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OPINION

Environmental Safety and Ecotoxicity of Biopesticides

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ABSTRACT

The growing increase in the world population, associated with increased demand for food, has promoted the increased use of synthetic Plant Protection Products (PPPs as pesticides) in agriculture, which can raise environmental concerns. Nowadays, it is generally believed that the use of Biopesticides (BioPPPs) may contribute to reducing the undesirable environmental effects usually associated with the use of synthetic pesticides. However, the risk assessment required by the EU Member States Authorities (EMSA) to evaluate the ecotoxicity of PPPs may not be the most suitable for BioPPPs due to their particular properties and mode of action that are distinct from those of synthetic PPPs.

Biopesticides Background

Given the human population growth rate (UN predicts that the global population will increase to 9.7 billion in 2050), associated with the increase in per capita consumption, results in an increasing demand for food production (UN estimated a double or increase by 60% to feed the growing population), the expansion of agricultural areas and, consequently, an increase in the use of PPPs [1,2]. Since 1990, there has been a growing environmental concern, which has favored the adoption of more sustainable agricultural production, balanced with the natural systems and cycles, which led to a tendency to replace synthetic pesticides, often associated with adverse side effects on environmental health, with Biopesticides (BioPPPs) [3-7]. Some BioPPPs are increasingly used in conventional and Organic Farming (OF), which may underestimate their currently recognized environmental impact since their authorization by EU Member States Authorities (EMSA) [4,8]. OF has been recognized as important for future global food security and for minimizing environmental problems (OF area in the EU up 46% between 2012 and 2019; EUROSTAT). North America formed the largest market for BioPPPs in 2015, whereas Europe accounted for the second-largest market since 2015 [9,10]. Despite being mostly photodegradable, residues of BioPPPs can affect the environment, since it has already been demonstrated that they can adsorb to organic matter and soil/sediment, due to the absence of light [8,11], and some commercial formulations contain stabilizers that retard both hydrolysis and photodegradation [1,12], enhancing the possibility of reaching several environmental compartments. The selectivity and safety of BioPPPs are not absolute [11] and some BioPPPs can be toxic [1]. More than 1,400 BioPPPs registrations have been made worldwide, although a much smaller number of registrations are considered in Europe (about 60 products) due to the complex EU regulatory system [13].

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Some studies suggest that BioPPPs could be as effective as other synthetic pesticides against target and non-target organisms [1,14,15]. Complementing the parameters currently required for all PPPs by the EU (e.g. evaluation of the behavior, growth, reproduction, feeding responses, and death using organisms from different ecosystems) with additional and more sensible parameters will allow a more complete and adequate assessment of BioPPPs to minimize/avoid more serious effects at higher organizational levels. It has been highly recommended the evaluation and validation of new ecotoxicological tools to properly assess the potential toxicity of BioPPPs, with additional sub-individual responses from the molecular, organelle, and cellular to the organism/population levels [16-18]. A multidisciplinary approach using several ecotoxicological tools (Figure 1) is essential (e.g. not only the required by Commission regulation of EU - No. 1107/2009; No 283/2013; No 284/2013) to ensure the sustainability of the environmental compartments (soil, water, and air).

Scientific Concerns about Biopesticides under the European Regulation

i) Is the considerable increase of biopesticides in recent decades free from adverse effects for different ecosystems, despite the requirements in terms of testing with non-target organisms for authorization to enter the EU being considered adequate?

ii) Are the tests and evaluation parameters currently required for all PPPs in the EU sufficient for an adequate, robust, and multidisciplinary assessment of the real toxicity of the BioPPPs?

iii) Can the effects of BioPPPs be neglected, considering that these natural and "environmentally friendly" pesticides have already demonstrated toxic effects on non-target species, albeit with a scarce number of ecotoxicological studies evaluating more sensitive and early warning tools (e.g. biomarkers)?

iv) If BioPPPs are very efficient against pests, due to their biological activity, are they possibly also bioactive in several environmental compartments, towards non-target species, since some metabolic pathways are conserved? May commercial formulations enhance their toxicity?

I consider that the data requirements for authorization and commercialization of PPPs by the EU (e.g. reproduction, growth, death evaluations; reported as toxicity values NOECs, LOECs, ECx), can be insufficient for an adequate and solid Environmental Risk Assessment (ERA). Several interdisciplinary ecotoxicological research have been defined (e.g. molecular and cell biology, biochemistry, genetics, agronomy, physiology, ecology, toxicology, and environmental science), to evaluate the potential ecotoxicity of widely used biopesticides, with an approach including

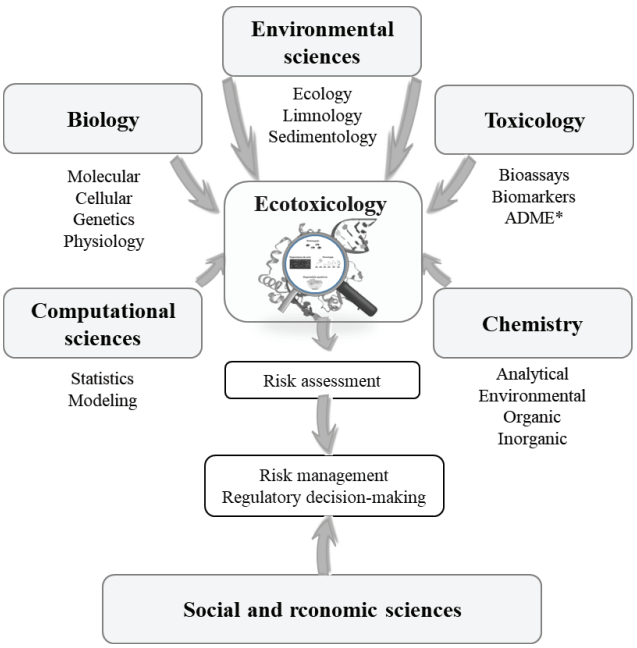

Figure 1 Interdisciplinary essential for risk assessment and management, and consequent regulatory decisions, through the assessment of the impacts of biopesticides on different ecosystems.

*Absorption, Distribution, Metabolism, Excretion. Adapted by [27].

more sensitive parameters and early warning tools (sub-individual parameters), to avoid and prevent damage at higher organizational levels, that can be used as a proxy of effects that may be detected in subsequent generations (Figure 1).

New information about the potential toxicity posed by several BioPPPS to non-target soil organisms is crucial, which are constantly exposed and perform essential functions. Literature on the toxicity of these compounds is still insufficient, based on the date of authorization and current levels of use in the world. Predicted Environmental Concentrations (PECs) for soil, groundwater, and surface water are described in the UE regulations No 283/2013 and No 284/2013 and EFSA [16-18]. Furthermore, it is also crucial to assess the potential toxicity of elutriates in soils to aquatic organisms. Biologically based soil elutriates tests using a battery of aquatic species may provide relevant information about the ability of soils to retain BioPPPs and may be used as a proxy for leachate runoff in environmental risk assessments for aquatic ecosystems [19,20]. So, the challenge focuses essentially on a screening assessment of acute and also chronic toxicity of BioPPPs on organisms of different trophic levels of the aquatic food chain. In this sense, biomarkers can be efficiently applied in studies of risk assessment providing an early evaluation of the actual effects of BioPPPs on the biota and preventing serious consequences for reaching higher levels of ecological organization (individual, population that are levels considered in the risk assessment by the EMSA) (Figure 1).

Additionally, it is also necessary to evaluate the effects of exposure to the active ingredient and commercial formulation on crops because research focused on commercial formulations is likely to provide more realistic results on the overall ecotoxicological impact of specific BioPPPs. Despite the IPM strategy, these BioPPPs can have ecotoxicity and residual levels not expected for the crops, after application and compliance with the safety intervals [16,17,21,22]. Thus, although different authors and entities, including the EU, consider BioPPPs as a low environmental risk in general, because of their rapid degradation, recent evidence suggests that residual amounts can even occur after the safety intervals, affecting non-target species, as crops [14-17,21,22]. So, is important to evaluate physiological indicators of growth performance in crops where these BioPPPS are used, with a particular focus on oxidative metabolism, since oxidative stress is a common consequence of in general toxicity xenobiotics, reactive oxygen species (ROS) production, and lipid peroxidation [23,24].

The compilation of information and the proposal of an integrated assessment of ecotoxicological and functional metrics [25] (beyond those required by the EU for PPPs) are relevant to future complementary evaluation studies of BioPPPs. Is vital to define a set of sensitive, reliable, and relevant ecotoxicological tools, for future risk assessment evaluations (e.g. definition of ecotoxicity classes of sub-individual parameters) and to contribute to the definition of regular toxicity screening tools, filling the current gaps regarding this information.

There are several criticisms about the process of validation and approval of BioPPPs, noting that different stakeholders (e.g. producers, industry, legislators) have different opinions [26]. The conclusion is that despite the EU recommending a regulatory framework for its crop protection strategy, with well-defined requirements, a more complete and consistent characterization of BioPPPs is needed, with clearer methodologies and analysis of results, with better monitoring of processes of the validation and updating of toxicity assessment tools. In this perspective, advances in scientific knowledge must ensure the sustainability and balance of environmental compartments (soil, water, and air), in the medium and long term.

The re-evaluation of safety data sheets and reports of environmental toxicity of studied BioPPPs will allow informing, complementing, and restructuring knowledge of analysis and management by national and international entities. This integrative approach can be a useful indication for the regulatory authorities, since possible risks detected for BioPPPs may alert them to the need to adopt restrictive measures. This topic is relevant if we consider the strong commitment of European and national policies to promote knowledge-based approaches to fill the knowledge gaps and complement classification and safety studies, to avoid toxicological, ecotoxicological, and environmental imprudences. In addition, this issue is in line with the objectives of the existing Organization for Economic Co-operation and Development (OECD) and strategic scientific development (H2030). For sustainable agricultural practices, fundamental and applied research constitutes pivotal support for adequate management plans, national and European Parliament's PEST Committee, on the use of PPPs, or for mitigation measures towards the restoration or maintenance of good agricultural practices and environmentally friendly.

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