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Risk assessment of pesticides and other stressors in bees: Principles, data gaps and perspectives from the European Food Safety Authority☆

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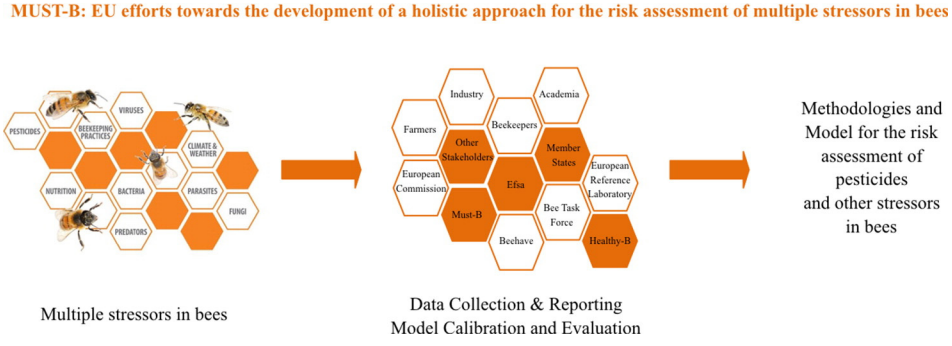
HIGHLIGHTS

- EFSA developed a risk assessment scheme for single/multiple chemicals in bees.
- Research is needed to fill gaps in risk assessments of multiple stressors in bees.
- A toolbox is available to assess honeybee health in field conditions.
- A model is designed to assess risk of pesticides and other stressors in honeybees.
- EFSA calls for an open-access database for risk assessments in bees.

GRAPHICAL ABSTRACT



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ABSTRACT

Current approaches to risk assessment in bees do not take into account co-exposures from multiple stressors. The European Food Safety Authority (EFSA) is deploying resources and efforts to move towards a holistic risk assessment approach of multiple stressors in bees. This paper describes the general principles of pesticide risk assessment in bees, including recent developments at EFSA dealing with risk assessment of single and multiple pesticide residues and biological hazards. The EFSA Guidance Document on the risk assessment of plant protection products in bees highlights the need for the inclusion of an uncertainty analysis, other routes of exposures and multiple stressors such as chemical mixtures and biological agents. The EFSA risk assessment on the survival, spread and establishment of the small hive beetle, *Aethina tumida*, an invasive alien species, is provided with potential insights for other bee pests such as the Asian hornet, *Vespa velutina*. Furthermore, data gaps are identified at each step of the risk assessment, and recommendations are made for future research that could be supported under the framework of Horizon 2020. Finally, the recent work conducted at EFSA is presented, under the overarching MUST-B project ("EU efforts towards the development of a holistic approach for the risk assessment on MUltiple STressors in Bees") comprising a toolbox for harmonised data collection under field conditions and a

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mechanistic model to assess effects from pesticides and other stressors such as biological agents and beekeeping management practices, at the colony level and in a spatially complex landscape. Future perspectives at EFSA include the development of a data model to collate high quality data to calibrate and validate the model to be used as a regulatory tool. Finally, the evidence collected within the framework of MUST-B will support EFSA's activities on the development of a holistic approach to the risk assessment of multiple stressors in bees. In conclusion, EFSA calls for collaborative action at the EU level to establish a common and open access database to serve multiple purposes and different stakeholders.

1. Introduction

The pollination of wildflowers and several key crops for food production rely on native and managed bees (Klein et al., 2007; NRC, 2007). In addition, managed colonies of honeybees (*Apis mellifera* spp.) represent an important source of goods and income with a yearly production of 1.6 million tonnes of honey and 65,000 t of beeswax (FAOSTAT, 2013). However, global declines in bee population pose threats to food security and the maintenance of biodiversity. For honeybees, large monitoring programmes indicate unprecedented rates of colony losses, in particular in Europe and North America (Laurent et al., 2015; Steinhauer et al., 2016), but similar observations, although less well documented, are being made in other parts of the world (IPBES, 2016).

Stressors affecting bees are multiple in nature and origin and these can be grouped into four broad classes: physical, chemical, biological and nutritional. Physical stressors are mostly governed by environmental changes (e.g. climate change, habitat fragmentation and destruction) while chemical stressors mostly include compounds of an anthropogenic nature (e.g. farming, urban/industrial/mining activities, beekeeping, gardening, etc.) as well as naturally occurring contaminants (e.g. mycotoxins, plant alkaloids, etc.). Biological stressors include bee pests and exotic diseases while nutritional stressors may be expressed as a change in the bee's nutritional status (e.g. proteins, lipids, sugars, vitamins and minerals). Both biological and nutritional stressors may be modulated by environmental changes and/or anthropogenic activities (e.g. an increase in bee pests and exotic diseases due to climate change and global trade; nutrition of bees related to resource availability in the landscape and beekeeping management practices). One of the challenges in environmental risk assessment is to include the combined effects of such stressors in risk assessment schemes (Holmstrup et al., 2010).

The European Food Safety Authority (EFSA) has the mandate to provide scientific advice related to food and feed safety issues in Europe. Bees represent a significant link in the food chain and ecosystem, and therefore it is critical that healthy stocks of bees are protected to enable the production of goods such as honey, pollen, propolis, royal jelly and wax (for honeybees), and the sustainable maintenance of the services that bees deliver (i.e. biodiversity and pollination). In this context, EFSA provides scientific advice and guidance on bee risk assessments related to a number of regulated stressors, that fall under its remit and are relevant to bees (i.e. plant protection products, animal diseases and pests and genetically modified organisms). In addition, EFSA provides scientific advice on peer-reviews of the risk assessment of all active substances used in plant protection products in Europe, which may include monitoring data. Furthermore, EFSA compiles and analyses in annual reports the information from the official controls of pesticide residues in food products (including honey) in European Member States (EFSA, 2015a). Further, it is under EFSA's strategic objectives 2016–2020 to prepare for future risk assessment challenges by generating, in cooperation with its partners, new scientific knowledge based on new developments and evidence (EFSA, 2015b). EFSA is proactively involved in the development of new risk assessment approaches with the integration of new scientific evidence regarding the impact of multiple stressors on bee health. However, developing new methods for the risk assessment of those multiple stressors in wildlife populations is challenging given the high uncertainties with respect to how such assessments should be performed (Munns, 2006).

Within the past few years, EFSA has initiated a series of actions towards the development of a holistic approach for the risk assessment of multiple stressors in bees (EFSA, 2013a, 2014a). This work has been developed by an internal and multidisciplinary task force, called the EFSA Bee Task Force, gathering scientists from different units involved in bee assessments. The Bee Task Force started its work by making an inventory of all EFSA's activities and outputs dealing with bee risk assessment, risk mitigation and monitoring since the establishment of EFSA, in 2002 (EFSA, 2012). The Bee Task Force also organised a scientific workshop with all involved stakeholders to discuss the latest scientific developments on the risk assessment of multiple stressors in bees (EFSA, 2013a) and on approaches to broaden environmental risk assessments to account for multiple stressors (Devos et al., 2016). The conclusions of this event, together with a scientific report prepared by the Bee Task Force reviewing existing research projects in Europe and identifying knowledge gaps in this area, led to a series of recommendations (EFSA, 2014a) that were further reviewed and prioritised for future research under the framework of Horizon 2020 (EFSA and EC DG-AGRI, 2016).

The objectives of this paper are to review the principles of risk assessment of pesticides in bees, to discuss the data gaps and research needs for each step of the risk assessment process, and to provide an overview on EFSA's ongoing work to move towards risk assessment of multiple stressors in bees.

2. Principles of the risk assessment of pesticides in bees

Environmental risk assessment deals with the assessment of the risk(s) posed by a single or multiple stressors to which the environment or species under study may be exposed to. Frameworks for environmental risk assessment often use tiered approaches, which may use laboratory data at low tier and semi field to field data at high tier. In natural ecosystems or agro-ecosystems, bees may be exposed to a variety of stressors, whether of natural or anthropogenic origin including infectious agents, pests and predators (biological stressors), climate (physical stressors), habitat (nutritional stressors) and chemicals such as pesticides and environmental contaminants (EFSA, 2014a). Principles and methods for the risk assessment of pesticides in bees have been extensively reviewed both by EFSA and the US-EPA and the section below provides a brief overview of the key steps, namely problem formulation, exposure assessment and hazard and risk characterisation (EFSA, 2013b; EFSA PPR Panel, 2012; US-EPA, 2014).

2.1. Problem formulation and protection goals for bees and pollination

The basis of pesticide risk assessment schemes is to evaluate whether the use of a compound is acceptable in terms of its environmental impact and whether protection goals as outlined in the regulation are fulfilled.

In the pesticide regulation (EC, 2009), protection goals are broadly defined as the absence of unacceptable effects on the environment,

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