EUROPEAN CHEMICALS AGENCY

Preliminary considerations for ECHA’s guidance on the “Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides”

Summary of consultation feedback

December 2020

Disclaimer

Version	Changes	

Preliminary considerations for ECHA’s guidance on the “Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides”

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Table of Contents

1. Introduction

1.1 Background and Terms of Reference (ToR) as provided by the requestor

On 2 December 2019, the European Commission mandated ECHA to develop a guidance for assessing the risks to arthropod pollinators (including bees) from biocides exposure to ensure a high and harmonised level of protection of the environment, taking into account *EFSA's Guidance Document on the Risk Assessment of Plant Protection Products on Bees* (currently under review). In addition, ECHA was requested to specify the information required to enable a conclusion by the evaluating authority on whether products comply with the criteria under Article 19(1)(b)(iv) of the Biocidal Products Regulation concerning bees and other arthropod pollinators.
According to the mandate, the following elements are to be considered by ECHA when addressing this question:

- In order to develop a specific guidance to assess the risk to arthropod pollinators (including bees) from the use of biocides, ECHA shall use any information already available, and in particular the past and current work of EFSA in this field.

- To ensure that all available information can be considered in the opinion a targeted consultation of stakeholders should occur. For this consultation, if ECHA considers it appropriate, an overview of biocidal active substances and biocidal products to which arthropod pollinators could be exposed and which may trigger directly or indirectly the occurrence of adverse effects in them could be prepared.

- The current references to the assessment of risk to arthropod pollinators included in the ECHA Guidance on the Biocidal Products Regulation shall also be considered, along with the work in this field already carried out by the competent authorities and scientific bodies from the EU Member States.

As a deadline for this work, the COM specified "ECHA shall inform DG SANTE on the outcome of this evaluation no later than 31 December 2021."

ECHA initiated during 2020 several actions to consider the elements included in the mandate:

- In reference to the work being done at EFSA, ECHA and EFSA are in constant communication in relation to risk assessment to bees. Both agencies are regularly attending the meetings being held by ECHA or EFSA in regards to this topic and reviewing the available documentation.

- In relation to the consultation of stakeholders, ECHA carried out a call for expression of interest to be part of the "Ad hoc ECHA Pollinators Guidance Stakeholder Consultation Group". The role, composition and responsibility of the group and the criteria to select the representatives of the group was specified in the call. The group will be consulted two or three times during the guidance development.

1.2 Overview of ECHA's Pollinator Expert Group approach

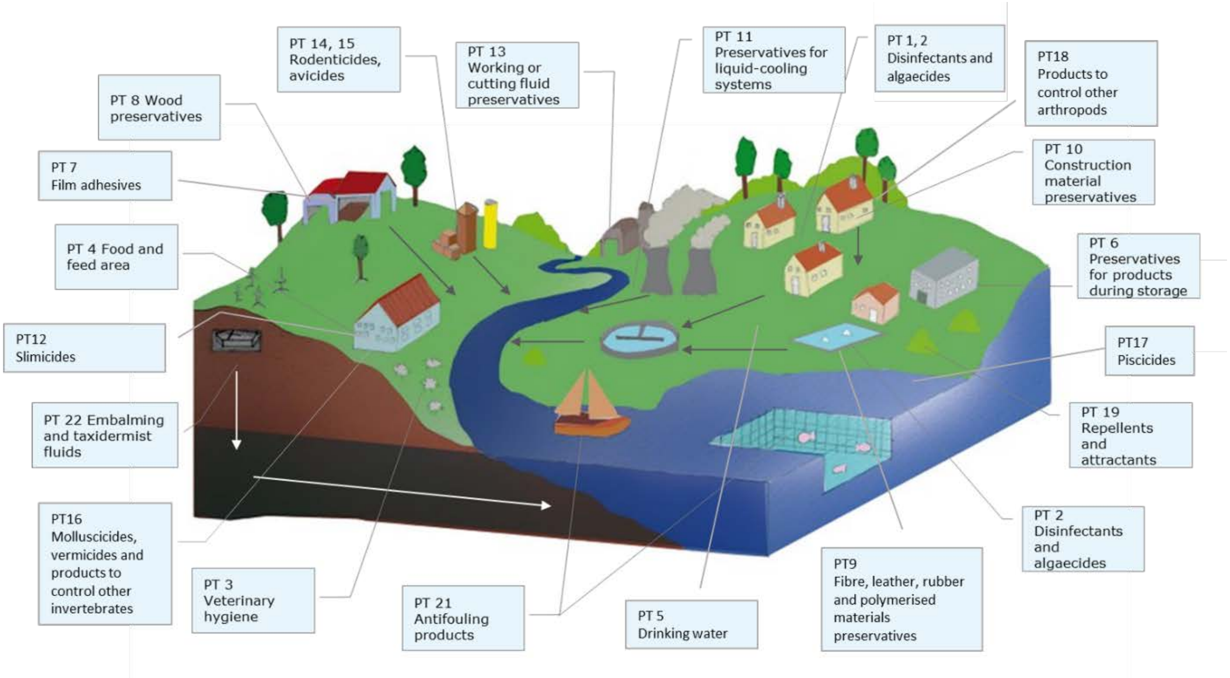
The preparation of this guidance will be dealt with by in-house experts from ECHA together with experts from MSCAs by forming a dedicated expert group (i.e. ECHA´s Pollinators Expert Group).

The work on the guidance started already in 2019 with the consolidation of the group and the group has met several times during 2020. As a first step, the group assessed the terms of reference (ToR) specified in the mandate from the Commission and decided to start with a scoping document before proceeding to the drafting phase. This is critically important in the guidance development for biocides as there is currently no specific guidance available to assess risk for arthropod pollinators.

According to the ToRs, ECHA shall use any information already available, and in particular the past and current work of EFSA in this field. In this regard it is important to highlight that there are fundamental differences between plant protection products (PPP) and biocidal products that explains also why the approach to this guidance may differ in some aspects to the EFSA guidance. It also underlines why it is so important to discuss the scope before the drafting phase starts.

On one hand, the type of application of biocides is fundamentally different to the type of application of PPP which leads to potentially different routes and levels of exposure of arthropod pollinators to active substances which may influence the focus of the guidance. Under biocides there are 22 different product types (as illustrated by Figure 1) and only a few of them can be compared to the type of use of PPP. The main uses of PPPs take place outdoors by direct application of the substance to plants or seeds in the field while in biocides most applications take place indoors and exposure to pollinators may only occur after the substance mobilizes through different compartments. As for outdoor uses of biocides, many are relatively limited in regard to spatial scale and/or are due to unintentional releases during application or leaching during service life. The only comparable biocidal applications with regard to scale and exposure pattern to PPPs are overspray applications (e. g. against oak processionary moths on oak trees or against mosquitos and fly larvae on surface water) and uses where the biocide ends up in in manure or Sewage Treatment Plant (STP) sludge which is later applied on agricultural soil or grassland.

Figure 1. Different Product Types under the BPR



On the other hand, there is a difference in the amount of data available for arthropod pollinators. While for PPP the generation of standard studies on bees is a core requirement, for biocides, conduction of studies on arthropod pollinators and on bees is only an additional data requirement according to the current legal text and guidelines. Studies are only required for insecticides, acaricides and substances in products to control other arthropods that are used outdoors, i.e. for large scale-outdoor applications like fogging (e.g. product-type 18 - products against mosquitoes for human health reasons). Finally, the Commission´s mandate for biocides includes a noticeable difference when compared to the current guidance and mandate sent for PPP. In the biocides mandate, the Commission has included in the scope of the guidance "arthropod pollinators (including bees)" while in the current guidance and mandate for PPP the scope is limited to the species *Apis mellifera*, the family *Bombus spp.* and the various groups of solitary bees. This has a major impact on the development of the guidance as there will be a need to develop risk assessment methodologies to cover other species of arthropod pollinators. In order to achieve this goal differences in sensitivity, ecology and living behaviour will need to be studied.

Due to these reasons, it is essential to find an efficient working approach while ensuring a high level of protection of arthropod pollinators. On one hand, it is necessary to screen through the numerous exposure scenarios for biocides to be able to focus on those scenarios and emission pathways that may lead to a relevant exposure to the protection target. On the other hand, there is a need to limit the generation of standard laboratory studies either based on the substance properties (including mode of action) or on the type of use and exposure pattern to substances and uses that really matter for their potential negative impact on arthropod pollinators.

In current available guidance on biocides only limited references are made to risk assessment for bees and other pollinators. The guidance states that no method is currently available on how to perform the risk assessment for bees and non-target arthropod pollinators for biocides. In regards to data requirements, the guidance states that tests on bees and/or other beneficial arthropods may be required for insecticides, acaricides and substances in products to control other arthropods that are used outdoors, i.e. for large scale-outdoor applications like fogging (e.g. product-type 18 - products against mosquitoes for human health reasons). Extracts referring to bees from current guidance on biocides can be found in Annex I of this document.

1.3 Scope and structure of this document

This document was drafted by ECHA´s Pollinators Expert Group. The aim of this document was to consult at an early stage the Member States and the ad hoc ECHA Pollinators Guidance Stakeholder Consultation Group on the approach for what should be in broader terms covered in the guidance for arthropod pollinators (including bees) with a focus on the terms of reference in the Commission´s mandate.

ECHA's Pollinator Expert Group decided to divide the scoping document in three main blocks. These blocks represent the three main areas of work and were identified as the main areas in which fundamental questions needed to be answered before starting with the drafting phase. The future guidance may not necessarily follow this structure.

ECHA´s Pollinators Expert Group may initiate other consultations in the future to solve questions or issues that they may encounter throughout the development of the guidance.

This document contains a questionnaire after each section and answers to these questions will help ECHA's Pollinator Expert Group get an insight of relevant aspects to be covered in the guidance. Stakeholders and MSCA experts were requested primarily to provide input to these questions and secondarily to provide comments regarding the rest of the text.

1.4 Collected feedback

The consultation of this document took place between 20th of May until 26th of June 2020. The ad hoc stakeholder's consultation group of the guidance on non-target arthropod pollinators for biocides and experts from Member States were included in the consultation. The responses to the questions were provided as a copy of this document and text proposals were added in track changes by the commenters.

Regarding Member States, Switzerland, Germany, Spain, France, The Netherlands and Sweden provided comments on the document. From the ad hoc stakeholder's consultation group, the International Association for Soaps, Detergents and Maintenance Products (AISE), Apimondia, BeeLife, Butterfly Conservation Europe, the European Chemical Industry Council (CEFIC), Eurpean Crop Protection (ECPA), Euroseeds and Norsk institutt for bioøkonomi (NIBIO) provided comments.

All written comments from this consultation group were considered by ECHA's Pollinator Expert Group nevertheless due to the time constraints, no responses to individual comments were provided.

ECHA gathered all responses and consolidated them in one single document (this document). For each individual question that was formulated a summary and conclusion has been drafted. Those questions for which a conclusion was difficult to reach were brought to the ECHA´s Pollinators Expert Group in order to conclude. Comments made directly to the text have been incorporated and some sections have been extensively modified.

Section 2.1.2 is accompanied by an Excel table (see Document Section 2.1 Biocides scenario overview.xls), for which comments were received in particular on the scenarios for which "TBD" is entered in column "Potential exposure to pollinators". Specific issues were raised in the "Remarks" column of the Excel sheet and questionable criteria were highlighted in orange. Comments received on the excel sheet have been added to the file (blue columns). For each scenario where comments were provided a summary and conclusion has been drafted. The comments made will affect the content of the excel table, but the revision remains to be done.

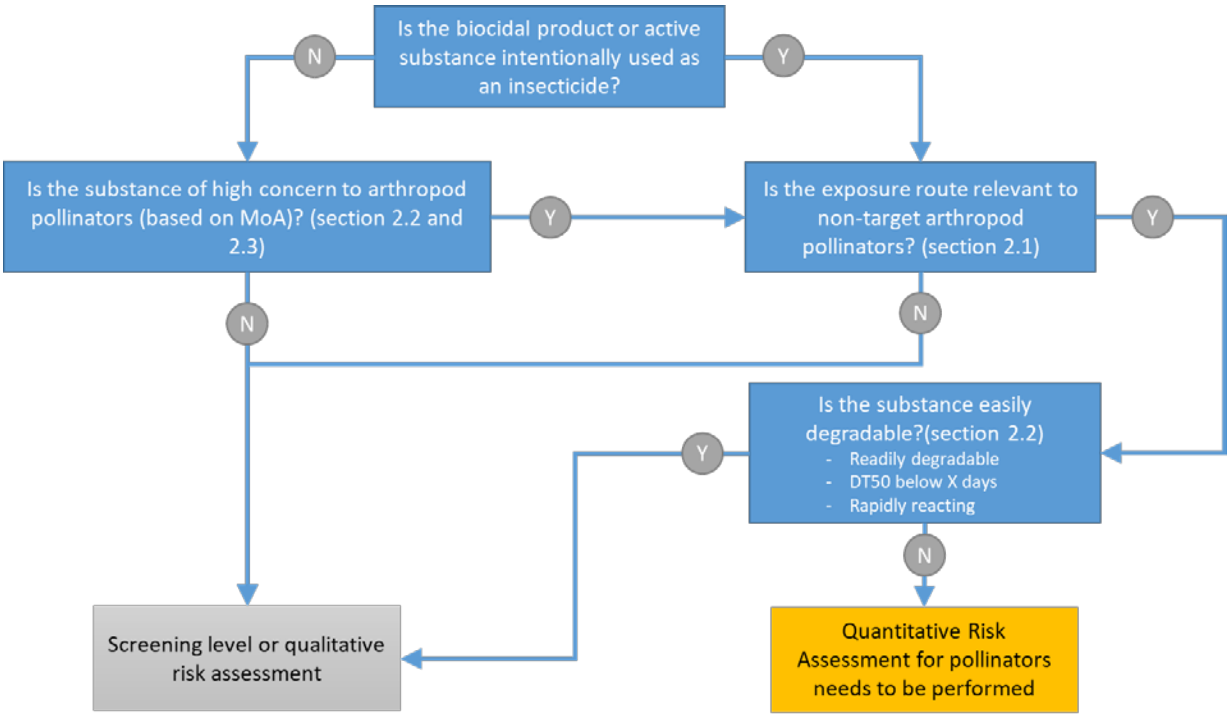
2. Scoping topics

ECHA's Pollinator Expert Group has identified three main areas of work before moving to the drafting phase: 1) Exposure routes relevant to arthropod pollinators, 2) Biocidal active substances and products relevant for risk assessment of arthropod pollinators and 3) Pollinators families and testing methods relevant for the risk assessment of substances for arthropods pollinators.

It is recognised that the strategy proposed in this document to identify biocides scenarios leading to potential exposure of pollinators (see section 2.1) cannot be used in isolation and should be considered in conjunction with the assumptions made on the substance properties and the families of pollinators to be considered. In this regard, a high-level decision hierarchy as shown in Figure 2 is foreseen. While the applicants according to BPR do not have an obligation to submit tests on arthropod pollinators as a core data set, assessment of relevance of exposure routes is considered an appropriate starting point. Where screening level or qualitative risk assessment is mentioned in Figure 2, the assessment could be fulfilled by providing argumentation on the different aspects (exposure, MoA, degradation, etc.). The important element to be considered is that in these cases, no specific ecotoxicity testing on arthropod pollinators may be requested. The individual criteria to answer each individual box are partially presented in this document and, provided the hierarchy is in principle agreeable, would be further elaborated in the guidance.

The presented hierarchy applies to biocidal active substances and their relevant metabolites and breakdown or reaction products.

Figure 2. High level hierarchy for decision making on risk assessment for arthropod pollinators



The figure was modified as a result of the comments received during the consultation

QUESTIONS:

Q 1 Do you consider it appropriate to apply an approach that will differentiate between the need to perform a qualitative or quantitative risk assessment?

Summary: NGOs generally agree with this approach. One commenter proposed the following reasoning as in EFSA guidance: is the exposure negligible? If YES, no further assessment. If NO, toxicity assessment and then risk assessment.
Industry and academia agree with this approach. Remarks: suggests to stretch more the flow chart putting other questions; for example, after the question "is the substance of high concern…" whether applicable RMMs can be identified, whether a quantitative risk assessment can be excluded considering the mode of application of a product, its frequency of use, its field of use.
MSs also agree. One Member State remarked that this would be only for substances with unknown effects on bees, insects, mites, ants and arthropods. A quantitative RA shall always be required for insecticides, acaricides and substances in products to control other arthropods that are used outdoors. An obligation conducting a quantitative RA may also be considered for substances known to be toxic to aquatic life as well as fungicides, pyrethroids and other substance groups or products known to present a risk for bees or other pollinators.

Conclusion: The majority considers it appropriate to apply an approach that will differentiate between the need to perform a qualitative or quantitative risk assessment.

Q 2 Do you consider the decision hierarchy as proposed, appropriate for deciding whether a quantitative or qualitative risk assessment of the substance on the risk assessment for arthropod pollinators (see Figure 2)?

Summary: NGOs agree with this approach. However, there are other physic-chemical characteristics of the biocidal product that are relevant for evaluating the potential exposure to pollinators, e.g. solubility in water, Kow, volatility potential, or co-formulants rendering the product more soluble/persistent/systemic.
Industry mostly agrees with this approach but expressed some concerns regarding degradation and MoA with "high concern to pollinators".

Academia also agrees but expressed some concerns regarding degradation.
MS mostly agree with this hierarchy but also expressed some concerns regarding degradation.

Conclusion: The decision hierarchy as proposed was considered as a pragmatic approach. However, there are some reservations regarding degradation and MoA. ECHA reworked the figure to find a more horizontal strategy and has added some text to better explain the figure. The new figure was discussed and agreed by the ECHA's Pollinator Expert Group.

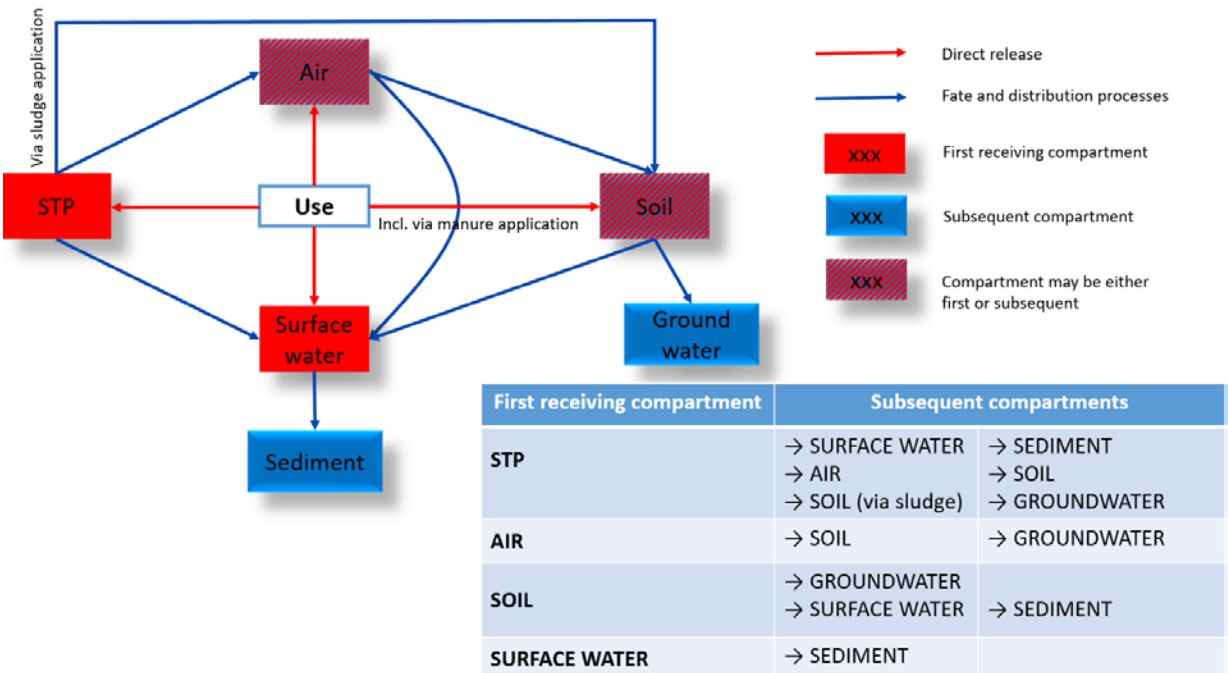
2.1 Exposure routes relevant to arthropod pollinators

2.1.1 Introduction

The aim of this section is to propose a strategy that would allow identifying emission scenarios for biocides which may lead to exposure to pollinators significant enough to be further considered by using standardised decision criteria.

To do that, it was considered necessary to look at the a) releases, i.e. emissions to the first receiving compartments, and b) emissions to subsequent compartments separately. This is mainly due to the fact that the exposure of pollinators through subsequent compartments is largely impacted by the substance properties such as degradability or adsorption/desorption, which need to be taken into account. Relationships between environmental compartments is illustrated in Figure 3 (see also Info-box 2 in the BPR Guidance Volume IV Part B). In cases, where for the first receiving compartment no risk assessment is performed e.g. because the substance does not remain in that compartment due to its properties but is transferred rapidly to the subsequent compartment, the subsequent compartment is dealt with as if it was a first receiving compartment. For example in case of cooling towers where substance is emitted to the air but right after that it is assumed to be deposited on soil, soil is considered a first receiving compartment in this document. Note that manure is not considered at the moment to be an "environmental compartment" as such and therefore for scenarios where manure is applied on soil, soil is treated as a first receiving environmental compartment. Sewage treatment plant (STP) on the other hand is defined as an environmental compartment due to the need to protect the microorganisms which facilitate the degradation of chemicals released to wastewater.

Figure 3. First versus subsequent environmental compartments



First receiving compartment	Subsequent compartments	
STP	→ SURFACE WATER → AIR → SOIL (via sludge)	→ SEDIMENT → SOIL → GROUNDWATER
AIR	→ SOIL	→ GROUNDWATER
SOIL	→ GROUNDWATER → SURFACE WATER	→ SEDIMENT
SURFACE WATER	→ SEDIMENT	

2.1.2 Potential exposure of pollinators via first receiving compartments (i. e. due to releases)

Table 1 shows four criteria which were considered relevant to be addressed in order to identify biocides emission scenarios which might potentially contribute to the exposure of pollinators following release, i.e. due to emissions to the first receiving compartments, which would deserve further consideration. The relevance of scenarios for the exposure of pollinators with regard to subsequent compartments is addressed in section 2.1.3.

Table 1. Criteria for the evaluation of biocides emission scenarios with regard to potential pollinator exposure due to emission to the first receiving compartment

Criterion name	Description	Criterion fulfilled when
Indoor/outdoor use	Outdoor or Indoor	Outdoor
Relevant application types/release pathway	Yes/No (Whether there is relevant type of application/release pathway)	Yes (e. g. Fogging, Spray drift, Overspray, Evaporation, Release to soil (incl. via manure application), Contact to bait, etc.…)
Release scale[1]	Whether spatial scale of release is small, medium or large	Large, Medium
Frequency of release[2]	Whether the frequency of release is daily weekly, monthly or annually.	Daily

It is proposed that the scenario is considered to be potentially contributing to the exposure to pollinators, if three out of four criteria are fulfilled.

To illustrate how the decision strategy works, all biocides scenarios have been screened and evaluated against the above criteria and the conclusion of this exercise is presented in the scenario overview excel table. In some cases, the biocides emission scenarios have been grouped.

Where there were doubts on whether a criterion is fulfilled or not, it has been flagged with orange font, column "Potential exposure to pollinators" is filled with "to be discussed" (TBD) and the respective considerations are provided in the "Remarks" field.

[1] **Release scale**
small: Household applications /limited applications in institutions (e.g. hand disinfection), therefore exposure considered negligible
medium: Industrial/institutional release via STP + outdoor applications on limited areas (e.g. railway sleepers)
large: Large scale applications like e.g. overspray or manure application

[2] **Frequency of release**
Daily, weekly, monthly, annually
Note: Frequency of release refers to emissions to the first receiving compartment and may not coincide with the frequency of application by an individual user. Where the scenarios operate with multiple sources (e. g. 4000 houses or multiple swimmers in a lake), the frequency of release is assumed daily. For manure application and service life e.g. for preservatives, daily release is considered applicable due to leaching. While application of some biocides is limited to spring-summer-autumn season, this limited part of the year still qualifies for daily or weekly release, considering it coincides with the period of the year relevant for pollinators.

Compared to the EFSA risk assessment for bees (2013), some additional potential "exposure matrices" relevant for exposure to pollinators have been identified, such as baits, wood and manure residues (for further discussion see section 2.1.4 of this document).

In this regard, it should be noted that the scenarios that have releases to STP only (first receiving compartment which is considered not relevant for arthropod pollinators) and which did not score for any other of the above mentioned criteria for other reasons than frequency of release ("Daily" release assumed by default) have been greyed out in this overview excel table. The relevance of these scenarios for the exposure to pollinators is subject of the decision strategy presented in section 2.1.3.1. This is the case also for the scenarios with multiple first compartments listed where STP is one of them. The evaluation of such scenarios on the part of the STP release also falls under the strategy covered by section 2.1.3.1.

QUESTIONS:

Q 3 Do you agree with the proposal for the assessment of the relevance of the emission scenarios for the exposure to pollinators focussing on the exposure due to release to the first receiving compartment? Do you consider the proposed criteria valid?

Summary: NGOs agree but point out a lack of consideration to the toxicological profile of the biocidal product.

Industry noted that the first receiving compartment is not necessarily the one to which bees might be exposed to referring to manure spreading on soil. In addition, industry suggested that the time of application should be considered as well and that the understanding that exposure is relevant at population level is critical. Academia agrees with this approach.

In general there is an agreement among MSs. However, one member noted that the strategy depends on the definition of the protection goal and that the (feeding) behaviour should be also added as a driver. One member did not agree with this approach as the relevance of a compartment is not solely dependent on timescale and environmental levels, since also small levels over time can lead to serious concerns (time-reinforced-toxicity, persistence, bioconcentration and bioaccumulation). According to this member, the relevance of compartments has instead to be decided on the basis of the potential of exposure to different life stages of the pollinating insects.

Conclusion: The majority in principle agreed on the proposal (noting also that the conclusions on questions 4-5 require further development and may impact the overall strategy).

As regards to the time of application and feeding behaviour as additional decision criteria it is considered that both have been implicitly covered (see e.g. swimming scenario where only summer season is relevant and feeding behaviour being a subject of data collection as presented in section 2.3 which results will be reviewed once finalised). In this context the outcome of the workshop held in the US describing the likelihood of pesticide exposure, by route, to commercially important Apis and non-Apis pollinators (https://academic.oup.com/ee/article/48/1/4/5216322 and the input in Q 14) will be reviewed. Where the time of application is adapted as a form of RMM, in line with RA practices under BPR those are considered once risk has been identified.

It is agreed that the strategy is dependent on the definition of the protection goals which needs to be clarified. It is considered that the current proposal is in line with the current BPR protection goals aiming at an overall protection at population level. As for the criticism of the lack of consideration of the substance properties such as time-reinforced-toxicity, persistence, bioconcentration and bioaccumulation, it is considered that this needs to be taken up under the substance properties topic (section 2.2) and remains to be discussed if such properties need to trigger case specific approaches. The proposed strategy nevertheless outlined in section 2.1.2 aims at providing pragmatic approach for filtering out relevant scenarios is considered still valid. The decision tree in Figure 2 was adapted.

Q 4 Do you find it appropriate that for the "Release scale" criterion it is considered fulfilled when the release scale is "Large"?

Summary: NGOs and academia consider medium scale as also relevant.
Industry agrees with this approach.
MS mostly consider medium and some even small scale relevant noting the possibility of a possible drastic impact on solitary bees even with releases at scale smaller than large or a beehive located in the vicinity of a biocide application. Definition of "large" scale was criticised as ambiguous and unclear.

Conclusion: In addition to "Large" also "Medium" release scale was added to consider the criterion of "Release scale" as fulfilled. The definitions of "Large", "Medium" and "Small" release scale will be revisited to improve the clarity of the definitions. Information collected under section 2.3 will be reviewed to understand the "strict nesting habitat requirements" and their link to exposure.

Q 5 Do you find it appropriate that for the "Frequency of release" criterion it is considered fulfilled when the frequency of release is "Daily"?

Summary: According to NGOs monthly and weekly frequency should also be considered.

Industry agrees with this approach, but they criticised that it is not filtering the scenarios well enough as most of the scenarios have daily releases.

Academia expressed that releases at any temporal frequency could be detrimental depending on the amount and toxicity of the substance and the timing of release. Some MS also consider weekly releases and some even less frequent releases as relevant. One expert noted that substances with an insecticide mode of action must be considered independently of the application frequency. Another expert highlighted the relation to the persistency of substances. It was also raised that a single release may be detrimental, whereas daily releases can be harmless. It is hard to judge scale and frequency without taking into account the protection goal and potential effect. It was suggested to focus rather on the duration of exposure. It was pointed out a lack of clarify of the definition of "daily".

Conclusion: The EG agreed that the criterion of the frequency of release could be maintained provided that daily and as well as weekly frequencies are considered as fulfilling the criterion. The EG however supported also that further reflection is needed to consider an option of removing the criterion altogether following the above comments. The EG agreed that insecticides should be the focus of the guidance nevertheless it considered that exposure route filtering should also apply to

insecticides (see Figure 2). Further consideration will be needed when drafting the guidance on how to approach insecticides.
In case the criterion is maintained, the definition of the criterion is something that should be discussed and clarified when drafting the guidance (e.g. considering duration). The definition of the criterion should also clarify that other frequencies of release do not lead to zero exposure/risk to pollinators.

Replacing the criterion with "duration" of release does not seem appropriate while it often relates to substance properties which is subject to the area discussed in section 2.2 which is also proposed to be considered when deciding on the need of a risk assessment. Solubility and Koc will be added as relevant substance properties for consideration is section 2.2.The relation to the toxicity highlighted in the comments should be also addressed by that same area of consideration.

Q 6 To illustrate the strategy, current biocides scenarios have been screened against the criteria and the result is presented in the document Section 2.1 Biocides scenario overview.xls. Do you agree with the values assigned by criterion to specific scenarios in the document Section 2.1 Biocides scenario overview.xls? Please, provide any views on the evaluation of scenarios in particular for those for which TBD is entered in column "Potential exposure to pollinators" – respective issues are presented in the "Remarks" column of the excel sheet/questionable criteria are highlighted in orange. Please, include your views in column "Comments". ***(We note that for several scenarios the value in the column "Frequency of release" is "??" which is due to uncertainties on how to assign respective value.)***

Summary:
Summaries of comments made in excel sheet have been provided in the excel sheet. From the comments provided to this question in the word document there were only the following additional issues raised:
One industry association expert noted that in PT 6, 7, 8 and 10 are classified "small", however according to the scoping document, page 11 the application on a façade would be per definition "medium" as it is application on a house wall.
One expert from Member State criticised that the strategy is unnecessarily complicated. The screening illustrates the scarcity of data to be able to establish the values for the criterion in many cases.

Conclusion:
Conclusions of comments made in excel sheet have been provided in the excel sheet.

In relation to the remark on the mistake in the respective classification of the PT 6, 7, 8 and 10 scenarios referring to the application and façade, it is considered that the scenarios should actually be treated as small scale in particular when comparing these uses to other "medium" uses which often refer to industrial applications. The respective footnote in the scoping document was corrected.
The excel sheet will be revised in line with the comments provided in regard to the individual scenarios and the adaptations of the decision strategy as implied by the conclusions under questions 3-5.

Q 7 Some publications suggest that the dust formed from dried manure/animal excreta generated by farms could be transported through air and later by settling could contaminate large areas. Do you consider such route of exposure relevant for biocides and having potential exposure to arthropod pollinators that should be subject for the risk assessment?

Summary: NGOs consider dust formed from dried manure relevant to pollinators. One of the experts highlighted that it is important if the quantity is noticeable. Industry only has knowledge of this scenarios in relation to a misuse of the product or in case of accident. Industry recommended looking into size, scope, frequency of this route of exposure and the timing of the dust formation in relation to the presence of blooming vegetation. Suggestions were made also considering high dilution in relation to this route of exposure. It was proposed to refer to good agricultural practice of manure application to address the relevance of this exposure route in particular when it comes to incorporation of manure into soil.

Academia confirmed relevance of this route referring to the PPP uses.

MS consider that this route cannot be excluded as a potential route of exposure to pollinators. Research showed unexpected presence of biocides (and PPP) in vegetation of nature reserves, indicating that substances can travel as aerosols or attached to particles in the air and additional environmental pathways may be relevant. It was pointed out that the exposure via dust should not be restricted to manure application on soil. One expert noted that dust might also be generated during the application of granular formulations. According to one expert, this route of exposure may be relevant in those cases when the biodegradation or decomposition of the active substance is low and potential accumulation in soil may occur.

In addition, this route may be also significant in southern European regions with large extensions of land subject to extensive dry season periods and potentially exposed to soil erosion by wind. One expert raised a question of appropriateness to look at dust as a relevant route of exposure while it is normally not considered for other non-target organisms.

Conclusion: It seems that the exposure route via dust formation from manure (handling and application on soil) is indeed relevant. The EG considered that the dust could be regarded as a potential route of exposure but according to the current knowledge, it is appropriate to consider this route as an area for further research. Further review of available information (among others GAP for manure application or through contact to agricultural associations) will need to be made with regard to the scale and frequency of the occurrence of this route of exposure (among others possibly making distinction between application on arable vs. grassland, dried vs liquid manure and also not limiting to the manure application on soil). The relevance of this route of exposure - via dust formed from dried manure should nevertheless be further discussed in particular in comparison with pesticide uses.

As for dust formed from granules this seems not relevant for biocides.

If the exposure to biocides due to dust formation is confirmed as relevant it will be investigated whether any elements of the granules or seed treatment applications under PPP are relevant to address dust formation due to manure handling.

2.1.3 Potential exposure of pollinators via subsequent compartments

2.1.3.1 Subsequent compartments following release to STP

Many of the biocides emission scenarios result in the releases to STP (first receiving compartment). While STP as such is not a relevant compartment for exposure to pollinators, the subsequent compartments could be.

The substance may be released from the STP to the following subsequent environmental compartments:

	→ ***Water***	→ Sediment (sea/freshwater)
STP →	→ ***Air***	→ ***Soil***
	→ ***Soil*** *(via sludge application)*	→ Groundwater

Those compartments which have location-wise theoretically a potential for exposure of pollinators are highlighted in bold (bees and pollinators are unlikely to be in contact with sediment or groundwater, therefore they are not considered relevant). From the location-wise relevant compartments, only the soil exposure due to application of sewage sludge is proposed to be further considered as a relevant route of exposure because of the scale and likelihood of contact to pollinators.

Here, though while the inherent purpose of the sewage treatment plant is biodegradation, the properties of the substance need to be taken into account. Another aspect to consider is the fact that sewage sludge originating from industrial sources is typically not applied on soil.

In contrast, emissions to surface water from STP are proposed to be disregarded since the substance will be heavily diluted.

Similarly, air emissions from STPs are normally considered negligible and immediately diluted to a large extent and therefore also proposed as not relevant for the exposure of pollinators.

Before analysing specific scenarios with releases to STP with regard to their relevance for the exposure to arthropod pollinators in subsequent compartments, it was considered more appropriate to agree on the overall strategy. The proposed strategy is as follows:
All scenarios with releases to STP should be assessed against the following criteria:

Table 2. Criteria for the evaluation of scenarios with releases to STP

Criterion name	Description	Criterion fulfilled when
User category	Whether the user is household, professional, industrial	Household or professional (sewage sludge from industrial plants is assumed not to be applied to soil)
Treated area/volume[3]	Whether the area/volume treated with biocides from which release to the STP occurs is small, medium or large	Medium or Large
Frequency of release[4]	Whether the frequency of release is daily weekly, monthly or annually. (“release” refers here to “release to STP”)	Daily

While the user category excludes industrial uses, two criteria are decisive - “treated area/volume” and “frequency of release”. If both of them are fulfilled the scenario is considered to be potentially relevant for the exposure of pollinators via application of sludge on soil.

2.1.3.2 Subsequent compartments after releases to soil and surface water

The main subsequent compartments following releases to soil and surface water (i.e. as first receiving compartments) are **groundwater** and **sediment**, respectively. It is questionable whether groundwater and sediment should be considered relevant for exposure to pollinators, therefore these compartments are suggested not to be further assessed.

2.1.3.3 Subsequent compartments after releases to air

Biocides guidance VOL IV Part B + C states that the air compartment receives its input from direct **emission to air, and volatilisation from the sewage treatment plant**. Figure 8 of the guidance assumes that the emissions are in gaseous phase and while in the atmosphere they may degrade and/or partition to water phase due to contact with rainwater or they may form aerosols. In all cases, they deposit on **soil or surface water**. Generally, gaseous emissions could be a source of exposure of pollinators via inhalation and when these emissions deposit on subsequent compartments - soil or surface water - pollinators might be affected due to oral or contact exposure through plants, soil or surface water. It is nevertheless proposed that the **emissions/releases to air in their gaseous phase as well as subsequent compartments (considering plants being part of soil compartment) are considered not relevant to pollinators thanks to dilution in air/surface water.** Large scale applications such as cooling towers (PT 11) could be of concern but further research is needed to support that.

In relation to **dust**, the Biocides guidance VOL IV Part B + C does not intend to cover it when describing the air emission and dust therefore is not addressed by the guidance.

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[3] **Treated area/volume**
Small: spot applications, gel applications, human body applications, etc.
Medium: private uses with application on house, limited area/volume treatments in institutions, stables etc/
Large: large area treatments in e. g. institutions, slaughterhouses, etc.

[4] **Frequency of release:** daily, weekly, monthly, annually

However, the term 'aerosol' is often used for both solid particles and droplets suspended in air. For dust, the size of the particles influences the rate at which particles deposit and therefore such emissions may be often local. In case of dust, contact as well as oral exposure would be the relevant pathways for pollinators (i.e. the dust can be consumed together with pollen). Exposure via inhalation is considered not relevant.

As for **overspray (vector control) or other spraying applications** (e.g. of facades if considered as relevant applications), spray drift can occur which may result in temporary releases to air (gaseous phase) as sprayed droplets are likely to settle to the ground rapidly due to their size. Furthermore, instant dilution and turbulence in air can also be assumed. Exposure to the air is limited in time and restricted to local scale. For these reasons, exposure via inhalation is considered not relevant. For these applications, contact exposure as well as oral exposure (due to deposition on soil, surface water, deposition on/uptake by plants) seems to be the relevant pathway for pollinators.[5]
As for **sludge and manure application on soil**, contact exposure (deposition on soil, plants) and oral exposure (deposition on soil, deposition/uptake by plants) are likely the key exposure routes. The likelihood of the exposure to dust from manure needs further investigation.

2.1.3.4 Plants as a source of potential poisoning

[The text was removed following comments provided in the stakeholder consultation while the plants are implicitly covered by exposure to soil discussed elsewhere in the document. The title was left in the document for the readers to understand the references made in the questions to the section of this document.]

QUESTIONS:

Q 8 Do you agree with the proposed strategy for the assessment of the relevance of the scenarios due to sewage sludge application on soil? Do you consider the proposed criteria valid? Do you agree with the overall strategy for the decision making? (Ref. section 2.1.3.1)

Summary: NGOs mostly agree with the proposed strategy. However, for one expert the treated area and frequency of release do not represent the complete picture. Units and precise levels of magnitude behind the ranges would be desirable. Industry and academia also agree with this approach but it was suggested to include RMM as a criterion.

MS mostly agree. It was suggested that also scenarios leading to releases to soil via manure should be assessed using this strategy. It was also noted that the strategy depends on the definition of the protection goal and that the feeding behaviour should be also added as a driver. One expert did not agree to exclude industrial/professional uses, since these may also end up in the municipal STP and from there to sludge and soil. It was noted that sewage sludge from industrial STPs is spread onto land in Spain or France. One Member State does not agree with this approach since they have some reservations on the approach to decide on the

[5] While pesticides are often applied by spraying EFSA 2013 covers primarily this type of application. In EFSA 2013 the contact exposure considers direct over spraying and exposure via the overs-prayed surface (spray dries up quickly e.g. in an hour, but during that time they can have the exposure). The two things are not distinguished. The same assumptions could be applicable for contact exposure for overspray/spraying applications for biocides. Inhalation route of exposure is not addressed in EFSA 2013 (most of the pesticides are not volatile and it would be unrealistic to consider that bees follow the tractor with the sprayer and would get continuous contact exposure from the air).

relevance of a compartment.

Conclusion: The majority agreed with this strategy regarding the assessment of the relevance of the scenarios due to sewage sludge application on soil. However, some MS have some reservations on this approach.
Three MS claimed that the exposure via sludge application on soil from industrial STPs/industrial uses should not be excluded from the scheme as it is spread on land especially when the industrial wastewaters are treated by municipal STP. The EG nevertheless decided that it is appropriate to exclude industrial uses from this strategy.

As to the remark on addressing the scenarios with manure application on soil by this strategy, while manure is not considered by BPR Guidance as a compartment, it is still considered more appropriate to keep the respective scenarios assessed following the strategy as provided in section 2.1.2 considering that the substance properties in case of scenarios with releases to manure will have less prominent role compared to scenarios with releases to STP.

In regard to the comments made some Member States related to sewage sludge from industrial STPs being spread onto land, see the conclusion under Q 3.
As for the suggestion to include applicability of RMM in the strategy for the assessment of the relevance of the scenarios it is considered not appropriate/in line with RA practices under BPR where RMM are considered only once risk has been identified.

Q 9 Do you find it appropriate that the "Treated area/volume" criterion is considered fulfilled when the treated area/volume is "Medium" or "Large"?

Summary: NGOs mostly agree with the proposed strategy. However, it was noted that treated area and frequency of release do not cover the complete picture. Units and precise levels of magnitude behind the ranges would be desirable.
Industry agrees with the approach, but some consider that only "large" should be covered to be consistent with the approach for first receiving compartment (Table 1).

Academia agrees with this approach.
The majority of MS find this approach appropriate. Some experts raised some doubts about the meaningfulness of small and large scale if high concentrations for small and low concentrations for medium scale may be in question. It was also noted that definition of small, medium and large needs to be specified taking simultaneity and aggregated use into account. One expert regard "medium" and "large" as ambiguous.

Conclusion:
The EG agreed that the definition of this criterion would need to be improved.
As for issue raised about the meaningfulness of small and large scale if high concentrations for small and low concentrations for medium scale may be in question, it is considered not relevant as it is not expected that the differences between small and high concentrations would be that high that they would make a big difference in overall releases.

As for the proposal to take simultaneity and aggregated exposure into account, since these are normally taken into account in the next steps, it is considered not appropriate to be added in the definition of this criterion. Standard risk assessment looks first at individual uses.

Q 10 Do you find it appropriate that the "Frequency of release" criterion is considered fulfilled when the frequency of release is "Daily"?

Summary: According to NGOs monthly and weekly frequency should also be considered.

Industry agreed with this approach.

Academia pointed that releases at any temporal frequency could be detrimental depending on the amount and toxicity of the substance and the timing of release in relation to life history events of the pollinators.

Part of the MS agreed with this approach. It was highlighted that all of the emissions to STP (wastewater) are referred to a day. Some experts argued that this depends on the substance characteristics and timing of application and so even "monthly" could be relevant. One Member State considered the term "daily" ambiguous and not clearly defined.

Conclusion: "Weekly" release frequency will not be added to consider the criterion of "Frequency of Release" as fulfilled since the storage time of the sludge before applying on soil is less than a week.

The definitions of "Daily", "Weekly", "Annually" release frequency will be drafted to clarify the meaning.

The definition of the criterion will be clarified in the text to explain among others that other frequencies of release do not lead to zero exposure/risk to pollinators. The intention of the criterion is to roughly indicate the cumulative amount of substance in the sludge accumulated during the sludge storage time which is common to all uses regardless of release (use) frequency or treated volume/area. The unit of the emissions to wastewater referring to a day as normally used by exposure scenarios should not be confused with "daily" frequency of release proposed in this document which looks rather at the frequency of use (and release) as spread throughout the year. Assuming that the risk assessment in the context of exposure of pollinators will use PEC soil to calculate possibly PEC nectar/pollen, the criteria of treated area/volume and frequency of release are considered substantiated to filter out scenarios for which quantitative RA is justified.

The relation to the substance (fate) properties highlighted in the comments is a subject for section 2.2 which is also proposed to be considered when deciding on the need of a quantitative/qualitative risk assessment. Substance properties therefore cannot be used as a criterion for filtering of exposure scenarios as such covered by section 2.1. Solubility and Koc will be added as relevant substance properties for consideration in section 2.2. Similarly, the relation to the toxicity highlighted in the comments is also in the scope of section 2.2.

Q 11 Do you agree that groundwater and sediment as subsequent compartments following other releases to soil and surface water respectively are not relevant to pollinators? Do you support that they do not need to be therefore assessed? (Ref. section 2.1.3.2)?

Summary: NGOs consider residues in groundwater and sediment as relevant or potential reservoirs for the substances and may lead to exposure.
Industry agrees that exposure to groundwater and sediment is not relevant to pollinators.
Academia and MS also agree that groundwater and sediment is not relevant for exposure to pollinators.

Conclusion: The majority agreed that groundwater and sediment exposure are not relevant to pollinators.

Q 12 Do you agree that soil and surface water as subsequent compartments following releases to air are not relevant to pollinators? Do you support that they do not need to be therefore assessed (except for overspray)? (Ref. section 2.1.3.3)

Summary:
NGOs do not agree with this approach.
Industry and academia support this approach.

Between MS there are some discrepancies. While some Member States agreed. One noted that also soil and surface water should be assessed in case of deposition of dust particles from the air and another expert highlighted the use of surface water by pollinators for drinking purposes. One Member State showed concerns for surface water referring to a potential concentration effect due to strong seasonal variations. It was stated that even if soil is the second receiving compartment the levels of a substance can be higher in the soil layers and soil living organisms than in the air above. There are many species of pollinators like bumble bees and others that build their hives in the soil. One member State suggested instead that a risk assessment strategy for overspray (vector control) where in 1st tier PEC/PNEC ratio for air is calculated and where risk is identified for air in 2nd tier (with applicable RMM) soil and water are assessed (justifiable for contact exposure, but not for oral exposure). It was suggested that the strategy could be applicable also for other uses provided relevant RMM would be applicable for those uses.

Conclusion: Several parties raised questions or made remarks in relation to the meaning of the "releases to air". NGOs expressed that they do not agree with the proposed approach but industry and academia do. There were some discrepancies between MS. It is considered that clarification of the meaning of the "releases to air" could help agreement on this question. The main lines are provided below on the basis of which sections 2.1.3.3 and 2.1.3.4 were rewritten.

Biocides guidance VOL IV Part B + C states that the air compartment receives its input from direct emission to air, and volatilisation from the sewage treatment plant. Figure 8 of the guidance assumes that the emissions are in gas phase and while in the atmosphere they may undergo in addition to degradation also partitioning due to contact with rainwater or they form aerosols and in both cases, they deposit on soil or surface water. Generally, gaseous emissions could be a source of exposure of pollinators via inhalation and when these emissions deposit on subsequent compartments - soil or surface water - pollinators might be affected due to oral or contact exposure through plants, soil or surface water. It is nevertheless proposed that the emissions/releases to air in their gaseous phase as well as subsequent compartments (considering plants being part of soil compartment) are considered not relevant to pollinators thanks to dilution in air/surface water. Large scale applications such as cooling towers (PT 11) could be of concern but further research is needed to support that (see Q 13 and excel).

It is considered that the Biocides guidance VOL IV Part B + C does not intend to cover dust by the above presentation of air emission and dust is not addressed by the guidance. At the same time, it is recognised that the term 'aerosol' is often used for both solid particles and droplets suspended in air. For dust, the size of the particles will also have impact on the rate with which particles deposit and such emissions may be largely local. Contact as well as oral exposure seem to be the relevant pathways for pollinators (while the dust can be consumed together with pollen). Exposure via inhalation is considered not relevant.

As for overspray (vector control) or other spraying applications (e.g. of facades if considered as relevant applications), spray drift can occur which may result in temporary releases to air (gaseous phase) as sprayed droplets are likely to settle to the ground rapidly due to their size. Furthermore, instant dilution and turbulence in air can also be assumed. Exposure to the air is limited in time and restricted to local scale. For these reasons, exposure via inhalation is considered not relevant. For these applications, contact exposure as well as oral exposure (due to deposition on soil, surface water, deposition on/uptake by plants) seems to be the relevant pathway for pollinators.

While pesticides are often applied by spraying EFSA 2013 covers primarily this type of application. In EFSA 2013 the contact exposure considers direct over spraying and exposure via the overs-prayed surface (spray dries up quickly e.g. in an hour, but during that time they can have the exposure). The two things are not distinguished. The same assumptions could be applicable for contact exposure for overspray/spraying applications for biocides.

Inhalation route of exposure is not addressed in EFSA 2013 (most of the pesticides are not volatile and it would be unrealistic to consider that bees follow the tractor with the sprayer and would get continuous contact exposure from the air).
As for sludge and manure application on soil, contact exposure (deposition on soil, plants) and oral exposure (deposition on soil, deposition/uptake by plants) are likely the key exposure routes. The likelihood of the exposure to dust from manure needs further investigation.

Note that the contact exposure to substance residues in soil and aerosols in air is discussed in Q 14 and Q 15 respectively.
EG agreed with the clarifications provided above.

Q 13 Would the exposure from biocides via <u>deposition</u> on plants following releases to air be relevant exposure route for pollinators?" (Ref. section 2.1.3.3 and 2.1.3.4)

Summary: NGOs and academia consider that the exposure from biocides via deposition on plants following releases to air is a relevant exposure route for pollinators.
Industry does not consider this route of exposure as relevant to pollinators as the

exposure could be negligible.

The majority of MS agree that exposure from biocides via deposition on plants following releases to air can be relevant to pollinators in case of overspray application (vector control), spray drift after spray application or cooling towers (because of the larger scale of emissions, in view of one expert). However, for emissions from the STP or in case of evaporation of a substance to air this route was proposed to be considered less relevant.

Conclusion: Several parties raised questions or made remarks in relation to the meaning of the "releases to air". NGOs and academia consider exposure from biocides via deposition on plants following releases to air as a relevant exposure route for pollinators. However, MS consider this route relevant for certain exposure routes and Industry does not consider it relevant. It is considered that clarification of the meaning of the "releases to air" could help agreement on this question. The question is linked to Q 12, where the conclusion covers also this question.

2.1.4 Exposure matrices relevant for pollinators due to biocides uses

As outlined in the UBA study (2018) with focus on PT 18 and as further observed during the compilation of the above mentioned scenario overview table looking at all PTs, there may be multiple sources and pathways of potential exposure of pollinators due to the use of biocides. In addition to the exposure matrices relevant to bees considered by the EFSA guidance (2013) - pollen, nectar, guttation droplets, puddle water and surface water - some additional ones have been identified which may be relevant in the context of biocides, such as baits, wood and manure (UNAF 2018). The purpose of Table 3 is to describe possible exposure situations arising from biocidal uses in relation to some of these matrices. Pollen, nectar and guttation water being part of "plants" are not listed considering that biocides exposure scenarios which involve emissions to soil are assumed to cover plants as well (see excel sheet). Surface water is also assumed to be covered by the overview of biocides emission scenarios that lead to emissions to surface water in the same excel sheet.

Table 3. Selected exposure matrices relevant for pollinators due to biocidal uses

Matrix	Biocidal use specific exposure situations possibly relevant for arthropod pollinators
Baits	Pollinator arthropods may directly forage on baits (containing sugar (relevance of baits containing proteins and ammonia to be confirmed), liquefied by rain, cleaning water or humidity).
Wood	Biocides treated wood could be used for pollinators for nesting. Beehives could be built from wood treated with biocides. Beehives could be disinfected.
Manure	Manure is treated with biocides or contains biocides applied in stables. Larvae stages of some pollinating arthropods may live in manure as well as adult arthropod pollinators may forage for water on manure.

Puddle water[6]	Arthropod pollinators drinking puddle water that may be formed - on agricultural soil/grassland due to rainfall after application of manure/sludge - on farm premises due to biocidal uses in general (e.g. due to treatment on vehicles, on buildings or around building) - around buildings after rain event due to rain falling on granules or solid baits used for insecticidal purposes (city or countryside) - after pouring liquid biocidal products on e.g. ant nests around buildings (city or countryside)

Further consideration is needed to confirm the pertinence of the exposure situations described in Table 3. Note that only some of these situations are also identified at scenario level in the Document Section 2.1 Biocides scenario overview.xls. Additionally, further consideration needs to be given from the point of view of relevance of these matrices to the arthropod pollinators and their respective life stages (adult individual versus larvae). Finally, it needs also to be considered if any other matrices so far not considered may be relevant in particular considering that other arthropod pollinators need to be covered by the guidance in addition to bees. This will be further investigated via literature review as explained in section 2.3. Identification of further exposure matrices may require revision of the strategies for identification of relevant exposure routes as presented in sections 2.1.2 and 2.1.3. Following from the comments on the scoping document, the Expert Group agreed that the wood treated with biocides is considered of low relevance to pollinators.

As for soil, although EFSA guidance (2013) acknowledges that exposure from residues in the soil to bees that nest in the ground is important, this is however not covered in EFSA's risk assessment schemes because it was not possible to link the concentration in the soil to the effects on bees.[7] It is nevertheless recognised that there is potential for the contact exposure in soil (and maybe manure) which should be a subject for further research. Uptake of substances from soil to plants is naturally covered by exposure matrices - nectar and pollen which are foraged by bees.

According to EFSA guidance (2013) exposure via inhalation is not considered relevant.

In order to be consistent with EFSA guidance (2013), it seems appropriate that the biocides guidance would not cover contact exposure of pollinators through soil, manure, wood and via inhalation.

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[6] Relevance of guttation water, puddle water and surface water for the exposure to bees was discussed in the context of revision of EFSA guidance (2013). In line with recent agreement of EFSA that water scenario will not be covered in their bee guidance, the EG agreed that the biocides guidance will not cover such route of exposure either.

[7] EFSA 2013: p. 11: "Bumble bees and many solitary bees make nests in the soil or use mud as nesting material. However, exposure by residues in the soil is not currently considered in the risk assessment scheme because it was not possible to link the concentration in the soil to the effects on bees" (ECHA note: this refers to contact exposure (missing transfer rate from the soil to the bee or to the larvae) as confirmed informally by EFSA) …p. 93: "Whilst it is acknowledged that **exposure from residues in the soil to bees that nest in the ground** is important, this is not covered in the risk assessment schemes."

QUESTIONS:

Q 14 According to EFSA guidance on bees (2013), exposure by residues in the soil (being used as nesting material) is not currently considered in the risk assessment scheme “because it was not possible to link the concentration in the soil to the effects on bees”. Is it justified that biocides guidance would follow the same principle and disregard contact exposure via soil? Is this conclusion equally relevant for manure and wood? Can the same assumption be made for other pollinators?

Summary: NGOs and academia consider contact exposure via soil should be considered. NGOs consider that concentration of the biocides in the soil must be addressed, especially for solitary bees and other ground nesting insects, same applies to wood and manure. In addition, in the EFSA guidance this risk is not assessed because there is a data gap, but the risk potential is recognised. According to one ASO, Lepidopteran and Dipteran larvae may be exposed during pupation in the soil, Dipteran larvae also in manure.

Industry agrees with this proposal as exposure might be negligible. Information was provided showing that even ground nesting bees in agricultural settings require well drained soils that are typically located in compressed farm tracks or located in more natural or semi-natural areas such as woodland and grassy banks, partially in sandy soils. These preferred nesting sites are unlikely to be subject to a manure or sludge application. According to one expert, the probability of applying matrices containing biocide residues onto bee nests should be discussed.

The majority of MS note that contact to soil is an important route of exposure that needs to be considered in particular for ground dwelling arthropods. However, they recognise that further research is needed. It was highlighted that the level of exposure may be highly variable between different pollinators. It was also noted that soil may be used also for nest construction. One expert proposed to be careful not to exclude any scenarios from the assessment consideration on the basis of the contact exposure to soil, manure or wood beforehand.

As for manure, it was noted that manure application on soil is the most relevant route of exposure and worst case for pollinators via oral exposure. Some concerns were raised also over contact exposure in manure.

As for wood, it was suggested that contact exposure via wood should be treated as negligible.

Conclusion: Considering the conclusion made in the EFSA guidance that the contact exposure to residues in soil might not be considered for the moment in the risk assessment scheme due to data gaps but majority of commenters suggesting that the contact exposure via soil may be highly relevant for some species of pollinating arthropods, it is suggested that the biocides guidance would recognise the potential for the contact exposure in soil and maybe manure and highlight it as an item for further research. The biocides guidance would follow the conclusion of the EFSA guidance stating that the contact exposure to residues in soil might not be considered for the moment in the risk assessment due to data gaps (which is by analogy applicable also to manure).

As regards contact exposure to wood, the difficulties with considerations in the

assessment also apply but it is additionally considered that exposure would be negligible as suggested also by the comments made under Q 6 and Q 16.
Further review may be needed to address the probability of using different matrices containing biocide residues by pollinators to build nests and the likelihood of contact exposure.

Q 15 According to EFSA guidance on bees (2013), contact exposure to air is not currently considered in the risk assessment scheme. Is it justified that biocides guidance would follow the same principle and disregard contact exposure via air?

Summary: The majority of NGOs agree with the proposal to exclude contact exposure to air (volatile and gaseous substances) in the risk assessment scheme. It was noted that risk could be identified as potentially relevant, but due to data gaps this is currently not possible. Academia would prefer further investigation.
Industry agrees with this approach. It was highlighted that the EFSA approach to contact risk assessment does not discriminate between the sources of contact exposure (contact from treated surfaces versus airborne) as it uses the HQ approach (unlike USEPA pollinator guidance). EFSA clarified that in the EFSA (2013) guidance contact exposure considers direct over spraying and exposure via the over-sprayed surface (spray dries up quickly e.g. in an hour, but during that time they can have the exposure) and indeed, the two things are not separated. Inhalation route of exposure is not addressed (most of the pesticides are not volatile) and it was considered that it would be unrealistic to consider that bees follow the tractor with the sprayer and would get continuous contact exposure from the air.

Most of the MS agree with this proposal although may be relevant in some scenarios. One Member State expert noted that contact exposure to air due to spray application should be addressed while it should not be assessed e.g. in case of cooling tower emission. One expert emphasised that exposure to dust should be assessed. One Member State disagrees with this proposal referring to some studies on pesticides present in dust from treated seeds and planter exhaust material (talc).

Conclusion: The majority seems to agree to exclude contact exposure via air (due to emissions of volatile or gaseous substances) in the risk assessment scheme (contact exposure to dust and also any spray applications were not a subject of this question). However, MS expressed concerns on some scenarios. From the feedback received it was realised that the "contact exposure to air" is not appropriate terminology. In line with EFSA guidance (2013), for air compartment distinction needs to be made between contact exposure due to direct over spraying and exposure via the over sprayed surface (inhalation route of exposure is not relevant). The text in section 2.1.3.3 and 2.1.3.4 was aligned with the clarifications made in some of the comments and the agreements made under this question. See the key lines for the revision of the sections presented under Q 12.

Q 16 Do you consider that baits, wood, manure and puddles[6] are relevant exposure matrices to bees and other arthropod pollinators? (Ref. Table 3) What is the relevance of the situations described in Table 3? (Note the relation of this question to the question on the contact exposure in wood and manure)

Summary: NGOs and academia consider baits, wood, manure and puddles relevant exposure matrices to bees and other arthropod pollinators. It was suggested that there are also baits containing protein and ammonia which are attractive to bees.

The majority of industry seems to agree that the exposure to wood, baits, manure and puddles is quite limited. Industry also recommended to consider any proposed RMMs as a potential starting point to evaluate whether qualitative RA has to be performed.

As for "biocides treated wood use by pollinators for nesting", it was claimed to be minor construction material for wild bees. Furthermore, as mentioned in comments under Q 6, the pollinators should be considered rather as pests damaging wood constructions. As for "biocides treated wood use for the construction of beehives" it was noted that bee keepers either prefer untreated wood or if treated the biocide is not bioavailable to the bees and bee keepers have a long history of using treated wood to avoid rotting of the hives or alternative material such as plastic. As for disinfection of beehives, it was claimed that such disinfection is performed with non-chemical disinfection methods. It was noted that for PT 8 "Treated wood in service" for all organic wood preservatives application of a top-coat is mandatory. This prevents that bees and other pollinators will come into contact with the actives on the treated wood during service life.

Regarding manure it was proposed to review the literature on whether pollinators' life cycles could be disrupted by standard agricultural practices. It was also claimed that the relevance of puddles depends on the proximity to the biocide source (puddles close to manure source vs. puddle from manure on the field). For agricultural soils it was proposed to consider that while water need for bees is highest in spring and early summer but the manure application to agricultural fields is performed only once a year between autumn and winter season that puddles formed from manure after spreading on fields should not be a problem.
The majority of MS agree that baits, wood, manure and puddles can be considered relevant exposure matrices. However, this should be further investigated. It was expressed (under Q 14) that wood should be considered a minor issue compared to other matrices. It was also noted the relevance of puddle water in particular in southern European regions during the dry season. One expert suggested a threshold of 60 % for sugar concentration in liquid/gel baits relevant for bees. In addition, it was suggested that granular forms in baits may be also carried by Apidae family to the hives. The most voluminous pollen collected by bees seems to reach 150-170 µm, which was suggested to be considered as a cut-off criterion for this type of product. It was highlighted that encapsulated or microencapsulated formulations are similar in shape and size to pollen grains, between 30 and 60 µm. One Member State suggested also new "puddle" situations.

Conclusion: Q 16 is partially answered also by replies to the question Q 6 related to the scenario level analysis as presented in the excel sheet Section 2.1 Biocides scenario overview.xls so the conclusions need to be considered jointly.
The majority agreed that baits, wood, manure and puddles can be considered relevant exposure matrices to bees and other arthropod pollinators. However, for the specific exposure situations some reservations were presented as well as some new situations were proposed:
Baits:
Use of baits containing protein and ammonia were proposed to be considered as relevant exposure route. It will be further investigated how relevant such baits could be.
Use of baits containing granular and encapsulated or microencapsulated formulations were proposed to be considered as relevant exposure situation. It will be further investigated how relevant such baits could be.
60 % for sugar concentration in liquid/gel baits will be considered as a potential RMM.

Wood:
In Industry's view none of the situations presented in Table 3 are relevant or they are minor. Pollinators nesting in biocide treated wooden structures could be also considered a target organism. EG agreed that the wood treated with biocides is considered of low relevance to pollinators.
Manure:
It will be investigated whether pollinators' life cycles may be disrupted by standard agricultural practices.
Puddle water: The ECHA guidance will follow the agreements taken at EFSA in regards to the relevance of the water scenarios.
As for the proposal of consideration of RMM, it is also considered not appropriate to use RMM as a starting point in line with RA practices under BPR where RMM are considered only when risk has been identified.

Q 17 Are there any other exposure matrices in addition to those mentioned in section 2.1.4 that are relevant for other arthropod pollinators than bees?

Summary: One NGO identified propolis as an exposure matrix. It was identified also by EFSA (2013) but not included due to lack of data.
Industry and Academia do not have any more information on the matter.
One Member State identified plant leaves as missing.

Conclusion: Propolis and plant leaves were identified as missing exposure matrices. As for propolis, if EFSA does not include it in the risk assessment scheme due to lack of data it is considered it should not be included for biocides either. Plant leaves are considered covered being a part of "plants" and therefore it is assumed that the exposure situations are sufficiently described by section 2.1.3.4. It may be investigated whether plant leaves would be relevant for arthropod pollinators other than bees.

Q 18 Are you aware of any other biocides uses not covered by the Excel document Section 2.1 Biocides scenario overview.xls which are of particular interest to pollinators?

Summary: NGOs, Industry and Academia do not have further information on other biocide uses that would not have been covered by the Excel document.

Two uses were identified which were not covered by the Excel. 1) The use of PT2 biocides to prevent algae proliferation in irrigation pools or into the irrigation system. 2) the use of PT18 biocidal products against mosquito larvae breeding in water holding features/aquatic areas like unused pools, ponds padded by geofoil, rainwater holding barrels, scuppers or also irrigation pools used in agriculture. In addition, some PT18 products may be used as well against mosquitoes in large waterlogged rice cultures close to urban areas in Spain.

Conclusion:
Disinfection of drip irrigation systems (PT2, TAB 2.1 ENV-A9, covering greenhouses and fields) and use of treated water for irrigation of private gardens (PT 18, TAB 2.1 ENV-A22, biocides use in (rain) water collection containers) will be added in the Excel table. There is no agreed scenario for "irrigation pools". Where the question is related to disinfectants it may be assumed that the impact on pollinators may be marginal as also supported by comments made in the excel sheet.
As for uses where a biocide is applied directly to water holding features/aquatic

areas or large waterlogged rice cultures against mosquito larvae breeding those are examples of uses which are presumed to be covered normally by national authorisations/derogations based on risk-benefit 5(2)(b) or (c) and therefore those may always involve risk to pollinators. There is also no standardised exposure scenarios for these uses. The EG agreed that the guidance should cover a general overspray scenario.

Q 19 Are you aware of any information in relation to the exposure of pollinators due to biocidal uses?

Summary: One NGO claimed to have knowledge of biocide residues in beekeeping products (abamectine in areas of walnut trees).
Industry provided information about biocide active ingredients detected in honeybee samples noting nevertheless that the exact source of the active ingredient cannot be determined from the residue data, particularly in the case of active ingredients used both as biocides and PPPs.

Academia does not have any further information on this matter.
One Member State expert noted of the use of bait boxes against ants outdoor which may be harmful for solitary bees.

Conclusion: It will be further investigated whether abamectine residues in the areas of walnut trees could be due to biocides uses and if so, what type of application is in question and whether it is indeed a new application so far not covered by this scoping documents.

As for use of bait boxes against ants, it is assumed that this use is already considered by this scoping document.

References related to section 2.1:

Environmental Research of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety: Opinion on specific issues in the context of the risk assessment of biocide uses towards bees. Completion date June 2018. Not published.
Arnold, G., Boesten, J. J. T. I., & Clook, M. (2013). EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, Bombus spp. and solitary bees). EFSA Journal, 11(7), [3295]. https://doi.org/10.2903/j.efsa.2013.3295

UNAF Report With The Cooperation Of Beelife European Beekeeping Coordination, Cntesa And The French Federation Of Professional Beekeepers (2018): How Pesticides Used In Livestock Farming Threaten Bees. Veterinary Treatments, Biocidal Products & Pollinating Insects,

https://www.apiservices.biz/documents/articles-en/how_pesticides_livestock_farming_threaten_bees.pdf

2.2 Biocidal active substances and products relevant for risk assessment of arthropod pollinators

2.2.1 Universe of biocidal active substances

Biocidal products are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. There are approximately 300 active substances in the Review program.
Biocidal products are classified into 22 biocidal product-types, grouped in four main areas:

Table 4. Grouping of biocidal products and product types

	BIOCIDAL PRODUCT TYPES
GROUP 1: DISINFECTANTS	1. Human hygiene
	2. Disinfectants and algaecides not intended for direct application to humans or animals
	3. Veterinary hygiene
	4. Food and feed area
	5. Drinking water
GROUP 2: PRESERVATIVES	6. Preservatives for products during storage
	7. Film preservatives
	8. Wood preservatives
	9. Fibre, leather, rubber and polymerised materials preservatives
	10. Construction material preservatives
	11. Preservatives for liquid-cooling and processing systems
	12. Slimicides
	13. Working or cutting fluid preservatives
GROUP 3: PEST CONTROL	14. Rodenticides
	15. Avicides
	16. Molluscicides, vermicides and products to control other invertebrates
	17. Piscicides
	18. Insecticides, acaricides and products to control other arthropods
	19. Repellents and attractants
	20. Control of other vertebrates
GROUP 4: OTHER BIOCIDAL PRODUCTS	21. Antifouling products
	22. Embalming and taxidermist fluids

Active substances under the different product types can be found in the ECHA website: https://echa.europa.eu/es/information-on-chemicals/biocidal-active-substances

2.2.2 Rapidly degrading, reacting and volatile substances

Among the biocidal active substances and their transformation products (i.e. metabolites and or reaction products) there are substances that either rapidly degrade, substances that are volatile and substances that quickly react. It may be justified to suggest that not all active substances should be assessed for their hazard to bees and other pollinators on the grounds of their fate properties. This seems particularly relevant in cases where the use of the compound involves exposure routes with multiple compartments in sequence - where the compound is degraded or transformed in the (first) receiving compartment and thereafter it reaches subsequent compartments (e.g. compounds reaching the soil compartment as a result of sludge application following degradation in STP). In principle, this could impact the potential exposure as a result of translocation of the chemical from soil to plants and to nectar and pollen and also the exposure via the soil compartment for organisms which nest in the soil.

It shall be noted that in cases where during degradation or transformation processes transformation products are built (i.e. metabolites and or reaction products), those should be assessed following the same principles as for the parent compound.
Further considerations need to be made whether waiving of the quantitative risk assessment for pollinators could be justified on the basis of substance fate properties also e. g. due to following circumstances:

a) emissions are to bare soil (agricultural soil) (i. e. sludge/manure application on agricultural soil[8]), or
b) substance is applied on soil not more than once a year (sludge[9] applied on agricultural soil/grassland, manure applied on agricultural soil)

In other situations where respective releases take place when the soil is covered with flowering vegetation (e.g. spray drift in PT18), waiving of the quantitative risk assessment to pollinators based on the degradation of the compound may not be appropriate.
EFSA guidance (2013) suggests using a trigger value of DegT50 in soil of less than 2 days for applications within the same year and 5 days for applications in different years to decide whether the risk assessment for that scenario needs to be conducted. The concept behind this trigger is that if the DegT50 in soil is short enough the pore water concentration in the root zone will be low enough one year after application to result in negligible exposure in nectar and pollen. Similar trigger could be applicable for biocides e. g. in cases where emission occurs to bare soil or the application on soil is done annually taking into account that the substance would have enough time to degrade before it could be taken up by plants that will grow in that soil later in the same year/next year. For manure applied on grassland, a stricter trigger may be relevant considering application of manure takes place four times in a year. Grassland in biocides constitutes in principle a form of a permanent crop. On the other hand, for agricultural land where manure is applied, little is known up to now with regards to the type of crops that is normally grown. In cases of releases to STP (i. e. first receiving compartment), it is proposed to waive the quantitative risk assessment for subsequent compartments, if the substance is readily biodegradable in STP or the substance is a rapidly reacting substance. In this situation it can be assumed that concentrations in the subsequent compartments and ultimately the concentration in nectar and pollen to which pollinators will be exposed can be considered negligible.

In the case of volatilisation, similar criteria could be applied as there is a very low chance that the substances will end up in soil and later be absorbed by roots and plants. If the substance is in gaseous state at ambient temperature and it is applied indoors, it can be

[8] According the ESD PT 18 manure can be applied on arable land between 1st September and 1st February.
[9] According to ECHA Biocides Guidance Volume IV Part B, sludge application is treated as a single event once a year for both agricultural soil as well as for grassland. Generally, it is impossible to indicate when the emission episode takes place within a year.

assumed that limited exposure to pollinators would occur when the substance reaches outdoors.

For these reasons, it would be desirable to enable cut-off criteria that would warrant waiving a full quantitative risk assessment for bees and other pollinators based on degradation/reaction/volatilisation properties of the substance.

QUESTIONS:

Q 20 Should the same cut-off criteria for risk assessment of pollinators be applied as in the EFSA guidance (2013) for biocides in situations a, b and c?

Summary:
All consulted parties generally agree to harmonise with the EFSA guidance. Industry associations pointed out that these values are under revision in the EFSA guidance as they are seen as overly precautionary. Following the current EFSA guidance (2013) most PPP don´t meet the cut-off and are therefore considered in the risk assessment. Some added that other physico-chemical properties such as solubility and adsorption to soil could be used.
MSCAs generally agreed but raised several comments.

Conclusion: The majority agreed to use the same trigger criteria for risk assessment of pollinators as in the EFSA guidance (2013), taking into account that these values are currently under revision. The proposed physico-chemical properties will be taken into account.

Q 21 In other situations than those described in a, b and c, is a more conservative cut off criteria for degradability or other substance fate properties appropriate? Can you give any example?

Summary: NGOs, Industry and academia cannot provide any other examples where a more conservative cut-off criteria is required. Industry remarked that the 2 days DegT50 is already over-precautionary.
One expert form a Member State suggested to choose a more conservative cut-off criteria for insecticidal active substances – e.g. if an insecticidal active substance is applied to bare soil, then perform a quantitative risk assessment.

Conclusion: In general, no examples were provided except for the case of insecticidal active substances. The information provided will be further discussed during the drafting of the guidance.

Q 22 Are there other specific substance fate properties that would allow waiving quantitative risk assessment for pollinators? What cut-offs do you propose?

Summary: NGOs and academia do not provide any more information on the matter. Industry proposed:

- The use of measurements such as log Kow to assess potential bioavailability in different matrices.
- The degradation rate in soil should be derived from the total extractable residues in soil; thus considering both the liquid (pore water) and soil adsorbed phase. This is an agreed degradation rate value that is used for modelling within biocides and also areas like plant protection products. If a distinction between the liquid and solid phase is

made, automatically the sorption coefficient should be taken into account. Attention was drawn to the discrepancy in data requirement regarding normalisation of degradation data (For biocides normalisation to 12 °C, for PPP to 20°C).

- To assess adsorption properties reducing bioavailability.

One Member State expert proposed to choose the toxophore rate of a metabolite below 10% as a cut-off for a quantitative risk assessment of biocides. Another expert also suggested to use an LD50 limit test as screening tool in addition.

Conclusion: Industry and MS made some suggestions regarding substance fate properties that could be used when assigning "trigger values". The information provided will be considered when drafting the guidance.

2.2.3 The process of translocation from roots to nectar, pollen and guttation water (systemicity)

According to EFSA's Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, Bombus spp. and solitary bees) (2013) when calculating concentrations in pollen and nectar in plants in permanent crops in the next year and in succeeding annual crops after spray application the following is stated:

"*For permanent crops it is possible that soil residues of substances may lead to root uptake in the following year and that these residues are subsequently transported via the plants to nectar and pollen (especially for systemic substances). This may also happen for annual crops that are grown one year after the treated annual crop. Vegetables such as cabbage, carrots and beans may be grown twice in a growing season (e.g. six of the nine FOCUS groundwater scenarios have been parameterised for such double crops (FOCUS (2009)). So a spray application to the first crop may lead to uptake of substances via the roots in the second crop, followed by accumulation in the nectar and pollen of this second crop. This may be relevant for attractive double crops such as beans. This section provides guidance for the exposure assessment for nectar and pollen in these three types of crop scenarios. Root uptake of substances seems to occur for all organic micropollutants, and seems to be mainly a function of the octanol–water partition coefficient and the molar mass (Sur et al., 2012). So it is impossible to assume a priori that non-systemic substances are not transported to nectar and pollen. Therefore, this exposure assessment applies to both non-systemic and systemic substances. We recommend analysing available data on residues in nectar and pollen resulting from root uptake to underpin the assumption that non-systemic substances are not transported to nectar and pollen in amounts that could become relevant for the risk assessment of bees. If this can, indeed, be underpinned, this exposure assessment scenario could be limited to systemic substances EFSA recommends analysing available data on residues in nectar and pollen resulting from root uptake to underpin that non-systemic substances are not transported to nectar and pollen in amounts that could become relevant for the risk assessment of bees.*"

Additionally, it is indicated: "*No clear definition of systemicity exists which could have been used as a trigger for the assessment of the risk from foraging the following year on a permanent crop or on succeeding crop for annual crops. Therefore ,an assessment of this scenario has to be conducted for all substances unless the DegT50 is less than 2 days for applications within the same year and 5 days for applications in different years. For further guidance on deriving the DegT50 see EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values (EFSA, 2014).*"

In the case of biocides, the situation differs. Firstly biocides are generally not intended to have the systemic mode of distribution. In addition, in contrast to PPPs, biocidal products are not applied to a specific crop (except in case of overspray e. g. against oak processionary moths) and in principle are not directly applied on an agricultural field. Most biocides are applied indoors in residential buildings, on industrial premises or in stables and will reach plants only after application of manure, slurry or STP sludge on arable land (bare) soil/grass land. In addition, some biocides will reach soil via deposition, accidental spray drift or via leaching from treated wood, walls etc. Direct emissions to plants may occur via deposition and drift from cooling towers, and after application in or around buildings.

Well known systemic substances such as some neonicotinoids are also used as biocides but are not widely spread in the field but rather used in small areas (e.g. ant boxes) or indoor.

The relevance of guttation water or any other source of water is still subject for further discussion. Alignment with EFSAs development is foreseen.

Due to these reasons it is critically important to define substance characteristics that would allow predicting whether the compound could reach nectar/pollen and therefore could lead to potential exposure of pollinators.

QUESTIONS:

Q 23 Is there any clear definition of systemicity that could enable deriving a cut-off value to disregard certain substances?

Summary: Majority of NGOs are not aware of any clear definition of systemicity. However, it was proposed that "Pertaining to an entire organism, embedded within and spread throughout and affecting a whole system". NGOs suggested to take a look at patents made by pesticide industry or polymer industry producing molecules increasing the systemicity of other compounds.

Industry stated that no clear definition exists, but is closely related to water solubility, the partition coefficient octanol/water (log Kow) and the plant uptake factor (PUF), but also to the dissociation coefficient (pKa), the molecular size of a compound, the root concentration factor and the transpiration stream concentration factor. There is also a suggestion to look into the residue section of plant protection product dossier and guidance document on residues in honey (provided in the comment).

MS also consider the systemicity correlated to several physico-chemical parameters of the substance like its water solubility, the partition coefficient octanol/water (log Pow or Kow) and the coefficient of dissociation (pKa). It was pointed out that EFSA does not prefer to use the term systemicity and therefore an update of the uptake/"systemicity" issue is expected for PPPs. It was also suggested to wait and follow the lead of EFSA in the matter.

Conclusion: There is no clear definition of systemicity, however, it is correlated to several physico-chemical parameters of the substance. Information provided will be considered when drafting this section as well as further developments in the EFSA guidance revision.

Q 24 How to generate and select relevant transfer factors (soil, plant, nectar and pollen)?

Summary: NGOs suggest that the whole plant is taken into account (bumble bees have been observed to bite the plants) as well as nectar, pollen and guttation water. Also, modelling with field or experimental validation could be useful.
Industry observed that EFSA 2013 has some worse case default values for pollen and nectar, however, these come from seed treated with PPP of highly systemic compounds so these values would be a large overestimate.

Industry provided some information from PPP. The literature suggests that four primary factors; the crop type, the application method, the physicochemical properties of a compound and the environmental conditions have the greatest influence on PPP residues in pollen and nectar.

MS also provided information on the frame of PPP, where for the registration of pesticides, residue data in relevant plant matrices (pollen, nectar) are provided by the applicant. It was suggested to check EUSES models, used for indirect exposure of humans. This model calculates concentrations in leaves and grass which may be used as surrogate.

Conclusion: The majority agreed that relevant transfer factors are pollen and nectar. However, the information provided was mostly based on the frame of PPP.

2.2.4 Grouping of active substances and mode of action (MoA)

Substances that have a specific mode of action, such as insecticides, contain a structural feature or moiety that gives the toxic property. This structural feature is referred to as the toxophore, or toxophoric moiety. The substance causes toxicity through the interaction of its toxophore with a biomolecular site (e.g. receptor). Substances that are structurally similar could contain the same toxophore (or may yield a common toxophore upon metabolism) and may therefore have a common toxic effect.

Some of the active substances used as biocides can be grouped in different clusters with similar structure. There are clearly groups of substances (e.g. pyrethroids, neonicotinoids, phenylpyrazoles, organophosphates, benzoylureas) which are well known for having negative effect on insects at very low concentrations and hence their target organisms are insects. These are families that will for sure need to be quantitatively assessed, nevertheless there are other groups which may be of lower concern for arthropods (e.g. quaternary ammonium compounds, isothiazolinones). For groups other than insecticides there is little or no information on their potential toxic effects for arthropod pollinators. For that reason, it would be important to be able to read-across from other compounds of the group or run QSARs to assess their toxicity.

In terms of the guidance a prioritisation could be made to 1) those groups of substances of high concern for pollinators, then 2) groups of known low concern for bees and then 3) substances which can be classified as unknowns for which a strategy would need to be defined but most likely further information would need to be generated.

Some insect repellents may be an example of substances of low concern for arthropod pollinators. Some references found in literature suggest that alternative methods to the use of insecticide treatments, should be favoured such as the use of insect repellents.

See grouping presentation prepared in the frame of a grouping project taking place in ECHA:

Grouping%20BPC%
20WGs.ppt

QUESTIONS:

Q 25 Are there specific families of compounds with known low toxicity to arthropods (e.g. certain insect repellents)?

Summary: Animal welfare stakeholders note that even insect repellents, which could be considered as low toxic to insects, might have an effect on the behaviour of social insects.

Industry stated that in general, insects are hard to kill due to their anatomy and ecology. They note that insects are rather resistant to exposure to most chemicals other than targeted insecticides. Analysis of available data on plant protection products (PPP) could help to identify groups of chemicals that are toxic to arthropod pollinators. It was also noted that NTA [non-target arthropod] screening data from PPPs may be used for this.

Industry stakeholders also state that repellents' low toxicity is due to reduced exposure and that chemicals with no specific mode of action for arthropods could be excluded from quantitative risk assessment if exposure is limited, i.e. there is no direct application or consumption of the chemical by arthropod pollinators. They propose that the biocides applicant, independently from grouping of substances, could be able to provide a justification to support a qualitative risk assessment instead of a quantitative one.

Conclusion: Little information is known regarding this matter. NGOs would consider even insect repellents (known low toxicity) as potentially harmful for arthropods. Industry stated that in general, substances with no insecticide activity will not display toxicity to arthropods, unless a product is targeted for insect control or broadly lethal. Industry and MS suggested to perform a screening of available data on plant protection products (PPP) which could help identify such groups of chemicals.

Q 26 Is it justified to require quantitative risk assessment only for substances with insecticidal mode of action and those compounds with unknown effect on arthropods?

Summary: Animal welfare stakeholders agree.
Industry agrees provided that substances with insecticidal mode of action and substances with unknown effects on arthropods trigger the first two stages of the screening step (i.e. persistence; scale & frequency of release). Some substances of unknown effect could be excluded from the quantitative risk assessment with the help of existing data from literature of similar substances, read-across or risk mitigation measures.

Academia asks whether remaining substances can be categorized as non-insecticides but with known effects on arthropods, and if in this case risk assessment would be performed.

One Member State noted that at this point it is not possible to agree on the proposal without first defining the substances that could be of "high" or "low concern" and that it is not possible to classify the substances of "high" or "low concern" without gathering or generating the (available) data from the three main domains presented (i.e. exposure, fate and behaviour, toxicity/ MoA). However, all insecticides should be quantitatively evaluated for their risks to pollinator arthropods, considering properties in the three main domains. Toxicity data on terrestrial arthropods and/or sediment organisms could be used to assess the potential toxicity. One Member State concluded that the proposal is not justified because all available information has to be taken into account to conclude with a weight of evidence approach if a quantitative risk assessment is needed.

It was also noted that sometimes substances are declared as "low toxic" but over time the opposite is confirmed. A detrimental effect on pollinators may be dependent on the mechanism behind the toxicity and not necessarily on the MoA of substances. Furthermore, species sensitivities have to be taken into account as well.
Several Member States considers it as the most practical way forward and agrees that insecticides must be investigated as a priority and for other substances data gaps must be completed. It was also noted that substances with non-insecticidal MoA or medium toxicity can have an impact on bees, and that in the current risk assessment where there is exposure, PNEC/PEC ratio is assessed therefore it was suggested that risk assessment for bees could be conducted the same way.
One Member State does not agree and prefers that exclusion of substances should be done via screening of data, and that it needs to be decided which arthropod data are relevant for screening. Literature data should be used as well.

Conclusion: The majority seems to agree to perform a quantitative risk assessment on arthropods only for substances with insecticidal mode of action and those compounds with unknown effect.

However, industry noted that some substances with unknown effect could be excluded from the quantitative risk assessment with the help of existing data from literature of similar substances, read-across or risk mitigation measures.
Between MS, there are different opinions.

Q 27 Are there specific compounds, families or groups of substances (apart from the known insecticides) which could pose a particular risk to arthropod pollinators?

Summary: NGOs know of that organosilicone surfactants (used as spray adjuvants), which may be harmful to pollinators.
Industry does not know any specific compounds or groups of substances besides insecticides.

MS provided some examples. Some Member States suggested that non-insecticidal substances such as fungicides and herbicides could have negative/sublethal effects arthropod pollinators. Fungicides can have synergistic toxic activity to bees when they are combined with insecticides. Furthermore, fungicides might induce sub-lethal effects on bees, like on the immune system of social bees. Besides fungicides, it was also noted that pyrethroids can persist and bioaccumulate in bee wax, and they are known to synergize with certain fungicides.

Conclusion: Concerns were raised concerning organosilicone surfactants, fungicides, herbicides and pyrethroids as specific compounds or groups of substances that could pose a particular risk to arthropod pollinators. Information provided will be considered when drafting the guidance.

Q 28 Are there QSARs available to screen the toxicity to bees or other arthropods pollinators?

Summary: NGOs provided examples of models to predict the acute contact toxicity of pesticides in honeybees, but not the sublethal effects.
Industry provided some information on QSARs available to predict toxicity based on acute contact toxicity data from honeybees, but not for other pollinator species.
MS also pointed out that there are several QSAR models available to predict the acute toxicity of pesticides/biocides on *Apis mellifera.* However, there are no QSAR models on non-*Apis mellifera*. VEGA software (v1.1.5) has a bee acute toxicity model (KNN/IRFMN) v1.0.0 that is available. However, this model is not considered robust enough.

Conclusion: There are several QSARs available to predict acute toxicity on honeybees. However, there is no information for other pollinator species. Information provided will be considered when drafting the guidance.

Q 29 Could high concentrations or volumes of “low toxicity” actives pose a risk to bees? Could you give examples?

Summary: NGOs provided the example of thiacloprid.
Industry considers this exposure to high concentrations of “low risk” actives as unlikely and non-realistic, as the volumes would need to be extremely high.
MS provide some examples. For instance indoor treatment and products or substances used in organic farming – sulphur, certain oils, copper, etc. It was pointed out that indirect effects on habitat are not taken into account and also there is a gap for other compartments/organisms.

Conclusion: NGOs and MS provided some examples where high concentrations of “low risk” actives could pose a risk to bees. However, industry regards these values as unrealistic and extremely high.

2.3 Pollinators families and testing methods relevant for the risk assessment of arthropods pollinators

2.3.1 Background

ECHA's Pollinators Expert Group has gathered information on the most relevant families of insect pollinators and classified them in different phylum (see Table 5).

Table 5. Taxonomic overview of insect pollinators

Common name	*Genus*	*Subfamily*	*Family*	*Superfamily*	*Order*	*Class*	*Phylum*
Mining bees			Andrenidae	Apoidea	Hymenoptera	Insecta	Arthropoda
			Anthophoridae	Apoidea	Hymenoptera	Insecta	Arthropoda
Honeybees	Apis	Apinae	Apidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Solitary bees		Apinae	Apidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Bumblebees	Bombus	Apinae	Apidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Plasterer bees			Colletidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Sweat bees			Halictidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Leafcutter bees			Megachilidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Melittid bees			Melittidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Wasps			Crabronidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Sand wasps			Sphecidae	Apoidea	Hymenoptera	Insecta	Arthropoda
Emerald wasps			Chrysididae	Chrysidoidea	Hymenoptera	Insecta	Arthropoda
Spider wasps			Pompilidae	Pompiloidea	Hymenoptera	Insecta	Arthropoda
Scoliid wasps			Scoliidae	Scolioidea	Hymenoptera	Insecta	Arthropoda

Common name	Genus	Subfamily	Family	Superfamily	Order	Class	Phylum
Tiphiid wasps			Tiphiidae	Tiphioidea	Hymenoptera	Insecta	Arthropoda
Pollen wasps	Pseudomasaris	Masarinae	Vespidae	Vespoidea	Hymenoptera	Insecta	Arthropoda
Paper wasps		Polistinae	Vespidae	Vespoidea	Hymenoptera	Insecta	Arthropoda
Paper wasps		Stenogastrinae	Vespidae	Vespoidea	Hymenoptera	Insecta	Arthropoda
Paper wasps		Vespinae	Vespidae	Vespoidea	Hymenoptera	Insecta	Arthropoda
Stem sawflies			Cephidae	Cephoidea	Hymenoptera	Insecta	Arthropoda
Sawflies			Megalodontesidae	Megalodontoidea	Hymenoptera	Insecta	Arthropoda
Sawflies			Tenthredinidae	Tenthredinoidea	Hymenoptera	Insecta	Arthropoda
Sawflies			Argidae	Tenthredinoidea	Hymenoptera	Insecta	Arthropoda
Sawflies			Cimbicidae	Tenthredinoidea	Hymenoptera	Insecta	Arthropoda
Bee flies			Bombyliidae	Asiloidea	Diptera	Insecta	Arthropoda
Hoverflies			Syrphidae	Syrphoidea	Diptera	Insecta	Arthropoda
Housefly/stable fly			Muscidae	Muscoidea	Diptera	Insecta	Arthropoda
Tangle-veined flies			Nemestrinidae	Nemestrinoidea	Diptera	Insecta	Arthropoda
Soldier flies			Stratiomyidae	Stratiomyoidea	Diptera	Insecta	Arthropoda
Horseflies			Tabanidae	Tabanoidea	Diptera	Insecta	Arthropoda
Thick-headed flies			Conopidae	Conopoidea	Diptera	Insecta	Arthropoda
Blow flies			Calliphoridae	Oestroidea	Diptera	Insecta	Arthropoda
Butterflies				Hedyloidea/ Papilionoidea	Lepidoptera	Insecta	Arthropoda
Swallowtail butterflies			Papilionidae	Papilionoidea	Lepidoptera	Insecta	Arthropoda

Common name	Genus	Subfamily	Family	Superfamily	Order	Class	Phylum
The Skippers			Hesperiidae	Papilionoidea	Lepidoptera	Insecta	Arthropoda
Pierids			Pieridae	Papilionoidea	Lepidoptera	Insecta	Arthropoda
The Gossamer-wings			Lycaenidae	Papilionoidea	Lepidoptera	Insecta	Arthropoda
Brush footed butterflies			Nymphalidae	Papilionoidea	Lepidoptera	Insecta	Arthropoda
Hawk moths			Sphingidae	Bombycoidea	Lepidoptera	Insecta	Arthropoda
Burnet moths			Zygaenidae	Zygaenoidea	Lepidoptera	Insecta	Arthropoda
Flower chafers		Cetoniinae	Scarabaeidae	Scarabaeoidea	Coleoptera	Insecta	Arthropoda
Soldier beetles			Cantharidae	Elateroidea	Coleoptera	Insecta	Arthropoda
Snout beetles			Curculionidae	Curculionoidea	Coleoptera	Insecta	Arthropoda
Longhorn beetles			Cerambycidae	Chrysomeloidea	Coleoptera	Insecta	Arthropoda
Rose chafers			Cetoniidae	Scarabaeoidea	Coleoptera	Insecta	Arthropoda
Checkered beetles			Cleridae	Cleroidea	Coleoptera	Insecta	Arthropoda
Tumbling flower/pintail beetle			Mordellidae	Tenebrionoidea	Coleoptera	Insecta	Arthropoda
Blister beetles			Meloidae	Cleroidea	Coleoptera	Insecta	Arthropoda
Soft-winged flower beetles			Melyridae	Cleroidea	Coleoptera	Insecta	Arthropoda
Jewel beetles			Buprestidae	Buprestoidea	Coleoptera	Insecta	Arthropoda

**The table was modified as a result of the comments received during the consultation*

Based on the report from a research project named "*Protection of wild pollinators in the pesticide risk assessment and management*" published on the UBA homepage in 2019 (https://www.umweltbundesamt.de/en/publikationen/protection-of-wild-pollinators-in-the-pesticide), pollinators are a subgroup of flower visiting insects (FVI), as not all flower visiting insects are also pollinators or contribute significantly to pollination. FVIs in the report are defined as "insect taxa that forage on flower resources such as nectar and pollen in at least one life stage." The following insect groups are considered as relevant FVI (chapter 1.2 'A definition of flower-visiting insect species'):

- Apiformes (bees)
- Diptera (flies)
- Lepidoptera (moths and butterflies)
- Vespinae and Coleptera (wasps and beetles)

According to Rader et al. (2015), "non-bee pollinators include flies, beetles, moths, butterflies, wasps, ants, birds, and bats among others". Besides ants and the non-insect species birds and bats, the groups specified as pollinators by Rader et al. are all contained in the above group of relevant FVI.

According to other references, ants do not significantly contribute to pollination. In addition, ants are also target species for certain insecticidal biocidal products. The same applies for mosquitoes, they do not significantly contribute to pollination and are also target species for insecticidal products. Consequently, it is proposed to exclude ants and mosquitoes from the list, but keep all other taxonomic groups as relevant pollinators.

According to Larson et al. (2001), Diptera (flies) are the second most important order among flower-visiting and flower-pollinating insects worldwide. Especially important are Syrphidae (hover flies), Bombyliidae (bee flies), and Muscoidea. Muscoidea superfamily comprises the following families:

- Anthomyiidae
- Fanniidae
- Muscidae - Flies
- Scathophagidae - Dung flies

Muscoidea are important pollinators. However, only some members of the Anthomyiidae and Muscidae are pollinators. In addition, several members of the Anthonylidae family are significant agricultural pests. Therefore, same as for ants and mosquitoes, Muscoidea contain target species for certain insecticidal biocide products (e.g. House fly and stable flies) and only certain Muscoidea members are actually pollinators, so we would propose to exclude this group from our examination.

Lepidoptera can be valuable pollinators in ecosystems because butterflies and moths show diurnal, crepuscular, and nocturnal habits, and a number of species visit flowers throughout an entire day; they transport pollen across a range of distances from short to long; and they are a species-rich group of potential pollinators (Travers et al. 2011). Hahn & Brühl (2016) concluded that "moths are abundant flower visitors that are capable of pollinating a range of plant species, of which a number are specialized for moth pollination (e.g. certain orchids). However, the role of moths as pollinators is most likely underestimated at present because only a limited number of studies on moth pollination are available." Furthermore, currently moths are also target species for certain insecticidal biocidal products.

Based on the data available, we are not aware of any further taxonomic insect groups that should be added to the list of relevant pollinators. However, it has to be kept in mind, that the different life stages of these species will be exposed by different exposure pathways as they live in different habitats and only the adult organisms act as pollinators e.g. most solitary bees build their nest in soil and the larvae feed on pollen, thus contact to the soil compartment and to pollen is a relevant exposure pathway for these pollinating species. While adult butterflies and moth feed on nectar, the larvae of most lepidopteran species are herbivore caterpillars feeding on plant material and could thus be exposed e.g. to systemic insecticides taken up by the plant from soil. Therefore, not only the pollinating adult but also the development stages need to be considered. In contrast to non-bee pollinators (as specified by Rader et al.), bees are more co-evolved with flowering plants and have specific behaviours such as visiting flowers constantly and repeatedly to forage for nectar and pollen to feed the colony, or larvae in the case of solitary bees. Other non-bee pollinators visit flowers for food and inadvertently lead to transfer of pollen between flowers. However, larval life stages of many non-Apiformes are not fed with pollen and nectar and thus the physical contact between these insects and flowers is at a much lower level and hence exposure with pollen and further pollination of flowers is not as frequent as with Apiformes.

The aim of an effects assessment for pollinators is the derivation of a $PNEC_{pollinator}$. Such a PNEC should be based, like for other protection goals, on a test battery with acute and chronic studies for representative species and different life-stages from which an extrapolation to the whole group of pollinators can be performed using assessment factors. Besides interspecies variation in sensitivity, also acute to long-term exposure, sub-lethal effects on reproduction and behaviour and effects on reproductive stages (larvae) have to be considered. Missing certain key information could be compensated by applying higher assessment factors; thus, a stepwise approach could be probable.

Concerning interspecies variation, data are already available, especially for bee species:
For **bees**, extensive research has been carried out to understand to what extent honey bees can be a surrogate test organism for other bee species. For example, the publication of Arena & Sgolastra (2014) compares the sensitivity of 19 different bee species (contact and oral acute LD_{50}, chronic LC_{50}) with honey bee endpoints, concluding that in approximately 95% of the cases the sensitivity ratio was below 10. This would mean, that the honey bee can be used as a surrogate for other bee species when using a bridging factor of 10 and "only" 5% of the species considered will not be sufficiently protected. Heard et al. (2017) concluded that *Apis mellifera* can be used as a surrogate when considering direct oral toxicity on survival, as long as an assessment factor is used. They do not give a specific value, but suggest a value >10. However, according to Thompson (2015), the 95^{th} percentile sensitivity ratio for contact and oral toxicity of honeybees relative to other bee species reduced from 10.7 (based on µg/individual bee) to 5.0 (based on µg/g bodyweight). In addition, the relative sensitivity of the honeybee *Apis mellifera* increased when the mass of individuals in all of the bee species was taken into account.

A recent publication by Uhl et al., (2019) compared regulatory LD_{50} values for honey bees with endpoint derived for the solitary bee *Osmia bicornis* when tested with different pesticides (e.g. alpha-cypermethrin, deltamethrin, imidacloprid). In two third of all cases *O. bicornis* was less sensitive than *A. mellifera.* When applying an AF of 10 to the honey bee endpoint, a protective level could be achieved for 87%, or 13 out of 15, of the evaluated plant protection products. Therefore, they concluded that for the time being, it would be appropriate to use the honey bee for acute endpoints as long as an appropriate assessment factor is used. Considering the above-mentioned literature, it should be discussed whether additional testing with *Bombus terrestris* and/or *Osmia bicornis* will be valuable.
A reason to add a solitary bee other than *Osmia bicornis* as test organisms could be, that sociality seems to have not only an impact on sensitivity on population level, but also on individuals (see e.g. Arena & Sgolastra, 2014). Solitary bees (and other solitary insects) reproduce individually and therefore the individual (species) sensitivity must be taken into account. Social bees tend to be less sensitive to pesticides due to social immune system, and behavioural and spatial mechanisms.

For **non-bee species** much less data is available in order to have a complete understanding of species sensitivity. Hardstone and Scott (2010) compared toxicity data for *A. mellifera* and other insect species based on an extensive literature review. They found that, in general, honey bees were no more sensitive than other insect species across the 62 insecticides examined, when comparing LD_{50} values after topical application of selected insecticides. This means that in some cases the honey bee was more sensitive, equally sensitive, or less sensitive than the other species examined, but overall there was no clear data that would support the hypothesis that the honeybee would be most sensitive to the chemicals examined. In addition, honey bees were not more sensitive to any of the six classes of insecticides (carbamates, nicotinoids, organochlorines, organophosphates, pyrethroids and miscellaneous) examined. They concluded that honeybees are not a highly sensitive species to insecticides overall, or even to specific classes of insecticides. However, evaluation of the supplementary information of Hardstone and Scott paper shows that from the 887 endpoints, more than half (456) are toxicity endpoints for potential pest species (not necessary target species). From the remaining 431 endpoints on other arthropods/beneficial organisms, 245 are for Apis species. It would be expected that potential target species are more sensitive than non-target arthropods like honey bees (since this is what the active ingredients are targeted against). Nevertheless, based on the data listed by Hardstone and Scott in their Supplemental Material, the honey bee seems to be quite sensitive when it comes to the comparison with other non-target species. Further research is necessary to identify sensitive species for a test battery.

Sensitivity of different pollinators compared to honeybees seems also to be dependent on the chemical class of the active substance studied (Arena & Sgolastra (2014); Hardstone & Scott (2010); Uhl et al. (2019)). In these publications it was found that e.g. for pyrethroids honeybees are most sensitive while for neonicotinoids other bees and insect species are more sensitive than honeybees. Arena & Sgolastra (2014) examined contact and oral acute LD_{50} and the chronic LC_{50}, whereas Hardstone & Scott (2010) and Uhl et al. (2019) investigated LD_{50}. Therefore, it could be considered to derive different extrapolation factors for different chemical classes.

A practical consideration when comparing data across species is that currently most bee studies are directed at an effect level based on dose (LD_{50}), whereas other taxa are based on an application rate (ER_{50} g a.i./ha) which makes direct comparison of data challenging. In addition, some publications refer to leaf dip assays, where the actual application rate is not known (only the concentration of the solution), and compare these with spray applications to conclude on relative sensitivity (e.g. Braak et al 2019). Therefore it is important to pay attention to the experimental design and the reported toxicity units (e.g. mg/kg, µg/g, g a.i./ha) when comparing results, and make sure that direct comparisons between dipped and sprayed applications are never done.

A recent study by Pamminger (2020, preprint) performed an interspecies sensitivity extrapolation for acute bee toxicity data based on body weight and phylogenetic background. Pamminger (2020, preprint) concluded that body weight is a predictor of bee sensitivity to insecticides for a range of insecticide classes and that *A. mellifera* is the most sensitive standard test species currently available and consequently a suitable surrogate species for ecotoxicological risk assessment.

Concerning acute to long-term exposure of adult bees, Heard et al. (2017) looked at the impact of prolonged test duration and could show, that there was a significant and large time dependency of toxicity for the tested chemicals and bee species. Also, Simon-Delso et al. (2018) could show, when testing toxicity of a fungicide on honey bees, that most of the toxic effects where observed after 10d, the tests lasted 33d.However, these studies have been criticised as not all the parameters of the studies met validity criteria.

At present there is no EU or other guidance that covers risk to pollinators other than bees, so in order to describe risk assessment methodologies for arthropod pollinators other than bees a literature search would be needed. In order to assess whether there could be enough literature a short literature search was performed looking for relevant words such as "pollinator", "toxicology", "sensitivity" or "pesticide" for different relevant species. According to the gathered information, there is extensive research data on pollinators and toxicity, especially on bees and lepidopterans. However not so much is known about other pollinator species such as beetles (coleopterans) or pollen wasps.

There are also several publications regarding adult and larvae toxicity in bees and lepidopterans, but not so much is known on other pollinator families concerning developmental stages. Regarding sensitivity to pesticides or insecticides most of the information available is concerning bees, however, there is also some published data on coleopterans and lepidopterans.

According to this preliminary search, ECHA's Pollinator Expert Group thinks there is enough information on bees and lepidopterans to initiate an extensive literature search, but for the other families the information is limited.

It should be noted nevertheless that in order to describe the ecology, behaviour and differences of sensitivity is resource intense and therefore the benefits should be carefully analysed before engaging in such activity.

It should also be considered that available test methods don't cover these species and therefore the information gathered should only serve as a basis to establish assessment factors using surrogate species (bees).

QUESTIONS:

Q 30 Should the guidance cover all families of pollinators? Or should we use the most sensitive and/or important pollinators as surrogates?

Summary: Environmental ASOs think that all pollinator families should be covered, unless directions/safety factors are given for other than most important pollinator families, or if the use of surrogates is justified.

Industry is in favour of selecting bees as surrogate species. They suggest to focus on the most important species, where reliable and reproducible toxicity testing is possible to conduct (i.e. internationally validated guidelines; e.g. OECD guidance or the battery of arthropod test guidelines, available for non-target arthropod testing in PPPs). Species should be relatively sensitive and there should be available data on which to base exposure estimates. A tiered approach, where species ecology is taken into account, was mentioned. E.g. exposure matrix and aquatic risk assessment with Daphnia could be used as a surrogate. Generation of further toxicity data should enable the risk assessment to be refined, but it should not be the default at the first tier as certain tools can be used to decrease the assessment factor. Extrapolation through risk assessment is also mentioned; studies are commonly performed on a limited number of species, and extrapolation to the species that are the most relevant regarding exposure is performed using standard exposure scenarios, where the life traits of relevant species are taken into account in order to quantify exposure appropriately.

Academia notes that pollinators are a very diverse group, and if a major part of them is left out of the risk assessment it could have detrimental effects at community/ecosystem level.

Member states note that ideally all pollinator families should be included but they also recognise that this is not feasible and therefore surrogates are accepted, however protected/endangered species are mentioned for consideration. A tiered approach on the most important and sensitive species seems like a reasonable approach, however it is mentioned that the importance of pollination may not possible to establish. In addition, it is stated that biocides and PPPs should be aligned in terms of using surrogate species. It is also mentioned that the sensitivity is dependent on the substance or substance-class (MoA), the presence of specific sensitive developmental stages and exposure duration in relation to life stages.

Conclusion: The EG group agreed to continue with the literature search. Ideally all pollinator families should be covered by the guidance but as this is not feasible taking into account availability of data and standard testing methods, it should be agreed that most appropriate and sensitive surrogate species can be used for the risk assessment, when justified. Directions and/or safety factors concerning other than surrogate species could also be given, taking into account the protected and/or endangered species as well.

A tiered approach for the risk assessment (tier 1 could entail e.g. exposure scenarios, available data, and extrapolation) would be the most appropriate, and further refinement of the assessment could be done via generation of additional toxicity data. There are also available arthropod test guidelines for non-target arthropod testing used in the plant protection products area which could be used when considering the generation of additional data.

Q 31 Can honey bee data be used as surrogate for the other taxa with an appropriate assessment factor (considering there might be inter and intraspecific variation between species within the taxa regarding their sensitivity)?

Summary: Environmental ASOs do not agree that honey bee data should be used as surrogate for other taxa; some agree with conditions and some not.

Industry agrees and states that honey bees are a sensitive test species and that standardised laboratory testing methods are available, they are easy to rear in large numbers and provide the highest level of certainty and scientific robustness, which is not the case for many of the other arthropod species listed in Table 5. However, it is noted that a single species is not likely to be the most sensitive across all chemical classes, and use of an assessment factor and exposure scenario representative for a wide range of species is therefore appropriate. In addition, direct comparison of available data is challenging due to the differences in the dosage and exposure to the studied chemical. Generation of further data could be done with agricultural pest species or commercially available beneficial species, which can be tested reliably under laboratory conditions. Industry notes that there is evidence to back up the claim that honey bee is the most sensitive standard test species currently available, and consequently a suitable surrogate specie for ecotoxicological risk assessment. They note that the key question is not whether the selected species is more sensitive than all others but rather whether the outcome of the risk assessment is protective of the wider range of species whilst allowing differentiation between uses of low risk and those requiring further refinement.

Academia does not agree and notes that focusing on honeybees does not represent the toxicity in other taxa.

Most member states agree that as a starting point, honeybees could be used as a surrogate. Other MSs agree that they could be used as a surrogate for other bee species but not for other taxa, unless there are available data to substantiate this approach. Instead a literature review is suggested to identify sensitive species and possible surrogate species. It is also noted that solitary non-bee pollinator species should be included in the assessment.

Conclusion: This question needs further discussion, as there is no clear agreement across the different ASOs and MS. A discussion on the species selection and what is possible and feasible to implement, considering e.g. the rearing and survival of the species in laboratory conditions, standardised testing methods, commercial availability of species etc. In general, a literature review would be the most appropriate method to identify sensitive and relevant species within the different arthropod taxa.
It was noted that "the key question is not whether the selected species is more sensitive than all others but rather whether the outcome of the risk assessment is protective of the wider range of species".

Q 32 Are there any species/taxa of arthropod pollinators missing or other relevant species that we should include based on their ecology or spatial distribution?

Summary: NGOs agree with the proposed list and suggested to include paper wasps. Industry also agrees with the list with a few comments; it was suggested that comparisons between taxa should be made in relation to concentration in food rather than per insect basis to ensure size and growth rate do not impact the conclusions. It was noted that it needs to be considered that exposure of flower visiting insects in most cases comes from indirect exposure pathways.

Academia suggested to include thrips and lacewings in the list.

MS generally agree with the proposed list and suggested to include at least one ground-nesting/cavity nesting species as well as bees with different levels of food specialisation. In addition, they proposed to include certain species of scoliid wasps. In fact, they suggests to add all wasps and hornet species in the list (despite not being primarily known as pollinators).

Member States also identified more taxa to be added to the list.
COLEOPTERA: Rutelidae, Cetoniidae, Tenebrionidae, Cleridae, Buprestidae, Melyridae, Mordellidae and Meloidae.
LEPIDOPTERA: all daytime butterflies (Families Papilionidae, Hesperidae, Pieridae, Lycaenidae, Nymphalidae) and, among the nocturnal butterflues, the families Sphyngidae and Zygaenidae.
DIPTERA: Nemestrinidae, Stratiomyidae, Tabanidae, Conopidae, and Calliphoridae.
HYMENOPTERA: Cephidae, Megalodontesidae, Tenthredinidae, Argidae, Cimbicidae, Chrysidae, Scoliidae, Tiphiidae, Pompilidae, Sphecidae, Crabronidae, Andrenidae, Colletidae, Halictidae, Melittidae, Megachilidae and Anthophoridae.

Conclusion: The table of species has been amended according to the comments received.

Q 33 On which species should we focus? Should we focus on representative species of sensitive groups?

Summary: NGOs agree with this approach and suggested to focus on species that can be tested.

Industry suggested to take into account representative and relevant exposure routes/scenarios.
Academia suggested to group species according to their life histories and then target sensitive species within the different groups.
MS agree with focusing on representative species of sensitive groups taking into account testing methods that are available. It was also proposed to make a list of species for which OECD test guidelines need to be developed in the future.

Conclusion: The guidance should focus on sensitive species from sensitive groups that can be tested based on the available knowledge and identify areas for which further research is needed.

Q 34 Should we use a tiered approach; that is honey bee (adult + larvae) as base data and additional species (e.g. solitary bees, lepidoptera) to lower the assessment factor (similar to RA for aquatic compartment) as assessment factor should be adjusted according to the available data?

Summary: Environmental ASOs agree, if justified.

Industry agrees and suggests details for the approach and assessment factors, see below.

Academia notes that available data cannot be the focus but data that is needed.

Member states agree with the tiered approach, although some with certain conditions. It is noted that in addition to honey bees, other social and solitary species as well as lepidopterans should have a representative species of sensitive groups.

Conclusion: A tiered approach is generally accepted, however the details of the approach need further discussion when drafting the guidance.

Q 35 Should we exclude ants and mosquitoes from the list of relevant taxa due to lack of relevance for pollination and considering the fact that they also are target organisms in certain products? Or should they only be excluded for products which have these insects as target organisms?

Summary: Environmental ASOs suggest that ants and mosquitoes should only be excluded for products for which they are target organisms.

Industry suggests that ants and mosquitoes should be excluded from the list of relevant taxa because they are not relevant for pollination and because they are target species.

Academia agrees that ants are not important pollinators in Europe and for biocides the focus should be on the risk to non-target organisms.

Member states have different views. Some agree to exclude ants and mosquitoes totally from the risk assessment and others suggest that they would only be excluded for products which have these insects as target organisms. It is also noted that the lack of pollination relevance is a reason to exclude taxa/species and not if a certain species is a target organism.

Conclusion: Even if the comments did not reach a consensus, the Commission mandated ECHA to evaluate the need to develop a "methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides". It is evident that it is outside of the mandate to include species that are not arthropod pollinators. In general the EG group considered appropriate to filter families or species in relation to their relevance for pollination. In addition the text added in page 44 was reworded to avoid conclusions from literature.

Q 36 Should sub-adult stages of hemi and holometabole insects, e.g Lepidopterans (e.g. caterpillars), be also included?

Summary: Industry does not agree that larval stages should be routinely tested unless a substance has insect growth regulator properties. It is noted that it's important to consider that caterpillars are often pests and biocide targets. Before including larval stages in the risk assessment, it should be determined if the risk assessment to be developed is protective of larval stages. Available data from pest larvae could be followed by selective non-target testing to assess true sensitivity differences between species and development stages.

Academia supports including sub-adult stages.

Most member states and environmental ASOs agree and note that the protection of pollinators should cover their entire life cycle. However it is noted that there could be a lack of knowledge and test protocols for these developmental stages.

Conclusion: In general MSCAs agree that sub-adult stages should be covered, especially considering that EFSA guidance covers these life stages.

Q 37 Should sub-adult stages of other taxa than lepidopterans be included?

Summary: Member states have different views. It is also noted that the need to include a species to the risk assessment depends on the species ecology, on the substance, its MoA, and its application.

Conclusion:
In general, MSCAs agree that sub-adult stages should be covered, especially considering that EFSA guidance covers these life stages.

Q 38 Should we take into account the ecological spatial and temporal distribution of the different taxa? If we had enough data, this would help us clarify which taxa are most affected by different and specific uses of biocides. This would also help us decide which tests should be conducted from the "testing battery". On the other hand we should take into account that there can be too much variation even within one taxa (e.g. between moths and butterflies).

Summary: Environmental ASOs agree and suggest to select target species according to the likelihood of exposure.

Industry noted that it is important to focus in ecological, spatial and temporal distribution instead of variation within taxa but note that it might be an ambitious approach. It is also mentioned that a generic approach making use of standard surrogate test species could be suitable to cover most of the biocidal product scenarios. They raised a point of how much value would the data on ecological, spatial and temporal distribution add to a generic approach, considering bee data, and other standard, non-target arthropod data.

Academia agrees that there are large differences between taxonomic groups and notes that all species cannot be assessed. The goal should be to be as detailed as possible, taking into account what can be done in practice.

Conclusion: Most member states agree that the ecological spatial and temporal distribution is to be considered but it is also noted that too many variables might make this strategy too uncertain and too resource- and time-consuming.

Q 39 Do you have any data in regards to ecological and spatial distribution of the different taxa? Are there any surveys / research ongoing at the moment?

Summary: NGOs provided data on butterfly distribution in Europe and on moths in north-western Europe.

Industry suggested to look at data from companies developing PPP and provided information on pollinators' distribution in north-west Europe and the UK.
Academia suggested to look into research being done in Germany.

MS did not provide more information except for one Member State, which provided information from The Swiss Centre for the Cartography of Fauna on publicly available distribution maps for several species of pollinators (http://www.cscf.ch/cscf/de/home.html). They also offered to request more data if needed.

Conclusion: Data on ecological and spatial distribution in the UK of butterflies and other pollinators was provided. Other databases were proposed. Also, it would be useful to investigate PPP databases. The information provided will be considered when drafting the guidance.

Q 40 Would a literature review be the best way to obtain the necessary information?

Summary: NGOs, industry, academia and MS agree that a literature review would be a good starting point.
In addition, to consider also other sources of information:

- National strategies or inventories of pollinators.
- Available databases on spatial distribution are available e.g. in the UK Biological Records Centre (https://www.brc.ac.uk/), UK Bees Wasps and Ants Recording Society (BWARS https://www.bwars.com/home), and Hoverfly Recording Scheme (http://www.hoverfly.org.uk/portal.php?page=4)
- GBIF

Conclusion: A literature review is considered a good way to move forward in addition with other sources of information that were provided.

2.3.2 Use of ecotox data performed with other insects or arthropods

ECHA has screened the available data on bees under the BPR for substances used in product-types 8, 18 and 19. As mentioned in section 1 of this document, according to the legal requirements under the BPR, testing on bees is only an additional data requirement, only performed for insecticides, acaricides and substances in products to control other arthropods which are used outdoors, i.e. for large scale-outdoor applications like fogging (e.g. product-type 18 - products against mosquitoes for human health reasons). For that reason, the data currently available with regard to toxicity to bees and other pollinators for biocides is scarce. Publicly available data on approved active substances under PT18, PT19 and PT08 for bees can be found in the Table 6 below (there are 3 substances under evaluation for which data is available but cannot be disclosed. Therefore, these substances have not been included in Table 6).

Table 6. Available public data on bees for approved active substances under PT18, PT19 and PT08

Active substance	Acute contact toxicity in Assessment Report	Acute oral toxicity in Assessment Report	PT
(Z,E)-tetradeca-9,12-dienyl acetate	n.a.	n.a.	PT19
1R-trans phenothrin	LD_{50} = 0.005 µg/bee	n.a.	PT18
Abamectin	LD_{50} = 0.0022 µg/bee	n.a.	PT18
Acetamiprid	24h-LD_{50} = 9.29 µg/bee / 48h-LD50 = 9.26 µg/bee	24h-LD_{50} = 9.26µg/bee / 48h-LD50 = 8.85 µg/bee	PT18
a-Cypermethrin (only indoor use)	n.a.	n.a.	PT08/PT18
ADBAC/BKC (C12-16)	n.a.	n.a.	PT08
Aluminium phosphide releasing phosphine	n.a.	n.a.	PT18
ATMAC/TMAC	n.a.	n.a.	PT08
Bacillus sphaericus 2362, strain ABTS-1743	n.a.	n.a.	PT18
Bacillus thuringiensis subsp. israelensis Serotype H14, Strain AM65-52	48-hour LD50 of >100 µg (1.8x106 CFU; 3x102 ITU) Vectobac WG/bee.	48-hour LD50 of > 108.4 µg (1.9x106 CFU; 3.2x102 ITU) Vectobac WG/bee	PT18
Bacillus thuringiensis subsp. israelensis, strain SA3A	n.a.	n.a.	PT18
Bacillus thuringiensis subsp. kurstaki, strain ABTS-351	48-hour LD50 of > 555 µg product/bee	48-hour LD50 of > 542 µg product/bee	PT18
Bardap 26	n.a.	n.a.	PT08
Basic Copper carbonate	n.a.	n.a.	PT08
Bendiocarb	n.a.	n.a.	PT18
Bifenthrin	48-72h-LD_{50} = 0.044 – 0.11 µg/bee	48-72h-LD_{50} = 0.12 – 0.13 µg/bee	PT08
Boric acid	n.a.	n.a.	PT08
Boric oxide	n.a.	n.a.	PT08
Carbon dioxide	n.a.	n.a.	PT18
Chlorfenapyr	96 h LD_{50} = 0.33 µg/bee	96 h-LD_{50} = 1.0 µg/bee	PT08

Active substance	Acute contact toxicity in Assessment Report	Acute oral toxicity in Assessment Report	PT
Clothianidin	48-LD_{50} = 0.044 µg/bee	48h-LD_{50} = 0.0038 µg/bee	PT08/PT18
Copper (II) oxide	n.a.	n.a.	PT08
Copper hydroxide	n.a.	n.a.	PT08
Creosote	n.a.	n.a.	PT08
Cu-HDO	n.a.	n.a.	PT08
Cyfluthrin	n.a.	n.a.	PT18
Cyphenothrin	n.a.	n.a.	PT18
Cyproconazole	24-h LD50 >100 mg ai/bee (n)	24-h LD50 >1000 mg ai/bee (n)	PT08
Cyromazine	48-hour LD_{50} > 200 µg/bee	48-hour LD_{50} = 186 µg/bee	PT18
Dazomet	n.a.	n.a.	PT08
DCOIT	n.a.	n.a.	PT08
DDAC	n.a.	n.a.	PT08
DDACarbonate	n.a.	n.a.	PT08
Decanoic acid (only indoor use)	n.a.	n.a.	PT18/PT19
Deltamethrin (indoor and outdoor use)	n.a.	n.a.	PT18
Dichlofluanid	n.a.	n.a.	PT08
Diflubenzuron	LD_{50} > 30 µg/bee (literature data)	LD_{50} > 25 µg/bee (literature data)	PT18
Dinotefuran (only indoor use)	n.a.	n.a.	PT18
Disodium octaborate tetrahydrate	n.a.	n.a.	PT08
Disodium tetraborate	n.a.	n.a.	PT08
Disodium tetraborate decahydrate	n.a.	n.a.	PT08
Disodium tetraborate pentahydrate	n.a.	n.a.	PT08
Epsilon-Momfluorothrin	48 h LD50 = 0.21 µg a.s./bee	48 h LD50 > 5.08 µg a.s./bee	PT18
Ethyl butylacetylaminopropionate	n.a.	n.a.	PT19
Etofenprox	72h-LD_{50} = 0.0145 µg/bee	96h-LD_{50} = 0.0238 µg/bee	PT08/PT18
Fenoxycarb	n.a.	n.a.	PT08
Fenpropimorph	LD50 > 100 µg/bee	LD50 > 95,6 µg/bee	PT08
Fipronil	LD_{50} = 0.00593 µg/bee	LD_{50} = 0.00417 µg./bee	PT18
Flufenoxuron	48h-LD_{50} > 100 µg/bee	48h-LD_{50} > 109 µg/ bee	PT08
Granulated copper	n.a.	n.a.	PT08
Hexaflumuron	48h-LC_{50}>>100 µg/bee	48h-LC_{50}>>100 µg/bee	PT18
Hydrogen cyanide	n.a.	n.a.	PT08/PT18
Imidacloprid	48h-LD_{50} = 0.081 µg/bee	48h-LD_{50} = 0.0037 µg/bee	PT18

Active substance	Acute contact toxicity in Assessment Report	Acute oral toxicity in Assessment Report	PT
Imiprothrin (only indoor use)	n.a.	n.a.	PT18
Indoxacarb	LD_{50} = 0.094 µg/bee	LD50 = 0.26 µg/bee	PT18
IPBC	n.a.	n.a.	PT08
K-HDO	n.a.	n.a.	PT08
Lambda-cyhalothrin	48h-LD_{50}= 0.038 µg./bee	48h-LD_{50} =0.91 µg/bee	PT18
Lauric acid	n.a.	n.a.	PT19
Magnesium phosphide releasing phosphine	n.a.	n.a.	PT18
Margosa extract	72h-LD_{50} = 63 µg/bee	72h-LD_{50} > 17.7 µg/bee	PT18/PT19
Methyl nonyl ketone	n.a.	n.a.	PT19
Metofluthrin (only indoor use)	n.a.	n.a.	PT18
Muscalure	n.a.	n.a.	PT19
Nitrogen	n.a.	n.a.	PT18
N,N-diethyl-meta-toluamide	n.a.	n.a.	PT19
Nonanoic acid, Pelargonic acid	LR_{50} > 90.28 µg/bee	LR_{50} > 98.35 µg/bee	PT19
Octanoic acid	n.a.	n.a.	PT18
OIT	n.a.	n.a.	PT08
Penflufen	n.a.	n.a.	PT08
Permethrin	48h-LD_{50} = 0.0235 µg/ bee	48h-LD_{50} = 0.163 µg/ bee	PT08/PT18
Piperonyl butoxide/PBO	48h-LD_{50} = 294 µg/bee	48h-LD_{50} = 611.6 µg/bee	PT18
Potassium Sorbate	n.a.	n.a.	PT08
Propiconazole	n.a.	n.a.	PT08
Pyriproxyfen	LD_{50} > 100 µg/bee	LD_{50} > 100 µg/bee	PT18
Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide	n.a.	n.a.	PT18
Silicium dioxide (Silicium dioxide/Kieselguhr)	n.a.	n.a.	PT18
S-Methopren (only indoor use)	n.a.	n.a.	PT18
Spinosad	48h-LD_{50} = 0.0036 µg/bee	48h-LD_{50} = 0.057 µg/bee	PT18
Sulfuryl fluoride	n.a.	n.a.	PT08/PT18
Synthetic amorphous silicon dioxide (nano)	n.a.	n.a.	PT18
Tebuconazole	n.a.	n.a.	PT08
Thiabendazole	48 h - LD50 > 34µg/bee	48 h - LD50 > 4µg/bee	PT08
Thiacloprid	48h-LD_{50} = 38.82 µg/bee	48h-LD_{50} = 17.32 µg/bee	PT08

Active substance	Acute contact toxicity in Assessment Report	Acute oral toxicity in Assessment Report	PT
Thiamethoxam	48h-LD_{50} = 0.024 µg/bee	48h-LD_{50} = 0.005 µg/bee	PT08/PT18
Tolylfluanid	n.a.	n.a.	PT08
Transfluthrin (indoor and outdoor use)	n.a.	n.a.	PT18

Note: n.a. = not available (either because it's not applicable for the intended use of the substance or because it's not required)

QUESTIONS:

Q 41 Organisms within a certain phylum or class share common traits. Could ecotox data from studies performed with other arthropods or insects that show "low toxicity" be used to waive further testing on arthropod pollinators? For example could data for insects or crustaceans that have been submitted for risk assessment in the soil and aquatic compartment be used for this purpose?

Summary: Environmental ASOs don't have consensus. Available data on other arthropods or insects could be used as an indication but new data should be generated taking into account the life histories and sub-lethal effects in pollinators.

Industry agrees with the proposal but notes that there are differences in the parameters in aquatic and terrestrial tests (e.g. µg/L vs. dose per insect). Weight of evidence approach could be considered.

Academia notes that the proposal might not work as there might be problems in extrapolating results from certain species to others.

Member states note that for low concern substances this might be feasible considering the exposure, fate and behaviour. Existing data from other species could be used in a WoE approach to possibly waive further testing and quantitative risk assessment. Efficacy data could be also used to determine the most sensitive group of arthropods. However, it is not recommended to be used as a cut-off criteria for testing. In addition, the suitability of data from other species than pollinator depends on the exposure route, taxonomic relationship and developmental stages. Information on aquatic insect species might be relevant to identify sensitive taxa/species, although it should be recognised that exposure and sensitivity of aquatic insect life stages may differ from those that are relevant for biocides, because of life history differences. Also differences in sensitivity among the insect group can be high. It is also mentioned that bees are more vulnerable to pesticides compared to other insects.

Conclusion: Weight of evidence/ initial consideration seems to be supported but the details of this strategy need further discussion when drafting.

Q 42 Do you know of any bee/arthropod pollinator toxicity data for the active substances listed in Table 6?

Summary: NGOs provided more information on abamactin, fipronil and imidacloprid. Industry noted that it does not make sense to include endpoints for active substances that are no longer approved and listed in the Union list of approved active substances or expire before the guidance enter into force, e.g. no renewal for the active/PT combination was supported by any applicant for the following active substances.

Also provided some databases:
EPA Ecotox Knowledge Base: https://cfpub.epa.gov/ecotox/
THE PPDB Pesticide Properties Database:
https://sitem.herts.ac.uk/aeru/ppdb/en/index.htm
Academia noted some studies currently going on with imidacloprid and clothianidin.
MS provided more data for spinosad. Also noted that relevant data can be extracted from the PPP database.
http://www.panna.org/sites/default/files/Bees&Pesticides_SOS_FINAL_May2012.pdf

Conclusion: More data was provided on bee/arthropod pollinator toxicity in addition to other databases. The provided information will be considered in the drafting phase of the Guidance.

2.3.3 Available guidance from other organisations

The ECHA's Pollinator Expert Group has screened through the available guidance regarding pollinating arthropods. The following relevant guidance documents have been identified:

- **EPA** (US Environmental Protection Agency) guidance for assessing pesticide risk to pollinators focuses on Honey bees

https://www.epa.gov/pollinator-protection/how-we-assess-risks-pollinators
https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance

- **EFSA** Guidance Document on the risk assessment of plant protection products on bees focuses on Honey bees (*Apis mellifera*), Bumblebees (*Bombus* spp.) and solitary bees (2013)

https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2013.3295

- **EFSA** Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods (see especially section 4.2.5. Non-target arthropods as drivers of plant pollination in agricultural landscapes)

https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2015.3996

- **EPPO/OEPP** (European and Mediterranean Plant Protection Organization) (2010) PP 3/10 (3): chapter 10: honeybees. They study the potential risks from the use of plant protection products to pollinating insects. It specifically addresses the assessment of risks to honeybees (*Apis mellifera*).

https://onlinelibrary.wiley.com/doi/10.1111/j.1365-2338.2010.02419.x

- **European Commission** (2002) SANCO/10329/2002 Rev 2 Guidance document on terrestrial ecotoxicology in Honeybees.

https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_ecotox_terrestrial.pdf

- **I.C.P.P.R. International Commission for Plant-Pollinator Relationships**

https://www.icppr.com/

QUESTIONS:

Q 43 Are you aware of any other guidance documents that can be useful or relevant for the development of this guidance?

Summary: NGOs suggested the French CEB and Apitox ring test.
Industry suggested ESCORT II and the EFSA 2013 guidance currently under review.
Academia does not have any more input on the matter.
Member States suggested NTA guidance from EFSA and test protocols, and noted to consider the recent policy analysis of pesticide management and regulations by Sgolastra et al. 2020, using the neonicotinoid lesson. In addition, suggested to consider The PANNA 2012 and stressed the need for additional targeted literature searches in the field.

Conclusion: More information was provided regarding other guidance documents/ test protocols which could be useful for the development of this guidance. The provided information will be considered in the drafting phase of the Guidance.

2.3.4 Testing methods and guidelines

As specified in the ToR, the guidance should cover also the information requirements. In order to gather information on available agreed testing methods, the group has screened through the available guidelines and testing methods regarding pollinating arthropods. The list of documents that ECHA's Pollinator Expert Group was so far able to identify is presented in Table 7.

Table 7. Guidelines for available testing methods[10]

Guideline	Testing method	Link
OECD 247	Bumblebee acute oral toxicity test	https://read.oecd-ilibrary.org/environment/test-no-247-bumblebee-acute-oral-toxicity-test_9789264284128-en
OECD 246	Bumblebee acute contact toxicity test	https://read.oecd-ilibrary.org/environment/test-no-246-bumblebee-acute-contact-toxicity-test_9789264284104-en
OECD 245	Honeybee *Apis mellifera L.* chronic oral toxicity test (10-day feeding)	https://read.oecd-ilibrary.org/environment/test-no-245-honey-bee-apis-mellifera-l-chronic-oral-toxicity-test-10-day-feeding_9789264284081-en
OECD 237	Honeybee (*Apis mellifera)* larval toxicity test, single exposure	https://read.oecd-ilibrary.org/environment/test-no-237-honey-bee-apis-mellifera-larval-toxicity-test-single-exposure_9789264203723-en
OECD 239	Honeybee (Apis mellifera) larval toxicity test, repeated exposure guidance	https://one.oecd.org/document/ENV/JM/MONO(2016)34/en/pdf
OECD 214	Honeybees acute contact toxicity test	https://read.oecd-ilibrary.org/environment/test-no-214-honeybees-acute-contact-toxicity-test_9789264070189-en
OECD 213	Honeybees acute oral toxicity test	https://read.oecd-ilibrary.org/environment/test-no-213-honeybees-acute-oral-toxicity-test_9789264070165-en
OECD 232	Collembolan reproduction test in soil	https://read.oecd-ilibrary.org/environment/test-no-232-collembolan-reproduction-test-in-soil_9789264264601-en

- [10] OECD test guidelines

https://www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm
https://www.oecd-ilibrary.org/environment/oecd-guidelines-for-the-testing-of-chemicals-section-2-effects-on-biotic-systems_20745761
https://www.oecd.org/chemicalsafety/risk-mitigation-pollinators/
https://www.oecd.org/chemicalsafety/testing/work-related-beespollinators.htm

- EPA test guidelines

https://www.epa.gov/measurements-modeling/index-epa-test-methods
https://www.epa.gov/test-guidelines-pesticides-and-toxic-substances

OECD 228	Determination of developmental toxicity to dipteran dung flies *Scathophaga stercoraria L.* (Scathophagidae), *Musca* autumnalis De geer (Muscidae))	https://read.oecd-ilibrary.org/environment/test-no-228-determination-of-developmental-toxicity-to-dipteran-dung-flies-scathophaga-stercoraria-l-scathophagidae-musca-autumnalis-de-geer-muscidae_9789264264571-en
OECD GD 75	Guidance document on the honey bee (Apis mellifera L.) brood test under semi-field conditions. Series on testing and assessment, No. 75 (2007)	http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2007)22&doclanguage=en
OECD TG Under development	Test Guideline: Homing flight test on honeybee (*Apis mellifera L.*) after single exposure to sublethal doses	
OECD TG Under development	Acute Contact Toxicity Test for the solitary living Mason Bee (Osmia spp.)	
EPPO 170	Guideline for the efficacy evaluation of plant protection products. Side effects on honeybees. OEPP/EPPO, PP1/170 (4) update 2010, 313 - 319.	https://pp1.eppo.int/standards/PP1-170-4
OCSPP 850.3000	Background and special considerations: tests with terrestrial beneficial insects, invertebrates and microorganisms.	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0015
OCSPP 850.3020	Honey Bee Acute Contact Toxicity Test [EPA 712-C-019]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0016
OCSPP 850.3030	Honey Bee Toxicity of Residues on Foliage [EPA 712-C-018]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0017
OCSPP 850.3040	Field Testing for Pollinators [EPA 712-C-017]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0154-0018
OPPTS 880.4350	Nontarget Insect Testing [EPA 712–C–96–285]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0158-0007
OPPTS 885.4000	Background for Nontarget Organism Testing of Microbial Pest Control Agents [EPA 712–C–96–328]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0159-0028
OPPTS 885.4340	Nontarget Insect Testing, Tier I [EPA 712–C–96–336]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0159-0036
OPPTS 885.4380	Honey Bee Testing, Tier I [EPA 712–C–96–337]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0159-0037
OPPTS 885.5000	Background for Microbial Pesticides Testing [EPA 712–C–96–056]	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0159-0042
IRAC insectide resistance tests		https://www.irac-online.org/methods
	M.P Candolfi., S. Blümel., Forster R. et al. 2000: Guidelines to evaluate side-effects of plant protection	https://www.iobc-wprs.org/pub/book2000.pdf

	products to non-target arthropods. IX + 158 pp., Gent, IOBC-WPRS, ISBN: 92-9067-129-7 Containing guidelines for *Aphidius rhopalosiphi*, *Coccinella septempunctata L.*, *Chrysoperla carnea*, *Aleochara bilineata Gyll. and other NTA species.*	
IOBC/WPRS Mead-Briggs et al. (2010)	An extended laboratory test for evaluating the effects of plant protection products on the parasitic wasp, *Aphidius rhopalosiphi (Hymenoptera, Braconidae).*	https://www.fera.co.uk/terrestrial-ecotoxicology
	Lang et al. (2019) Laboratory tests with Lepidoptera to assess non-target effects of Bt maize pollen: analysis of current studies and recommendations for a standardised design	https://doi.org/10.1186/s12302-019-0220-2

**The table was modified as a result of the comments received during the consultation*

QUESTIONS:

Q 44 Are there any test methods for butterflies or other arthropod pollinator besides bees, in addition to those listed above?

Summary: NGOs, academia and MS do not have any more information on the matter. Industry provided some information on lepidopterans by Lang et al. 2019 https://doi.org/10.1186/s12302-019-0220-2

Conclusion: Industry provided some testing methods on butterflies. NGOs, academia and MS did not provide more information on the matter. The information provided will be considered in the drafting phase of the Guidance.

Q 45 Are there (standardized) test methods available for other insect groups?

Summary: NGOs, academia and MS do not have more information on the matter. Industry suggested to look into EPPO PP (1) standards and Candolfi et al. 2000. In addition, they provided information on a test method for the soil mite Hypoaspis OECD guideline 226, IOBC methods and a China government silkworm leaf dip method. Member States suggested that maybe there are testing methods on dung beetles and stressed the need for standardised specific tests on pollinators to be able to evaluate the biocides potential to bioaccumulate and the potential of time-reinforced-toxicity (TRT). For information on possible test methods and strategies for pollinators involving bioaccumulation and TRT some publications were suggested.

Conclusion: Industry provided some studies to look into. NGOs and academia don't have more information on the matter. One Member State made a comment on the need for standardised specific tests on pollinators to be able to evaluate the biocides potential to bioaccumulate and the potential of TRT. The provided information will be considered in the drafting phase of the Guidance.

Find below general publications on Test Guidelines in Ecotoxicology:
- A.Valavanidids, T. Vlachogianni (2015): Ecotoxicity Test Methods and Ecological Risk Assessment. Aquatic and Terrestrial Ecotoxicology Tests under the Guidelines of International Organizations, Science Advances on Environmental Chemistry, Toxicology and Ecotoxicology Issues.
https://www.researchgate.net/publication/281061444_Ecotoxicity_Test_Methods_and_Ecological_Risk_Assessment_Aquatic_and_Terrestrial_Ecotoxicology_Tests_under_the_Guidelines_of_International_Organizations
- The EFSA *Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods* (2015) lists an overview of laboratory test systems identified as potentially relevant in appendix G, mainly for coleoptera but also lepidoptera species.
https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.3996
- Schuppener, M. (2011): Risikobewertung von gentechnisch verändertem Mais im Hinblick auf ausgewählte Schmetterlinge der Agrarlandschaft. Fachgruppe Biologie. PhD thesis. RWTH Aachen, Aaachen. (In German)
http://publications.rwth-aachen.de/record/62906/files/3926.pdf
- Schuppener er al. (2012): Environmental risk assessment for the small tortoiseshell *Aglais urticae* and a stacked Bt-maize with combined resistances against Lepidoptera and Chrysomelidae in central European agrarian landscapes. Molecular Ecology Vol 21/18, 4646 –

4662
https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1365-294X.2012.05716.x

2.3.5 Literature & Publications

- **Honey bee / Bumblebee / Solitary bees**

- P. Medrzycki, et al. (2013): Standard methods for toxicology research in *Apis mellifera*, Journal of Apicultural Research, 52:4, 1-60

  https://www.researchgate.net/publication/256403383_Standard_methods_for_toxicology_research_in_Apis_mellifera

- M. Eeraerts et al. (2020): Recommendations for standardized oral toxicity test protocols for larvae of solitary bees, Osmia spp., Apidologie 51, pp. 48–60

  https://www.researchgate.net/publication/337452447_Recommendations_for_standardized_oral_toxicity_test_protocols_for_larvae_of_solitary_bees_Osmia_spp

- According to Arena M., Sgolastra F. (2014) "A meta-analysis comparing the sensitivity of bees to pesticides" (2014), Honeybees are considered as a good environmental indicator of pesticide pollution due to its sensitivity to pesticides compared to other insect species. When *A. mellifera* is used as surrogate test species in environmental risk assessment, an assessment factor of 10 applied to honey bees LD_{50} endpoints would also be protective for other bee species LD_{50} in 95% of the cases. However, in some cases, the sensitivity of other bee species can be tenfold higher than honey bees.

  https://link.springer.com/article/10.1007%2Fs10646-014-1190-1

- Sgolastra et al. (2020) Bees and pesticide regulation: Lessons from the neonicotinoid experience. Biological Conservation 241.

  https://www.boerenlandvogels.nl/sites/default/files/2019-12/Sgolastra%20et%20al%20Biological%20Conservation%202020.pdf

- **Pesticide Risk Assessment for Pollinators (Book)** 1 Jul 2014 by David Fischer (Author), Tom Moriarty (Author). Pesticide Risk Assessment for both *Apis* and non-*Apis* species of pollinators.

  https://onlinelibrary.wiley.com/doi/book/10.1002/9781118852408

- **Protecting Pollinators: How to Save the Creatures That Feed Our World Paperback (Book)** 28 Jun 2019 by Jodi Helmer (Author). Stresses the importance of the decline in populations of certain species of bees and certain species of butterflies in North America during the lasts years.

  https://books.google.fi/books?id=_QOHDwAAQBAJ&pg=PA7&hl=fi&source=gbs_toc_r&cad=3#v=onepage&q&f=false

- Uhl et al., 2019: "Is *Osmia bicornis* an adequate regulatory surrogate? Comparing its acute contact sensitivity to *Apis mellifera*", PLOS ONE, 14 (8)

  https://www.researchgate.net/publication/335071793_Is_Osmia_bicornis_an_adequate_regulatory_surrogate_Comparing_its_acute_contact_sensitivity_to_Apis_mellifera

- Heard et al., 2017: "Comparative toxicity of pesticides and environmental contaminants in bees: Are honey bees a useful proxy for wild be species?", Science of the Total Environment 578 (2017): 357-365
- https://www.sciencedirect.com/science/article/pii/S0048969716323683/pdfft?md5=6763ad91d1b58594b6f47c38acb8b24f&pid=1-s2.0-S0048969716323683-main.pdf
- Hardstone M.S., Scott J.G.;2010 "Is *Apis mellifera* more sensitive to insecticides than other insects?"

  https://onlinelibrary.wiley.com/doi/10.1002/ps.2001 (Abstract)
- Simon-Delso et al., 2018: "Time-to-death approach to reveal chronic and cumulative toxicity of a fungicide for honeybees not revealed with the standard ten-day test"; Scientific Reports (2018) 8:7241

  https://www.nature.com/articles/s41598-018-24746-9.pdf
- Pisa, L. W., Amaral Rogers, V., et al. "Effects of neonicotinoids and fipronil on non-target invertebrates". Environ Sci Pollut Res (2015) 22:68–102
  https://link.springer.com/article/10.1007/s11356-014-3471-x
- Straub L et al. 2016 Neonicotinoid insecticides can serve as inadvertent insect contraceptives. Proc. R. Soc. B 283: 20160506. http://dx.doi.org/10.1098/rspb.2016.0506
- Siviter et al. 2018. Sulfoxaflor exposure reduces bumblebee reproductive success. Nature Research Letter. https://doi.org/10.1038/s41586-018-0430-6
- Kopit et al. 2018. Routes of Pesticide Exposure in Solitary Cavity-Nesting Bees. Environmental Entomology, 47(3), 499–510. doi: 10.1093/ee/nvy034
- Fourrier et al. 2015. Larval Exposure to the Juvenile Hormone Analog Pyriproxyfen Disrupts Acceptance of and Social Behavior Performance in Adult Honeybees. PLoS ONE 10(7): e0132985. doi:10.1371/journal.pone.0132985
- Christen et al. 2018. Endocrine disruption and chronic effects of plant protection products in bees: Can we better protect our pollinators? Environ Pollut. 2018 Dec;243(Pt B):1588-1601. doi: 10.1016/j.envpol.2018.09.117.
- Tomé et al., 2015 (Chemosphere 124: 103-109): Spinosad in the native stingless bee Melipona quadrifasciata: Regrettable non-target toxicity of a bioinsecticide https://doi.org/10.1016/j.chemosphere.2014.11.038

- **Lepidopterans**

- T.C Hoang (2011): Use of butterflies as nontarget insect test species and the acute toxicity and hazard of mosquito control insecticides, Environmental Toxicology and Chemistry 30 (4), pp. 997 – 1005

  https://www.ncbi.nlm.nih.gov/pubmed/21309017
- T.A Bargar (2011): Risk Assessment for adult butterflies exposed to the mosquito control pesticide naled, Environmental Toxicology and Chemistry 31 (4), pp. 885-891

  https://consensus.fsu.edu/MC/naled-files/Barger%202012%20Risk%20assessment%20for%20adult%20butterflies.pdf

- T.C Hoang and G.M Rand (2015): Acute toxicity and risk assessment of permethrin, naled, and dichlorvos to larval butterflies via ingestion of contaminated foliage, Chemosphere 120, pp. 714 – 721

  https://www.sciencedirect.com/science/article/pii/S0045653514012259

- R. Mulé et al (2017): Systematic Review of the Effects of Chemical Insecticides on Four Common Butterfly Families, Frontiers in Environmental Science 26 (5), pp. 1 – 5

  https://www.frontiersin.org/articles/10.3389/fenvs.2017.00032/full

- N. Braak et Al (2018): The effects of insecticides on butterflies – a review, Environmental Pollution, 242 (A), pp. 507-518

  http://nora.nerc.ac.uk/id/eprint/520448/

- Hahn & Brühl, 2016: "The secret pollinators: an overview of moth pollination with a focus on Europe and North America."; Arthropod-Plant Interactions (2016) 10:21–28 https://link.springer.com/content/pdf/10.1007/s11829-016-9414-3.pdf

- **Hover flies**

- J. Klecka et al (2018): Flower visitation by hoverflies (Diptera: Syrphidae) in a temperate plantpollinator network, Peer J – the Journal of Life and Environmental Sciences 6

  https://peerj.com/articles/6025.pdf

- Larsen et al., 2001: "Flies and flowers: taxonomic diversity of anthophiles and pollinators"; The Canadian Entomologist 133: 439 - 465 (2001) https://www.researchgate.net/publication/207223435_Flies_and_flowers_Taxonomic_diversity_of_anthophiles_and_pollinators

- **General**

- L.S Adler (2000): The ecological significance of toxic nectar, Oikos 91, No 3, pp. 409 – 420

  https://www.jstor.org/stable/3547516?seq=1

- Rader et al. 2015: Non-bee insects are important contributors to global crop pollination https://www.pnas.org/content/113/1/146

- Travers et al., 2011: The hidden benefits of pollinator diversity for the rangelands of the Great Plains: western prairie Fringed Orchids as a Case Study; Rangelands 33:20–26 https://bioone.org/journals/rangelands/volume-33/issue-3/1551-501X-33.3.20/The-Hidden-Benefits-of-Pollinator-Diversity-for-the-Rangelands-of/10.2111/1551-501X-33.3.20.full

- **Literature regarding transfer factors**

- Hwang J-I, Lee S-E, Kim J-E (2017): Comparison of theoretical and experimental values for plant uptake of pesticide from soil. PLoS ONE 12(2): e0172254. doi:10.1371/journal.pone.0172254 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5315371/

Annex I. Reference to pollinators in current biocides guidance

Several sections should be highlighted from the Volume IV part B (Guidance on the Biocidal Products Regulation Volume IV Environment - Assessment and Evaluation (Parts B + C):
"Risk assessment and data requirements for bees and beneficial arthropods: At the moment no method is available for biocides on how to perform the risk assessment for bees and non-target arthropods. The methods applied under the pesticides EU framework are not directly applicable. However, if tests on bees or non-target arthropods are performed, or are available, these could be used for a qualitative risk assessment if exposure pattern is comparable. Based on the outcome of these tests risk mitigation measures can be considered. If tests on non-target arthropods have to be performed, tests on soil dwelling organisms like springtails are preferred. With respect to the data requirement for bees and non-target arthropods (NTA) tests are required only in case of large scale-outdoor applications like fogging (e.g. products against mosquitoes for human health reasons). Additionally, for neonicotinoid substances or other insecticide substances with high toxicity to bees, exposure to bees should also be quantified. When no data is available, a qualitative assessment should be performed."
In relation to guidance already available related to information requirements for bees and other pollinators, several sections should be highlighted from the Volume IV part A (Guidance on the Biocidal Products Regulation Volume IV: Environment Part A: Information Requirements):
"Effects on arthropods: A test on bees and/or other beneficial arthropods may be required for insecticides, acaricides and substances in products to control other arthropods which are used outdoors, i.e. for large scale-outdoor applications like fogging (e.g. product-type 18 - products against mosquitoes for human health reasons). Additionally, for systemic insecticides exposure to bees should also be quantified. When no data is available, a qualitative assessment should be performed.
Effects on arthropods do not usually have to be assessed for uses with indoor applications only. Tests may be needed in case of drift occurring from e.g. large cooling water systems or outdoor spray uses.

- Effects on honeybees: Tests on acute oral and/or contact toxicity on bees should be done according to OECD Test Guideline 213 (Honeybees, Acute Oral Toxicity Test) and respectively OECD Test Guideline 214 (Honeybees, Acute Contact Toxicity Test). Guidelines are also available for trials for side-effects on bees as the EPPO PP 1/170/(3) (Side-Effects on Honeybees), and for brood test under semi-field conditions the OECD Series on Testing and Assessment No. 75 (Guidance Document on the Honey Bee (*Apis Mellifera L.)* Brood Test Under Semi-Field Conditions).
- Other non-target terrestrial arthropods, e.g. predators: Possible species to be tested in addition to honeybees are for instance, *Chrysoperla carnea* (common green lacewing), *Trichogramma cacoeciae* (Hymenoptera egg parasitoid), *Coccinella septempuna* (ladybird) *or Aleochara bilineata* (rove beetle) according to the IOBC 'Guidelines to evaluate side-effects of plant protection products to non-target arthropods' (IOBC, 2000). Tests involving sensitive life stages, special routes of uptake or other modifications may be necessary. The rationale for the choice of test species and exposure conditions used should be provided."

The main guidance's from ECHA on the assessment and evaluation of biocidal active substances and products can be found under the following links:
https://www.echa.europa.eu/documents/10162/23047722/bpr_guidance_vol-iv_env_part_bc_draft_ca_en.pdf/13459e06-ecf7-85d8-d4d4-eaa5806b6dbf
https://echa.europa.eu/documents/10162/23036412/bpr_guidance_vol_iv_part_a_en.pdf/4a70aa9e-7491-7fc5-0734-6777ade10b02

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