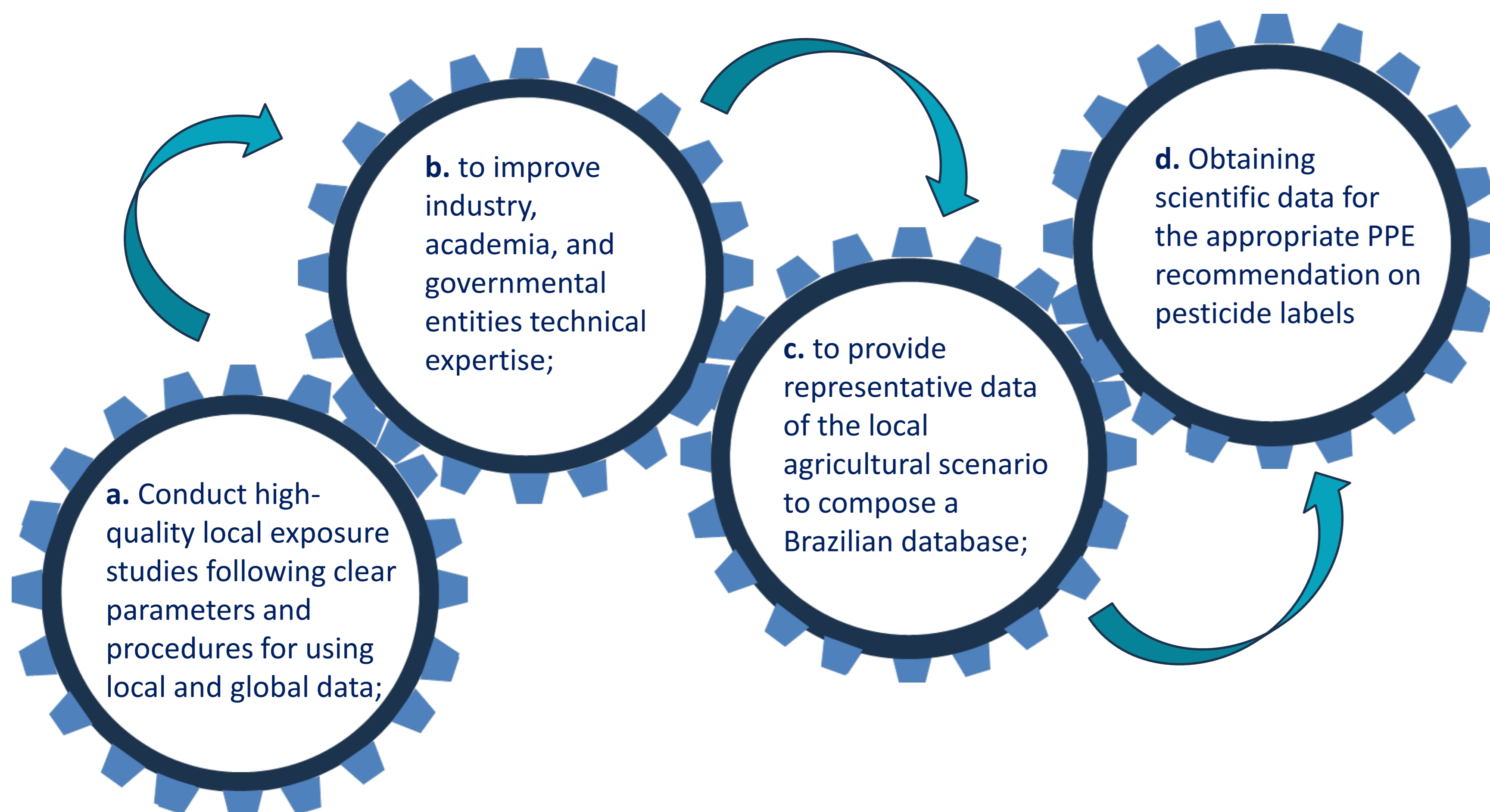


Results:

Once the study design and the preliminary risk assessment were carried out, consents from regulatory bodies and the Ethics Committee were granted. The field and analytical phases of the study were successfully carried out in 2022 and 2023. Several professionals were trained and mentored by international experts; field phase was followed by members of ANVISA staff. These interactions have improved exposure study expertise of key partners in Brazil.

Conclusion:

The main benefits of the conduction of such studies in Brazil are:



Fortification of inhalation dosimeters to be analyzed as quality control



Weathering of dermal and inhalation dosimeters to be used as quality control



Sampling of dermal exposure sample through hand washing



Worker dressed with internal dermal dosimeters



Worker dressed with inhalation and internal dermal dosimeters, plus working clothes

As a final result, by considering not only the hazard but also exposure, the health and safety of the agricultural workers are prioritized, including their comfort, which will result in increased adherence to the use of PPEs.

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