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Content

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Abstract

An inventory and review of current pesticide regulatory risk assessment procedures for bees and other pollinators is presented. For North America, the European Union, Brazil, China, and Australia, the work is based on a review of the published literature, covering pesticide regulatory risk assessment approaches of high-income countries. For low- and middle income countries in the African, Pacific and Caribbean region, the work is based on an online questionnaire, conducted during the summer of 2021, followed by ad-hoc questions for further details and clarifications. In hindsight, the focus on the above-mentioned high-income countries is justified, as the expectations were met that it is a widespread practice for low- and middle-income countries to consult assessments by APVMA (Australia), USEPA (USA) and EFSA (European Union). Protection goals in the published approaches focus on bees, especially the honey bee as a prevailing model organism. Approaches incorporating further taxa, in particular with regard to local pollination services, may be adopted in the future, but are currently prevented by knowledge gaps. All established risk assessment procedures follow a tiered approach, and establishing a lower-tier system in regions

currently lacking risk assessment procedures is a much more important step toward improved pollinator protection compared to risk refinement at higher tiers. Several established risk assessment approaches include toxicity classification, which are similar to each other in general, offering an opportunity to assess risks at a screening level without data on exposure. However, basic toxicity data on pesticides are currently not required at all in many low- and middle-income countries. Thus, establishment of a general requirement of data on acute toxicity for honey bees would markedly improve risk assessment in these countries, given that obtaining and assessing such data is a comparatively standardized endeavour and not particular resource demanding. Exposure is handled in different ways by the established risk assessment procedures, with similarities in considered application methods, but marked differences between further parameters of exposure scenarios, e.g. regarding spatial and temporal relation between pesticide application and exposure event, contaminated matrices considered etc. There is a general consensus in the established risk assessment procedures with regard to adopted guidelines and guidance documents used for effect assessment. Approaches established by EPPO, EFSA and USEPA all compare exposure-toxicity quotients to predefined levels of concern for identification of unresolved unacceptable risks to bees, while the calculative basis for these quotients and/or threshold values differs between these approaches, reflecting particular application or situation specific factors or models, accounting inter alia for background mortality, interspecific extrapolation, uncertainty, measured residue data. The other established risk assessment procedures largely follow the approaches of EPPO, EFSA or USEPA. Risk enveloping might offer a resource saving strategy to assess risks of pesticides with similar use patterns in similar cropping systems, and adopting an approach similar to a working example set by IBAMA in Brazil might be feasible, at least for similar geographic regions, given that there are some commonalities in pollinator depend crops among the surveyed low- and middle-income countries. Risk management and uncertainty analysis should always be linked to the risk assessment at all stages, and resulting risk mitigation measures should be practicable in the local agricultural context and comprehensible, while not compromising product efficacy.

Keywords: pesticide regulatory risk assessment, bee, Apiformes, pollinator, pesticide, risk mitigation

Introduction

Pesticide risks to pollinators

Insecticides and other pesticides are used in the agricultural landscape as part of crop protection to maintain the health of cultivated plants and crops and therefore to contribute to crop yields and quality (Jaskolla 2006). However, as part of the agricultural landscape, non-target organisms are also exposed to agrochemicals. Due to their mobility and foraging activity, this particularly affects flower-visiting insects (Bereswil et al. 2019), which have a high economic and ecological value for agriculture and the ecosystem (reviewed in Kremen et al. 2007). One of the most important ecosystem services is the pollination of wild and cultivated plants, which is provided by bumble bees, solitary bees, butterflies, moths, wasps, flies, or beetles, but especially by honey bees (Williams 2002; Kremen et al. 2007). Thus, the protection of bees is of major importance; the ongoing decline in insect populations that has been observed for several decades (Sánchez-Bayo and Wyckhuys 2019) underlines the need for regulatory measures to protect the environment.

Among other factors, pesticides may have negative lethal and sublethal effects on individual bees, bee brood, or even entire colonies, depending on the mode of action, application method, and dosage (reviewed for insecticides in Belzunces et al. 2012). Thus, measures must be taken to minimize the pesticide-related risk in order to maintain the ecological balance and biodiversity resulting from the pollination services of bees (IPBES 2016). Consequently, a risk assessment is required when substances with potentially harmful properties are used in the environment or when exposure of bees cannot be ruled out (Alix and Lewis 2010).

The objective of such a risk assessment is to identify potential hazards, and quantify risks of adverse effects on pollinators (Foudoulakis 2006). This is to prevent unacceptable negative impacts of pesticide use in agriculture on biodiversity (European Commission 2009). In this context, risk assessment and risk management decisions need to be closely linked and well coordinated, because only in combination with specific risk mitigation measures a balance can be achieved to apply toxic substances in such a way that crops are adequately protected against pests, while at the same time the protection of beneficial pollinators is ensured (Alix and Lewis 2010).

The extent to which the use of insecticides may pose a risk to bee health depends on many factors including the active ingredients and formulations applied, crops, application rates, application timing, season, risk mitigation measures and use conditions. While the applications may be restricted with regard to spray timing, concentrations, application rates, application machinery, or to use by only trained staff, such restrictions also may have an impact on the efficacy of treatments against pests.

The risks of adverse effects therefore may need to be weighed against the need for an efficient pest reduction, and in some cases, risks weighed against benefits. For high-risk pesticides effective alternatives with better ecotoxicological profiles may not always be available. For instance, in some scenarios, it is unavoidable that bee-attractive flowers are target of insect pests and the necessity arises to treat crops in full flower. In such cases, some adverse effects may not be fully avoidable, but mitigation measures such as "apply after daily foraging activity" may contribute to a reduction of exposure and adverse effects.

Risk assessment schemes are intended to refine the risk assessment opposed to a toxicity-and-hazard based approach. More information often refines the risk assessment, allows a qualitative and quantitative information on risks for adult bees, bee brood and colony development and reduces uncertainty of the risk assessment. Risk assessment schemes have been developed to be relatively conservative at tier-I level[1], with triggers that ensure to be sufficiently conservative to detect effects on the level of laboratory studies. If triggered, higher-tier studies assess adverse side effects, such as acute mortality, colony development, or brood development, in a more realistic setting.

History of pollinator risk assessment

With the first use of pesticides in agriculture, such as arsenic dusts in the 1930s, adverse side effects on bees and bee poisoning incidents were observed (Hilgendorff and Borchert 1926). Consequently, testing of side effects of pesticides was performed, risk mitigation measures identified and in some countries official regulations put into place, e.g. in Germany the *bee protection ordinance* (current version: BienSchV 1992[2]).

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[1] Pollinator risk assessment is often designed to follow different steps or tiers, where the lower tiers require less data but are also less precise and subsequent higher tiers are more realistic but also more complex (see chapter 1.4)

[2] Bienenschutzverordnung vom 22. Juli 1992 (BGBl. I S. 1410), die zuletzt durch Artikel 6 der Verordnung vom 27. Juni 2013 (BGBl. I S. 1953) geändert worden ist (*Bee Protection Ordinance of 22 July 1992, BGBl. (Federal Law Gazette) I p. 1410*)

Thereafter, in some countries different toxicity tests in the laboratory and field tests were combined to establish a first risk assessment methodology. Risk mitigation measures were developed and over the course of years refined step-by-step; even more, test methods and risk assessment schemes have evolved over the course of time. Subsequently, numerous different laboratory tests were developed for assessing side effects on bees, ranging from studies with adult bees, bee larvae and bee brood, to those on the colony level. With progressing scientific and technical knowledge, numerous new pesticides and product formulations were developed, as means to optimize control efficacy. As a consequence, risk assessment schemes were required to proactively cover new areas of potential concern. Since different countries have put a different emphasis on some aspects of pollinator risks, various risk assessment systems were established across the world. These mostly used similar testing methodology and test guidelines, but varied in specific aspects such as the use of different studies and the triggers that lead to higher testing requirements.

International activities to refine and harmonize methodological approaches and procedural steps started in the late 1950s as part of the International Commission for Bee Botany (ICBB). In 1980, the international Commission for Plant-Bee Relationships (ICP-BR) was founded. With the bee risk assessment methodology being discussed, refined, improved and standardized, national guidance was also harmonized within EU member states. The ICP-BR provided technical input for guideline development as undertaken by the European and Mediterranean Plant Protection Organisation (EPPO 2003; Lewis 2009), which were then amended, adopted and harmonized by European national bodies and later the European Union. The work of ICP-BR, later called International Commission for Plant-Pollinator Relationships (ICP-PR), also served as foundation for validated and ring-tested OECD guidelines, which are used internationally.

The EPPO risk assessment and testing guidelines were used in many countries in the world, and were based on a set of laboratory, semi-field and field studies in a tiered approach that are combined in a risk assessment scheme. Both risk assessment scheme and study descriptions have been reviewed and refined over the course of time and extended in scope and detail. The most recent guidance on both methodology as well as a risk assessment scheme for pesticide risks to bees was published in 2010 (EPPO 2010a). In the US, a combination of OECD guidelines and US-specific OCSPP guidelines were used for risk assessment, taking into account specifically required tests, such as on toxicity of residues on foliage.

In 2008, in several countries across the word bee poisoning incidents took place and fuelled discussions on a need for more specific investigations and development of risk assessment methods to cover potential side effects from insecticidal systemic seed treatments. This included a specific route of pesticide dust exposure, which was identified as the cause of the incidents, but also exposure via guttation as a potential water source for bees.

New risk assessment methodology and current guidance

To address new information on pollinator protection, both authorities in the EU and US worked on including relevant aspects in new guidance documents, which contain similar elements, describe similar aims and protection goals but also have some differences in underlying approaches and procedural steps. In Europe, the first EFSA bee guidance was published in 2013/2014 (EFSA 2013), but it is not yet formally adopted at the EU level, and is currently under revision with an expected publication of the revised guidance in 2022. In the US, new Pollinator risk assessment guidance was published in 2014 and 2016 (USEPA et al. 2014; USEPA 2016). Furthermore, roadmaps or guidance have been published by the Brazilian IBAMA (IBAMA 2017)[3], Australian APVMA (APVMA 2017) and also Chinese ICAMA (ICAMA 2016).

While these may differ in the level of detail, all of them – ranging from simpler to more sophisticated approaches – aim at protecting bees and to some extent also other invertebrate pollinators. Newer risk assessment schemes have developed some degree of complexity which allows a detailed description of risks for individuals, different castes of bees up to the colony level. Additionally, these schemes often allow a more differentiated view on specific application scenarios, such as the risks from systemic seed treatments or trunk injections. In contrast, older risk assessment schemes, such as hazard based evaluations or basic risk assessment as outlined by EPPO, may be easier to conduct, especially when resources for assessing risks are limited. However, such older schemes tend to be limited to pesticide spray applications, even though the tests still may be adapted to other, more specific uses.

Achieving pollinator protection – linking risk assessment and risk management

Risk assessment can start with a hazard assessment and may be refined depending on the available data and resources. For many substances further published information about risks and mitigation measures are available online from authorities such as USEPA, EFSA and others. As an outcome of the hazard or risk assessment, and for both risk assessments using newer or more traditional schemes and guidance, mitigation measures and product labelling with restrictions may be required. These may be prescribed regardless of the underlying risk assessment scheme.

Pollinator protection may be considered the sum of risk assessment outcome, mandatory and voluntary mitigation measures as well as their implementation at the field level. Appropriate mitigation measures and labeling instructions may help to reduce risks from pesticides to acceptable levels; they may be based on a sophisticated risk assessment, but also on a simple hazard assessment. To protect bees and other pollinators, risk assessment and risk management always need to be closely linked. In real life and under field conditions, the efficacy of such risk mitigation measures further depends on their practicability, training of users, allegiance and comprehensibility.

This report therefore focuses on giving an outline of various risk assessment schemes, ranging from relatively easy to more sophisticated, their procedural differences and commonalities, as well as risk mitigation measures. As such, the report attempts to provide a toolkit, which intends to enable or advance countries to undertake a stepwise pollinator risk assessment depending on resource availability, climatic conditions and geographic location.

Part 1: Established risk assessment approaches in high-income countries

The present review focuses on risk assessment approaches for bees in high-income reference countries: USA and Canada (USEPA et al. 2014; USEPA 2016), EU countries (EFSA 2013), Brazil (IBAMA 2017), China (ICAMA 2016) and Australia (APVMA 2017). Primary sources of information are the aforementioned official documents published by the relevant authorities. Additional sources of information include further publicly available documents, such as guidelines and guidance

[3] A newer version is available in Portuguese and will become available in English in the future

documents. For the EU, although the main focus was on the Bee Guidance Document published in 2013 (EFSA 2013), some information concerning later developments of this guidance document were also considered. Most information presented in this document was presented to the relevant authorities, who reviewed the summaries and provided comments, many of which were incorporated into this latest version.

In the following chapters, a summary on specific aspects of the risk assessment is provided for each of the reviewed approaches. Acknowledging that the different aspects are intertwined in the risk assessment, a separation of the review according to these aspects was nevertheless deemed useful for pointing out exactly where the commonalities and differences lie in the reviewed risk assessment approaches. The order in which these aspects appear was chosen to proceed from simpler issues to more complex issues (e.g., toxicity classification before effect assessment). The order also reflects, to some degree, the order in which a typical risk assessment would be performed (e.g., uncertainty analysis after effect assessment). However, because the different aspects are interconnected, can be treated in various simple to complex ways, and appear at various stages in a typical risk assessment, the order in which the different aspects are presented is somewhat arbitrary.

Many similarities exist among the reviewed risk assessment approaches, all of which aim at more or less specific protection goals (chapter 1.1) and proceed in a stepwise manner (tiered approach, chapter 1.4), depending on exceedance of specific trigger values (chapter 1.5). Assessments include hazard and toxicity (chapter 1.2), exposure (1.3), effects (1.4), and analyses of uncertainty (1.6). The risk enveloping approach (chapter 1.7) may be an option to facilitate risk assessment of similar products and/or applications. Finally, risk assessment on the one hand and risk management, including risk mitigation measures, on the other (chapter 1.8) need to be closely linked, in order to effectively protect bees and other pollinators from unacceptable risks from pesticide application.

1.1 Protection goals

Protection goals are generally required for characterizing the protection of human, animal and plant health in legal frameworks (EFSA Scientific Committee 2015). Protection goals describe the overall status of bees and other pollinators that risk managers intend to achieve. In order to apply the often more generally defined protection goals for actual risk assessments, they need to be translated into measurable endpoints and hypotheses which can be scientifically tested (EFSA Scientific Committee 2015). The resulting specific protection goals enable pragmatic risk assessment approaches and facilitate communication among stakeholder groups (Peeters et al. 2014).

In Europe, EPPO (2010a) focused the risk assessment scheme for plant protection products on risks to honey bees arising from exposure of foraging worker bees. Although the need to protect other bees and pollinator species was emphasised, an assessment for these species comparable to the honey bee assessment was considered unfeasible, due to a lack of knowledge. Moreover, extrapolation from honey bee assessment to other pollinators was described as a promising approach to be further investigated before implementation.

For the European Union, EFSA (2013) developed specific protection goals (SPGs) defining the dimensions related to the level of protection for different organisms (service providing units) and the ecosystem services they provide. Organisms taken into account by EFSA (2013) include the three groups of honey bees, bumble bees and solitary bees. Levels of protection are specified with regard to attributes of these groups that are thought to describe the delivery of ecosystem services. For honey bees and bumble bees, the attributes include colony strength (defined as colony size), while for solitary bees they include population abundance. The spatial scale defined is the edge of the field, while the temporal scale is not defined. The agreed magnitude of still acceptable effects was 'negligible', which in EFSA (2013) was quantitatively considered as a reduction in colony size not exceeding 7%; this was based on expert judgement. For bumble bees and solitary bees, EFSA (2013) uses the same magnitude of effects as for honey bees, combined with safety factors to account for uncertainties with regard to vulnerability, since data on mortality rates in bumble bees and solitary bees were scarce at the time.

Currently, the risk assessment procedure of EFSA is under revision, with a new guidance to be published in 2022, pending on the input from risk managers on the revision of the specific protection goal. So far a decision has been taken regarding a specific protection goal for honey bees for the entire EU, corresponding to a value of 10% as the maximum permitted level of honey bee colony size reduction following pesticide exposure. The process is still ongoing regarding bumble bees and solitary bees.

The U.S. Environmental Protection Agency (USEPA) focuses its risk assessment process on honey bees, which are used as surrogates for other social and solitary bees (USEPA et al. 2014). They consider three protection goals: contribution to bee biodiversity, provision of pollination services and production of hive products. For honey bees, preservation of pollination services and production of hive products can be assessed via population size and stability or via quantity and quality of hive products, respectively. As described in the agency's guidance (USEPA et al. 2014), the USEPA uses these assessment endpoints, tested on managed honey bee colonies, to derive information for assessing development and survival of social and solitary bee species, addressing the protection goal for bee biodiversity. However, data on other species such as bumble bees (*Bombus* spp.), blue orchard bee (*Osmia lignaria*) and alfalfa leafcutter bee (*Megachile rotundata*) may be considered on a case-by-case basis in the risk assessment if these data are available and provided they meet the agency's standards for inclusion in risk assessment intended to inform regulatory decisions.

In Australia, APVMA (2017) bases the risk assessment on the same protection goals and assessment endpoints as USEPA et al. (2014), but separating protection goals between commercially-orientated protection goals and an ecologically-orientated protection goal. In addition to hive products, the first group includes commercial pollination services only provided by honey bees, since these services are essentially all provided by honey bees in Australia (APVMA 2017). Protection of pollinator diversity is specified as the "protection of adequate numbers and kinds of bee species that contribute to the health of the environment (primarily non-*Apis* bees)".

ICAMA (2016) in China aims its risk assessment at avoiding unacceptable risks to the survival of dominant honey bee populations, which include, among others, *Apis mellifera* and *Apis cerana*, from pesticide application and possible exposure.

IBAMA (2017) assesses overall protection objectives (OPO) and specific protection objectives (SPO) for Brazil. The OPO, reflecting society values and defining what, where and how long to protect, include the protection of pollinators and their biodiversity, and protection of ecosystem services provided by pollinators (including pollination, provision of genetic resources and production of colony products such as honey, propolis and wax). The SPO, connecting OPO and the practical risk assessment procedures, address colony viability and are specified by the focus organisms (bee species grouped according to legal requirements and related ecosystem services: *Apis mellifera*, stingless bees, native bees, social native species, solitary native species), the relevant ecological entity (colony), attributes to be measured (survival, vigor, production of colony products, colony size, foraging behaviour, reproduction or population size), the relevant spatial scale (inside and outside the cultivated area), the relevant temporal scale (two cycles, evaluation at each developmental stage), and the degree of certainty required, with which a particular protection objective should be achieved. Although further species are addressed by the SPO, *Apis mellifera* is used as a substitute for these species in the risk assessment. IBAMA (2017) establishes relations between toxicity endpoints derived from studies and protection objectives.

In summary, all of the presented approaches base the risk assessment for bees and other pollinators on protection goals. Despite this commonality, the approaches differ markedly regarding the details of formulated protection goals. Thus, protection goals are formulated more or less concrete, with EFSA (2013) providing the most concrete level of protection to be maintained. Moreover, the approaches differ in setting the focus on particular target (bee) organisms, thus formulating protection goals that are relevant to the particular faunal context of the region. Finally, differences also are found in the conceptual classification of the protection goals which, for example, can be based on ecosystem services (APVMA 2017; USEPA et al. 2014) or the groups of organisms to be protected (EFSA 2013).

1.2 Hazard assessment and toxicity classification

Identifying the hazard of a plant protection product (PPP) and/or its active substance(s) is generally the first step in the risk assessment (screening step). Hazard, in this context, describes a situation or property that has the potential to cause harm (e.g. toxicity of the PPP), whereas the risk assessment determines the probability that a detected hazard will result in adverse side effects.

The hazard assessment is a stepwise procedure, often based on available information of the active substance and the results from tier-I studies on acute toxicity under laboratory conditions (LD_{50}-values for main routes of exposure of adult honey bees, i.e. oral and contact) representing a standardized measurement of the toxicity of the PPPs or the active substance (a.s., also abbreviated as a.i. (active ingredient)). The outcome, which is the sum of all hazards identified, serves as basis for the further steps in the risk assessment.

It is therefore not surprising that this hazard assessment can also be found at the beginning of the risk assessment scheme according to EPPO (2010a). In this scheme, the exposure possibility is estimated based on the product-specific use pattern, followed by a preliminary screening based on the toxicity data from the acute laboratory studies with contact and oral exposure.

In USEPA et al. (2014), APVMA (2017) and the spreadsheet analysis provided in IBAMA (2016), the toxicity of the active substance or the PPP is classified on the basis of the tier-I level data , i.e. the acute oral and contact LD_{50} values from the laboratory studies (Table 1.1). With regard to the toxicity classification in USEPA et al. (2014) and in the spreadsheet analysis in IBAMA (2016), there are virtually no differences in the LD_{50} ranges defining the toxicity classes, and only slight differences in the nomenclature. Another classification was discussed in 1985 by the International Commission for Bee Botany (ICBB 1985)[4] (Table 1.1), while EFSA (2013) and ICAMA (2016) do not provide a toxicity classification.

In addition to toxicity data, information on the characteristics of the active substance and/or formulation/product (e.g. mode of action, systemic properties, persistence, degradation, residue levels, natural background concentration) may be used in the hazard assessment.

[4] since 2011 the International Commission on Plant Pollinator Relations (ICPPR)

The United States Environmental Protection Agency (USEPA) requires laboratory-based acute and chronic toxicity data on adult honey bees and honey bee larvae with technical grade active ingredients (TGAI) for terrestrial, forestry and residential outdoor uses (USEPA et al. 2014). Furthermore, these data are conditionally required for pesticides with aquatic uses. Unless the acute contact toxicity data with adult bees indicate that the pesticide is practically non-toxic, and in case exposure of honey bees cannot be excluded, a combined field/laboratory-based test on the toxicity of residues on foliage to honey bees using the typical end-use product (TEP) may be required. If data are available that indicate greater toxicity of a TEP compared to the TGAI, toxicity data using the TEP may be needed in addition to data on the TGAI. While the acute and chronic toxicity tests with adult bees and bee larvae provide toxicity values which are used to quantify risks, the toxicity of residues on foliage study is intended to provide an estimate of the length of time that foliar residues remain toxic (*i.e.*, kill) 25% of the bees tested (*i.e.*, the residue toxicity 25% or RT_{25} value). This value is used to inform environmental hazard statements on labels.

Table 1.1 Established systems for toxicity classification (LD_{50} ranges and nomenclature of toxicity classes). LD_{50} is expressed in terms of µg/bee.

USEPA et al. (2014)	<2 *highly toxic*		2< LD_{50} < 10.9 *moderately toxic*	≥11 *practically non-toxic*	
APVMA (2017)	< 0.1 *highly toxic*	0.1-1.0 *toxic*	1.0-10 *moderately toxic*		
IBAMA (2016) (spreadsheet analysis)	< 2 *highly toxic*		2 ≤ LD_{50} ≤ 11 *moderately toxic*	> 11 *low-toxic*	
ICBB (1985) (now ICPPR)	<1 *highly toxic*		1-10 *moderately toxic*	10-100 *slightly toxic*	> 100 virtually non-toxic

Health Canada Pest Management Regulatory Agency (PMRA) requires acute oral and contact toxicity data for adult honey bees in case of potential exposure (USEPA et al. 2014). These data are general gathered in laboratory studies using the TGAI. Additional studies supplementing TGAI studies may include TEP studies and studies concerning transformation products.

APVMA (2017) uses hazard classifications for hazard-based label statements. With LD_{50} > 10 µg/bee, no hazard-based label statement is required. As an additional hazard-based label statement, APVMA suggests stating systemic action of active substances on product labels.

In Brazil, a Potential Environmental Hazard (PEH) Assessment has been carried out since 1990 (IBAMA 2017). Acute contact and oral toxicity studies are used for hazard classification, the former being required for Technical Products and Formulated Products, while the latter are required only for Formulated Products.

In summary, differences in the established toxicity classification systems exist, in particular with regard to the LD_{50} ranges in the moderately to highly toxic classes and with regard to the nomenclature in the less toxic classes. Further differences in the hazard assessment approaches concern the data requirements underlying the hazard assessment, i.e. whether and under which conditions LD_{50} values are obtained from studies with active substances and/or formulated products.

1.3 Exposure assessment

Exposure assessment is defined as "*the process of estimating or measuring the magnitude, frequency, and duration of exposure to an agent, along with the number and characteristics of the population exposed. Ideally, it describes the sources, routes, pathways, and uncertainty in the assessment.*" (WHO 2008). Thus, a quantitative and/or qualitative evaluation can be conducted to estimate the exposure level or dose values. The major exposure routes for bees include contact and oral pathways and are taken in consideration in all representative international risk assessment approaches listed below. However, various factors such as application methods (Table 1.2), drift, contaminated matrices (e.g. nectar, pollen, water), and scenarios (e.g. treated crop, adjacent crop, weeds in the field) play an important role in the estimation of the exposure level which are briefly presented.

Table 1.2 Pesticide application methods taken into account for exposure scenarios in established risk assessment approaches.

	EPPO (2010a)	EFSA (2013)	USEPA et al. (2014)	ICAMA (2016)	IBAMA (2017)
spray/foliar	●	●	●	●	●
seed treatment	●	●	●	●	●
soil treatment	●		●	●	●
granules		●			
tree trunk			●		●

EPPO (2010a) distinguishes between exposure via spray versus exposure via seed or soil treatments. Before the preliminary screening based on toxicity, the likelihood of exposure is established.

According to USEPA et al. (2014), the tier-I exposure assessment intends to generate reasonably conservative estimates of pesticide exposure to honey bees in the absence of empirical residue values. USEPA et al. (2014) separate four relevant application scenarios: foliar applications, soil treatments, seed treatments and tree trunk applications. Contact exposure is relevant only for foliar applications, while dietary exposure is important for all application scenarios. Tier-I estimated environmental concentrations (EEC) are calculated using the Bee-REX model. Food consumption rates are based on open-literature studies and reflect worst-case scenarios by choosing bee castes/development stages with known high-end consumption rates. By default, nectar is regarded as a more important source of exposure than pollen in the assessment. However, pollen consumption should be considered if residues in pollen result in risk of concern. In the absence of empirical data on the concentration of residues in nectar and pollen, generic residue data from other substances and/or other plant tissues are used in tier-I exposure assessment. For soil, seed and tree trunk applications, without further data it is assumed that substances are transported systemically to all plant tissues. The exposure assessment can be refined by using measured pesticide concentrations in nectar and pollen of the treated crop and through calculations for further bee castes, using provided consumption rates.

According to EFSA (2013), the risk assessment for bees considers different exposure routes resulting from contact exposure via spray deposits (i.e. overspray or spray drift) or from dust particles as well as oral exposure via consumption of pollen, nectar and contaminated water. Spray applications, seed treatments and granules are considered to lead to a contact exposure when bees are foraging on the treated crop, weeds in the field, plants in the field margin or the adjacent crop. A consumption of pollen and nectar is also taken into consideration from the treated crop, plants in the field margin, an adjacent crop, and succeeding annual crops for those application scenarios. Consumption of pollen and nectar from weeds in the treated field, and from permanent crops also the following year, are taken into account for spray applications, and consideration of these additional scenarios are also suggested for granule application. Furthermore, a risk assessment scheme for metabolites in pollen and nectar is provided. Equally, a scheme is proposed for consumption of contaminated water for the risk assessment from exposure to guttation fluid, surface water and water in puddles. It is noted that not all routes are relevant for all uses. However, the assessment still needs to consider all routes and determine whether the route is relevant for the particular use under consideration.

EFSA (2013) proposes an exposure assessment goal to provide concentrations corresponding to a worst case for hives at edges of treated fields in the area of use. The worst-case concentration is defined as the 90th percentile, the relevant area for assessing the 90th percentile depending on the type of registration (e.g., the whole EU, a regulatory zone, a climatic zone, or the EU member state). The specification of the exposure assessment goal applies to the risk resulting from consumption of nectar and pollen entering the hive, guttation water, surface water and puddle water, but not to the consumption of nectar during foraging, due to a potentially greater risk for hives at greater distances from the treated field.

According to ICAMA (2016), spray applications and soil or seed treatments are considered to lead to relevant exposure scenarios for bees. Oral exposure is considered for consumption of pollen and nectar from bee-attractive (flowering) plants after spray applications and for systemic pesticides used for soil or seed treatment, whereas contact exposure is only relevant for spray applications in the treated crop. If pesticides are used indoors, in greenhouses, grain stores and domestic premises the risk to honey bees is expected to be negligible.

According to APVMA (2017), bees (adults, eggs, larvae, pupae) are exposed to pesticides if these are applied to pollinator-attractive crops and if pesticides drift to pollinator-attractive plants during periods when bees are likely to be foraging. Following USEPA et al. (2014), foliar application of pesticides to pollinator attractive crops before flowering may also result in exposure if the pesticide is persistent and translocated to nectar and pollen after spray application. Appendix D in EFSA (2013) is referred to as providing useful information with regard to the attractiveness of main agricultural crops to bees. Further exposure routes include deposition onto surface water and soil. For non-systemic substances, the resulting residues in soil and surface water are not considered to be major exposure routes. For systemic substances, however, a further exposure route for residues in nectar, pollen, exudates and honey dew may become relevant. This exposure route can be based on root uptake of residues in the soil, or on foliar translocation of residues on plant surfaces. While guttation fluid is considered to be only a minor route of exposure, deposition of dust from abraded seed coatings onto plants, soil and surface water may represent a significant route of exposure.

With regard to the exposure assessment described in IBAMA (2017), in the first phase the possibility of exposure is identified and relevant routes of exposure are recognized and evaluated. In the second phase, the (optional) opportunity for exposure refinement is offered, followed by a exposure characterization. IBAMA (2017) differentiates exposure assessment between foliar spraying and applications into the soil, trunk or seed treatment. Main exposure occurs in crop (direct over-spraying; contact with residues on contaminated surfaces; consumption of nectar and pollen, via spray deposition or translocation following seed, trunk or soil application) or off-crop (direct contact with spray drift or dust drift from treated seeds; direct contact with residues on contaminated surfaces; consumption of nectar and pollen contaminated following spray drift, dust drift from treated seeds or translocation after soil application).

Risk assessment considers two scenarios, exposure of *Apis* bees in the crop and exposure of non-*Apis* bees in the off-crop area. Exposure is estimated using the Bee-REX model. For estimation of exposure to foliar spraying drift, the AgDRIFT® model developed by USEPA is used, while a Hazard Ratio is calculated in order to estimate exposure to dust drift from treated seed. The risk refinement consists of determining residues in matrices relevant to bees under field-realistic conditions. In general, a worst-case approach is followed with regard to, inter alia, treated crop, application mode and dosing as well as timing of application.

In conclusion, as the risk is a function of exposure and hazard, the exposure assessment is an important step to estimate the nature and likelihood of adverse effects on bees. Furthermore, the estimation of exposure level may play an important role to define the data requirements. Consequently, with regard to wild bees, the potential additional exposure routes (e.g. leaf material, soil) compared to honey bees are critically discussed in the scientific community. Risk assessments differ in which exposure scenarios are taken into account, and how these scenarios are grouped. Most approaches separate exposure scenarios based on the PPP application method (foliar spray, seed treatment, soil treatment/ granules, tree trunk applications). Scenarios are then further defined by the exposure route (oral or contact exposure), by the residue bearing matrix (nectar, pollen, contaminated water from guttation, puddles or surface water bodies) and by the spatial and temporal relation of the exposure event to the PPP application (e.g., in-crop vs. off-crop; adjacent crop; succeeding crop).

1.4 Effect assessment and tiered approach

To provide robust, reliable, repeatable and reproducible data for regulatory risk assessment, several internationally agreed and adopted or noted testing guidelines and guidance documents are used. Table 1.3 summarizes the available international guideline/guidance documents for testing the effects of plant protection products on bees.

Generally, a tiered approach is followed to assess the effects of plant protection products. This approach includes the stepwise assessment at three or two tiers. With each next higher-tier level, the results become more ecologically relevant, but the evaluation is more challenging to standardize and interpret. Tier-I studies include the results of laboratory testing which are used for calculation of hazard quotients or risk quotients. This tier is often referred to as a screening stage, where obtained endpoints will be compared with established trigger values (see section 1.5 for further information).

In case of exceedance of the trigger values, or other concerns identified based on tier-I data, tier-II effect studies at the whole-colony level may be used to reduce uncertainty related to the extrapolation of effects solely based on individual bees under laboratory conditions. Tier-II effect studies are conducted under semi-field conditions in which absolute worst-case exposure at the colony level is expected. Moreover, other stressors like caging effect and small colony size may affect the outcome of such studies. Feeding studies using colonies with free-foraging bees are usually conducted using sugar solution spiked with known concentrations of the pesticide.

Table 1.3 International available guideline/guidance documents for testing the effect of plant protection products on bees.

	Test guideline/ guidance	Study type	Test organism	Application/ Test duration	Observations	Endpoints	Strengths/limitations
Laboratory toxicity studies (tier I)	OECD 213 (OECD 1998a)	Acute oral toxicity	Honey bee adult	Single oral dose, duration 48-96h	Mortality, behavioural abnormality	LD_{50}	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	OECD 214 (OECD 1998b)/ OCSPP 850.3020 (USEPA 2012a)	Acute contact toxicity	Honey bee adult	Single contact dose, duration 48-96h	Mortality, behavioural abnormality	LD_{50}	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	OECD 237 (OECD 2013)	Acute oral toxicity	Honey bee larvae	Single oral exposure to larval stage, duration 7 days	Mortality	LD_{50}	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	OECD GD 239 (OECD 2016)	Chronic oral toxicity	Honey bee larvae	Chronic exposure to larval stage, duration 22 days	Mortality, sublethal effects hatching success	NOEC/NOED	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	OECD 245 (OECD 2017a)	Chronic oral toxicity	Honey bee adult	Chronic oral exposure over 10 days	Mortality, behavioural abnormality	LC_{50}/LDD_{50} NOEC/ NOEDD	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	OCSPP 850.3030 (USEPA 2012b)	Acute residual toxicity	Honey bee adult	Acute contact test on treated alfalfa, duration 24h	Mortality, behavioural abnormality	RT_{25}	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	OECD 246 (OECD 2017b)	Acute contact toxicity	Bumble bees adult	Single contact dose, duration 48-96h	Mortality, sublethal effects	LD_{50}	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	OECD 247 (OECD 2017c)	Acute oral toxicity	Bumble bees adult	Single oral dose, duration 48-96h	Mortality, sublethal effects	LD_{50}	Standardized and quantifiable test doses Limited to one exposure route, effects at the individual level
	EFSA (2013)	Acute contact toxicity	Solitary bees (*Osmia* sp.)	Single contact dose, duration 48h	Mortality, sublethal effects	LD_{50}	No valid guideline, but recommendation and test protocol
	EFSA (2013)	Acute oral toxicity	Solitary bees (*Osmia* sp.)	Single oral dose, duration 48h	Mortality, sublethal effects	LD_{50}	No valid guideline, but recommendation and test protocol

	Test guideline/ guidance	Study type	Test organism	Application/ Test duration	Observations	Endpoints	Strengths/limitations
Higher-tier studies	OECD GD 75 (OECD 2007)	Tunnel/ semi-field study	Honey bee colony	Spray application on bee attractive crop, direct exposure in tunnel 7 days and 19 days observation outside the tunnel	Mortality, flight activity, brood de-velopment, behavioral abnormality, colony strength	-	Multiple exposure routes (contact, oral), effects at colony level High stress from tunnel conditions, Used surrogate crop
	Oomen brood study (Oomen et al. 1992)	Field study	Honey bee colony	Oral exposure by inhive feeding in open field. Observation time not limited.	Brood de-velopment, colony strength	-	Effects at colony level Uncertainties regarding consumed doses compared to field one
	EPPO 170 (EPPO 2010b)	Semi-field and field study	Honey bee colony	General description of the testing procedures	Mortality, flight activity, behavioral abnormality, colony strength	-	Effects at colony level under realistic conditions High cost, often low replication and statistical power
	OCSPP 850.3040 (USEPA 2012c)	Field study	Honey bee colony	No clear testing procedures described	-	-	-
	EFSA (2013)	Semi-field and field study	Honey bee colony	General description of the testing procedures	Mortality, flight activity, colony strength	-	-

The assessment of such studies investigating effects at colony level is more complex than interpreting tier-I studies, and relies on comprehensive considerations of whether adverse effects are likely to occur at the colony level (USEPA et al. 2014). Furthermore, the information from these studies, e.g. residue concentrations in pollen and nectar, may be particularly useful to extrapolate the results to other crops.

Tier-III field studies are highly complex and require a high level of effort to design and conduct the experiments. Several factors may affect colony survival (e.g., disease, pests, nutrition) and thus need comprehensive considerations in the interpretation of results from such studies. On the other hand, these studies have high importance to refine any concerns and uncertainties from lower-tier studies, to provide robust weight of evidence for the risk assessment conclusions.

For wild bees (bumble bees and solitary bee species) there are currently no official guidelines or guidance documents available for higher-tier assessments (semi-field and field studies). However, there are recommendations from an international working group that offer an initial approach (e.g., Franke et al. 2021).

1.5 Trigger values/ levels of concern

A trigger value is the measurable information (threshold) used as reference for an evaluation in the risk assessment at tier-I level. In cases that the calculation exceeds the defined trigger value, the risk is considered unacceptable and higher tier tests (tier II-III) or other refinements are necessary (e.g. risk mitigation measures; see chapter 1.8).

EPPO

The HQ (Hazard Quotient)[5] for acute toxicity evaluations of spray applications is used according to EPPO (2003). The HQ is the ratio between application rate and LD_{50} (contact or oral):

$$HQ = \text{g a.s./ha (application rate)} \div LD_{50} \text{ (in µg a.s./bee)}$$

If the value is ≤ 50, the risk is considered to be acceptable.

EFSA

To ensure that the General Protection Goal set in the Regulation 1107/09 for non-target organisms (European Commission 2009) is met and the use of a PPP causes a low or acceptable risk, EFSA (2013) operates with trigger values such as Hazard Quotient (HQ), Exposure and Toxicity Ratio (ETR) and Toxicity Exposure Ratio (TER) approaches for the tiered risk assessment scheme.

For bees, HQ and ETR trigger values were defined in EFSA (2013) in order to meet the agreed Special Protection Goal (SPG). An HQ or ETR less than the value in Table 1.4 and 1.5 is considered an acceptable risk.

HQ

The HQ is used as trigger value for contact toxicity of spray applications as ratio between application rate and LD_{50} as well as additional special factors and daily mortality rates. See proposed values in Table 1.4.

Table 1.4 HQ values indicating acceptable risk, as proposed in EFSA (2013).

Test method	Endpoint	HQ honey bee	HQ bumble bee*	HQ solitary bee*
Acute contact adult toxicity (downwards spray)	LD_{50}	< 42	< 7	< 8
Acute contact adult toxicity (upwards and sideward spray)	LD_{50}	< 85	< 14	< 16

* an additional assessment factor of 5 for different species is included and optional an assessment factor of 10, if assessment relies on endpoint of honey bees

ETR

Calculating trigger values for the lower-tier endpoints like acute and chronic oral toxicity, larval toxicity and hypopharyngeal glands, the ETR (Exposure Toxicity Ratio approach) is used:

$$ETR = \text{exposure} \div \text{toxicity}$$

Proposed trigger values are provided in Table 1.5. For both approaches (HQ and ETR) EFSA (2013) takes into account the average individual background mortality for honey bee foragers ranging from 5.3% to 20.8 %. An additional uncertainty factor of 5 is included for other bee species. Furthermore, it is recommended to use an additional uncertainty factor of 10, if the toxicity endpoints of honey bees are used to estimate pesticide risks to the other bee groups.

[5] In EPPO 2003, this is termed “Hazard Ratio”, the calculation basis being the same as for the Hazard Quotient.

Table 1.5 ETR trigger values indicating acceptable risk, as proposed in EFSA (2013).

Test method	Endpoint	ETR honey bee	ETR bumble bee*	ETR solitary bee*
Acute oral adult toxicity	LD_{50}	< 0.2	< 0.036	< 0.04
Chronic oral adult toxicity	LC_{50}	< 0.03	< 0.0048	< 0.0054
Development of hypopharyngeal glands	NOEC	< 1	-	-
Larval toxicity	NOEC	< 0.2	< 0.2	< 0.2

* an additional assessment factor of 5 for different species is included and optional an assessment factor of 10, if assessment relies on endpoint of honey bees

TER

Another approach for calculating trigger values is the TER (Toxicity Exposure Ratio). It is a generalized approach for non-target organisms and a PPP:

$$TER = D_{50} \div E \text{ (Level of environmental exposure)}$$

D_{50} is defined as the dose required reducing the performance on any variable (lethal and sub-lethal). For calculating trigger values for adult honey-bee testing methods on lower tier level, a factor for background mortality (Increment (*I*)) and the daily mortality rate is included. For bumble bees and solitary bees an additional factor is included, to extrapolate from the model organism honey bee to other bees, as well as individual daily mortality rates.

USEPA

USEPA et al. (2014) and USEPA (2016) use a deterministic (point estimate based) approach to assessing pesticide risks to bees. This approach compares point estimates of exposure (*i.e.*, estimated environmental concentration; EEC) to point estimates of toxicity (*e.g.*, acute LD_{50}; chronic NOAEL) to estimate a risk quotient (RQ) which is in turn compared to a Level of Concern (LOC). The LOCs represent thresholds above which risk estimates may trigger regulation. The acute risk LOC for adult and larval bees is 0.4 while the chronic risk LOC for adult and larval bees is 1.0. In case the RQ exceeds its LOC, the PPP is estimated to be a risk of concern and depending on whether the risk can be mitigated and/or whether risk managers need additional characterization, higher-tier assessments may be recommended.

At the screening level, RQs are calculated for individual honey bees using EECs from the Bee-REX (REX = residue exposure) model coupled with toxicity analysed from standardized laboratory tier-I studies:

$$RQ = EEC \div \text{Toxicity parameters (}e.g.\text{, } LD_{50}\text{, NOAEL)}$$

While USEPA bases exposure estimates for foliar applications on the same Kenaga nomogram (T-REX model) used by the agency to assess exposure for other terrestrial animals (*e.g.*, birds, mammals), exposure estimates for soil applications are based on the Briggs's model where pesticide concentration in pollen and nectar are based on measured residue data in the xylem of barley. For seed treatments, residue concentrations in nectar and pollen equate to a default value of 1 mg/L or 1 mg/kg. For tree trunk injections, application rates are converted into a tree-foliage weight basis.

Although tier-I risk estimates are quantified based on model-generated default EECs, RQ values can be further refined using measured residue data in pollen and nectar collected through targeted tier II residue monitoring studies.

IBAMA

IBAMA (2017) uses the Hazard Quotient (HQ), Risk Quotient (RQ) and Estimated Exposure Concentration (EEC) approach for *Apis* and non-A*pis* bees.

The HQ is calculated following EFSA (2013) for contact exposure with regard to dust from sowing of treated seeds. RQ and EEC are calculated in accordance to USEPA et al. (2014) and USEPA (2016). If the RQ exceeds 0.4 for acute risk and 1.0 for chronic risk, higher tier assessment follows. The USEPA Bee-REX model is used in connection with the AgDRIFT® model to estimate RQ for non-*Apis* bees in non-target areas (e.g. spray drift outside sprayed fields).

ICAMA

The ICAMA (2016) approach differs between two exposure scenarios, sprayed pesticides (subscript "spray") and pesticides used for soil or seed treatment (subscript "syst"). For these scenarios, adapted Risk Quotients (RQ), Predicted Exposure Dose (PED) and Predicted No Effect Dose (PNED) are used to calculate trigger values in lower-tier assessments. Non-*Apis* bees are not addressed. If the RQ is ≤ 1, the risk is considered to be acceptable. If the RQ is above 1, risk is considered to be unacceptable, and higher-tier testing may follow.

RQ/PED/PNED

In general, the RQ approach is used for calculating trigger values:

$$RQ = PEC \div PNEC,$$

where PEC = Predicted Exposure Dose, which is calculated for each exposure route, exposure being calculated on a body weight basis;

and where PNEC = Predicted No Effect Dose, which is calculated by using toxicity data and associated uncertainty factors.

RQ_{spray}

RQ_{spray}, corresponding to HQ from EFSA (2013), is calculated as follows (with the exception of insect growth regulating products/substances):

$$RQ_{spray} = AR \text{ (kg a.i./ha)} \div (LD_{50} \text{ (µg a.i./bee)} \times 50)$$

RQ_{syst}

RQ_{syst} is used as Risk Quotient for systemic pesticides.

$$RQ_{syst} = PEC_{syst} \div PNEC_{syst}$$

APVMA

APVMA (2017) uses the Level Of Concern (LOC) as trigger value according to USEPA et al. (2014). For acute risk, the LOC is 0.4, for chronic risk, the LOC is 1. For determination of the LOC, Risk Quotient (RQ), Predicted Exposure Concentration (PEC) and Estimated Exposure Concentrations (EEC) is calculated for different potential exposure routes. Values are regarded suitable for both *Apis* and non-*Apis* bees.

Foliar spray, adult, contact exposure (acute)

$$RQ = PEC_{contact} \div \text{Acute } LD_{50\ contact}$$

Foliar spray / Seed treatment / soil applied (via calculating EEC) / Tree trunk injection

Adult, oral exposure (acute, chronic):

$$RQ_{acute} = PEC_{adult,\ oral} \div \text{Acute } LD_{50adult,\ oral}$$

$$RQ_{chronic} = PEC_{adult,\ oral} \div NOAEL_{adult,\ oral}$$ (NOAEL: No-Observed-Adverse-Effect Level)

Larvae, oral exposure (acute, chronic):

$$RQ_{acute} = PEC_{larvae,\ oral} \div \text{Larval } LD_{50}$$

$$RQ_{chronic} = PEC_{larvae,\ oral} \div NOAEL_{larvae,\ oral}$$

1.6 Uncertainty analysis

In general, uncertainty is defined as lack, gap or limitation of knowledge, depending on the context and the regulatory framework. The uncertainty analysis represents a process that is carried out through any type of evaluation (exposure and hazard assessment, risk characterization) and characterizes the identified uncertainties/problems/issues. Therefore, qualitative and quantitative approaches for explanation or clarification can be used. In individual special cases that require a detailed analysis, other more complex approaches can be used (statistics, probabilities, expert judgement).

Thus, the uncertainty analysis is part of the risk assessment for bees of plant protection products and their active substances.

According to EPPO (2010a), the uncertainty analysis takes place after completing the risk assessment based on the toxicity data and all information with regard to the recommended use and conditions of the PPP and/or its active substances. This is especially necessary if there are any uncertainties in higher-tier studies (e.g. with regard to special effects such as larval toxicity, persistence of residues, abnormalities in behaviour of bees). Uncertainty analysis is done at the end of the risk assessment and confirms the previous evaluation or shows that further refinements or management measures are necessary.

EFSA (2013) offers a very detailed presentation of the uncertainty analysis, its interrelationships in the risk assessment and methods for the characterization. It is pointed out that all uncertainties should be reported at least qualitatively, i.e. with their source, effect size and potential impact. For this purpose, a tabular overview is recommended that includes all lines of evidence. In cases where qualitative evaluation is not sufficient, a quantitative method should be used to refine the uncertainties. To form a conclusion in the risk assessment it may be necessary to use the 'weight-of-evidence' approach, which takes into account all previously identified uncertainties in all lines of evidence and balances these against study findings. The analysis of uncertainties is always related to the underlying specific protection goals (SPGs). In addition, there are corresponding working examples in the relevant appendix to EFSA (2013). Furthermore, EFSA (European Food Safety Authority) Scientific Committee et al. (2018) provide a general 'Guidance on Uncertainty Analysis in Scientific Assessments' with basic aspects, backgrounds and further information.

USEPA et al. (2014) and USEPA (2016) also deal with uncertainty analysis in detail. USEPA et al. (2014) also refer to the 'weight-of-evidence' approach at the end to be able to complete the risk characterization. The individual sources of the uncertainties are described and explained in detail and the connections between the different tiered approaches (tier I-III) are clarified.

APVMA (2017) gives an overview of the approaches provided in EFSA (2013), USEPA et al. (2014) and USEPA (2016) and recommends to consider these in the uncertainty analysis. IBAMA (2017) refers to

USEPA et al. (2014) and USEPA (2016), providing a schematic overview in which phases of the risk assessment uncertainties should be taken into account. Peeters et al. (2014) mention uncertainties in context with the endpoints and the risk calculation in which an uncertainty factor (based on the safety factor recommended by EPPO 2009) should be used to enable the extrapolation from data of acute to chronic toxicity.

As indicated above, uncertainty analysis can be found in all the assessed international and national guidance documents, whereby the main content can be attributed to EFSA (2013), USEPA et al. (2014) and USEPA (2016), briefly summarized already in APVMA (2017)[6]. The importance of addressing uncertainties in the risk assessment is recognised in both, the North American and European guidance documents. Uncertainties can arise in all tiers and are linked to the risk assessment as follows (Figure 1.1).

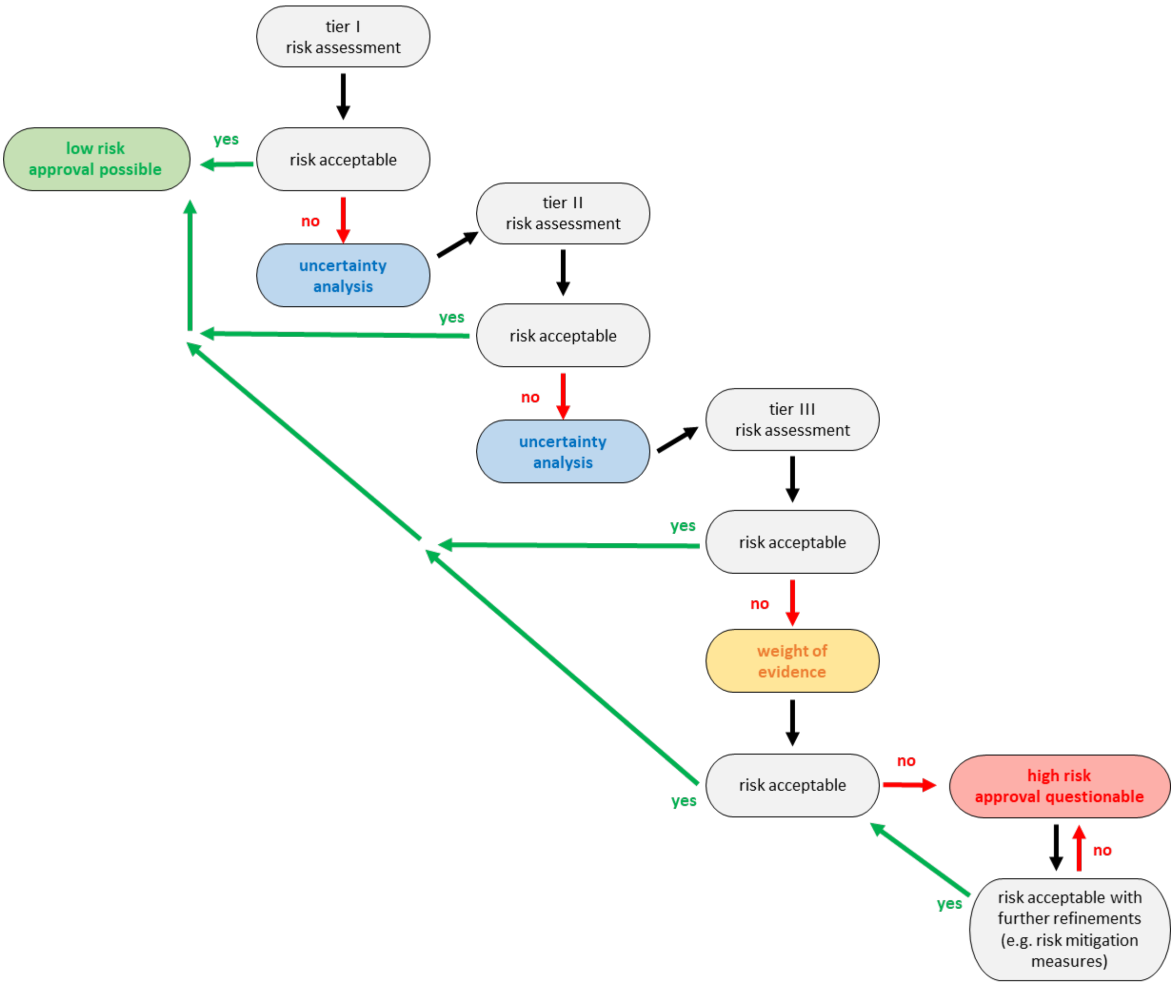

Figure 1.1 Position and Relationship of the Uncertainty analysis in the risk assessment.

The scheme clarifies the position of the uncertainty analysis and its relationships in the risk assessment. It should be noted that even in the case that no risk is evident after tier-I assessment, an uncertainty analysis can be helpful to confirm the results/outcome (e.g. trigger values near the threshold, minor limitations).

A brief explanation of the scheme: it starts with the studies and data in tier I, where possible effects on the level of the individual are examined. A presumably unacceptable risk should be verified by

[6] Some helpful information on the uncertainty analysis can also be found in ECHA 2012.

data on measured residues in the relevant matrices (pollen and/or nectar) as well as studies in tier II. The effects on the colony or population level (e.g. in solitary wild bees) are now being observed in tier II and later in tier III. Accordingly, any unacceptable risk that persists should be checked through studies in tier III. If there are still uncertainties, all other sources of information must be consulted (e.g. open literature). Ultimately, it is then decided on the basis of the evaluation (e.g. expert judgment) whether the risk can be excluded or exist.

There are various sources of uncertainties at all of these tiers, such as:

- exposure estimates (e.g. tier I acute, chronic)
- use of residue data (compare the toxicity value ,e.g. LD_{50}, NOED, with the residue levels determined in the different matrixes, e.g. pollen, nectar; reference approach according to the scheme in EPPO 2010a)
- agricultural practices (e.g. time of application, application method)
- pollination biology (e.g. harvest and bloom period, attractiveness of the crop, pollen vs. nectar content of the crop)
- differences in bee life history (e.g. social vs. solitary, oligolectic vs. polylectic, epigaic vs. endogaic)
- differences in pests/pathogens/nutrition/management
- uncertainty in study designs (e.g. feeding, tier II and tier III)

The discussion in the risk assessment of the identified uncertainties from the various sources and all further information (‘weight-of-evidence’ approach) then leads to the overall conclusion about the risk to bees. At this point, appropriate requirements or risk mitigation measures would be considered. If there are no uncertainties or if these could be resolved, risk is low or acceptable. Alternatively, in cases in which not all uncertainties can be excluded, and higher tier assessments are not possible, risk will often be established as unacceptable risk.

1.7 Risk enveloping

According to SANCO (2011), the risk envelope approach consists of grouping the supported uses of a product based on certain criteria relevant for exposure. The risk assessment can then focus on the resulting group rather than on individual uses. Moreover, identification of a worst-case group representative for all other groups may be possible.

In the EU, according to SANCO (2011), the aim of the risk envelope approach is to identify the good agricultural practice (GAP) leading to the highest exposure of non-target organisms to plant protection products, to the highest HQ-values or to the lowest ETRs. In case a refinement becomes necessary, the coverage of lower risk GAPs by the critical GAP needs to be reconsidered. For honey bees, key parameters leading to identification of a critical GAP include application method, growth stage and application rate, and the crop. For seed treatments, sowing method and coating type may be additional relevant parameters.

In the exposure refinement, for selecting crops in which residues should be determined, IBAMA (2017) uses a system of crop grouping and priority ordering. This system takes into account relatedness of the crops (at the family level), plant size and structure, supply of pollen and nectar to bees, native and solitary bee visitation, dependence of the crop on pollination service, and cultivated area. In general, the crop to be used for residue studies is selected based on crop group and priority order: within one group, the relevant crop with the highest priority order has to be chosen. The crop residue studies performed with this crop then cover other relevant ones within the same group.

1.8 Risk assessment, risk management and risk mitigation measures

Risk assessment and risk management are both essential and need to be closely linked. While the assessment may identify risks for certain scenarios, applications and doses, risk mitigation measures (RMM) may be concluded at any stage in a hazard assessment (e.g. toxic to bees), but may also be the result of a detailed risk assessment and extend to certain application scenarios, concentrations or intended applications with unacceptable exposure or unacceptable risks (e.g. no application when bees are actively foraging or no application when crop is in flower). While some measures may be voluntary, in most cases RMM are mandatory for pesticide operators. In the course of an assessment, the conclusions on specific measures may be drawn from the available information, which means that in some cases measures are recommended even when only limited information is available (e.g. only from laboratory studies). On the other hand, also when refining assessments, potential mitigation may be kept in mind and reduce uncertainties.

Whereas some measures aim at excluding an exposure, other measures may contribute to a reduction of exposure. As bees may be exposed through different routes, and different measures are recommended, the following overview entails common important measures, while for specific applications and scenarios specific measures may be ideal.

When risk assessment is conducted and risks are identified, risk mitigation measures can be followed to control or reduce exposure and risk to a level considered acceptable. In general, risk mitigation measures comprise pesticide labelling, but non-labelling instructions such as implementation of best management practices, or education and training of operators, may also reduce pollinator risks. Thus, the selection of appropriate mitigation measures and mandatory labelling instructions play an important role for pesticide registration. An acceptable use of a plant protection product may only be possible when one or more risk mitigation measures are implemented. However, some measures may not be fully applicable or not realistic under proposed conditions of use. Therefore, such measures should be effective, practicable, comprehensible, and not compromise product efficacy.

Several mitigation measures for the protection of bees and other pollinators are internationally described to reduce exposure, including:

- Reduction of application rates or intervals
- Restriction of application methods (equipment/machinery used, nozzle type)
- Restrictions of application time
- Restrictions of target-crop species
- Restrictions of treatment type (spray, drip irrigation, seed treatment, …)
- Restrictions of applications on growth stages of the target crop (e.g. according to BBCH-index)
- Restrictions of use conditions with regard to environmental situations (e.g. do not apply at high wind speed)
- Restrictions of application in specific circumstances (e.g. avoid pesticide application in case of aphid honeydew production that may create attractivity to pollinators even of non-bee attractive plants)

In Europe, standard phrases for safety precautions for the environment (SPe) are provided under Regulation (EU) No 547/2011 (European Commission 2011). To protect bees and pollinating insects, the *„SPe 8"* includes: "Dangerous to bees./To protect bees and other pollinating insects do not apply on flowering crops./Do not use where bees are actively foraging./Remove or cover beehives during application and for (state time) after treatment./Do not apply when flowering weeds are present./Remove weeds before flowering./Do not apply before (state time).”

EFSA (2013) sees this SPe8 as more relevant for spray applications than for soil applications, seed treatments, trunk injections and other uses. The second SPe statement may be specified further with regard to particular flowering crops, when only for some crops/application scenarios a risk is predicted. As the SPe8 does not cover all exposure scenarios from different application types and is mainly applicable to spray application, EFSA (2013) suggests development of further adapted risk mitigation phrases. EFSA (2013) also suggests definitions of key elements of risk mitigation phrases, such as ‘bloom’ and ‘flowering weeds’, and proposes possible risk mitigation measures for different exposure scenarios, alongside associated phrases.

In Europe, standard SPes are recommended while European member states may add or refine the restrictions and use conditions and adapt mitigation measures to local conditions.

USEPA (2015) and USEPA (2017) propose an acute risk mitigation strategy and describe additional label statements to protect managed bees from foliar applications during the flowering phase. In the case of products with short residual toxicity time (RT_{25}), the application can be conducted in the time period between 2-hours prior to sunset and 8 hours prior to sunrise.

Further RMMs reported by IBAMA (2017) include “do not apply highly toxic product during the flowering period or immediately after cutting, such as sugarcane; use the available techniques to avoid spraying or seed sowing drift; do not spray the product on flower buds if studies indicate a high concentration of residues on pollen and nectar resulting from this application.”

APVMA (2017) suggests to use a ’pollinator area’ defined as an area which includes managed bee hives. In terms of risk management, the following statement is suggested “If there is potential for managed hives to be affected by the spray or spray drift, notify beekeepers 48 hours before spraying to move hives to a safe location.”

ICAMA (2016) suggests temporary closure of bee hives in the case where residual toxicity of the pesticide does not pose unacceptable risk.

Furthermore, there are specific routes and risks which may require a combination of mandatory and voluntary measures, such as labelling as well as respecting certain use conditions. For example, insecticidal dust drift has been the cause of bee poisoning for specific seed treatments and crops. For some crops and treatments, mitigation measures may start at the seed treatment process in the treatment facility, include mandatory labelling instructions and extend to including the farmer´s responsibility to make use of best management practice (BMP) and avoid avoidable dust drift to non-target areas.

1.9 Appraisal

All reviewed risk assessment approaches share the same fundamental principles

In general, all reviewed current risk assessment approaches rely on the same fundamental steps. Current risk assessment approaches are always based on protection goals, and to a large extend focus on honey bees. Protection goals vary in their level of concreteness and, more importantly, are adapted to the regional context, in terms of the (bee) fauna (e.g. considering stingless or solitary bees) and/ or in terms of ecosystem services provided by bees (pollination). Thus, consideration of the regional/ local situation is regarded as an important way forward when developing an risk assessment approach or adapting an established approach from another region.

Exposure is addressed in all risk assessment approaches, but decision may need to be taken without exposure differentiation

Determining the likelihood of pollinator exposure to applied pesticides is an initial step in all approaches. For example, application in areas inaccessible to bees (such as closed storehouses) may lead to minimal exposure, rendering risks to bees negligible. Once exposure is established to be likely or cannot be excluded, different exposure routes are analysed and evaluated to determine the data required for the risk assessment. However, exposure is not always investigated. Quantification of exposure levels for different exposure routes is not always provided in detail. In such cases, the necessity to quantify exposure may differ depending on the crops. Depending on available lower and higher tier studies submitted for risk assessment, decisions may be taken even without differentiation of exposure.

Oral and contact exposure is separated in all risk assessment approaches, but detailed exposure scenarios differ considerably

In all approaches, exposure is separated into oral and contact exposure in first tier calculations. Main exposure classification is generally based on application method (e.g., foliar spray and seed treatment), and exposure scenarios may further be defined based on exposure site (e.g., in-crop vs. off-crop). For oral exposure, various matrices may be considered relevant (e.g., nectar, pollen, but also puddle water and guttation water). Thus, the combinations of the different exposure characteristics lead to multiple exposure scenarios that may be investigated in the risk assessment However, the reviewed risk assessment approaches differ markedly how detailed relevant exposure scenarios are defined from the beginning.

If provided, toxicity classification is very similar among risk assessment approaches

Hazard assessment is another fundamental step covered in all reviewed risk assessment approaches. Historically, hazard assessments had often been in place before risk assessment approaches were established. Toxicity classification is very similar among most reviewed approaches providing such a classification. Differences exist between the approaches as to whether and under which conditions required toxicity data need to be based on the active substances or formulated products.

The tiered approach is adopted in all reviewed risk assessment schemes

All reviewed risk assessment approaches follow the tiered approach, moving from the lower to the higher tier in case a predefined trigger value is exceeded, and allowing refinements to address specific uncertainties resulting in lower tiers. In this way, a high degree of standardization is obtained in most cases (at lower tiers), and this degree of standardization is only lowered for the sake of greater ecological relevance (at higher tiers) when necessary (i.e. when unacceptable risks to bees cannot be ruled out at lower tiers). The risk assessment becomes increasingly data and resource demanding at higher tiers, and a high proportion of low-risk products/applications may already be evaluated as such at lower tiers. Therefore, establishing a lower-tier system is arguably more important when developing/adopting an risk assessment approach, compared to risk refinement at higher tiers. Different trigger values, such as HQ (Hazard Quotient), TER (Toxicity Exposure Ratio), RQ (Risk Quotient) have been proposed in the different risk assessment approaches. Also, different risk assessment approaches derived triggers on a different calculative basis. While these are a sound basis for decision-making, an adaption to local conditions or specific concerns may be useful in some cases.

Additional data may provide pivotal information for risk assessment of bees and other pollinators

Unlike historically used risk assessment schemes, current approaches provide triggers and calculation methods to determine specific risks to larvae or due to chronic exposure and thus may, if data are available and may be requested, be more suitable to assess risks in such scenarios. However, in practice not always data considered useful are available or submitted. Therefore, it is always recommended not only to consider submitted studies on adverse side effects on bees and other insect pollinators, but also studies on the efficacy against insect pests. This approach is suited to properly address potential risks to bee brood, for substances that may have only low toxicity for adults but may have effects on brood development.

Risk mitigation measures are generally linked to the risk assessment

Risk mitigation measures are the logic outcome of a risk assessment. For toxic substances that may have adverse side effects, the refinements and higher tiers in RA may allow a detailed investigation of the extent and nature of side effects, and may result in acceptable or unacceptable risks. In some cases, products that would cause unacceptable risks in case of exposure, can still be used with no side effects on bees if exposure is averted, for example through admission of an application only after flowering of the crop. However, the suitability of risk mitigation also depends on the implementation and the feasibility in local agricultural context. If mitigation measures cannot be realised or are unrealistic, e.g. because these measures counteract product efficacy, there may be cases in which authorisations may not be granted.

Part 2: Risk assessment approaches in low- and middle-income countries

2.1 Survey methodology

While the legislative basis underlying pesticide regulatory risk assessment for bees and other pollinators has been the subject of a recent review (Garthwaite 2022)[7], the focus of the following section is set on the risk assessment practice rather than the legal framework for risk assessors. In this section the outcomes of a survey among low- and middle-income countries are presented. The survey was conducted in August 2021 as an online questionnaire sent to all project countries (see Appendix 1 for the complete questionnaire). Some answers were categorized by the authors for simplifying the presentation of results and to receive responses that are as equivalent as possible. Moreover, while efforts were made to cover all information provided through the survey, some information could not be assessed, especially ambiguous answers rendering correct interpretation impossible and answers not matching the questions. In some cases, follow-up questions were sent to the responding countries in September 2021, asking for more details regarding answers from the survey.

In the following, “country” will generally refer to the relevant registration authority within a country.

[7] Review of Existing Legislation to Protect Pollinators from Pesticides in Selected Countries

2.2 Crops depending on pollinators and receiving regular pesticide treatments

The survey countries cover a wide variety of pollinator-dependent and pesticide-treated crops (Table 2.1). Because of the variety in the survey answers, and in particular because there are multiple crops associated with only a single country, classification of the countries according to similarities of relevant crops is rendered impossible. However, across the survey countries, some generalizations may be derived. More than half of the survey countries (9 out of 16) named members of the Cucurbitaceae family as relevant crops (Pumpkin: 5 countries; Watermelon: 5; Cucumber: 3). Half of the responding countries (8 out of 16) named members of the Solanaceae family (Peppers: 4 countries; Tomato: 4; Eggplant: 2). Moreover, crops of additional plant families were named by 3 or more responding countries, i.e. Coffee, Bean, Cotton and Avocado.

Table 2.1 Crops depending on animal pollination and regularly treated with pesticides. Countries are listed alphabetically, while crops are primarily sorted according to plant family (*Brassicaceae*: Cabbage; *Cucurbitaceae*: Cucumber, Pumpkin, Water Melon; *Fabaceae*: Bean; *Lauraceae*: Avocado; *Malvaceae*: Cotton; *Pedaliaceae*: Sesame; *Poaceae*: Corn; *Rubiaceae*: Coffee; *Rutaceae*: Citrus; *Solanaceae*: Egg Plant, Peppers, Tomato; Ornamentals could not be attributed to a plant family).

Country	Cabbage	Cucumber	Pumpkin	Watermelon	Bean	Avocado	Cotton	Sesame	Corn	Citrus	Coffee	Eggplant	Peppers	Tomato	Ornamentals
Antigua and Barbuda[1]															●
Burundi							●		●		●				
Fiji[2]	●		●									●			
Kenya					●	●					●				
Malawi[3]			●		●	●				●					
Rwanda[4]											●			●	
Sahelian Pesticides Committee (SPC)[5]			●	●			●		●					●	
Saint Lucia			●	●									●		
Samoa															●
Solomon Islands				●	●							●		●	
South Sudan[6]								●							
St. Vincent and the Grenadines		●											●		
Tanzania		●		●		●									
Tonga[7]				●											
Uganda								●			●		●		
Zimbabwe[8]	●	●	●		●		●			●	●		●	●	

Further crops named by single countries: [1]fruit trees, vegetable crops; [2]Pawpaw; [3]Mango, Litchi, Macadamia; [4]Tamarilo; [5]vegetables, rice; [6]Sorghum, Ground Nuts; [7]fruit trees; [8]Pea, vegetables

2.3 Pollinators requiring protection from adverse pesticide effects

All but one country named one or more pollinator group as requiring protection from adverse effects caused by pesticides. Bees were the pollinator group predominantly listed by the responding countries (Figure 2.1). All but one country included one or more bee taxa in their list of relevant pollinators. Further pollinator taxa named by more than one responding country include butterflies (5 countries), birds (4) and wasps (3). Ants, bats, beetles and flies were named as additional relevant pollinators by one country, respectively.

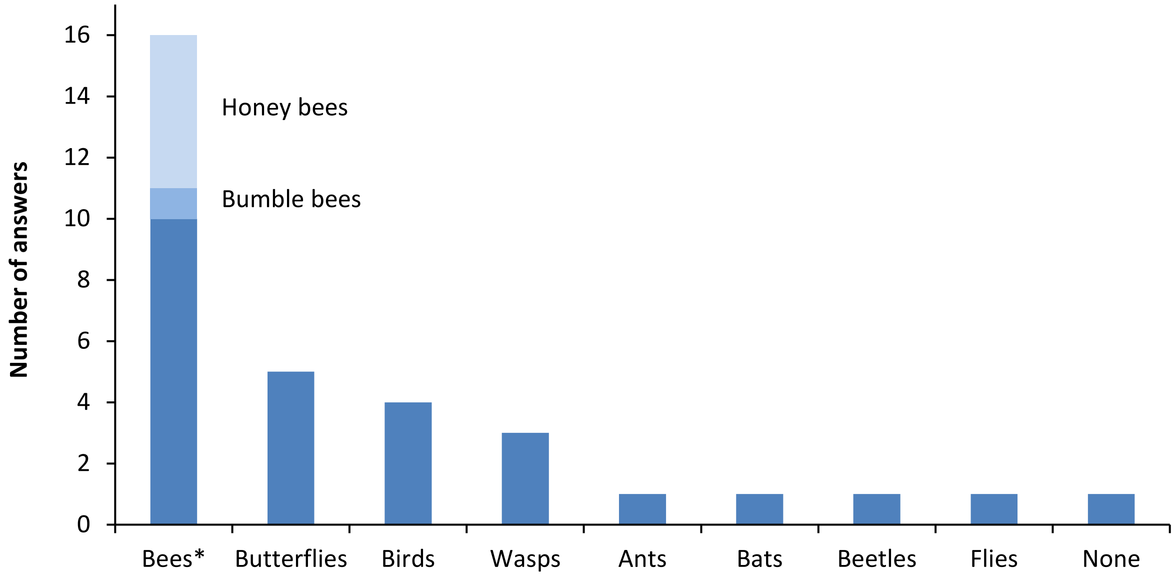

Figure 2.1 Pollinators named as requiring protection from adverse effects caused by pesticides (multiple answers per responding country possible). *Specific bee groups were distinguished only when responses explicitly referred to honey bees and bumble bees; otherwise, answers referred to and pooled as "bees" in general.

2.4 Pollinator data requirements for pesticide registration

The majority of responding countries (11 out of 16) at least sometimes require pesticide toxicity data for bees or other pollinators as part of the registration application (Table 2.2). Among responding countries, acute oral and contact toxicity data for adult honey bees are most often named as minimum requirements (always required) for pesticide registration application (7 countries), followed by field studies (4 countries). Only one country always requires cage or tunnel studies and pesticide residue data in pollen or honeydew, respectively. Further obligatory or potential requirements include MSDS (2 countries), Material Safety Data for aquatic organisms (1), environmental impacts (1), ecotoxicology data on relevant predators (1), toxicity of residues on foliage (1), data on adverse effects that may be required in Bee Risk Exposure models (1), and data on side effects not specific to honey bees (1).

Table 2.2 Pollinator-relevant data required for registration of pesticides[1].

Country	Acute oral toxicity for adult honey bees	Acute contact toxicity for adult honey bees	Chronic toxicity for adult honey bees	Chronic toxicity for honey bee larvae	Acute or chronic toxicity for other pollinator species	Cage or tunnel studies	Field studies	Pesticide residue concentrations in pollen or honeydew
Antigua and Barbuda	●	●	○	-	●	○	○	○
Kenya	●	●	-	-	-	-	-	-

Country	Acute oral toxicity for adult honey bees	Acute contact toxicity for adult honey bees	Chronic toxicity for adult honey bees	Chronic toxicity for honey bee larvae	Acute or chronic toxicity for other pollinator species	Cage or tunnel studies	Field studies	Pesticide residue concentrations in pollen or honeydew
Malawi	-	○	○	-	○	-		-
Rwanda							●	
Sahelian Pesticides Committee (SPC)	●	●	●	●	○	●	●	○
Samoa	○	○	○	○	○	○	○	○
Solomon Islands	○	○	-	-	○	-	-	-
St. Vincent and the Grenadines	●	●	○	-	○	-	○	-
Tanzania	●	●	●	●			●	●
Uganda	●	●					●	
Zimbabwe	●	●	●	●	○	-	○	-

● data always required; ○ data sometimes required; - data never required; blank cells: not answered. [1]Only responding countries are included which require pesticide toxicity data for bees or other pollinators as part of the registration application, thus excluding Burundi, Fiji, Saint Lucia, South Sudan, and Tonga (not requiring such data), but including Samoa (sometimes requiring such data).

2.5 Hazard and risk assessment

Registration Authorities in more than half of the responding countries (9 out of 16) at least sometimes conduct a hazard evaluation of pesticides and classify their toxicity for honey bees or other pollinators. Among the countries sometimes conducting a hazard evaluation, Zimbabwe does not conduct a local hazard evaluation for honey bees or other pollinators, but relies on toxicity studies provided by the applicant for the classification of the level of toxicity on honey bees or other pollinators. Zimbabwe also cross-references the data using databases of the FAO Pesticide Registration Toolkit (FAO 2021). In Solomon Islands, hazards are not evaluated by the registration authority, but by a separate screening committee instead.

Registration Authorities in half of the responding countries (8 out of 16) at least sometimes review pesticide risk assessments conducted by one or more pesticide regulators in other countries, and then draw conclusions about pollinator risks under local circumstances (Table 2.3; always: 7 countries; sometimes: 1). EFSA risk assessments are consulted by most responding countries, followed by APVMA and USEPA. Risk assessments conducted by IBAMA and ICAMA are generally not consulted by the responding countries. At the national level, pollinator risk assessments of pesticides are conducted in 4 out of 16 countries (always: 2 countries; sometimes: 2). Two of these countries (Kenya and Sahelian Pesticides Committee) developed a national/regional pollinator risk assessment procedure, which for Kenya is described in more detail below, while one country (Antigua and Barbuda) applies the FAO Pesticide Registration Toolkit and another country (Uganda) takes into account the intended use of the pesticide and does not allow use, if the product is to be used on crops that are grown in a region that carries out massive bee keeping.

Table 2.3 Regulatory authorities generally consulted for reviewing risk assessments[1].

Country	APVMA (Australia)	EFSA (European Union)	EPA/PMRA (U.S.A./ Canada)	Other
Antigua and Barbuda	●	●	●	Jamaica, Trinidad and Tobago, Guyana
Burundi		●		East African Community partner states
Kenya	●	●	●	
Sahelian Pesticides Committee (SPC)	●	●	●	
Saint Lucia		●	●	
Samoa	●	●		ERMA (New Zealand)
Tanzania	●	●	●	
Uganda		●	●	Kenya

[1]Only responding countries are included which at least sometimes review pesticide risk assessments conducted by one or more pesticide regulators in other countries, and then draw conclusions about pollinator risks under local circumstances, thus excluding Fiji, Malawi, Rwanda, Solomon Islands, South Sudan, St. Vincent and the Grenadines, Tonga, and Zimbabwe. Risk assessments from IBAMA and ICAMA are generally not consulted by responding countries.

Pollinator risk assessment in Kenya

In Kenya, the Pest Control Products Board (PCPB) is currently implementing the guidance document on dossier evaluation for registration, which was developed in December 2019, including a chapter on Pesticide Risk assessment for Pollinators (Bees). Pollinator risk assessment is conducted for products used in pollinator attractive crops for in-crop and off-crop exposure scenarios. PCPB refers to assessment reports of regulatory authorities in other countries with a more elaborate risk assessment process, in order to obtain ecotoxicological endpoints. These endpoints are fed into the Bee-REX model, as are the Kenyan GAP data (the local application rates) to predict the Bee exposure levels of the assessed pesticide product when used locally. The outcome of the assessment is either low, moderate or high risk to bees in both in-crop and off crop exposure scenarios.

Risk mitigation measures are prescribed based on the results from the Bee-REX model for both in-crop and off-crop exposure. Mitigation measures proposed in the guidance document include statements regarding the distance (buffer) from the field edge within which the pesticide should not be sprayed. This buffer distance is not captured in any Kenyan legal instrument and could have fit in the currently proposed Livestock Bill 2021 under restrictions on setting up hives (see also Garthwaite 2022[8]).

Risk assessment in Kenya is embedded in an East Africa Community (EAC) harmonization process. In 2019, the EAC Council of Ministers adopted the Guidelines on Data Requirements for the Registration of Conventional Chemical Pesticides Used in Agriculture and Forestry in EAC Partner States. Harmonized data requirements for applicants in relation to pollinator protection include data on acute oral and contact toxicity in honey bees, honey bee toxicity of residues on foliage for outdoor uses and bee brood-feeding tests. The ecotoxicological endpoints from the described data may be used by member states to conduct risk assessment in their countries. Kenya is currently reviewing the PCP Bill and Registration regulations which has incorporated these data requirements so as to

[8] See footnote 7

domesticate them nationally (see also Garthwaite 2022[9]). There is no East African Community Guidance document for dossier evaluation prescribing how regional risk assessment may be conducted yet.

2.6 Risk management

Risk mitigation measures play a role in the pesticide registration procedures of virtually all participating countries. Registration authorities in all responding countries at least sometimes apply risk mitigation measures upon pesticide registration (Table 2.4). Denial of registration for all proposed uses or for high risk uses, as well as registration with mandatory risk mitigation measures are mitigation options often or at least sometimes applied in most responding countries (often applied in 5 and 6, at least sometimes applied in 11 countries, respectively). Denial of registration for high-risk formulations (often applied in 5, at least sometimes applied in 9 countries) or registration with non-mandatory precautionary label statements (often applied in 3, at least sometimes applied in 9 countries) appear of slightly lower importance. Registration without specific risk mitigation measures seems to be the least applied option stated in the survey (often applied in 3, at least sometimes applied in 5, never chosen in 7 countries).

[9] See footnote 7

Table 2.4 Mitigation measures taken by authorities.

Country	Deny registration of pesticides			Allow registration of pesticides		
	...for all proposed uses	...for high-risk uses	...for high-risk formulations	...with mandatory risk mitigation measures	...with precautionary (non mandatory) statements on the label	...without specific risk mitigation measures
Antigua and Barbuda	○	○	○	●	●	-
Burundi	○	○	○	-	○	●
Fiji	●	●	●	○	○	●
Kenya	○	○	-	○	○	-
Malawi	○	○	○	-	-	○
Rwanda[1]				●		
Sahelian Pesticide Committee (SPC)[2]	●	●	○	●	●	-
Saint Lucia[1, 3]				●		
Samoa	●	●	●	-	-	-
Solomon Islands	-	○	-	○	○	○
South Sudan						
St. Vincent and the Grenadines	○	●	●	○	○	-
Tanzania	●	●	●	○	○	-
Tonga	-	-	-	●	●	●
Uganda	●					
Zimbabwe	○	○	●	●	-	-

● decision often taken; ○ decision sometimes taken; - decision never taken; blank cells: not answered. [1]Rwanda and Saint Lucia also impose further use restrictions upon registration, which were not specified in more detail, Rwanda often so. [2]SPC also sometimes allows registration of pesticides under the requirement of environmental monitoring. [3]In Saint Lucia, the product label should have the appropriate instruction for the protection of wildlife.

2.7 Appraisal

Overall, some preliminary conclusions may be derived from the survey answers:

Bees are the most relevant pollinator focus group, the honey bee presently being the best model organism for risk assessment

Bees were by far the most important pollinator group requiring protection from adverse effects caused by pesticides, while butterflies, birds, wasps and further taxa were nominated only by a minority of the respondents. This justifies the focus of pollinator risk assessments on bees. At the same time, this result raises the question, how representative the often honey-bee focussed data are for the bee communities within the different countries. While especially the risk assessment approaches of EFSA (2013), USEPA et al. (2014) and IBAMA (2017) try to expand their honey-bee centred view towards other regionally relevant bee species, future research might be necessary to identify and incorporate the relevant bee fauna in other regions into then more regionally adapted risk assessment procedures. Nevertheless, given the lack of robust knowledge and techniques to include non-*Apis* taxa in the risk assessment at the same level of honey bees in all available approaches, the focus on honey bees emerges as the best option for project countries at present.

General requirement of acute honey bee toxicity data and their basic incorporation into the risk assessment according to established approaches may improve risk assessment

The majority of authorities at least sometimes require pesticide toxicity data for bees or other pollinators as part of the registration procedure, the minimum requirements generally being acute oral and contact toxicity studies. However, only a minority generally requires such data, and almost no project country performs a risk assessment. Acute toxicity data offer the opportunity to enter the risk assessment at a basic level in virtually all established risk assessment approaches (see chapters 1.2 and 1.5). There are established procedures for how to use these data in terms of hazard and basic effect assessment, for example through classification of the level of toxicity to honey bees (see chapter 1.2), and by calculating quotients of toxicity and the readily available application rate (see chapter 1.5). Following these procedures already enables risk assessors to derive meaningful conclusions, without the need to apply more sophisticated methods, which generally require additional data and/or have to rely on certain assumptions. Thus, establishing the requirement of acute toxicity data (for honey bees; see above) for pesticide registration, and disseminating the basic methodology to process these data in the risk assessment, may be the most important step towards improved risk assessment for bees and pollinators in the project countries.

Common crop families might offer opportunities for a risk-envelope approach

The main pollinator dependent crops belong to only a few plant families. This may offer the opportunity for a risk enveloping approach, i.e. to extrapolate from one crop to another within the same plant family. However, there is a large variety of crops within the most important plant families, and at the crop (plant species) level, overall there are few commonalities among respondents. Because cropping systems and plant protection approaches may differ markedly between crops of the same plant family, risk enveloping at the plant family level may be limited. Still, IBAMA (2017) set a working example of crop grouping for risk enveloping across a large geographic area, taking into account plant family of crops (see chapter 1.7). Thus, this kind of risk envelope approach might be an option, at least for countries of the same region.

Adoption of risk management and mitigation measures may improve the protection of bees and other pollinators

Common risk management and mitigation options include both application and product focussed approaches. In addition, product registration without specific risk mitigation measures occurs in several project countries. In addition to internationally common mitigation measures, there are examples of regionally-adapted measures (see chapter 1.8). Therefore, an exchange among project countries with regard to regionally adapted mitigation measures may be a worthwhile endeavour. Moreover, further risk management options, such as monitoring after (preliminary) product registration, as well as non-labelling instructions such as implementation of best management practices and training of operators, may be useful for bee and pollinator protection in project countries.

Part 3: Synthesis

At the basic level, established pesticide regulatory risk assessment approaches have similar qualities to serve as a framework for project countries

One main objective of the present review was to compare the established risk assessment approaches among each other and with the risk assessment work practiced in project countries. An important finding is that in general, the established risk assessment approaches tend to be rather similar at the basic level from the end-user perspective for acute oral and contact toxicity, taking the same fundamental steps through the assessment procedure. Differences at the basic level tend to be rather subtle, with more pronounced differences occurring at the more detailed level and, in terms of the tiered approach, at higher tiers, where risks are addressed at a relatively high resolution. Thus, for project countries developing or adapting a risk assessment procedure for bees and other pollinators to their needs, one key message of this review is that choosing which established approach to follow for guidance is not likely to make a huge difference in many aspects for acute and larval toxicity.

No huge differences exist especially with regard to the basic steps, acute toxicity assessments and lower tiers of the assessment procedure. This includes, inter alia, toxicity classification and default calculations to link potential exposure and toxicity. For countries that are currently developing and establishing a stepwise risk assessment framework, we recommend focussing in the first steps on acute adult toxicity, followed by larval toxicity. As there are some differences regarding the evaluation and interpretation of chronic toxicity triggers, we recommend establishing the assessment of chronic triggers at a later step.

In the foreseeable future, the honey bee is the best model organism for project countries

There are fundamental differences between established risk assessment approaches regarding protection goals. These differences mirror the need to assess risks for pollinators considering the regional or local situation in terms of the pollinator fauna and the ecosystem services provided by pollinators. Of course, speaking more generally, these differences also reflect the willingness of different societies to take or to avoid particular risks. In practice, however, bees are by far the most important pollinator group, both in countries with established risk assessment approaches and in project countries, and there is no doubt that the honey bee is the best available model organism. Until further knowledge is accumulated in terms of the ecotoxicology for relevant pollinator taxa and with regard to ecosystem services they provide, the honey bee will remain the pivotal model organism for risk assessment approaches in the project countries.

Focussing on lower-tier risk assessment, using mandatory basic toxicity data, is the most important step to be taken in project countries for improving the protection of pollinators through risk assessment

The tiered approach is followed by all currently established risk assessment approaches. It means a stepwise procedure going from simpler to more complex methods. The increase in complexity not only applies to the data, i.e. the designs of the studies needed to generate the data and the kind of data to be assessed; it also applies to the assessment methods and the level of personal expertise of the risk assessor required to handle the data in a meaningful way during the risk assessment procedure. Therefore, when developing or adopting risk assessment approaches for bees and other pollinators in project countries, or when adjusting established risk assessment approaches to the local or regional context, it is highly recommended to focus on the lowest tier. With regard to changes in the risk assessment in project countries, this will be most promising in improving the protection of bees and other pollinators from risks posed by pesticide applications. The data to be assessed at the lowest tier have the highest degree of standardization, and both methods underlying the studies and the assessment of the data can be regarded as well established for a long time, at least for acute toxicity data for adult honey bees. The assessment, based on the ratio between exposure estimation (e.g., application rate) and product or substance specific toxicity, is straight forward and possible even with relatively limited expertise and personal capacities among local risk assessors. Moreover, in practice a high proportion of products/ substances can be handled at the lower tiers during risk assessment, with only a minority of cases triggering the option of higher-tier assessment. Also, risk mitigation measures (see below) offer the possibility to address potential risks at the lower tier, avoiding the need for a refined risk assessment at higher tiers.

In order to protect bees and other pollinators through lower-tier focussed risk assessment, project countries are recommended to introduce a general requirement of acute contact and oral toxicity data for adult honey bees in the registration procedure for pesticides. These data represent the best established methodology for data generation and assessment and are thus handled most easily during risk assessment, in terms of personal expertise and capacity of risk assessors.

Adoption of established trigger values and basic exposure scenarios should be the current focus for risk assessment development in project countries

In general, all established risk assessment approaches start by assessing the likelihood of exposure. If exposure cannot be excluded, potential risks are assessed comparing calculated exposure-toxicity ratios against predefined threshold values (levels of concern or trigger values). In the simplest case, basic toxicity measures (acute LD_{50} values) and easy-to-obtain proxies for exposure (product or substance specific application rates) can be used for calculating the exposure-toxicity ratio. Local or regional adaptations of threshold values may improve pollinator protection in the project countries. For example, trigger values may be designed more or less conservative in order to reflect the sensitivity of the relevant pollinator fauna. Likewise, exposure scenarios considered relevant may differ depending on the local or regional context. Established approaches differ considerably in the exposure scenarios taken into account, and project countries may decide upon their specific set of exposure scenarios, potentially including additional scenarios that have not been presented yet. However, both in terms of adapting trigger values and exposure scenarios, the knowledge base on local pollinators will have to be strengthened in most cases in order to take informed decisions. Until sufficient knowledge is available, project countries should refer to the easier solutions provided in the available publications, i.e. using established trigger values and a compact system of exposure scenarios, e.g. as system focussing on application methods rather than including additional categories describing the spatial and temporal relation between pesticide use and potential exposure.

Setting the focus on lower-tier risk assessments will lead to a relatively conservative approach

Lower-tier assessments are intended to identify and distinguish substances of concern from those of no concern and are to be refined in higher tier risk assessment, if an unacceptable risk is indicated by exceedance of a trigger value. Newer, more elaborated risk assessment schemes have a tendency to be more conservative and thus trigger more substances for higher tier assessments.

Based on the review, we suggest that countries with no established risk assessment procedure identify substances of concern by limiting to a lower-tier risk assessment, distinguishing potential risk based on substance toxicity and application rates. Subsequently, suitable risk mitigation measures may be identified.

This will lead to a relatively conservative approach (i.e. risk mitigation measures will be required for a relatively large number of pesticides). However, in real life some insect pests damage flowers or seed set, and therefore insecticides are sometimes needed to protect bee attractive flowers in full bloom. In this case, exposure cannot be avoided. It may be slightly reduced by applying the pesticide after or out of daily bee flight, as in this case no contact exposure takes place and residues on flowers may degrade to a small extent. However, with many toxic products this mitigation measure would not be sufficient, neither for bee protection, nor for pest control. In such cases, higher tier risk assessments will be needed. For countries with little resources for pollinator risk assessment, we advise to reflect the principles outlined in the EPPO 170/PP4 scheme (EPPO 2010b) for risk assessment and study conduct. Furthermore, many national and international bodies and institutions may provide support on request.

Risk envelope approaches might reduce risk assessors' workload to manageable levels

Improved pollinator protection through risk assessment in project countries is often impeded by a lack of personal capacities. Risk enveloping, i.e. selective assessments for products and/or uses representative of other products or uses, might pave a way towards more comprehensive protection from potential risks in situations of tight resource budgets. Risk enveloping may even be possible across project countries or regions, depending on the degree of similarity of their cropping systems and agricultural practice. The establishment of discussion forums are recommended as first steps in this direction, and role models for cross-country exchange are already in place in some regions, e.g. the Sahelian Pesticides Committes and the harmonization process pursued by the East Africa Community.

Established risk mitigation measures provide examples for further local adaptation

Risk mitigation measures provide opportunities to permit application of potentially hazardous products when exposure is avoided. Risk mitigation is always linked to risk assessment, and extensive catalogues of different risk mitigation measures exist in countries with established risk assessment approaches. Thus, examples are available which may inspire project countries to develop risk mitigation measures that are, in the local agricultural settings, suitable to mitigate risks for pollinators and feasible to implement. National collaborations for risk mitigation are already taking place, at least in some project countries. Their experiences are likely to be valuable for other project countries and should be involved in future discussion rounds. Applicability and appropriateness of the different kinds of risk mitigation measures is largely depending on the actions of farmers, who are ultimately responsible for the efficacy of risk mitigation measures. Therefore, the decision to focus on mandatory or non-mandatory, labelling or rather educational risk mitigation measures has to take the attitudes of farmers into account, as well as the setting in which farmers act.

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Appendices

Appendix 1: Online questionnaire

Questionnaire about pesticide risk assessment methods for pollinators.

Introduction

FAO will be organizing a Global seminar on strengthening regulations to protect pollinators from pesticides, on 23 and 24 February 2022. One of the objectives of the seminar is to conduct a review of regulatory pesticide risk assessment procedures for insect pollinators, and identify ways to strengthen such risk assessments in low and middle income countries. Through this questionnaire, we hope to learn what are current and actual practices in your country with respect to pesticide hazard and risk assessment for insect pollinators. This will help us to identify gaps and develop ways to strengthen insect pollinator risk assessments in the future. It is therefore important to get your feedback about current risk assessment procedures; not what are (legally) prescribed or intended practices. The Global Seminar will be organized by the FAO Programme for Building Capacity Related to Multilateral Environmental Agreements in African, Caribbean and Pacific countries (ACP MEAs 3). More information can be found at: http://www.fao.org/in-action/building-capacity-environmental-agreements/activities/global/pollinator-seminar/en/

1 OF 7 - AGREEMENT TO PARTICIPATE IN THE QUESTIONNAIRE

Information collection and use

The information collected in this questionnaire will be reviewed by the Julius Kühn Institute (JKI) - Federal Research Centre for Cultivated Plants, Institute for Bee Protection, at the request of the ACP MEAs 3 Programme of FAO. Any information you may provide will be confidential and will not be shared with any third party, other than the German Institute for Bee Protection and FAO, who retain the right to publish results without sharing your identity. Results of the questionnaire may be presented at the Global Seminar. This questionnaire is not anonymous because we would like to be able to contact you in case further information or clarifications are needed. However, your email address and the raw data collected in this questionnaire will not be used for commercial purposes, nor will they be transferred to institutions or entities other than the German Institute for Bee Protection and FAO. Once the study has been concluded, your personal data will be deleted from all storage devices of the research team, or destroyed if in paper form, and will therefore remain exclusively with FAO. For more information, please contact: ACP-MEAs@fao.org.

Using this questionnaire

While you are filling out the questionnaire, you can make changes and corrections in your responses to the questions by using the "back" and "next" buttons at the bottom of each screen. However, you cannot make any changes anymore after you submit the questionnaire. You can only submit one (1) response! This questionnaire will take about 15-20 minutes of your time. We would like to stress that we would like to get your feedback about CURRENT risk assessment procedures; not what may be (legally) prescribed or intended practices.

Consent statement

Clicking on the "agree" button below indicates that you have ready the above information and that you agree to participate in the questionnaire. If you do not wish to participate, please decline participation by clicking on the "disagree" button.

- o I agree
- o I disagree

2 OF 7 - RESPONDENT INFORMATION

Your name

We are asking your name and email address so we can contact you in case we have further questions.

Your country

Your affiliation

Name of the institution or authority that you work for

Your email address

Do you consent that your name is mentioned in the Acknowledgements Section in the report?

- o Yes, you can add my name to the acknowledgements section in the report
- o No, I prefer to remain anonymous; only refer to my institution in the acknowledgements section in the report

3 OF 7 - POLLINATOR IMPORTANCE

Which crops in your country are much/partially dependent on pollinators for pollination, and also receive regular treatments by pesticides?

Please note down up to 3 priority crops or cropping systems that respond to the above question.

Which pollinators in your country require the most protection from adverse effects caused by pesticides?

Pollinators may require priority protection because of their importance in agriculture; because they are rare or threatened; because they are much exposed to pesticides; because they are an important element of biodiversity; etc. Please note down up to 3 groups/families/species of priority pollinators.

4 OF 7 - DATA REQUIREMENTS

Pollinator data requirements for registration

A Pesticide Registration Authority may require that the applicant for registration of a pesticide submits toxicity data for honeybees or other pollinators.

Does the Registration Authority in your country require pesticide toxicity data for bees or other pollinators as part of the registration application/dossier?

- o Yes
- o No
- o Sometimes

Which data do you require as part of the registration application/dossier?

- o Always
- o Never
- o Sometimes
    - – Acute oral toxicity for adult honeybees
    - – Acute contact toxicity for adult honeybees
    - – Chronic toxicity for adult honeybees

- Chronic toxicity for honeybee larvae
- Acute or chronic toxicity for other pollinator species
- Cage or tunnel studies
- Field studies
- Pesticide residue concentrations in pollen or honeydew
- Other (specify below

Please specify the other data that you (may) require

5 OF 7 - HAZARD AND RISK ASSESSMENT

Hazard and risk assessment procedures

The Pesticide Registration Authority may evaluate the hazard of a pesticide to honeybees or other pollinators; i.e. assess and possibly classify the toxicity of the pesticide. The Authority may also review a pollinator risk assessment that has been conducted by regulators in another country, and then assess whether its conclusions are also relevant for the local situation in your country. Another option is that the Authority conducts its own risk assessment; i.e. evaluates the likelihood and degree of exposure and risk of the pesticide to pollinators under the local conditions of use.

Does the Registration Authority conduct a hazard evaluation of pesticides and classify their toxicity for honeybees or other pollinators (e.g. as low, moderate, high toxicity)?

- Yes
- No
- Sometimes

Does the Registration Authority review pesticide risk assessments conducted by one or more pesticide regulators in other countries, and then draw conclusions about pollinator risks under local circumstances?

- Yes
- No
- Sometimes

From which countries do you generally consult the pollinator risk assessment?

More than one country can be selected.

- Australia (APVMA)
- Brazil (IBAMA)
- China (ICAMA)
- European Union (EFSA)
- United States of America (EPA) or Canada (PMRA)
- Other (specify below)

Please specify the other country or countries from which you consult the pollinator risk assessments

Does the Registration Authority conduct its own pollinator risk assessment of pesticides that are submitted for registration?

- Yes
- No
- Sometimes

Which pollinator risk assessment procedure do you apply?

- o The North American procedure
- o The EFSA procedure
- o The (former) EPPO procedure
- o We have developed our own national/regional pollinator risk assessment procedure
- o Other (please specify below)

Please specify which other pollinator risk assessment procedure you apply

6 of 7 - Risk mitigation

Measures to mitigate the risks of pesticides to pollinators

Based on the identified hazards and/or risks to pollinators, the Registration Authority may take a decision to mitigate such risks. These can include denying the registration, restricting the registration to certain uses, requiring precautionary statements on the label, or authorizing the use of the pesticide without specific measures to protect pollinators, among others.

If high hazards or risks of a pesticide have been identified for pollinators, which risk mitigation measures are taken by the Authority?

- o Often
- o Sometimes
- o Never
  - – Deny the registration of the pesticide for all proposed uses
  - – Deny the registration of the pesticide for the uses (e.g. crops, pests) where the risks are high
  - – Deny the registration of specific pesticide formulations which pose a high risk (e.g. wettable powders, micro-encapsulated formulations, …)
  - – Allow the registration of the pesticide, but with mandatory risk mitigation measures (e.g. do not apply when the crop is flowering; only apply with drift reducing nozzles to minimize exposure of field margins; inform beekeepers at least 48 hours in advance of the treatment, …)
  - – Allow registration, but with precautionary (non mandatory) statements on the label (e.g. do not apply when the crop is flowering; only apply after sunset)
  - – Allow registration without specific risk mitigation measures
  - – Other (please specify below)

Please specify which other pollinator risk mitigation measure(s) the Authority may take

7 of 7 - FAO Global Seminar

Global seminar

Your suggestions for the outcomes of the FAO Global seminar on strengthening regulations to protect pollinators from pesticides, in February 2022

In your view, what would be useful outcomes or products of the Global Seminar that would strengthen pollinator risk assessment in your country?

„Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft“ erscheinen seit 1995 in zwangloser Folge

Seit 2008 werden sie unter neuem Namen weitergeführt:
„Berichte aus dem Julius Kühn-Institut“

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