|  |
| --- |
| DRAFT REGISTRATION REPORT  Part B  Section 9  Ecotoxicology  Detailed summary of the risk assessment |
| Product code: xxx  Product name(s): xxx  Chemical active substance(s):  Active substance 1, xxx g/L or g/kg Active substance 2, xxx g/L or g/kg Active substance 3, xxx g/L or g/kg Active substance 4, xxx g/L or g/kg |
| Northern/Central/Southern Zone/Interzonal  Zonal Rapporteur Member State: zRMS |
| CORE ASSESSMENT/  NATIONAL ADDENDUM country  (authorization/extension of use/…) |
| Applicant: company name  Submission date: dd/mm/yyyy  MS Finalisation date: dd/mm/yyyy |

Version history

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Table of Contents

[9 Ecotoxicology (KCP 10) 2](#_Toc480804349)

[9.1 Critical GAP and overall conclusions 2](#_Toc480804350)

[9.1.1 Overall conclusions 2](#_Toc480804351)

[9.1.1.1 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3) 2](#_Toc480804352)

[9.1.1.2 Effects on aquatic organisms (KCP 10.2) 2](#_Toc480804353)

[9.1.1.3 Effects on bees (KCP 10.3.1) 2](#_Toc480804354)

[9.1.1.4 Effects on arthropods other than bees (KCP 10.3.2) 2](#_Toc480804355)

[9.1.1.5 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5) 2](#_Toc480804356)

[9.1.1.6 Effects on non-target terrestrial plants (KCP 10.6) 2](#_Toc480804357)

[9.1.1.7 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7) 2](#_Toc480804358)

[9.1.2 Grouping of intended uses for risk assessment 2](#_Toc480804359)

[9.1.3 Consideration of metabolites 2](#_Toc480804360)

[9.2 Effects on birds (KCP 10.1.1) 2](#_Toc480804361)

[9.2.1 Toxicity data 2](#_Toc480804362)

[9.2.1.1 Justification for new endpoints 2](#_Toc480804363)

[9.2.2 Risk assessment for spray applications 2](#_Toc480804364)

[9.2.2.1 First-tier assessment (screening/generic focal species) 2](#_Toc480804365)

[9.2.2.2 Higher-tier risk assessment 2](#_Toc480804366)

[9.2.2.3 Drinking water exposure 2](#_Toc480804367)

[9.2.2.4 Effects of secondary poisoning 2](#_Toc480804368)

[9.2.2.5 Biomagnification in terrestrial food chains 2](#_Toc480804369)

[9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed 2](#_Toc480804370)

[9.2.4 Overall conclusions 2](#_Toc480804371)

[9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2) 2](#_Toc480804372)

[9.3.1 Toxicity data 2](#_Toc480804373)

[9.3.1.1 Justification for new endpoints 2](#_Toc480804374)

[9.3.2 Risk assessment for spray applications 2](#_Toc480804375)

[9.3.2.1 First-tier assessment (screening/generic focal species) 2](#_Toc480804376)

[9.3.2.2 Higher-tier risk assessment 2](#_Toc480804377)

[9.3.2.3 Drinking water exposure 2](#_Toc480804378)

[9.3.2.4 Effects of secondary poisoning 2](#_Toc480804379)

[9.3.2.5 Biomagnification in terrestrial food chains 2](#_Toc480804380)

[9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed 2](#_Toc480804381)

[9.3.4 Overall conclusions 2](#_Toc480804382)

[9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3) 2](#_Toc480804383)

[9.5 Effects on aquatic organisms (KCP 10.2) 2](#_Toc480804384)

[9.5.1 Toxicity data 2](#_Toc480804385)

[9.5.1.1 Justification for new endpoints 2](#_Toc480804386)

[9.5.2 Risk assessment 2](#_Toc480804387)

[9.5.3 Overall conclusions 2](#_Toc480804388)

[9.6 Effects on bees (KCP 10.3.1) 2](#_Toc480804389)

[9.6.1 Toxicity data 2](#_Toc480804390)

[9.6.1.1 Justification for new endpoints 2](#_Toc480804391)

[9.6.2 Risk assessment 2](#_Toc480804392)

[9.6.2.1 Hazard quotients for bees 2](#_Toc480804393)

[9.6.2.2 Higher-tier risk assessment for bees (tunnel test, field studies) 2](#_Toc480804394)

[9.6.3 Effects on bumble bees 2](#_Toc480804395)

[9.6.4 Effects on solitary bees 2](#_Toc480804396)

[9.6.5 Overall conclusions 2](#_Toc480804397)

[9.7 Effects on arthropods other than bees (KCP 10.3.2) 2](#_Toc480804398)

[9.7.1 Toxicity data 2](#_Toc480804399)

[9.7.1.1 Justification for new endpoints 2](#_Toc480804400)

[9.7.2 Risk assessment 2](#_Toc480804401)

[9.7.2.1 Risk assessment for in-field exposure 2](#_Toc480804402)

[9.7.2.2 Risk assessment for off-field exposure 2](#_Toc480804403)

[9.7.2.3 Additional higher-tier risk assessment 2](#_Toc480804404)

[9.7.2.4 Risk mitigation measures 2](#_Toc480804405)

[9.7.3 Overall conclusions 2](#_Toc480804406)

[9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4) 2](#_Toc480804407)

[9.8.1 Toxicity data 2](#_Toc480804408)

[9.8.1.1 Justification for new endpoints 2](#_Toc480804409)

[9.8.2 Risk assessment 2](#_Toc480804410)

[9.8.2.1 First-tier risk assessment 2](#_Toc480804411)

[9.8.2.2 Higher-tier risk assessment 2](#_Toc480804412)

[9.8.3 Overall conclusions 2](#_Toc480804413)

[9.9 Effects on soil microbial activity (KCP 10.5) 2](#_Toc480804414)

[9.9.1 Toxicity data 2](#_Toc480804415)

[9.9.1.1 Justification for new endpoints 2](#_Toc480804416)

[9.9.2 Risk assessment 2](#_Toc480804417)

[9.9.3 Overall conclusions 2](#_Toc480804418)

[9.10 Effects on non-target terrestrial plants (KCP 10.6) 2](#_Toc480804419)

[9.10.1 Toxicity data 2](#_Toc480804420)

[9.10.1.1 Justification for new endpoints 2](#_Toc480804421)

[9.10.2 Risk assessment 2](#_Toc480804422)

[9.10.2.1 Tier-1 risk assessment (based screening data) 2](#_Toc480804423)

[9.10.2.2 Tier-2 risk assessment (based on dose-response data) 2](#_Toc480804424)

[9.10.2.3 Higher-tier risk assessment 2](#_Toc480804425)

[9.10.2.4 Risk mitigation measures 2](#_Toc480804426)

[9.10.3 Overall conclusions 2](#_Toc480804427)

[9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7) 2](#_Toc480804428)

[9.12 Monitoring data (KCP 10.8) 2](#_Toc480804429)

[9.13 Classification and Labelling 2](#_Toc480804430)

[Appendix 1 Lists of data considered in support of the evaluation 2](#_Toc480804431)

[Appendix 2 Detailed evaluation of the new studies 2](#_Toc480804432)

[A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates 2](#_Toc480804433)

[A 2.1.1 KCP 10.1.1 Effects on birds 2](#_Toc480804434)

[A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds 2](#_Toc480804435)

[A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) 2](#_Toc480804436)

[A 2.2 KCP 10.2 Effects on aquatic organisms 2](#_Toc480804437)

[A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes 2](#_Toc480804438)

[A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms 2](#_Toc480804439)

[A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms 2](#_Toc480804440)

[A 2.3 KCP 10.3 Effects on arthropods 2](#_Toc480804441)

[A 2.3.1 KCP 10.3.1 Effects on bees 2](#_Toc480804442)

[A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna 2](#_Toc480804443)

[A 2.4.1 KCP 10.4.1 Earthworms 2](#_Toc480804444)

[A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms) 2](#_Toc480804445)

[A 2.5 KCP 10.5 Effects on soil nitrogen transformation 2](#_Toc480804446)

[A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants 2](#_Toc480804447)

[A 2.6.1 KCP 10.6.1 Summary of screening data 2](#_Toc480804448)

[A 2.6.2 KCP 10.6.2 Testing on non-target plants 2](#_Toc480804449)

[A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants 2](#_Toc480804450)

[A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna) 2](#_Toc480804451)

[A 2.8 KCP 10.8 Monitoring data 2](#_Toc480804452)

# Ecotoxicology (KCP 10)

This document is to be used by the applicant of a plant protection product for authorization at Member State level. It has been designed to provide guidance on the preparation of Section 9 (Ecotoxicology) of the draft registration report (dRR) and on the information required specifically for this section. The guidance is applicable to the core assessment and the national addenda.

Notes: Text in turquoise shading provides general information/support and should be deleted when the document is finalised. Text highlighted in yellow should be changed as specified. It shows **example** text. Explanation may be added and text that is not relevant may be removed.

Tables are provided as examples and may be adapted to suit the product being evaluated (columns can be added or deleted). Moreover, some tables are not relevant for all products or all submission types and can be added or deleted.

Fields shaded in grey are reserved for the Member State assessors and should not be filled in by the applicant.

If risk assessments for metabolites are required, the assessment should be presented as proposed for active ingredients and respective tables should be inserted.

The template addresses the basic case of one single active substance in a plant protection product. When relevant, endpoints and risk assessments for further active substances should be presented in separate tables. Endpoints for metabolites are presented in the table of their respective parent compound.

When relevant, the potentially increased risk resulting from mixture toxicity has to be addressed for all areas of the risk assessment, following applicable guidance. The same tables as for individual active ingredients should be used and adapted if necessary. Explanatory notes and calculations should be included either under the heading “Toxicity data” or the heading “Risk assessment”, as appropriate.

Studies from the open literature should be evaluated and summarised in Appendix 2 and included in the risk assessment, if relevant.

In case the risk assessment is performed to other Guidance Documents than specified in the respective chapters below, the Guidance Documents should be specified and a justification should be provided.

## Critical GAP and overall conclusions

The following table is supposed to be a subset of the uses listed in the GAP table of appendix 1 in part B section 0. Rows are to be deleted as appropriate. Guidance for completing the GAP table is annexed to that table.

Table 9.1‑1: Table of critical GAPs

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Use-No. \* | Member state(s) | Crop and/or situation  (crop destination / purpose of crop) | F, Fn, Fpn G, Gn, Gpn or  I \*\* | Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI  (days) | Remarks:  e.g. g saf­ener/ syner­gist per ha | Conclusion | | | | | | |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product/ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min/max | Birds | Mammals | Aquatic organisms | Bees | Non-target arthropods | Soil organisms | Non-target plants |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms) | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Minor uses according to Article 51 (field uses) | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Minor uses according to Article 51 (interzonal uses) | | | | | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 “Conclusion”

|  |  |
| --- | --- |
| A | Acceptable, Safe use |
| R | Further refinement and/or risk mitigation measures required |
| C | To be confirmed by cMS |
| N | No safe use |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| **Remarks**  **table:** | (1) Numeration necessary to allow references  (2) Use official codes/nomenclatures of EU  (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)  (4) F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application  (5) Scientific names and EPPO-Codes of target pests/diseases/ weeds or when relevant the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named  (6) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench  Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated |  | (7) Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3‑8263-3152-4), including where relevant, information on season at time of application  (8) The maximum number of application possible under practical conditions of use must be provided  (9) Minimum interval (in days) between applications of the same product.  (10) For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products  (11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).  (12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.  (13) PHI - minimum pre-harvest interval  (14) Remarks may include: Extent of use/economic importance/restrictions |

### Overall conclusions

Insert a brief summary (at most one page) of the conclusions for all chapters. The conclusion should include only the outcome of the risk assessment but no TER-calculations or summary of endpoints.

It is noted that currently no EU-harmonised approach and no method officially accepted by EFSA for the assessment of indirect effects on biodiversity (including trophic interactions) is available. Hence, for the time being the potential impact on biodiversity cannot be considered as mandatory part of the ecotoxicological risk assessment. As a consequence, based on the present risk assessment, negative effects on biodiversity (including trophic interactions) cannot be ruled out. [delete if not applicable, e.g. greenhouse/indoor use]

#### Regulatory background

#### In the table below the regulatory documents of the relevant active substance(s) relied on within this evaluation are presented.

Table 9.1‑4 Details on the regulatory background of the active substance(s)

| Active substance | Date of approval  (Expiration of approval) | SANCO Review Report | EFSA Scientific Report |
| --- | --- | --- | --- |
| A.s. name | dd/mm/20xx  (dd/mm/20xx) | Review Report number | EFSA Journal number |

#### Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

#### Effects on aquatic organisms (KCP 10.2)

#### Effects on bees (KCP 10.3.1)

#### Effects on arthropods other than bees (KCP 10.3.2)

#### Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

#### Effects on non-target terrestrial plants (KCP 10.6)

#### Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

### Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

The risk envelope concept exploits the idea that uses with similar characteristics can be assessed group-wise and that the risk assessment for all use groups can be simplified by focusing on the group with worst-case characteristics as a representative for all other use groups. Insofar, the concept requires i) grouping of the intended uses according to certain criteria (e.g. crop, application rate, number of applications, timing, etc.) and ii) sorting of those groups according to their estimated risk levels as determined by the target of the respective assessment. It should be noted that this will often result in different grouping and sorting results for the different areas of environmental risk assessment, which needs to be documented transparently in the table.

Table 0‑1 Critical use pattern of formulation grouped according to criterion

| Grouping according to criterion | | | |
| --- | --- | --- | --- |
| Group | Intended uses | relevant use parameters for grouping | relevant parameter or value for sorting |
| xxx | xxx | xxx | xxx |
| xxx | xxx | xxx | xxx |

### Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of formulation is indicated in the table.

The table of metabolites is identical in structure to the respective table in Section 8 (Environmental Fate); hence, the data on metabolite names, structure, molar mass, and occurrence in environmental compartments should be copied from there. The column on the possible need for a specific risk assessment can be used to indicate the background of the decision for not conducting a risk assessment (always required) or the scope of the required risk assessment, e.g., “not relevant (EU assessment)”, “yes, soil organisms” or similar. No specific risk assessment is normally required for metabolites that have already been identified as not relevant in the EU assessment of their respective parent compound, unless new data for active substance or metabolite indicate the need for a re-evaluation of relevance.

Table 0‑2 Metabolites of active substance 1

| Metabolite | Chemical structure | Molar mass | Maximum occurrence in compartments | Risk assessment required? |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |

### Regulatory background

In the table below the regulatory documents of the relevant active substance(s) relied on within this evaluation are presented.

Table 9.1‑4 Details on the regulatory background of the active substance(s)

| Active substance | Date of approval  (Expiration of approval) | SANCO Review Report | EFSA Scientific Report |
| --- | --- | --- | --- |
| A.s. name | dd/mm/20xx  (dd/mm/20xx) | Review Report number | EFSA Journal number |

## Effects on birds (KCP 10.1.1)

### Toxicity data

Avian toxicity studies have been carried out with active substance 1and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as Appendix 2 of this document (new studies).

Effects on birds of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Or

However, the provision of further data on the formulation is not considered essential, because xxx

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Possible conversion or extrapolation, endpoint recalculations, or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Table 9.2‑1: Endpoints and effect values relevant for the risk assessment for birds

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Species sp. | active substance 1 | Oral 1 d Acute | LD50 = xxx mg/kg bw | EFSA Conclusion or Review Report  Author/Date/Study code |
| Species sp. | active substance 1 | Dietary 8 d Short-term | LDD50 = xxx mg/kg bw/d | EFSA Conclusion or Review Report  Author/Date/Study code |
| Species sp. | active substance 1 | Dietary Reproductive toxicity | NOEL = xxx mg/kg bw/d  (reproduction / offspring effects on xxx) | EFSA Conclusion or Review Report  Author/Date/Study code |

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for birds from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed upon in the EU peer review.

#### First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

As mentioned in EFSA/2009/1438, the screening steps are an option and the assessment may start at the first-tier assessment as well. Therefore, they only need to be documented when the resulting TER values exceed the applicable acceptability criteria. In that case, “indicator species for screening” should be written into the box for the indicator/generic focal species. Otherwise, the description of the generic focal species from Annex 1 of EFSA/2009/1438 should be copied into that box. In a crop scenario with several generic focal species, it is possible to omit calculations for generic focal species with smaller shortcut values when the TER value for a generic focal species with higher shortcut value already exceeds the applicable acceptability criterion. This should be indicated by a respective note.

Table 9.2‑2: First-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | |
| Active substance/product | | active substance 1 | | | | |
| Application rate (g/ha) | | n × xxx | | | | |
| Acute toxicity (mg/kg bw) | |  | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
|  |  | |  |  |  |  |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
|  |  | |  |  |  |  |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

#### Higher-tier risk assessment

Present a higher-tier risk assessment in line with EFSA/2009/1438, taking into account any information agreed on in the EU peer review. Every refinement of a parameter has to be fully justified, and higher-tier data should always be considered in the context of the whole available information (e.g., in an overall risk characterisation or weight-of-evidence assessment). Note that studies used for deriving refined assessment parameters are documented in Appendix 2.

Table 9.2‑3: Higher-tier assessment of the acute and long-term/reproductive risk for birds due to the use of formulation in crop (use/use group) – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | | | |
| Active substance/product | | active substance 1 | | | | | | |
| Application rate (g/ha) | | n × xxx | | | | | | |
| Acute toxicity (mg/kg bw) | |  | | | | | | |
| TER criterion | |  | | | | | | |
| Focal species | Food category,  % in diet | | FIR/bw | RUD90 × DF  (mg/kg food) | MAF90 | PT | DDD90  (mg/kg bw/d) | TERa |
| *Species sp.* | xyz, x % | |  |  |  |  |  |  |
|  | yzx, y % | |  |  |  |  |  |  |
|  | zxy, z % | |  |  |  |  |  |  |
|  | whole diet | |  |  |  |  |  |  |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | | | |
| TER criterion | |  | | | | | | |
| Focal species | Food category,  % in diet | | FIR/bw | RUDm × DF  (mg/kg food) | MAFm × TWA | PT | DDDm  (mg/kg bw/d) | TERlt |
| *Species sp.* | xyz, x % | |  |  |  |  |  |  |
|  | yzx, y % | |  |  |  |  |  |  |
|  | zxy, z % | |  |  |  |  |  |  |
|  | whole diet | |  |  |  |  |  |  |

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

#### Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (*cf*. Appendix K of EFSA/2009/1438).

Leaf scenario

Since formulation is not a product for spray applications / not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Or

Since formulation is intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario must be considered.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group … also covers the risk for birds from all other intended uses in groups … (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.2‑4: Assessment of the acute risk for birds due to exposure to active substance 1 via contaminated drinking water in leaf whorls

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | | |  | | | | |
| Active substance | | | active substance 1 | | | | |
| Application rate (g/ha) | | | n × xxx | | | | |
| Acute toxicity (mg/kg bw) | | |  | | | | |
| TER criterion | | | 10 | | | | |
| (Single) applic. rate  (g/ha) | Water applic. rate  (L/ha) | Cspray-sol.  (g/L) | | PECleaf-whorl = Cspray-sol./5  (mg/L) | DW uptake  (L/kg bw/d) | Daily dose  (mg/kg bw/d) | TERa |
|  |  |  | |  | 0.46 |  |  |

Cspray-sol: concentration in spray solution; PECleaf-whorl: concentration in pools in leaf whorls; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of xxx, active substance 1belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for birds from all other intended uses in groups xxx (see 9.1.2).

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = |  |  |  |
| Acute toxicity (mg/kg bw) = |  | quotient = |  |
| Reprod. toxicity (mg/kg bw/d) = |  | quotient = |  |

Or

With a K(f)oc of xxx, active substance 1belongs to the group of less/more sorptive substances. Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) exceeds the critical value of 50/3000 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is necessary.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for birds from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.2‑5: Assessment of the risk for birds due to exposure to active substance 1 via contaminated drinking water in puddles

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | |
| Active substance | | active substance 1 | | | | |
| Application rate (g/ha) | | n × xxx | | | | |
| Acute toxicity (mg/kg bw) | |  | | | | |
| TER criterion | | 10 | | | | |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | |
| TER criterion | | 5 | | | | |
| Soil-relevant applic. rate  (g/ha) | Koc  (L/kg) | | PECpuddle  (mg/L) | DW uptake  (L/kg bw/d) | Daily dose  (mg/kg bw/d) | TERa |
| TERlt |
|  |  | |  | 0.46 |  |  |
|  |

PECpuddle: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

#### Effects of secondary poisoning

The log Pow of active substance 1 amounts to xxx and thus does not exceed/exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating birds via secondary poisoning

Not required.

Or

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for birds from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review. When an assessment is intended based on concentrations in porewater, thereupon considering the applicable default parameters from the Technical Guidance Document (TGD), the following lines of the table must be altered. Line 1: PECporewater instead of PECsoil; line 4: foc not relevant for this approach; line 5: BCFworm/water = (PECworm,ww/PECporewater) = (0.84 + 0.12 × Pow); line 6: consider gut content of earthworms, if relevant.

Table 9.2‑6: Assessment of the risk for earthworm-eating birds due to exposure to active substance 1via bioaccumulation in earthworms (secondary poisoning) for the intended use in crop (use group)

| Parameter | active substance 1 | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) |  |  |
| log Pow / Pow |  |  |
| Koc |  | Mean (n = xxx) |
| foc |  | Default |
| BCFworm |  | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.12 × Pow) / foc × Koc |
| PECworm |  | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) |  | DDD = PECworm × 1.05 |
| NOEL (mg/kg bw/d) |  |  |
| TERlt |  |  |

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating birds via secondary poisoning

Not required.

Or

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of active substance 1 in water.

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.2‑7: Assessment of the risk for fish-eating birds due to exposure to active substance 1 via bioaccumulation in fish (secondary poisoning) for the intended use in crop (use group)

| Parameter | active substance 1 | comments |
| --- | --- | --- |
| PECsw (twa = 21 d) (mg/L) |  |  |
| BCFfish |  |  |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish |  | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) |  | DDD = PECfish × 0.159 |
| NOEL (mg/kg bw/d) |  |  |
| TERlt |  |  |

TER values shown in bold fall below the relevant trigger.

#### Biomagnification in terrestrial food chains

Not relevant.

Or:

Present an assessment addressing the potential of the active substances for biomagnification in terrestrial food chains if relevant.

### Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

Or:

Complete this section in case of application as baits, pellets, granules, prills or treated seed with the same sub-chapters as for the assessment for spray applications (“Not relevant” should then be stated under 9.2.2.)

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

### Toxicity data

Mammalian toxicity studies have been carried out with active substance 1/ and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Section 6 (Mammalian Toxicology) of this report (new studies).

Effects on mammals of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 and summarised in Section 6 (Mammalian Toxicology) of this report.

Or

However, the provision of further data on the formulation formulation is not considered essential, because …

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Possible conversion or extrapolation, endpoint recalculations, or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Table 9.3‑1: Endpoints and effect values relevant for the risk assessment for mammals

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Species sp. | active substance 1 | Oral 1 d Acute | LD50 = xxx mg/kg bw | EFSA Conclusion or Review Report  Author/Date/Study code |
| Species sp. | active substance 1 | Dietary Reproductive toxicity Two-generation study | NOAEL = xxx mg/kg bw/d  (parental / reproductive / offspring effects on …) | EFSA Conclusion or Review Report  Author/Date/Study code |
| Species sp. | active substance 1 | Oral Developmental toxicity | NOAEL xxx mg/kg bw  (parental / reproductive effects on …) | EFSA Conclusion or Review Report  Author/Date/Study code |

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for mammals from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

#### First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

As mentioned in EFSA/2009/1438, the screening steps are an option and the assessment may start as well at the first-tier assessment. Therefore, they only need to be documented when the resulting TER values exceed the applicable acceptability criteria. In this case, “indicator species for screening” should be written into the box for the indicator/generic focal species. Otherwise, the description of the generic focal species from Annex 1 of EFSA/2009/1438 should be copied into that box. In a crop scenario with several generic focal species, it is possible to omit calculations for generic focal species with smaller shortcut values when the TER value for a generic focal species with higher shortcut value already exceeds the applicable acceptability criterion. This should be indicated by a respective note.

Table 9.3‑2: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of formulation in crop (use/use group)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | |
| Active substance/product | | active substance 1 | | | | |
| Application rate (g/ha) | | n × xxx | | | | |
| Acute toxicity (mg/kg bw) | |  | | | | |
| TER criterion | | 10 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SV90 | MAF90 | DDD90  (mg/kg bw/d) | TERa |
|  |  | |  |  |  |  |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | |
| TER criterion | | 5 | | | | |
| Crop scenario  Growth stage | Indicator/generic focal species | | SVm | MAFm × TWA | DDDm  (mg/kg bw/d) | TERlt |
|  |  | |  |  |  |  |

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

#### Higher-tier risk assessment

Present a higher-tier risk assessment in line with EFSA/2009/1438, taking into account any information agreed on in the EU peer review. Every refinement of a parameter has to be fully justified, and higher-tier data should always be considered in the context of the whole available information (e.g., in an overall risk characterisation or weight-of-evidence assessment). Note that studies used for deriving refined assessment parameters are documented in Appendix 2.

Table 9.3‑3: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of formulation in crop (use/use group) – refined parameters (\*) are further described and justified in the text

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | | | |
| Active substance/product | | active substance 1 | | | | | | |
| Application rate (g/ha) | | n × xxx | | | | | | |
| Acute toxicity (mg/kg bw) | |  | | | | | | |
| TER criterion | |  | | | | | | |
| Focal species | Food category,  % in diet | | FIR/bw | RUD90 × DF  (mg/kg food) | MAF90 | PT | DDD90  (mg/kg bw/d) | TERa |
| *Species sp.* | xyz, x % | |  |  |  |  |  |  |
|  | yzx, y % | |  |  |  |  |  |  |
|  | zxy, z % | |  |  |  |  |  |  |
|  | whole diet | |  |  |  |  |  |  |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | | | |
| TER criterion | |  | | | | | | |
| Focal species | Food category,  % in diet | | FIR/bw | RUDm × DF  (mg/kg food) | MAFm × TWA | PT | DDDm  (mg/kg bw/d) | TERlt |
| *Species sp.* | xyz, x % | |  |  |  |  |  |  |
|  | yzx, y % | |  |  |  |  |  |  |
|  | zxy, z % | |  |  |  |  |  |  |
|  | whole diet | |  |  |  |  |  |  |

FIR/bw: Food intake rate per body weight; RUD: residue unit dose; DF: deposition factor (considering possible interception by the crop); MAF: multiple application factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

#### Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (*cf*. Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg).

With a K(f)oc of xxx, active substance 1belongs to the group of less/more sorptive substances. To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for mammals from all other intended uses in groups xxx (see 9.1.2).

|  |  |  |  |
| --- | --- | --- | --- |
| Effective application rate (g/ha) = |  |  |  |
| Acute toxicity (mg/kg bw) = |  | quotient = |  |
| Reprod. toxicity (mg/kg bw/d) = |  | quotient = |  |

Or

With a K(f)oc of xxx, active substance 1belongs to the group of less/more sorptive substances. Since the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) exceeds the critical value of 50/3000 for at least one use scenario, a quantitative risk assessment (calculation of TER values) is necessary.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for mammals from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.3‑4: Assessment of the risk for mammals due to exposure to active substance 1 via contaminated drinking water in puddles

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | |
| Active substance | | active substance 1 | | | | |
| Application rate (g/ha) | | n × xxx | | | | |
| Acute toxicity (mg/kg bw) | |  | | | | |
| TER criterion | | 10 | | | | |
| Reprod. toxicity (mg/kg bw/d) | |  | | | | |
| TER criterion | | 5 | | | | |
| Soil-relevant applic. rate  (g/ha) | Koc  (L/kg) | | PECpuddle  (mg/L) | DW uptake  (L/kg bw/d) | Daily dose  (mg/kg bw/d) | TERa |
| TERlt |
|  |  | |  | 0.24 |  |  |
|  |

PECpuddle: concentration in puddles; DW: drinking water; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

#### Effects of secondary poisoning

The log Pow of active substance 1 amounts to xxx and thus does not exceed/exceeds the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required.

Risk assessment for earthworm-eating mammals via secondary poisoning

Not required.

Or

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for mammals from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review. When an assessment is intended based on concentrations in porewater, thereupon considering the applicable default parameters from the Technical Guidance Document (TGD), the following lines of the table must be altered. Line 1: PECporewater instead of PECsoil; line 4: foc not relevant for this approach; line 5: BCFworm/water = (PECworm,ww/PECporewater) = (0.84 + 0.12 × Pow); line 6: consider gut content of earthworms if relevant.

Table 9.3‑5: Assessment of the risk for earthworm-eating mammals due to exposure to active substance 1 via bioaccumulation in earthworms (secondary poisoning) for the intended use in crop (use group)

| Parameter | active substance 1 | comments |
| --- | --- | --- |
| PECsoil (twa = 21 d) (mg/kg soil) |  |  |
| log Pow / Pow |  |  |
| Koc |  | Mean (n = xxx) |
| foc |  | Default |
| BCFworm |  | BCFworm/soil = (PECworm,ww/PECsoil,dw) = (0.84 + 0.12 × Pow) / foc × Koc |
| PECworm |  | PECworm = PECsoil × BCFworm/soil |
| Daily dietary dose (mg/kg bw/d) |  | DDD = PECworm × 1.28 |
| NOEL (mg/kg bw/d) |  |  |
| TERlt |  |  |

TER values shown in bold fall below the relevant trigger.

Risk assessment for fish-eating mammals via secondary poisoning

Not required.

Or

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water / is based on the regulatory acceptable concentration for aquatic organisms as a limit value for admissible concentrations of active substance 1 in water.

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.3‑6: Assessment of the risk for fish-eating mammals due to exposure to active substance 1 via bioaccumulation in fish (secondary poisoning) for the intended use in crop (use group)

|  |  |  |
| --- | --- | --- |
| Parameter | active substance 1 | comments |
| PECsw (twa = 21 d) (mg/L) |  |  |
| BCFfish |  |  |
| BMF |  | biomagnification factor (relevant for BCF ≥ 2000) |
| PECfish |  | PECfish = PECwater × BCFfish |
| Daily dietary dose (mg/kg bw/d) |  | DDD = PECfish × 0.142 |
| NOEL (mg/kg bw/d) |  |  |
| TERlt |  |  |

TER values shown in bold fall below the relevant trigger.

#### Biomagnification in terrestrial food chains

Not relevant.

Or:

Present an assessment addressing the potential of the active substances for biomagnification in terrestrial food chains if relevant.

### Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

Or:

Complete this section in case of application as baits, pellets, granules, prills or treated seed with the same sub-chapters as for the assessment for spray applications (“Not relevant” should then be stated under 9.3.2.)

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Available and relevant data, including data from the open literature for the active substance of concern, regarding the potential effects to reptiles and amphibians shall be presented and taken into account in the risk assessment. If relevant and where it cannot be predicted from the active substance data, the risk to amphibians and reptiles from the plant protection products shall be addressed. The type and conditions of the studies to be provided shall be discussed with the national competent authorities.

## Effects on aquatic organisms (KCP 10.2)

### Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with active substance 1 / and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents, as well as in Appendix 2 of this document (new studies).

Effects on aquatic organisms of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Or

However, the provision of further data on the formulation is not considered essential, because …

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Endpoint recalculations or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Table 9.5‑1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – active substance 1 / and relevant metabolites

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Oncorhynchus mykiss | active substance 1 | 96 h, s | LC50 = xxx mg a.s./L mm | EFSA Conclusion or Review Report  Author/Date/Study code |
| Pimephales promelas | active substance 1 | 278 d (FLC), f | NOEC = xxx mg a.s./L mm | EFSA Conclusion or Review Report  Author/Date/Study code |
| Daphnia magna | active substance 1 | 48 h, s | EC50 = xxx mg a.s./L mm | EFSA Conclusion or Review Report  Author/Date/Study code |
| Daphnia magna | active substance 1 | 21 d, ss | NOEC = xxx mg a.s./L mm | EFSA Conclusion or Review Report  Author/Date/Study code |
| Chironomus riparius | active substance 1 | 28 d, spiked sediment | NOEC = xxx mg a.s./L nom  NOEC = xxx mg a.s./kg sed. (dw) nom | EFSA Conclusion or Review Report  Author/Date/Study code |
| Pseudokirchneriella subcapitata | active substance 1 | 72 h, s | ErC50 = xxx mg a.s./L mm  EyC50 = xxx mg a.s./L mm  EbC50 = xxx mg a.s./L mm | EFSA Conclusion or Review Report  Author/Date/Study code |
| Lemna gibba | active substance 1 | 7 d, ss | ErC50 = xxx mg a.s./L mm  EyC50 = xxx mg a.s./L mm  EbC50 = xxx mg a.s./L mm | EFSA Conclusion or Review Report  Author/Date/Study code |
| Higher-tier studies (micro- or mesocosm studies) | | | | |
|  | | | | |

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5‑2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – formulation

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Oncorhynchus mykiss | formulation | 96 h, s | LC50 = xxx mg/L nom | EFSA Conclusion or Review Report  Author/Date/Study code |
| Daphnia magna | formulation | 48 h, s | EC50 = xxx mg/L nom | EFSA Conclusion or Review Report  Author/Date/Study code |
| Pseudokirchneriella subcapitata | formulation | 72 h, s | ErC50 = xxx mg/L nom  EyC50 = xxx mg/L nom  EbC50 = xxx mg/L nom | EFSA Conclusion or Review Report  Author/Date/Study code |
| Higher-tier studies (micro- or mesocosm studies) | | | | |
|  | | | | |

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS Step 1, 2 and 3 PECSW for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the table below.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for aquatic organisms from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review. Assessment factors to be used with refined effect values from species sensitivity distributions or higher-tier studies (micro- or mesocosms) must always be justified with regard to the necessary level of protection for potentially affected aquatic organisms.

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PECSW, PECSED) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

Table 9.5‑3: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for active substance 1 for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of formulation in crop (use/use group)

| Group |  | Fish acute | Fish prolonged | Inverteb. acute | Inverteb. prolonged | Algae | Sed. dwell. prolonged | Higher-tier information |  | group |  | Sed. dwell. prolonged |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Test species |  | *Oncorhynchus mykiss* | *Oncorhynchus mykiss* | *Daphnia magna* | *Daphnia magna* | *Pseudokirchn. subcapitata* | *Chironomus riparius* | *Species sp.* |  | *Species sp.* |  | *Chironomus riparius* |
| Endpoint |  | LC50 | NOEC | EC50 | NOEC | ErC50/EyC50 | NOEC | xxx |  | xxx |  | NOEC |
| (µg/L) |  | xxx | xxx | xxx | xxx | xxx | xxx | xxx |  | xxx |  | xxx |
| AF |  | 100 | 10 | 100 | 10 | 10 | 10 | xxx |  | xxx |  | 10 |
| RAC (µg/L) |  | xxx | xxx | xxx | xxx | xxx | xxx | xxx |  | xxx |  | xxx |
| FOCUS Scenario | PEC gl-max (µg/L) |  |  |  |  |  |  |  | xx-d PECtwa (µg/L) |  | PEC gl-max (µg/kg) |  |
| Step 1 |  |  |  |  |  |  |  |  |  |  |  |  |
|  | xxx |  |  |  |  |  |  |  |  |  |  |  |
| Step 2 |  |  |  |  |  |  |  |  |  |  |  |  |
| N-Europe | xxx |  |  |  |  |  |  |  |  |  |  |  |
| S-Europe | xxx |  |  |  |  |  |  |  |  |  |  |  |
| Step 3 |  |  |  |  |  |  |  |  |  |  |  |  |
| D1/ditch | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D1/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D2/ditch | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D2/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D3/ditch | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D4/pond | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D4/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D5/pond | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D5/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |
| D6/ditch | xxx |  |  |  |  |  |  |  |  |  |  |  |
| R1/pond | xxx |  |  |  |  |  |  |  |  |  |  |  |
| R1/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |
| R2/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |
| R3/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |
| R4/stream | xxx |  |  |  |  |  |  |  |  |  |  |  |

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses xxx, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for xxx as characterised by an EC50/LC50/NOEC/… for species of xxx in connection with an assessment factor of xxx) in several/all FOCUS Steps 1‑3 scenarios. Therefore, no further assessment is necessary / further PEC/RAC ratios were calculated based on FOCUS Step 4 PECSW considering reduced exposure of surface water bodies.

If FOCUS Step 4 calculations are required to demonstrate a safe use, a short description of the mitigation measures and their implementation in modelling should be provided. Preferably, such a statement is taken from Section 8 (Environmental Fate) of this report. The following table refers to typical widths of non-sprayed buffer zones and typical reduction classes for spray-drift reducing nozzles. With regard to run-off mitigation, meaningful values for vegetated filter strips must be selected case-specifically. PEC/RAC ratio calculations are necessary only for the organism group exposed to the highest level of risk (as identified above) and only for FOCUS scenarios with PEC/RAC ratios above 1.

Table 9.5‑4: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for active substance 1 based on FOCUS Step 4 calculations and toxicity data for group with mitigation of spray drift and run-off for the use of formulation in crop (use/use group)

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | | |
| Active substance | | active substance 1 | | | | | |
| Application rate (g/ha) | | n × xxx | | | | | |
| Nozzle reduction | No-spray buffer (m) | 1/3 | 5 | 10 | 15 | 20 | 30 |
| Vegetated filter strip (m) | xxx | xxx | xxx | xxx | xxx | xxx |
| None | scenario |  |  |  |  |  |  |
| 50 % |  |  |  |  |  |  |
| 75 % |  |  |  |  |  |  |
| 90 % |  |  |  |  |  |  |
| None | scenario |  |  |  |  |  |  |
| 50 % |  |  |  |  |  |  |
| 75 % |  |  |  |  |  |  |
| 90 % |  |  |  |  |  |  |
| RAC (µg/L) | |  | | | | | |
| … | | PEC/RAC ratio | | | | | |
| None | scenario |  |  |  |  |  |  |
| 50 % |  |  |  |  |  |  |
| 75 % |  |  |  |  |  |  |
| 90 % |  |  |  |  |  |  |
| None | scenario |  |  |  |  |  |  |
| 50 % |  |  |  |  |  |  |
| 75 % |  |  |  |  |  |  |
| 90 % |  |  |  |  |  |  |

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on bees (KCP 10.3.1)

This template for the bee risk assessment is based on the EPPO bee guidance from 2010 (EPPO Standard PP3/10 (3) Environmental risk assessment scheme for plant protection products. Chapter 10: Honeybees), as updated from the EPPO 2001 guidance, which is referred to in the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002). The recently developed EFSA bee guidance document is not noted yet. Thus, the assessment scheme currently addresses only honeybees, and does not mention bumblebees and/or solitary bees. However, in the case that studies or information on bumblebees and/or solitary bees are available, the information should be included. See points 9.6.3 and 9.6.4.

### Toxicity data

Studies on the toxicity to bees have been carried out with active substance 1 / and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on bees of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Or

However, the provision of further data on the formulation is not considered essential, because xxx

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Endpoint recalculations or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Table 9.6‑1: Endpoints and effect values relevant for the risk assessment for bees

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Apis mellifera | active substance 1 | Oral | LD50 = xxx µg/bee | EFSA Conclusion or Review Report  Author/Date/Study code |
| Apis mellifera | active substance 1 | Contact | LD50 = xxx µg/bee | EFSA Conclusion or Review Report  Author/Date/Study code |
| Apis mellifera | formulation | Oral | LD50 = xxx µg/bee | EFSA Conclusion or Review Report  Author/Date/Study code |
| Apis mellifera | formulation | Contact | LD50 = xxx µg/bee | EFSA Conclusion or Review Report  Author/Date/Study code |
| Higher-tier studies (tunnel test, field studies) | | | | |
|  | | | | |

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment

The evaluation of the risk for bees was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for birds from all other intended uses in groups xxx (see 9.1.2).

#### Hazard quotients for bees

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.6‑2: First-tier assessment of the risk for bees due to the use of formulation in crop (use/use group)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intended use | |  | | |
| Active substance | | active substance 1 | | |
| Application rate (g/ha) | | n × xxx | | |
| Test design | LD50 (lab.)  (µg/bee) | | Single application rate  (g/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity |  | |  |  |
| Contact toxicity |  | |  |
| Product | | formulation | | |
| Application rate (g/ha) | | n × xxx | | |
| Test design | LD50 (lab.)  (µg/bee) | | Single application rate  (g/ha) | QHO, QHC  criterion: QH ≤ 50 |
| Oral toxicity |  | |  |  |
| Contact toxicity |  | |  |

QHO, QHC: Hazard quotients for oral and contact exposure. QH values shown in bold breach the relevant trigger.

#### Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

Or:

Include a risk assessment based on the results of higher-tier studies. New higher-tier studies should be summarised in Appendix 2. The design of such studies as well as the selection of endpoints for the risk assessment must always be justified with regard to the necessary level of protection for bees. Higher-tier data should always be considered in the context of the whole available information (e.g., in an overall risk characterisation or weight-of-evidence assessment).

### Effects on bumble bees

Include a summary of the available data/information.

### Effects on solitary bees

Include a summary of the available data/information.

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on arthropods other than bees (KCP 10.3.2)

### Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with active substance 1 / and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target arthropods of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Or

However, the provision of further data on the formulation is not considered essential, because …

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Endpoint recalculations or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Table 9.7‑1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| Typhlodromus pyri  (protonymphs) | formulation | Laboratory test glass plates (2D) | LR50 = xxx g/ha  ER50 = xxx g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |
| Aphidius rhopalosiphi  (adults) | formulation | Laboratory test glass plates (2D) | LR50 = xxx g/ha  ER50 = xxx g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |
| Typhlodromus pyri  (protonymphs) | formulation | Extended laboratory test xxx leaves (2D/3D) | LR50 = xxx g/ha  ER50 = xxx g/ha  Or  Mortality:  x % at xxx g/ha y % at yyy g/ha z % at zzz g/ha  Red. of reproduction:  x % at xxx g/ha y % at yyy g/ha z % at zzz g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |
| Aphidius rhopalosiphi  (adults) | formulation | Extended laboratory test barley plants (3D) | LR50 = xxx g/ha  ER50 = xxx g/ha  Or  Mortality:  x % at xxx g/ha y % at yyy g/ha z % at zzz g/ha  Red. of fecundity:  x % at xxx g/ha y % at yyy g/ha z % at zzz g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |
| Species sp. | formulation | Aged-residue test xxx leaves (2D/3D) | Mortality at xxx g/ha:  x % at 0 DA(L)T y % at y DA(L)T  Or  Red. of <endpoint> at xxx g/ha:  x % at 0 DA(L)T y % at y DA(L)T | EFSA Conclusion or Review Report  Author/Date/Study code |
| Field or semi-field tests | | | | |
|  | | | | |

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev.2 (final), October 17, 2002), and in consideration of the recommendations of the guidance document ESCORT 2.

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review. This also holds for the ESCORT‑2 specific parameters MAF, vdf (depending on the design of the toxicity test) and CF.

#### Risk assessment for in-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for non-target arthropods from all other intended uses in groups xxx (see 9.1.2).

Calculate PERin-field values according to ESCORT 2 as:   
Application rate × MAF.

Table 9.7‑2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of formulation in crop (use/use group)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Intended use | |  | | |
| Active substance/product | |  | | |
| Application rate (g/ha) | | n × xxx | | |
| MAF | |  | | |
| Test species  Tier I | LR50 (lab.)  (g/ha) | | PERin‑field  (g/ha) | HQin-field  criterion: HQ ≤ 2 |
| *Typhlodromus pyri* |  | |  |  |
| *Aphidius rhopalosiphi* |  | |  |
| Test species  Higher-tier | Rate with ≤ 50 % effect\*  (g/ha) | | PERin‑field  (g/ha) | PERin-field below rate with ≤ 50 % effect? |
| *Species sp.* |  | |  | yes/no |
| Test species  Higher-tier | Rate with ≤ 50 % effect  (g/ha) at xxx DALT | | PERin‑field  (g/ha) | PERin-field below rate with ≤ 50 % effect? |
| *Species sp.* |  | |  | yes/no |

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

\* If an LR50 or ER50 from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

#### Risk assessment for off-field exposure

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for non-target arthropods from all other intended uses in groups xxx (see 9.1.2).

Calculate PERoff-field values according to ESCORT 2 as:   
Application rate × MAF × (drift factor/vegetation distribution factor)

Calculate the corrected PERoff-field values according to ESCORT 2 as:   
corr. PERoff-field = PERoff-field / correction factor

Table 9.7‑3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of formulation in crop (use/use group)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | | |
| Active substance/product | |  | | | | |
| Application rate (g/ha) | | n × xxx | | | | |
| MAF | |  | | | | |
| vdf | | 10 (Tier 1) / xxx (Higher-tier) | | | | |
| Test species  Tier I | LR50 (lab.)  (g/ha) | | Drift rate | PERoff‑field  (g/ha) | CF | HQoff-field  criterion: HQ ≤ 2 |
| *Typhlodromus pyri* |  | |  |  | 10 |  |
| *Aphidius rhopalosiphi* |  | |  |
| Test species  Higher-tier | Rate with ≤ 50 % effect\*  (g/ha) | | Drift rate | PERoff‑field  (g/ha) | CF | corr. PERoff-field below rate with ≤ 50 % effect? |
| *Species sp.* |  | |  |  | 5 | yes/no |

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

\* If an LR50 or ER50 from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

#### Additional higher-tier risk assessment

Not relevant.

Or:

Include a risk assessment based on the results of higher-tier studies. New higher-tier studies should be summarised in Appendix 2. The design of such studies as well as the selection of endpoints for the risk assessment must always be justified with regard to the necessary level of protection for non-target arthropods. Higher-tier data should always be considered in the context of the whole available information (e.g., in an overall risk characterisation or weight-of-evidence assessment).

#### Risk mitigation measures

No risk mitigation needed.

Or

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.7‑4: Assessment of the off-field risk for non-target arthropods due to the use of formulation in crop (use/use group) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | |
| Active substance/product | |  | | | |
| Application rate (g/ha) | | n × xxx | | | |
| MAF | |  | | | |
| vdf | |  | | | |
| Buffer strip  (m) | Drift rate  (%) | corr. PERoff-field  (g/ha) | corr. PERoff-field  50 % drift red.  (g/ha) | corr. PERoff-field  75 % drift red.  (g/ha) | corr. PERoff-field  90 % drift red.  (g/ha) |
| 1/3 |  |  |  |  |  |
| 5 |  |  |  |  |  |
| 10 |  |  |  |  |  |
| Tier 1 toxicity value | | HQoff-field | | | |
| LR50 = xxx g/ha | | criterion: HQ ≤ 2 | | | |
| 1/3 | |  |  |  |  |
| 5 | |  |  |  |  |
| 10 | |  |  |  |  |
| Higher-tier toxicity value | |  | | | |
| ER50/LR50 = xxx g/ha  Or  x % effect at xxx g/ha | | corr. PERoff-field below rate with ≤ 50 % effect  Or  ≤ ER50/LR50? | | | |
| 1/3 | | yes/no | yes/no | yes/no | yes/no |
| 5 | | yes/no | yes/no | yes/no | yes/no |
| 10 | | yes/no | yes/no | yes/no | yes/no |

MAF: Multiple application factor; PER: Predicted environmental rates; HQ: Hazard quotient; Criteria values shown in bold breach the relevant trigger.

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on non-target soil meso- and macrofauna (KCP 10.4)

### Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with active substance 1 and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Or

However, the provision of further data on the formulation is not considered essential, because …

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Endpoint recalculations or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Table 9.8‑1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Eisenia fetida* | active substance 1 | Mixed into substrate / Overspray 28 d, acute 5/10 % peat content | LC50 = xxx mg/kg dw  LC50,corr = xxx mg/kg dw\* | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Eisenia fetida* | active substance 1 | Mixed into substrate / Overspray 56 d, chronic 5/10 % peat content | NOEC = xxx mg/kg dw  NOECcorr = xxx mg/kg dw\* | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Folsomia candida* | active substance 1 | Mixed into substrate / Overspray 21 d, chronic 5 % peat content | NOEC = xxx mg/kg dw | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Hypoaspis aculeifer* | active substance 1 | Mixed into substrate 14 d, chronic 5 % peat content | NOEC = xxx mg/kg dw | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Eisenia fetida* | formulation | Mixed into substrate / Overspray 28 d, acute 5/10 % peat content | LC50 = xxx mg/kg dw  LC50,corr = xxx mg/kg dw\* | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Eisenia fetida* | formulation | Mixed into substrate / Overspray 56 d, chronic 5/10 % peat content | NOEC = xxx mg/kg dw  NOECcorr = xxx mg/kg dw\* | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Folsomia candida* | formulation | Mixed into substrate / Overspray 21 d, chronic 5 % peat content | NOEC = xxx mg/kg dw | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Hypoaspis aculeifer* | formulation | Mixed into substrate 14 d, chronic 5 % peat content | NOEC = xxx mg/kg dw | EFSA Conclusion or Review Report  Author/Date/Study code |
| Field studies | | | | |
|  | | | | |
| Litter bag test | | | | |
|  | | | | |

\* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

#### First-tier risk assessment

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3. According to the assessment of environmental-fate data, multi-annual accumulation in soil is / does not need to be considered for active substance 1.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for earthworms and other non-target soil organisms (meso- and macrofauna) from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.8‑2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of formulation in crop (use/use group)

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use |  | | |
| Acute effects on earthworms | | | |
| Product/active substance | LC50  (mg/kg dw) | PECsoil  (mg/kg dw) | TERa  (criterion TER ≥ 10) |
| active substance 1 |  |  |  |
| formulation |  |  |  |
| Chronic effects on earthworms | | | |
| Product/active substance | NOEC  (mg/kg dw) | PECsoil  (mg/kg dw) | TERlt  (criterion TER ≥ 5) |
| active substance 1 |  |  |  |
| formulation |  |  |  |
| Chronic effects on other soil macro- and mesofauna | | | |
| Product/active substance | NOEC  (mg/kg dw) | PECsoil  (mg/kg dw) | TERlt  (criterion TER ≥ 5) |
| active substance 1 |  |  |  |
| formulation |  |  |  |

TER values shown in bold fall below the relevant trigger.

#### Higher-tier risk assessment

Not relevant.

Or:

Include a risk assessment based on the results of higher-tier studies. New higher-tier studies should be summarised in Appendix 2. The design of such studies as well as the selection of endpoints for the risk assessment must always be justified with regard to the necessary level of protection for earthworms and other non-target soil organisms (meso- and macrofauna). Higher-tier data should always be considered in the context of the whole available information (e.g., in an overall risk characterisation or weight-of-evidence assessment).

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on soil microbial activity (KCP 10.5)

### Toxicity data

Studies on effects soil microorganisms have been carried out with active substance 1 and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on soil microorganisms of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Or

However, the provision of further data on the formulation is not considered essential, because …

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Endpoint recalculations or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Table 9.9‑1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

| Endpoint | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| N-mineralisation | active substance | 28 d, aerobic soil type | Nitrate formation rate  x mg/kg soil dw ± y % | EFSA Conclusion or Review Report  Author/Date/Study code |
| C-mineralisation | active substance | 14 d, aerobic soil type | CO2 formation  x mg/kg soil dw ± y % | EFSA Conclusion or Review Report  Author/Date/Study code |
| N-mineralisation | formulation | 28 d, aerobic soil type | Nitrate formation rate  x mg/kg soil dw ± y % | EFSA Conclusion or Review Report  Author/Date/Study code |
| C-mineralisation | formulation | 14 d, aerobic soil type | CO2 formation  x mg/kg soil dw ± y % | EFSA Conclusion or Review Report  Author/Date/Study code |

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment

The evaluation of the risk for soil microorganisms was performed in accordance with the recommendations of the “Guidance Document on Terrestrial Ecotoxicology”, as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

The relevant PECsoil for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for the soil microorganisms from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review.

Table 9.9‑2: Assessment of the risk for effects on soil micro-organisms due to the use of formulation in crop (use/use group)

|  |  |  |  |
| --- | --- | --- | --- |
| Intended use |  | | |
| N-mineralisation | | | |
| Product/active substance | Max. conc. with effects ≤ 25 % (mg/kg dw) | PECsoil  (mg/kg dw) | Risk acceptable? |
| active substance 1 | xxx (at xxx d) |  | yes/no |
| formulation | xxx (at xxx d) |  | yes/no |
| C-mineralisation | | | |
| Product/active substance | Max. conc. with effects ≤ 25 % (mg/kg dw) | PECsoil  (mg/kg dw) | Risk acceptable? |
| active substance 1 | xxx (at xxx d) |  | yes/no |
| formulation | xxx (at xxx d) |  | yes/no |

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on non-target terrestrial plants (KCP 10.6)

### Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with active substance 1 and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents as well as in Appendix 2 of this document (new studies).

Effects on non-target terrestrial plants of formulation were not evaluated as part of the EU assessment of active substance 1. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

Or

However, the provision of further data on the formulation is not considered essential, because xxx

The selection of studies and endpoints for the risk assessment is in line with / deviates from the results of the EU review process. Justifications are provided below.

The endpoints which are actually listed in the List of Endpoints (EFSA Conclusion, Review Report) should be included in the table. Endpoint recalculations or the use of a newly submitted endpoint should be documented in the table and discussed in the justification part. For all studies evaluated in the EU assessment, the reference to the final endpoint list (EFSA Conclusion or Review report) must be provided, but information on author(s), study data, and study code may be added as supplementary information.

Guideline-compliant toxicity tests are conducted with 6 or more species, of which those with the respective lowest ER50 values for each investigated biological endpoint should be listed in the toxicity data table. The calculation of an HC5 from a species-sensitivity distribution should be considered a probabilistic assessment of toxicity and thus also be reported in the toxicity data table.

Table 9.10‑1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

| Species | Substance | Exposure  System | Results | Reference |
| --- | --- | --- | --- | --- |
| *Species sp.*m/d1)  *Species sp.*m/d 2)  *Species sp.*m/d 3) | formulation | 21 d Seedling emergence | 1) ER50 emergence = xxx g/ha  2) ER50 plant weight = xxx g/ha  3) ER50 plant height = xxx g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Species sp.*[1] m/d  *…*  *Species sp.*[n] m/d | formulation | 21 d Seedling emergence | HC5 = … g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Species sp.*m/d1)  *Species sp.*m/d 2) | formulation | 21 d Vegetative vigour | 1) ER50 plant weight = xxx g/ha  2) ER50 plant height = xxx g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |
| *Species sp.*[1] m/d  *…*  *Species sp.*[n] m/d | formulation | 21 d Vegetative vigour | HC5 = xxx g/ha | EFSA Conclusion or Review Report  Author/Date/Study code |

m: monocotyledonous; d: dicotyledonous

#### Justification for new endpoints

Present a justification for any deviation from the EU agreed endpoints (see also SANCO/10328/2004– rev 8, 24.01.2012).

### Risk assessment

#### Tier-1 risk assessment (based screening data)

Not relevant.

Or

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for non-target terrestrial plants from all other intended uses in groups xxx (see 9.1.2).

Limit tests at rates up to xxx were conducted with formulation and effects were below the critical threshold as defined by the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). The limit test rates equal/exceed the highest field application rate in use group xxx and are thus considered an indicator for an acceptable risk.

#### Tier-2 risk assessment (based on dose-response data)

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

To achieve a concise risk assessment, the risk envelope approach is applied. Here, the assessment for the use group xxx also covers the risk for non-target terrestrial plants from all other intended uses in groups xxx (see 9.1.2).

In case of deviations from the standard risk assessment approach, present respective explanations and justifications, in particular on relevant aspects as agreed on in the EU peer review. Any selection of a MAF that is lower than the maximum number of applications in an intended use must be explained.

Calculate PERoff-field values as:   
Application rate × MAF × drift factor

If an HC5 from a species-sensitivity distribution is available and addresses the relevant endpoints, it should directly be applied in the risk assessment instead of the corresponding lowest ER50 for a single species.

Table 9.10‑2: Assessment of the risk for non-target plants due to the use of formulation in crop (use/use group)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | |
| Active substance/product | |  | | | |
| Application rate (g/ha) | | n × xxx | | | |
| MAF | |  | | | |
| Test species | ER50  (g/ha) | | Drift rate | PERoff‑field  (g/ha) | TER  criterion: TER ≥ 5 |
|  |  | |  |  |  |

MAF: Multiple application factor; PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

#### Higher-tier risk assessment

Not relevant.

Or:

Include a risk assessment based on the results of higher-tier studies. New higher-tier studies should be summarised in (see Appendix 2). The design of such studies as well as the selection of endpoints for the risk assessment must always be justified with regard to the necessary level of protection for non-target terrestrial plants. Higher-tier data should always be considered in the context of the whole available information (e.g., in an overall risk characterisation or weight-of-evidence assessment).

#### Risk mitigation measures

No risk mitigation needed.

Or

In order to reduce the off-field exposure, risk mitigation measures can be implemented. These correspond to unsprayed in-field buffer strips of a given width and/or the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (no-spray buffer zones of 5 or 10 m; drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table.

Table 9.10‑3: Risk assessment for non-target terrestrial plants due to the use of formulation in crop (use/use group) considering risk mitigation (in-field no-spray buffer zones, and drift-reducing nozzles)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Intended use | |  | | | |
| Active substance/product | |  | | | |
| Application rate (g/ha) | | n × xxx | | | |
| MAF | |  | | | |
| Buffer strip  (m) | Drift rate  (%) | PERoff-field  (g/ha) | PERoff-field  50 % drift red.  (g/ha) | PERoff-field  75 % drift red.  (g/ha) | PERoff-field  90 % drift red.  (g/ha) |
| 1/3 |  |  |  |  |  |
| 5 |  |  |  |  |  |
| 10 |  |  |  |  |  |
| Toxicity value | | TER | | | |
| ER50 = xxx g/ha | | criterion: TER ≥ 5 | | | |
| 1/3 | |  |  |  |  |
| 5 | |  |  |  |  |
| 10 | |  |  |  |  |

MAF: Multiple application factor; PER: Predicted environmental rates; TER: toxicity to exposure ratio. Criteria values shown in bold breach the relevant trigger.

### Overall conclusions

Insert a brief summary of the conclusions of the risk assessment. Only data and information considered in the previous sections, but no new information should be accounted for in the overall conclusions.

## Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Present and discuss any relevant information on possible adverse impacts of the product on organisms in the environment, which are not already addressed in the sections above.

## Monitoring data (KCP 10.8)

Present and discuss any relevant data from monitoring schemes aimed at gathering information on possible adverse effects of the product or its active ingredients on organisms in the environment.

## Classification and Labelling

Provide a justification for the proposed classification and labelling of the product.

**Table 9.13‑1: Critical endpoints and effect values relevant for the classification/labelling of aquatic organisms**

| **Organism** | **Species** | **Endpoint** | **Value** | **Reference** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **If applicable, please reference the details of the harmonised classification/labelling.**  **Substance name:**  **CAS-Nr.:**  **ATP/EU Regulation:**  **Hazard class:**  **M-factor:** | | | | |

**Table 9.13‑2: Implications for labelling resulting from ecotoxicological assessment:**

|  |  |
| --- | --- |
| **Classification under Regulation (EC) 1272/2008** | |
| Category: |  |
| Pictogram: |  |
| Signal word: |  |
| Hazard statement: |  |
| Precautionary statement: |  |
| **Justification of the classification proposal:** | |
| [Insert short summary which most critical endpoint was chosen, short summary of the summation method calculation etc.] | |

1. Lists of data considered in support of the evaluation

The following lists should include all product data considered in support of the evaluation, even if they may have been evaluated previously, e.g. in the EU peer review of the active substance(s), and thus, are not summarised in this document in detail. New data evaluated for the active substance(s) should be included as well.

Please sort by data points and within one data point by names of authors.

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report No  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
|  |  |  |  |  |  |

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
|  |  |  |  |  |  |

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
|  |  |  |  |  |  |

List of data relied on not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
| KCP XX | Author | YYYY | Title  Company Report N  Source  GLP/non GLP/GEP/non GEP  Published/Unpublished | Y/N | Owner |
|  |  |  |  |  |  |

1. Detailed evaluation of the new studies

In the following, summaries of all studies that were not previously assessed on EU level should be provided. Studies should be sorted by data points and within one data point by names of authors.

A grey box like presented below is intended for documenting the results of the study evaluation by the zRMS and must therefore be attached to each study summary.

* 1. KCP 10.1 Effects on birds and other terrestrial vertebrates
     1. KCP 10.1.1 Effects on birds
        1. KCP 10.1.1.1 Acute oral toxicity
           1. Study 1

|  |  |
| --- | --- |
| Comments of zRMS: | Comment on study; acceptable or not; deficiencies, corrections, according to recent guidelines or not, used in evaluation or only as additional information |

|  |  |
| --- | --- |
| Reference: | Data point |
| Report | Title, author(s), year, report No, document No, Authority registration No |
| Guideline(s): | Yes/No (If yes, give guidelines; If no, give justification, e.g., “ no guidelines available” or “ methods used comparable to guideline(s) xxx” ) |
| Deviations: | Yes/No (If yes, describe deviations from test guidelines) |
| GLP: | Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed) |
| Acceptability: | Yes/No/Supplementary |
| Duplication  (if vertebrate study) | Yes/No (If yes, provide justification of the steps taken to avoid animal testing in line with Art.33 (3) c.) |

**Materials and methods**

**Results and discussions**

**Conclusion**

* + - 1. KCP 10.1.1.2 Higher tier data on birds
    1. KCP 10.1.2 Effects on terrestrial vertebrates other than birds
       1. KCP 10.1.2.1 Acute oral toxicity to mammals
       2. KCP 10.1.2.2 Higher tier data on mammals
    2. KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)
  1. KCP 10.2 Effects on aquatic organisms
     1. KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes
     2. KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms
     3. KCP 10.2.3 Further testing on aquatic organisms
  2. KCP 10.3 Effects on arthropods
     1. KCP 10.3.1 Effects on bees
        1. KCP 10.3.1.1 Acute toxicity to bees
           1. KCP 10.3.1.1.1 Acute oral toxicity to bees
           2. KCP 10.3.1.1.2 Acute contact toxicity to bees
        2. KCP 10.3.1.2. Chronic toxicity to bees
        3. KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages
        4. KCP 10.3.1.4 Sub-lethal effects
        5. KCP 10.3.1.5 Cage and tunnel tests
        6. KCP 10.3.1.6 Field tests with honeybees
     2. KCP 10.3.2 Effects on arthropods other than bees
  3. KCP 10.4 Effects on non-target soil meso- and macrofauna
     1. KCP 10.4.1 Earthworms
        1. KCP 10.4.1.1 Earthworms - sub-lethal effects
        2. KCP 10.4.1.2 Earthworms - field studies
     2. KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)
        1. KCP 10.4.2.1 Species level testing
        2. KCP 10.4.2.2 Higher tier testing
  4. KCP 10.5 Effects on soil nitrogen transformation
  5. KCP 10.6 Effects on terrestrial non-target higher plants
     1. KCP 10.6.1 Summary of screening data
     2. KCP 10.6.2 Testing on non-target plants
     3. KCP 10.6.3 Extended laboratory studies on non-target plants
  6. KCP 10.7 Effects on other terrestrial organisms (flora and fauna)
  7. KCP 10.8 Monitoring data