Webinar: Getting familiar with ECHA's guidance to assess risks of biocides to bees

Questions and answers

This document is based on the questions received during the webinar organised on 5 March 2024. Editorial changes have been made to improve clarity and similar questions have been combined.

For the most up-to-date advice, contact us or refer to our website.

#	Question	Answer
General		
1	When do the companies and authorities need to start applying the guidance for active substances and products?	The applicability date of the guidance was discussed in the meeting of Competent Authorities for Regulation (EU) No 528/2012 on biocidal products in March 2023. It was agreed that the guidance: • will not be applicable to active substances dossiers in the review programme (RP), in line with the agreement reached in document CA-Dec23-Doc.5.4 - Final - Extension of RP beyond 2024.docx; • will be applicable to procedures (active substances, products), for which the application will be submitted two years after the date of publication of the

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		guidance, so as from 1st February 2026. It will therefore not be applied to applications submitted before that date.
2	What are the next steps in the preparation of the guidance for non-bee pollinators?	Development of a risk assessment scheme is under the planned activities by ECHA at a later stage when it has been possible to address the identified data gaps for non-bee pollinators. Further data is needed for instance on the feeding behaviour, relevant route of exposure, and life stages to allow conclusion on species sensitivity and selection of representative species. A number of scientific projects are already on-going where such information is collected with the aim to advance the assessment of NBPs, for instance iPOL-ERA funded by EFSA which aims to advance the environmental risk assessment of chemicals for insect pollinators.
3	As of what date will it become mandatory to address the risks of biocides to bees in an environmental risk assessment?	See question 1.
4	Is it also possible that other pollinators need protection from honey bees (which are usually livestock)?	The possible effects of honey bees on e.g. wild bees, if they forage in the same region, is not in the scope of the guidance. The scope of the guidance is to protect bees from a possible impact of biocidal products.
5	Has any impact assessment been conducted to determine how many product uses fail screening step and tier 1 in the risk assessment of honey bees?	No, an impact assessment has not been conducted. See also question 6.
6	Bees and non-bee pollinators are essential to have and those organisms must be kept healthy under all circumstances, now and in the future. Has ECHA and COM tried to assess how many biocidal active substances and biocidal products will be ruled out by the given guidance, approximately?	So far, such impact assessment has not been performed for biocides. It was under consideration by the expert group during the guidance development phase but for instance lack of toxicity data hindered performing such assessment. However, on account of the scope of the guidance, possible changes are mainly expected in active substance and biocidal product under PT18.
7	At product authorization level, if no data on active substance is available, for example active substance approved before the entry in force of this guideline, how it will be possible to compare the acute toxicity of the active substance and the product?	If at product authorisation phase a need for the risk assessment of bees is identified and relevant data was not provided at active substance stage, necessary data can be requested by the evaluating authority and needs to be generated in the product authorisation step. The procedure for the submission, evaluation and dissemination of data generated after active substance approval will be applied according to the BPC-47 document and CG-17-2016-13 Evaluation of alternative dossiers during product authorisation.

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8	How is the new bee guidance from ECHA related to the implementation and utilization of New Approach Methodologies (NAM) in bee testing? Are there specific provisions or considerations within the guidance that address the integration of NAM techniques, and if so, how will they be applied in practice?	In this first version of the ECHA guidance for the risk assessment of bees, there are no specific considerations for NAMs. These methodologies and their implementation in bee risk assessment require further research. This development areas are being addressed by on-going scientific initiatives such as iPOL-ERA (see also question 2).
9	When will the ECHA guidance become applicable in the assessment of biocides?	See question 1.
Scope of the guidance		
10	How did the expert group conclude that bee risk assessment is required for PT18?	In the early steps of the guidance development procedure, the exposure group performed filtering for all of the biocides scenarios (Scoping document). In this exercise, all PTs and all scenarios regarding potential exposure of bees were reviewed including an assessment of scenarios with "direct releases" to environment and scenarios with indirect releases to environment. The expert group furthermore reviewed all the PT 18 AS and AS which have high toxicity to bees use in other PTs than PT 18. In addition, example calculations and consultation of accredited stakeholder organisation were carried out. These actions together with expert judgement by the EG lead to the conclusion to focus the bee risk assessment on PT 18 AS. In this way, most of the expected exposure and risks from use of biocides are covered while still maintaining a pragmatic approach. In the ECHA Bee guidance, the main conclusions of the exercise are captured in section 2.1. Once more experience is gained, revisions of the guidance can be done as necessary.
11	Is the ECHA bee guidance only relevant for PT18 substances, or also for substances with insecticidal MoA, such as PT19 and PT8?	The focus of the ECHA bee guidance is on PT 18 substances. However, there may be instances where a biocidal product in another PT containing an active substance with an insecticidal mode of action warrants an assessment if the potential exposure is considered to be significant enough (see Figure 3 in the ECHA bee guidance). In such a case, if the intended use of such a biocidal product from another PT falls within one of the presented sources of emission (e.g., treatment of façades), a bee risk assessment should indeed be performed by the applicant. The above conclusion was reached through a filtering exercise performed during the guidance development (see question 10). The first version of the guidance therefore focuses on the sources of exposure derived from the large-scale uses presented in the PT 18 emission scenario documents. Regarding PT19 substances, the Applicant may need to show that the level of exposure to the active substance is much lower under PT19 than under PT18, or that the active substance does not exert a killing effect on the target

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		organism. Nevertheless, further elaboration may be needed in the assessment of PT19 substances with regard to the exposure and toxicity to bees. Once more experience is gained, revisions of the guidance can be done as necessary.
12	Shall the guidance relate only for PT18 or also for other PTs related outdoor uses?	See questions 10 and 11.
13	In the summary slide, it was stated that this guidance only concern PT18 uses, however could other PTs be of concern?	See questions 10 and 11.
14	Why can't the guidance from EFSA and ECHA be harmonized in one?	The risk assessment scheme and the principles of the methodology developed for PPPs are applied also in the ECHA guidance for biocides. Consequently, especially the effect part of the assessment is similar to the EFSA guidance. However, a number of adaptations and biocide-specific considerations were needed in the ECHA guidance since the area and type of biocidal applications is much more diverse than for PPPs. Also, a combined guidance would have contained considerable amount of information not relevant for biocides. In addition, in the biocide area, we need to gain experience in the risk assessment of bees for a number of topics. From a procedural point of view, revisions and updates of the guidance can be easier to govern for separate documents. The ECHA guidance expert group therefore concluded that a biocide specific guidance is required.
15	Will the ECHA guidance on the risk assessment of bees be extend for other PTs such as PT2 algicide for example?	See questions 10 and 11.
16	Why is there no risk assessment of bees for outdoor spray products of PT19 or PT8 products?	See questions 10 and 11.
Exposure assessment		
17	Why is there a need to calculate multiple exposure scenarios for large scale spraying? What to do with multiple results for multiple exposure scenarios?	The need arises because exposure levels (PEQs) vary depending on which plants are assumed to be contaminated due to the application of the biocidal product. If the treated tree(s) are not attractive to bees, the treated area scenario is not relevant. The scenario for weeds in treated areas considers exposure of bees due to contamination of plants growing in the same treated area, always assumed to be attractive. Since spray application may contaminate adjacent areas, the vegetation margin scenario is also necessary. The only difference between the scenarios is the exposure factor, which may be refined by applicants. It is uncertain which scenario is the worst case. Also, risk mitigation measures (RMMs) may vary by scenario. The next growing season scenario addresses persistent substances.

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18	Is outdoor spot application by spraying also covered by the spraying of walls?	Spot application by spraying is a small-scale use for which in ECHA bee guidance a risk assessment is not considered to be warranted due to the scale of exposure of bees. Certainly, for a product that is used both for wall spraying and spot application, the risk calculation for wall spraying would cover the spot application.
19	How will the on-going revision of ESD PT18 impact the ECHA Bee guidance for biocides?	At the moment, we are unable to provide exact details until the revision of the ESD PT18 is finalized. Depending on the extent of changes required, our actions may include issuing either a corrigendum for the ECHA Bee guidance or developing TAB (Technical agreements for Biocides) entries, in order to amend the guidance.
20	For indoor uses we have also emissions to STP and then the sewage sludge is put on the grassland/arable land, and similar to sewage sludge from animal housing, bees can be exposed. However, this is not considered in the guidance as a source of exposure. Could you please clarify this?	This question was thoroughly examined during the development of the guidance. We looked at how PT18 active substances are released from stable and household products into sewage treatment plants (STP). For household products, we found acceptable risks in all/majority of example cases using nevertheless incomplete effect data (chronic endpoints were not always available). With the data available, no risks for indoor household uses were identified in the calculations by the guidance expert group.
21	The direct uptake of treated irrigation water is not included. In dry and warm periods and in case there is no sufficient clean water source, this can be a highly relevant source of exposure to honey bees.	The consumption of contaminated water is currently not considered in the ECHA Bee guidance which is in line with EFSA Bee guidance. However, this exposure route might become relevant once more knowledge has been acquired. Please see section 1.4 (page 19) and section 5 (page 32) in the ECHA Bee guidance for more information
22	Is the outstanding 'memory' abilities of Bees Wax to preserve pesticide molecules (over decades) protecting from oxidation or other degradation processes, considered?	Similarly to the above question, the consumption of other contaminated plant matrices such as bee wax is currently not considered in the ECHA Bee guidance in line with EFSA bee guidance. However, this exposure route might become relevant once more knowledge has been acquired. Please see section 1.4 (page 19) and section 5 (page 32) in the ECHA bee guidance for more information.
23	When risk mitigation measures (RMM) are proposed by the applicant at Tier 1 or at higher tier, should we still calculate the risk? How integrate the proposed RMM to determine if they really reduce the risk?	Normally in the environmental risk assessment process for biocides, the calculations must first be carried out for the situation without any RMMs. If an unacceptable risk is then identified, RMMs can be proposed to minimize this risk. This means that the RMM can only be used with a determined risk. The RMMs must be reasonable in each case and demonstrate well that the risk is acceptable. However, a list of potential RMMs is not yet available for the exposure of bees and is foreseen to be established when the guidance is applied in the biocide assessment.
24	If there is not risk at screening step, are tests still mandatory?	The screening step is a simplified approach for the exposure assessment. To calculate the risk with the screening step, effect tests need to be available, otherwise the lower-tier risk assessment approach cannot be conducted. In other words, effect data are always needed.

#	Question	Answer
Information requirements, lower tier risk assessment, higher tier risk assessment		
25	Which toxicity studies are a mandatory requirement?	Data on honey bees (HB) are always mandatory for biocidal products with an insecticidal mode of action. To cover the 4 risk cases, the following studies with HB are needed for the active substance: acute oral toxicity, acute contact toxicity, chronic oral adult, toxicity larvae. For the biocidal product, always acute data are mandatory to see whether the biocidal product is more toxic than the active substance. For formulations with 2 or more active substances honeybee data for the biocidal product are required (for all four risk cases). Data on bumble bees and solitary bees can be provided or may be requested if relevant for the assessment. For further information see Chapter 6 of the guidance.
26	It was stated that no risk assessment is required for bumble bees or solitary bees, so also no data is required for this for biocides?	In principle, risk assessment is required for bumble bees (BB) and solitary bees (SB) as well, but at the moment the specific protection goal (SPG) has been defined. Data on BB and SB can be provided or may be requested if relevant for the assessment, but it is not mandatory to provide this data at the moment. Until there will be a SPG defined, BB and SB data can be used for predicting effects. This can be used as an additional line of evidence considered in the risk assessment.
27	Chronic tests will only be required if acute toxicity tests are positive. Doesn't this risk overlooking effects of a.s. that have only chronic effects?	We understand that this question relates to the requirement to provide data on products, depending on the comparison of toxicity between the active substance and the product. For the active substance and biocidal products with two or more active substances a chronic oral test with adults is always required. For biocidal products with only one active substance, which have been shown to be less toxic based on acute effects than the active substance itself however, no chronic test must be conducted for the biocidal product. See also Chapter 8 for the Time-reinforced toxicity in the guidance.
28	Is product data needed when the product only contains one active substance? Or only for 2 or more active substances?	Product data on oral acute and contact toxicity for honey bees is always needed to clarify whether the biocidal product is more toxic than the active substance (see Chapter 6 in the guidance). If this is the case, also chronic oral and larvae toxicity studies are needed for the product. When a product comprises of 2 or more insecticidal active substances, data for all 4 risk cases (acute oral toxicity, acute contact toxicity, chronic oral adult, toxicity larvae) are needed for the product.
29	From our understanding ALL Product types would have to be tested, according to the bee guidance. As PT representatives other than PT	In the guidance Section 6.1.2 it is stated that toxicity studies are required if the active substance has insecticidal mode of action, and, there is relevant exposure. This implies that both potential hazard and non-negligible exposure are triggering the need for toxicity studies. See also questions 10 and 11 for the scope of the guidance.

#	Question	Answer
	18 and PT 8 may also have lethal or sublethal effects on bees and non-bee pollinators.	
30	The EFSA guidance uses only non-linear regression equations, but studies are usually analysed using linear regression statistics. Can the calculator tool include linear regression equations as an option, as the parameters are different?	No, the calculator tool under development by EFSA (and the future ECHA tool) will use 4 non-linear regression models (Hill (log-logistic), log-normal, Weibull1 and Weibull2) and it is not foreseen to have linear regression as an option. The rationale behind this is, that non-linear regression models have the advantage that they use more information from the test results and avoid using inaccurate assumptions, which are made by linear models.
31	Is a risk assessment needed for bumble bees and solitary bees?	The same risk assessment scheme provided in the guidance will be applicable for bumble bees and solitary bees as well once the magnitude dimension of SPG for these groups is defined. Also, standard test guidelines are not yet available for all risk cases for these bee groups. Toxicity data on solitary bees and bumble bees is currently not mandatory but can be requested by the eCA if considered necessary for the assessment.
32	Why the PEC/PNEC approach was not followed in the risk assessment of bees?	Under the COM mandate, ECHA was asked to take into account the available guidance on plant protection products (PPPs) and use any information already available from EFSA. The aim is to harmonise the approach for the regulatory frameworks under the one-substance one-assessment approach. The same protection goal as well as the same assessment procedure were chosen for biocides as for PPPs to prevent contradicting assessments and duplication of efforts.
33	Regarding the lower tier risk assessment "Step 1: Effects at individual level" specifically states a log-logistic DRC function - can other non-linear (or linear) models also be used?	The future calculator tool will not only use the log-logistic (or Hill) model, but also 3 other non-linear regression models (log-normal, Weibull1 and Weibull2). The LD50 and the slope from the model with the best fit is then used for further analysis.
34	When test guidelines are available for bumble bees (BB) and solitary bees (SB), will the toxicity extrapolation factors (Tef) from EFSA be used (e.g. Tef >100 for Osmia will mean that most biocides may fail the risk assessment for bees)?	The Toxic extrapolation factors (TEFs) can already be used. Yet as there are no specific protection goals defined yet for BB and SB, it is not possible to use this data for risk calculation. Nevertheless, TEFs can be used for predicting effects and considered as an additional line of evidence in the risk assessment.
35	Is it possible to perform a higher tier risk assessment for biocides?	Higher tier studies are usually designed for plant protection products (PPP), and may not be directly applicable to biocides, especially field studies. Therefore, a case-by-case assessment is always needed for biocides and the companies are advised to discuss with the evaluating Competent Authority. In this first version of the ECHA Bee guidance, the section on the higher tier studies is quite short. Once experience on the biocide bee risk assessment has been gained, more detailed recommendations may be included in a future revision of the guidance.

#	Question	Answer
Time reinforced toxicity (TRT) and sublethal effects (SLE) assessment		
36	Is there guidance provided to know how to use GUTS models (General Unified Threshold model of Survival)?	GUTS models will be embedded in the calculator developed for the EFSA Bee guidance and will be used for the future calculator developed for the ECHA Bee guidance. Further reference to the methodology and software of this GUTS models will also be given in the calculator tool. More information on GUTS can be found online (DEBtox info: GUTS book openGUTS).
37	The standard GUTs model does not have outputs for 27d and 180d - how will these be evaluated?	The GUTS models enable to fit the chronic test dataset (from mandatory OECD test guideline 245) to calculate the LDD50 values for the summer bee life-span (estimated to 27 days) and the winter bee life-span (estimated to 182 days).

38	EFSA has exclusions for TRT based on toxicity of the active substance (less than 10% mortality at >100 ug/bee) - is this also applied in the ECHA guidance?	The TRT assessment strategy has been taken over from the EFSA guidance and is identical for biocides. The first step of the TRT hazard assessment is a screening step that enables to determine if the TRT assessment really needs to be carried out for the active substance, which may be of low toxicity to bees. Mortality data of the 10-day chronic test (OECD 245) is used for this screening step:
		- Is the mortality ≤ 10% at any dose ≥ 100 µg/bee/day?
		  ○ If yes, then a TRT assessment is not necessary
		  ○ If no, continue the assessment

39	Will TRT only be needed for active substances and not products?	The TRT assessment can also be performed with data from toxicity tests performed with the biocidal product. For the lower tier risk assessment, a chronic toxicity study with the biocidal product is also required if, based on acute data, the product was found to be more toxic compared to the active substance, or when the biocidal product contains multiple active substances. Thus, if chronic data with the biocidal product are available, the TRT assessment should also be performed with these data.
40	How is the SLE connected to the 'standard' bee risk assessment?	The data from the standard toxicity tests are used in a first step of the SLE strategy and a risk assessment is carried out. At each step of the SLE strategy, the toxicity values are compared to the exposure values calculated with the 'standard' bee exposure assessment. However, as no direct link between the sublethal effects and the SPGs could be established, the outcome of the SLE assessment is not 'risk/no risk', but 'potential concern for SLE/no potential concern for SLE'.
41	Are there any proposals from the expert group for the regulatory consequences when the outcome of the SLE assessment is "concern for SLE"?	Some discussion took place in the expert group and at CA level but there are no concrete proposals yet. Currently, the discussion is still ongoing at the biocide CA level, and a similar discussion is taking place for PPPs.
42	What happens in the sublethal effects assessment if the substance is repellent (e.g pyrethroids) so food consumption is reduced - this is seen as a positive impact in reducing exposure in real use (bees would forage on	It is true that exposure to a repellent might reduce the food source and lead to reduced consumption and sublethal effects. However, this would require bees to be exposed to the repellent on a large scale. For the exposure to PT19 products, see also questions 10 and 11.

#	Question	Answer
	other sources of pollen and nectar) but would be seen as adverse in this approach.	
43	Why can the homing flight test only be used for acute dietary assessment? The guidance in OECD GD 332 could be easily applied to an acute contact exposure.	The protocol of the OECD GD 332 is quite recent and has been ring tested over the past few years. According to the protocol, the experimental bees of the colonies that are tagged to identify them by radio-frequency are exposed orally to the sublethal doses of the test chemical. Therefore, this test has been validated for oral exposure, and not for contact exposure.
44	It was mentioned that sublethal effects might trigger regulatory impact. Could you share what is being considered? Labelling, usage restrictions, etc.	See question 41.
Mixtures and metabolites		
45	What happens if the MDR is <0.33 or >3.0? Surely the measured endpoint should be used as this represents the actual state.	As shown in Figure 18 in the ECHA bee guidance, if the MDR is <0.3 and antagonistic effects are not plausible, the calculated effect endpoints need to be used for the risk assessment. The same is true for MDR > 3 and synergistic effects not being plausible. In the above-mentioned cases the calculated mixture endpoint covers the more worst-case situation compared to the measured endpoint if no explanation for antagonism or synergism can be given.
46	Should we calculate mixture toxicity when an active substance of the product is not registered as PT18 (e.g. algicide) but data shows some toxicity to bees? Would the substance considered to have insecticidal MoA?	For the risk assessment for mixtures, at least 2 active substances with an insecticidal mode of action need to be present in product (Chapter 12 of the ECHA bee guidance). In the scope of the ECHA bee guidance, an active substance approved or notified under another PT other than PT 18, may have a mode of action relevant for insects for instance (see Chapter 2.1.1 of the ECHA bee guidance). Based on the data requirement for products (Chapter 6.1.3 of the ECHA bee guidance), the effect studies of the formulations could indicate that the second non-PT 18 active substance could have an insecticidal mode of actions (product is 3 times more toxic than the PT18 active substance alone). In this case, it needs to be investigated by the applicant and the evaluating competent authority whether the second non-PT 18 active substance could be indeed classified as a substance with an insecticidal mode of action and thus further formulation effect studies would be triggered and a mixture risk assessment would be required.
47	Why an assessment factor (AF) of 10 is foreseen for metabolites? Sometimes metabolites are known to be less toxic in general than the parent compound. Should this AF be used in case by case basis or/and	The assessment factor of 10 is in line with general principles for safety factors – an order of magnitude difference as worst-case assumption to address the uncertainty. Metabolites can also be more toxic than the parent compound, as stated in the 'Guidance on tiered risk assessment for edge-of-field surface waters' (EFSA 2013), which states that a significant proportion of metabolites (30 %) were more toxic than their

#	Question	Answer
	qualitatively waived?	parent compound. In general, the metabolite scheme should be applied as explained in the guidance for all substances. However, if there are available data on the toxicity of metabolites to bees, then this may be used to lower the AF (depending on relevance and reliability of the data). However, currently there is no experience on bee risk assessment for biocides and hardly any data available on effects of active substances to bees, let alone on effects of metabolites to bees.
48	Does the metabolite assessment concern only metabolites identified in soil biodegradation studies, or also metabolites formed by biotransformation inside the plant?	First step of the metabolite assessment is to identify the source/scale of exposure, as the assessment is only required for larger scale applications, including large scale spraying, irrigation, and manure/sewage sludge applications. If data are available on biotransformation inside plants, then this may be used for the assessment (depending on relevance and reliability of the data). However, currently there is no experience on bee risk assessment for biocides and hardly any data available on active substance levels in plants, let alone on levels of metabolites in plants. Moreover, differences in metabolism may occur between plants species and for use of biocides the plant species is not specified (various species may be exposed). Therefore, determination of relevant metabolites and metabolite levels is complex, and requires a case-by-case evaluation, if an unacceptable risk is identified in the stepwise approach as described in the guidance.
49	Can we request test on metabolite to refine the assessment if the default applied AF of 10 show some risk?	See question 47. In addition, for the manure/sludge scenario, please refer to the ECHA Bee guidance Section 11.1.2. After the screening step, first refinement of the porewater concentration can be performed (with PEARL). If the risks are still unacceptable, then further data on the metabolites are required.
Calculator tool		
50	Will a calculator be available and what data will be needed for this (EFSA are developing a calculator for their risk assessment due to the complexity)? The slope and intercept for calculating the PIEj from the exposure depends on the model and software used - how will this be assessed?	ECHA is planning to develop a tool to support the implementation of the ECHA bee guidance (biocides calculator tool). For the calculator the raw data will be needed to derive LD50/intercept and slope, as well as the exposure estimates. As prescribed in the guidance, the calculator tool will use four non-linear regression models (Hill (log-logistic), log-normal, Weibull1 and Weibull2) and the parameters (LD50/Inflection point, slope) of the regression model giving the best fit will be used for further analysis.
51	Will ECHA develop excel sheets or another tool for performing the risk assessment? If so, when will it be available?	ECHA is planning to develop a tool (other than excel) to support the implementation of the ECHA bee guidance (see question 50). This tool is likely to be available in 2025 - 2026.
52	Will the GUTS modelling be incorporated into a calculator tool provided by ECHA?	Yes, the intention is that GUTS will be included into the biocide calculator tool.
53	How advanced is the work on the ECHA calculator tool?	ECHA is currently at the very early stage, primarily analysing synergies with EFSA and the integration needs with other ECHA tools such as IUCLID and CHESAR Platform.

#	Question	Answer
54	How transparent will the calculator be - can the applicant see the calculations to check it is correct? (there have been errors in some calculators in the past)	This has not yet been addressed in our analyses. We may take this into consideration, provided that ECHA has a possibility to influence the core features of the tool, and which is pending the decision on the tool itself and potential reuse of EFSA bee tool modules.