Evaluation Manual for the Authorisation of plant protection products and biocides

EU part

Biocides

Chapter 6 Ecotoxicology; terrestrial organisms bees and non-target organisms

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Board for the Authorisation of plant protection products and biocides

Chapter 6 Ecotoxicology; terrestrial organisms

Category: biocides

III BEES AND NON-TARGET ARTHROPODS

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the risk to bees and non-target arthropods of a biocide and the active substance, and which evaluation methodologies are applied for the EU framework (§1 - §1.5)..

1. EU FRAMEWORK

The procedure for inclusion of active substances in Annex I to Biocides Directive 98/8/EC [1] is described under EU framework (§1 - §1.5) where only the procedure laid down in the EU is described. The NL procedure for evaluation of a substance, described in the NL part §2 - §2.5 of this chapter, is reverted to where no EU procedure has been laid down.

1.1. Introduction

This chapter serves to estimate the risk to bees and non-target arthropods.

This chapter has no relationship with other chapters of the HTB Biocides.

Described are the guidelines for assessment of the aspect bees and non-target arthropods are described in the TNsG on Data Requirements [2].

Determination of the relevance of the emission routes and quantification of emissions are based on emission scenarios drawn up for various product types in emission scenario documents (see the ex-ECB web site [3]). Objective of these emission scenarios is the harmonisation of the annex I inclusion and authorisation process for biocidal products. They are briefly described in Appendix A to the environmental section.

A decision tree with corresponding explanatory notes is included in Appendix 1.
This decision tree summarises the evaluation system for bees and non-target arthropods.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The National further provisions can also be used for inclusion of an active substance in Annex I to 98/8/EC.

1.2. Data requirements

The data requirements laid down in the TNsG on data requirements [2] corresponding with the Biocides Directive (98/8/EC) are listed below; the data requirements for the active substance and the product for evaluation of the risk for bees and non-target arthropods. This is the verbatim text of the Directive (grey frames). Numbering of the studies corresponds with the numbering of the TNsG on data requirements. Numbering in square brackets follows the numbering of the Biocides Directive. Where relevant, the result of the study has been added.

The data requirements are divided into standard data requirements (core data) that apply for each product type. There are no standard data requirements for bees and non-target arthropods. In addition, product-type-specific data should be submitted for different product types. The different product types are elaborated in the relevant chapters. Additional data must be submitted in case a higher tier evaluation must be carried out.

It should be noted that legislation is not clear as regards the definition of relevant metabolites. It is neither clear when these data on relevant metabolites must be submitted and how these should be evaluated. For bees and non-target arthropods, more clarity in EU framework will be waited for.

The TNsG on data requirements stipulates a number of principles, that reason the requirement of a data set including the data quality:

- The ability of the active substance or its degradation product(s) to damage the function and structure of biotic systems is to be clarified with a selection of ecotoxicity tests. Effects in the ecologically functional groups of producers, consumers and decomposers in relevant media (water, soil, and air) are addressed in these tests.

- There is a need to report all potentially adverse effects found during routine eco-toxicological investigations and to undertake and report, where required by the competent authorities, such additional studies which may be necessary to investigate the probable mechanisms involved and to assess the significance of these effects. All available biological data and information which is relevant to the assessment of the ecotoxicological profile of the active substance must be reported.

- In the case of studies in which dosing extends over a period, dosing should preferably be done using a single batch of active substance if stability permits. Whenever a study implies the use of different doses, the relationship between dose and adverse effect must be reported.

- In order to facilitate the assessment of the significance of test results obtained, including the estimation of intrinsic toxicity and the factors affecting toxicity, the same strain (or recorded origin) of each relevant species should, where possible, be used in the various toxicity tests specified.

- As required by EC test methods, concentrations of the test substance should be measured at least at the beginning as well as at the end of the test. Normally, however, it will be necessary to monitor the concentrations more frequently. The LC50's, EC50's and NOEC's should be calculated based on the measured concentrations. However, where the measured concentrations are close to the nominal concentrations (i.e. > 80% of nominal), it is acceptable to calculate the LC50's, EC50's and NOEC's based on nominal concentrations of the tested substance. In other cases, the geometric average measured concentrations should be used.

In addition to the latter approach for the derivation of concentrations from tests guidance developed for rapid degrading substances [**Fout! Bladwijzer niet gedefinieerd.**]

Data requirements for the active substance

Standard data requirements
There are no standard data requirements for bees and non-target arthropods.

Product-type-specific and additional data
Product-type-specific and additional data are required for a number of product types.

Product type 18: Insecticides, acaricides and products to control other arthropods and
Product type 19: Repellents and attractants
A test with bees is necessary:

7.5.3.2 Acute toxicity to honeybees and other beneficial arthropods, for example predators.

These studies as described in the TNsG on data requirements [2] are summarised below.

7.5.4 Effects on honeybees

7.5.4.1 Acute toxicity to honeybees and other beneficial arthropods, for example predators [Ann. IIIA, XIII.3.1.]

- At least one test on bees and one on another beneficial arthropod may be generally required for insecticides, acaricides and substances in products to control other arthropods which are used outdoors (product type 18). Such tests are usually not needed for other product types.
- A test on acute oral and contact toxicity on bees should be done according OECD guideline 213 (acute oral) and/or 214 (acute contact) or to EPPO Guideline 170 and OECD guidelines.
- Possible species to be tested in addition to honeybees are, for instance, *Chrysoperla carnea* (according to IOBC methods, IOBC 1985), *Trichogramma cacoeciae* (according to BBA guideline Part VI, 23-2.1.1, BBA 1989a), *Coccinella septempunctata* (according to BBA guideline Part VI, 23-2.1.5, BBA 1989b) or *Aleochara bilineata* (according to BBA guideline Part VI, 23-2.1.10, BBA 199X).

Result bees:
→ LD_{50} (oral)
→ LD_{50} (contact)

Result non-target arthropods:
→ LR_{50}
→ Reduction percentage

Higher tier studies
Submission of a higher tier study may be required in the context of a further (adequate) risk assessment. This needs to be provided if the PEC exceeds the trigger value. The EU framework biocides does not indicate which higher tier studies may be submitted and how these must be carried out.

This lacuna has for the national framework been elaborated in the NL part §2.2. The procedure described in the NL part §2.2 is followed as long as this has not been elaborated in EU framework.

Data requirements for the product
The TNsG on data requirements [2] reads as follows as regards the submission of product data:

Information on the ecotoxicology of the active substance in the product, where this cannot be extrapolated from the information on the active substance itself [Ann. IIB, VII.7.2.]

- Required, for example, if the composition (formulation) of or the application technique for the product is suspected to influence the degradation and transformation, mobility and adsorption properties or effects on aquatic or terrestrial organisms in a way that may considerably alter the conclusions of the risk characterisation. For instance, assessment by an expert on the effect of formulation on the ecotoxicology of the active substance should be submitted (see Chapter 1.2, point 4). Guidelines of the Council

Directive 88/379/EEC (as amended) on assessing the effect of a single substance in causing hazard in a preparation may be partly applicable here.
- In addition, a qualitative or, preferably, a quantitative estimate on the possibility of formation of by-products of the active substance during normal use should be submitted on the basis of available data on the active substance and the intended use of the biocidal product.
- Ecotoxicology testing with a product might be required in those cases where a direct release of a product to a compartment is possible (see Chapter 2.5, part B).

In some situations the following product data must be submitted as additional product data. Product data are required if the submitted data on the active substance do not give sufficient information or if there are indications of risks to be ascribed to specific properties of the product.

7.8.2 Acute toxicity to honeybees

7.8.3 Effects on other beneficial arthropods other than bees

1.3. Risk assessment

Assessment of the risk to bees and non-target arthropods has not been elaborated the EU framework Biocides. This especially concerns the derivation of the PNEC. These lacunas are for the National framework elaborated in the NL part §2.3. The procedure described in the NL part §2.3 is followed as long as these have not been elaborated in EU framework. If in EU framework clarity will be provided about these currently not elaborated aspects, these will be followed.

Research into the behaviour of an active substance is relevant for a correct estimation of the exposure concentration of this active substance to bees or non-target species (PEC = Predicted Environmental Concentration. This PEC is an important parameter in the risk assessment for bees and non-target arthropods. The PEC is calculated according to the TGD [**Fout! Bladwijzer niet gedefinieerd.**] and the Emission Scenario Documents [3].

1.4. Approval

According to the Directive of the European Parliament and the Council of 16 February 1998 concerning the placing of biocides on the market (98/8/EG) it should be investigated whether biocides have, when approved, no unacceptable effect on the environment and in particular the health humans and animals (consideration 8) if used properly for the envisaged purpose, in the light of the current scientific and technical knowledge.

Article 5, 1, b ii), iii) and iv) stipulates that Member States may only authorise a biocide if the product, when used consistent with the authorisation and taking into account:
- all conditions under which the biocide is normally used,
- the way in which material treated with the product can be used,
- the consequences of use and removal,

ii) has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates,

(iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking water, food or feed, indoor air or consequences in the place of work) or on surface water and groundwater,

(iv) has no unacceptable effect itself, or as a result of its residues, on the environment having particular regard to the following considerations:
- its fate and distribution in the environment; particularly contamination of surface waters (including estuarian and seawater), groundwater and drinking water,
- its impact on non-target organisms;

1.4.1. Evaluation

The Common Principles (Annex VI to 98/8) present the starting points for evaluation as regards the effects on the environment.
These concern the relevant parts of the introductory principles, the common principles, and the specific principles for the effects on the environment.
The specific principles for the risk to bees and non-target arthropods are in the text below printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI to Directive 98/8/EC.

36. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota following the use of the biocidal product.
37. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product. If this results in the biocidal product being classified according to the requirements of this Directive then dose (concentration) — response (effect) assessment, exposure assessment and risk characterisation shall be required.
38. In those cases where the test appropriate to hazard identification in relation to a particular potential effect of an active substance or a substance of concern present in a biocidal product has been conducted but the results have not led to classification of the biocidal product then risk characterisation in relation to that effect shall not be necessary unless there are other reasonable grounds for concern. Such grounds may derive from the properties and effects of any active substance or substance of concern in the biocidal product, in particular:
    - any indications of bioaccumulation potential,
    - the persistence characteristics,
    - the shape of the toxicity/time curve in ecotoxicity testing,
    - indications of other adverse effects on the basis of toxicity studies (e.g. classification as a mutagen),
    - data on structurally analogous substances,
    - endocrine effects.
39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as the predicted no-effect concentration (PNEC). However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.
40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Article 8 of this Directive. It shall be calculated by applying an assessment factor to the values resulting from tests on organisms, e.g. LD50 (median lethal dose), LC50 (median lethal concentration), EC50 (median effective concentration), IC50 (concentration causing 50% inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)).
41. An assessment factor is an expression of the degree of uncertainty in extrapolation

from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller is the degree of uncertainty and the size of the assessment factor.
The specifications for the assessment factors shall be elaborated in the notes for technical guidance which, to this end, shall be based particularly on the indications given in Commission Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and environment from substances notified in accordance with Council Directive 67/548/EEC(*).
(*) OJ L 227, 8.9.1993, p. 9.

42. For each environmental compartment an exposure assessment shall be carried out in order to predict the concentration likely to be found of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.
43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions including any relevant contribution from material treated with biocidal products are known or are reasonably foreseeable.
44. The PEC, or qualitative estimation of exposure, shall be determined taking account of, in particular, and if appropriate:
    - adequately measured exposure data,
    - the form in which the product is marketed,
    - the type of biocidal product,
    - the application method and application rate,
    - the physico-chemical properties,
    - breakdown/transformation products,
    - likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
    - the frequency and duration of exposure.
45. Where adequately measured, representative exposure data are available, special consideration shall be given to them when conducting the exposure assessment. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in paragraph 33. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.
46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.
47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.

1.4.2. Decision making

The Common Principles (Annex VI to 98/8) present the starting points for decision making as regards the effects on the environment.
These concern the relevant parts of the introductory principles, the common principles, and the specific principles for the effects on the environment.
The specific principles for risk to bees and non-target organisms are in the text below

printed in a grey frame. This text, including numbering, is the verbatim text of Annex VI to Directive 98/8/EC.

78. The Member State shall not authorise a biocidal product if the risk assessment confirms that the active substance, or any substance of concern, or any degradation, or reaction product presents an unacceptable risk in any of the environmental compartments, water (including sediment), soil and air. This shall include the assessment of risks to non-target organisms in these compartments.

87. The Member State shall not authorise a biocidal product where there is a reasonably foreseeable possibility of non-target organisms being exposed to the biocidal product if for any active substance or substance of concern:
- the PEC/PNEC is above 1 unless it is clearly established in the risk assessment that under field conditions no unacceptable effects occur after use of the biocidal product according to the proposed conditions of use.

1.5. Developments

Developments
- None
- EU developments will be followed.

Lacunas
- The EU framework Biocides does not indicate which higher tier studies may be submitted and how these should be carried out.
- Risk assessment for bees and non-target arthropods has not been elaborated.

2. REFERENCES

1 Biocides Directive (98/8/EC).
2 Technical notes for guidance in support of Directive 98/8/EC concerning the placing of biocidal products on the market. Guidance on data requirements for active substances and biocidal products. October 2002.
3. Emission Scenario Document for Biocides (esd) > Documents > Emission scenario Documents > ESD per product type: E.g. Emission scenarios for all 23 product types of EU Directive 98/8/EC, report RIVM 601450009/2002. P. van der Poel en J. Bakker & Development of Environmental Emission Scenarios for active substances used in Biocidal Products. Final Report, January 2004. European Commission DG ENV, RIVM Service contract B4-3040/2001/326154/Mar/C3