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

Central Zone/Interzonal

Zonal Rapporteur Member State: zRMS

NATIONAL ADDENDUM The Netherlands

(authorization/extension of use/…)

Applicant: company name

Submission date: dd/mm/yyyy

MS Finalisation date: dd/mm/yyyy

Version history

When	What

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9 Ecotoxicology (KCP 10)

The text in the risk assessment of this NL-addendum represents the ecotoxicological risk assessment of The Netherlands. The applicant's point of view, when differing from the Dutch ecotoxicological risk assessor, is reported in the text of the risk assessment in Italic and is in this way clearly distinguishable as applicant's text. Thus, only the Italic text areas reflect statements or proposals which are not supported by the Dutch ecotoxicological risk assessor.

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.

This NL addendum template was made by NL based on the EU Core template of April 2015. The text highlighted in green should be deleted when the document is finalised.

General note on higher tier:
In case of Member State specific refinements or inconclusive core dossiers, a risk assessment similar to the core (but refined for the Netherlands) should be included.

Combination toxicology:
Combination toxicology is assessed for formulations containing more than one active substance, and for combinations of products, which are made according to the Instructions for Use as a tank mixture. Based on the precautionary principle, concentration-addition is assumed.

For pesticides the TER (Toxicity-Exposure Ratio) is used as a standard in the risk assessment (except for bees and other non-target arthropods and aquatic organisms, where HQ-values or PEC/RAC-ratios, respectively, are calculated).

The TER must be higher than a trigger value to comply with the standards.
The combination risk of formulations containing more than one active substance and for tank mixtures is calculated as follows:

When for each substance the trigger values are equal, the combined TER value can be calculated according to:

- TER_{combi} = trigger/((trigger/$TER_{substance\ 1}$)+(trigger/$TER_{substance\ 2}$)+(trigger/$TER_{substance\ 3}$))

An acceptable risk is expected when TER_{combi} > trigger.
In case of unequal triggers, the combined TER value can be calculated using the following formula:

- $Trigger_{combi}$ = $trigger_{substance\ 1}$/$trigger_{substance\ 2}$/$trigger_{substance\ i}$
- TER_{combi} = $trigger_{combi}$ /(($trigger_{substance\ 1}$ /$TER_{substance\ 1}$)+($trigger_{substance\ 2}$ /$TER_{substance\ 2}$)+($trigger_{substance\ i}$ /$TER_{substance\ i}$))

An acceptable risk is expected when TER_{combi} > $trigger_{combi}$.
In this formula, 'triggers' are the trigger values as mentioned in the corresponding chapter of the HTB (v1.0).

In the EFSA (2013) aquatic guidance, the determination of the possibility of adverse effects is expressed in PEC/RAC ratios. These ratios may be summed up for the different active substances and related to the trigger (default trigger is 1). If the summed PEC/RAC ratio (i.e. PEC/RAC_{combi}) is lower than the trigger value, the risk is considered acceptable.

In case toxicity of the formulation has been measured, the TER or the PEC/RAC ratio of the formulation is calculated with the PEC of the formulation and the toxicity value of the formulation. The PEC of the formulation is the sum of the PECs of the individual active substances. The toxicity value of the formulation is expressed in total amount active substance. Trigger/TER or PEC/RAC ratio must be smaller than 1.

In the risk assessment, the risk of combination toxicology is assessed using the highest trigger/TER or PEC/RAC ratio from the one based on the sum of the individual substances and the one based on formulation studies. When the standard of 1 is breached, the product is not permissible, unless an adequate risk assessment shows that there are no unacceptable effects under field conditions after application of the product according to the proposed GAP.

9.1 Critical GAP and overall conclusions for authorisation in The Netherlands

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: devel-opmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	**Conclusion of NL adden-dum*** **						
					Method / Kind	Timing / Growth stage of crop & season	Max. num-ber 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 arthro-	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
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

9.1.1 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 groupwise 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 9.1-2: 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

9.1.2 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 9.1-3 Metabolites of active substance 1

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

9.2 Effects on birds (KCP 10.1.1)

9.2.1 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 in Appen-

dix 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 of the core. In case a study is submitted specifically for NL, it should be summarised in Appendix 2 of this NL-addendum.

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	LD_{50} = xxx mg/kg bw	EFSA Conclusion or Review Report Author/Date/Study code
Species sp.	active substance 1	Dietary 8 d Short-term	LDD_{50} = 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 / off-spring effects on xxx)	EFSA Conclusion or Review Report Author/Date/Study code

9.2.1.1 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).

9.2.2 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 9.1.1).

Note NL: A justification must be provided to show that the national GAP is covered by the critical GAP.

In the case where the GAP is covered by the critical GAP used in the core assessment then no national specific addenda are required as there are currently no national specific requirements.

However, a few examples are shown below where a national specific assessment may be needed:

- When the GAP is not covered by the GAP in the core assessment.
- Where the PECsw in the core assessment is not performed to National requirements. The concentration in the surface water affects birds via secondary poisoning (see 9.2.2.4).
- Where member states have specific indicator species.
- Where higher tier refinement is needed.

The applicant should provide risk assessments as required, please refer to guidance for the core assessment for examples of the level of detail to provide.

In case of refinement based on so-called 'ecological parameters' (e.g. focal species with PD and/or PT), the applicant should provide support for the extrapolation of the risk assessment in the core dossier to the conditions in the Netherlands.

Please consider the Central Zone agreements of the harmonization workshops birds and mammals for the cases when the risk to birds and mammals should be addressed at national level. These agreements can be found on the Ctgb website in the Evaluation Manual, chapter 7, Ecotoxicology; terrestrial; birds and mammals; EU part.

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.

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

Note NL: Provide calculations of the TER to national requirements and/or support for the extrapolation of the core dossier risk assessment, if necessary.

9.2.2.2 Higher-tier risk assessment

Note NL: Provide calculations of the TER to national requirements and/or support for the extrapolation of the core dossier risk assessment, if necessary. In case of refinement based on so-called 'ecological parameters' (e.g. focal species with PD and/or PT), the applicant should provide support for the extrapolation of the risk assessment in the core dossier to the conditions in the Netherlands.

9.2.2.3 Drinking water exposure

Note NL: Provide information relevant for the national submission or cross reference the core assessment.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} 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

Note NL: Provide information relevant for the national submission or cross reference the core assessment.

Risk assessment for fish-eating birds via secondary poisoning

Note NL: Provide information relevant for the national submission as the NL specific drift rates are used to calculate exposure to the off-field surface water.

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 9.2-2: 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
PEC_{sw} (twa = 21 d) (mg/L)		
BCF_{fish}		
BMF		biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}		$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)		$DDD = PEC_{fish} \times 0.159$
NOEL (mg/kg bw/d)		
TER_{lt}		

TER values shown in bold fall below the relevant trigger.

9.2.2.5 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.

Note NL: Provide information relevant for the national submission or cross reference the core assessment.

9.2.3 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.)

Note NL: In case of higher tier: provide calculations of the TER to national requirements and/or support for the extrapolation of the core dossier risk assessment, if necessary. In case of refinement based on so-called 'ecological parameters' (e.g. focal species with PD and/or PT), the applicant should provide support for the extrapolation of the risk assessment in the core dossier to the conditions in the Netherlands.

9.2.4 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to birds.

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

9.3.1 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	LD_{50} = 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

9.3.1.1 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).

9.3.2 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 9.1.1).

Note NL: A justification must be provided to show that the national GAP is covered by the critical GAP. In the case where the GAP is covered by the critical GAP used in the core assessment then no national specific addenda are required as there are currently no national specific requirements.

However, a few examples are shown below where a national specific assessment may be needed:

- When the GAP is not covered by the GAP in the core assessment.
- Where the PECsw in the core assessment is not performed to National requirements. The concentration in the surface water affects birds via secondary poisoning (see 9.2.2.4)..
- Where member states have specific indicator species.
- Where higher tier refinement is needed.

The applicant should provide risk assessments as required, please refer to guidance for the core assessment for examples of the level of detail to provide.

In case of refinement based on so-called 'ecological parameters' (e.g. focal species with PD and/or PT), the applicant should provide support for the extrapolation of the risk assessment in the core dossier to the conditions in the Netherlands.

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.

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

Note NL: Provide calculations of the TER to national requirements and/or support for the extrapolation of the core dossier risk assessment, if necessary.

9.3.2.2 Higher-tier risk assessment

Note NL: Provide calculations of the TER to national requirements and/or support for the extrapolation of the core dossier risk assessment, if necessary. In case of refinement based on so-called 'ecological parameters' (e.g. focal species with PD and/or PT), the applicant should provide support for the extrapolation of the risk assessment in the core dossier to the conditions in the Netherlands.

9.3.2.3 Drinking water exposure

Note NL: Provide information relevant for the national submission or cross reference the core assessment.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} 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

Note NL: Provide information relevant for the national submission or cross reference the core assessment.

Risk assessment for fish-eating mammals via secondary poisoning

Note NL: Provide information relevant for the national submission as the specific drift rates are used to calculate exposure to the off-field surface water.

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 pre-

dicted 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 9.3-2: 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
PEC_{sw} (twa = 21 d) (mg/L)		
BCF_{fish}		
BMF		biomagnification factor (relevant for BCF ≥ 2000)
PEC_{fish}		$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)		$DDD = PEC_{fish} \times 0.142$
NOEL (mg/kg bw/d)		
TER_{lt}		

TER values shown in bold fall below the relevant trigger.

9.3.2.5 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.

Note NL: Provide information relevant for the national submission or cross reference the core assessment.

9.3.3 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.)

Note NL: In case of higher tier: provide calculations of the TER to national requirements and/or support for the extrapolation of the core dossier risk assessment, if necessary. In case of refinement based on so-called 'ecological parameters' (e.g. focal species with PD and/or PT), the applicant should provide support for the extrapolation of the risk assessment in the core dossier to the conditions in the Netherlands.

9.3.4 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to mammals.

9.4 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.

Note NL: A reference to the core dossier can be made.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Note NL: **For the national addendum, national specific drift rates are used to calculate exposure to off-field areas (both surface water and land). Based on these national specific exposure calculations, national specific risk calculations for aquatic organisms should be performed below.** 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 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	LC_{50} = 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	EC_{50} = 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	E_rC_{50} = xxx mg a.s./L $_{mm}$ E_yC_{50} = xxx mg a.s./L $_{mm}$ E_bC_{50} = xxx mg a.s./L $_{mm}$	EFSA Conclusion or Review Report Author/Date/Study code
Lemna gibba	active substance 1	7 d, ss	E_rC_{50} = xxx mg a.s./L $_{mm}$ E_yC_{50} = xxx mg a.s./L $_{mm}$ E_bC_{50} = 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	LC_{50} = xxx mg/L $_{nom}$	EFSA Conclusion or Review Report Author/Date/Study code
Daphnia magna	formulation	48 h, s	EC_{50} = xxx mg/L $_{nom}$	EFSA Conclusion or

Species	Substance	Exposure System	Results	Reference
				Review Report Author/Date/Study code
Pseudokirchneriella subcapitata	formulation	72 h, s	E_rC_{50} = xxx mg/L $_{nom}$ E_yC_{50} = xxx mg/L $_{nom}$ E_bC_{50} = 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

9.5.1.1 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).

9.5.2 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).
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 9.1.1).

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 (PEC_{SW}, PEC_{SED}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for TOXSWA PEC_{SW} (n.b. see section B8) 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 TOXSWA calculations for the use of formulation in crop (use/use group)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophyte**	**Sed. dwell. prolonged**	**Higher-tier information**		**Sed. dwell. prolonged**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemna gibba***	***Chironomus riparius***	***Species sp.***		***Chironomus riparius***
Endpoint		LC_{50}	EC_{10}/ NOEC	EC_{50}	EC_{10}/ NOEC	E_rC_{50}[1]	E_rC_{50}[1]	EC_{10}/ NOEC	xxx		EC_{10}/ NOEC
(µg/L)		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx		xxx
AF		100	10	100	10	10	10	10	xxx		10
RAC (µg/L)		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx		xxx
TOXSWA (…% drift)	**PEC sw (µg/L)**									**PEC sed (µg/kg)**	
Scenario	xxx									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;
[1] See Ctgb Evaluation Manual on E_rC_{50} (E_yC_{50}), chapter 4.3 point 3.

Table 9.5-4: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for active substance 1 based on TOXSWA calculations and toxicity data for group with mitigation of spray drift (describe which mitigation measure you did consider) for the use of formulation in crop (use/use group)

Group		**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophyte**	**Sed. dwell. prolonged**	**Higher-tier information**		**Sed. dwell. prolonged**
Test species		***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemna gibba***	***Chironomus riparius***	***Species sp.***		***Chironomus riparius***
Endpoint		LC_{50}	EC_{10}/ NOEC	EC_{50}	EC_{10}/ NOEC	E_rC_{50}[1]	E_rC_{50}[1]	EC_{10}/ NOEC	…		EC_{10}/ NOEC
(µg/L)		…	…	…	…	…	…	…	…		…
AF		100	10	100	10	10	10	10	…		10
RAC (µg/L)		…	…	…	…	…	…	…	…		…
TOXSWA (…%drift)	**PECsw (µg/L)**									**PEC sed (µg/kg)**	
Scenario	…									…	

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold;[1] See Ctgb Evaluation Manual on E_rC_{50} (E_yC_{50}), chapter 4.3 point 3.

NL: Combination toxicology

At the ecotoxicology harmonization workshop held in Vienna in April 2015, the combination toxicology as per the new EFSA aquatic GD was discussed. It was concluded that there are many points in need for further clarification in order to understand how the equations given in Chapter 10 can be applied. Therefore, for the NL addendum, the calculation of the combination toxicology should be performed as explained above in Chapter 9.

Table 9.5-5: Aquatic organisms: Combination toxicology and acceptability of risk (ΣPEC/RAC < 1) for the use of formulation in crop (use/use group)

Group	**Fish acute**	**Fish prolonged**	**Inverteb. acute**	**Inverteb. prolonged**	**Algae**	**Aquatic macrophyte**	**Sed. dwell. prolonged**	**Higher-tier information**	**Sed. dwell. prolonged (sed.)**
Test species	***Oncorhynchus mykiss***	***Oncorhynchus mykiss***	***Daphnia magna***	***Daphnia magna***	***Pseudokirchn. subcapitata***	***Lemna gibba***	***Chironomus riparius***	***Species sp.***	***Chironomus riparius***
$PEC/RAC_{a.s.1}$									
$PEC/RAC_{a.s.2}$									
$PEC/RAC_{a.s.3}$									

Group	Fish acute	Fish pro-longed	Inver-teb. acute	Inver-teb. pro-longed	Algae	Aquatic macro-phyte	Sed. dwell. pro-longed	Higher-tier in-for-mation	Sed. dwell. pro-longed (sed.)
ΣPEC/RAC									

9.5.3 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to aquatic organisms. Please specify if drift reducing measures are necessary.

9.6 Effects on bees (KCP 10.3.1)

Note NL: In the case where the GAP is covered by the critical GAP used in the core assessment then no national specific addenda are required as there are currently no national specific requirements.

In the case where the GAP is not covered then a national addendum will need to be prepared. The applicant should provide risk assessments as required, please refer to guidance for the core assessment for examples of the level of detail to provide.

9.6.1 Toxicity data

9.6.2 Risk assessment

9.6.3 Effects on bumble bees

9.6.4 Effects on solitary bees

9.6.5 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to bees.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

Note NL: For the national addendum, national specific drift rates are used to calculate exposure to off-field areas (both surface water and land). Therefore, the off-field risk assessment for non-target arthropods should be always addressed in the NL addendum.

In the case where the GAP is covered by the critical GAP used in the core assessment then no in-field risk assessment needs to be conducted and only off-field risk needs to be addressed. In the case where the GAP is not covered then the in-field risk assessment along with off-field risk assessment should be included in the national addendum.

9.7.1 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 the core or 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 of the core. In case a study is submitted specifically for NL, it should be summarised in Appendix 2 of this NL-addendum.

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)	LR_{50} = xxx g/ha ER_{50} = xxx g/ha	EFSA Conclusion or Review Report Author/Date/Study code
Aphidius rhopalosiphi (adults)	formulation	Laboratory test glass plates (2D)	LR_{50} = xxx g/ha ER_{50} = xxx g/ha	EFSA Conclusion or Review Report Author/Date/Study code

Species	Substance	Exposure System	Results	Reference
Typhlodromus pyri (protonymphs)	formulation	Extended laboratory test xxx leaves (2D/3D)	LR_{50} = xxx g/ha ER_{50} = 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)	LR_{50} = xxx g/ha ER_{50} = 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				

9.7.1.1 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).

9.7.2 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.

9.7.2.1 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 9.1.1).

Calculate $PER_{in\text{-}field}$ 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)** **MAF**	n × xxx		
Test species **Tier I**	**LR_{50} (lab.)** **(g/ha)**	**$PER_{in\text{-}field}$** **(g/ha)**	**$HQ_{in\text{-}field}$** **criterion: HQ ≤ 2**
Typhlodromus pyri			
Aphidius rhopalosiphi			
Test species **Higher-tier**	**Rate with ≤ 50 % effect*** **(g/ha)**	**$PER_{in\text{-}field}$** **(g/ha)**	**$PER_{in\text{-}field}$ below rate with ≤ 50 % effect?**
Species sp.			yes/no
Test species **Higher-tier**	**Rate with ≤ 50 % effect** **(g/ha) at xxx DALT**	**$PER_{in\text{-}field}$** **(g/ha)**	**$PER_{in\text{-}field}$ 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 LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 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 9.1.1).

Note NL: For the national addendum, national specific drift rates are used to calculate exposure to off-field areas (both surface water and land). Please note that the exposure of the natural enemies/ beneficials for integrated pest management should be considered in the NL addendum as well.
Based on these national specific exposure calculations, national specific risk calculations for non-target arthropods off-field are performed below.

For the off-field risk assessment on non-target arthropods in accordance with ESCORT2, drift values are used to estimate the off-crop risk. The risk for non-target arthopods is assessed by calculating Hazard

Quotients. For this, Lethal Rate values (LR_{50}) are needed. In the first tier risk assessment, based on LR_{50}-values from laboratory studies with the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri,*an off-field Hazard Quotient (HQ) can be calculated according to the assessment method established in the SETAC/ESCORT 2 workshop. Hazard Quotients should be below the trigger value of 2 to meet the standards. The resulting Hazard Quotients are presented in the Table below. Please note that the drift factor depends on crop, see the Dutch Evaluation Manual and the WDC drift calculator tool.

Note to the applicant: Please note that for higher tier studies the CF is 5 and not 10. In the case the study was conducted on plants (i.e. 3-D system), then no VDF should be used.

Calculate $PER_{off\text{-}field}$ values according to ESCORT 2 as:
Application rate × MAF × (drift factor/vegetation distribution factor)

Calculate the corrected $PER_{off\text{-}field}$ values according to ESCORT 2 as:
corr. $PER_{off\text{-}field}$ = $PER_{off\text{-}field}$ / 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	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri				10	
Aphidius rhopalosiphi					
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ 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 LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

Or:

Include a risk assessment based on the results of higher-tier studies. New higher-tier studies not evaluated in the core should be summarised in Appendix 2 of this NL-addendum. 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).

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

Or

In order to reduce the off-field exposure, risk mitigation measures can be implemented..The results of the risk assessment using typical mitigation measures (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 (drift-reducing nozzles)

Intended use	
Active substance/product	
Application rate (g/ha)	n × xxx
MAF	
vdf	10 (Tier 1) / xxx (Higher-tier)

Test species Tier I	**LR_{50} (lab.) (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**$HQ_{off\text{-}field}$ criterion: HQ ≤ 2**
Typhlodromus pyri				10	
Aphidius rhopalosiphi					
Test species Higher-tier	**Rate with ≤ 50 % effect* (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**CF**	**corr. $PER_{off\text{-}field}$ 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 LR_{50} or ER_{50} from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.3 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to non-target arthropods. The need for drift reducing measures or warning sentences for IPM uses should be stated here.

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

Note NL: In the case where the GAP is covered by the critical GAP used in the core assessment then no national specific addenda are required. In the case where the GAP is not covered then a national addendum will need to be prepared.

9.8.1 Toxicity data

9.8.2 Risk assessment

9.8.3 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to earthworms and other soil macro-organisms.

9.9 Effects on soil microbial activity (KCP 10.5)

Note NL: In the case where the GAP is covered by the critical GAP used in the core assessment then no national specific addenda are required. In the case where the GAP is not covered then a national addendum will need to be prepared.

9.9.1 Toxicity data

9.9.2 Risk assessment

9.9.3 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to soil micro-organisms.

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

For the national addendum, national specific drift rates are used to calculate exposure to off-field areas (both surface water and land). Therefore, the effects on non-target terrestrial plants will need to be addressed in the national addendum.

9.10.1 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 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/d [1] *Species sp.* m/d [2] *Species sp.* m/d [3]	formulation	21 d Seedling emergence	[1] ER_{50} emergence = xxx g/ha [2] ER_{50} plant weight = xxx g/ha [3] ER_{50} 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/d [1] *Species sp.* m/d [2]	formulation	21 d Vegetative vigour	[1] ER_{50} plant weight = xxx g/ha [2] ER_{50} 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

9.10.1.1 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).

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based on 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 9.1.1).
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.

9.10.2.2 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 when necessary. 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 9.1.1).

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 $PER_{off\text{-}field}$ 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 ER_{50} for a single species.

Note NL: The risk assessment for non-target plants is based on an off-crop situation with a drift percentage which depends on the type of use and application. The exposure equals: application rate * drift percentage * MAF (in case of multiple application). The drift percentage depends on the crop type, please refer to the Dutch Evaluation Manual and the WDC drift calculator tool.
A TER is calculated with the lowest EC50 value from a laboratory test with higher plants and the exposure concentration. The lowest EC50 is xxx for [plant species]. See the Table below for TER calculation.

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)** **MAF**	n × xxx			
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (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.

9.10.2.3 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 of this NL-addendum when not included in the core.. 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).

9.10.2.4 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 the usage of drift reducing nozzles. The results of the risk assessment using typical mitigation measures (drift-reducing nozzles with reduction by 50 %, 75 %, or 90 %) are summarised in the following table. Please note that if HC5 is used for refinements the TER criterion is 1 and not 5.

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 (drift-reducing nozzles; mention here the possible drift reducing measures)

Intended use **Active substance/product** **Application rate (g/ha)** **MAF**	n × xxx			
Test species	**ER_{50} (g/ha)**	**Drift rate**	**$PER_{off\text{-}field}$ (g/ha)**	**TER criterion: TER ≥ 5**

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

bold breach the relevant trigger.

9.10.3 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.

Note NL: The overall conclusions should refer to whether or not for the uses applied in the Netherlands, the product can be regarded as safe to non-target terrestrial plants. Please mention the drift reducing measures required, if necessary.

9.11 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.

9.12 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.

9.13 Classification and Labelling

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

Appendix 1 Lists of data considered in support of the evaluation

The following lists should include all data considered in support of the NL evaluation.

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 specifically for NL 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

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

Appendix 2 Detailed evaluation of the new studies – only submitted for the product's evaluation in NL

In the following, summaries of all studies that were not previously assessed on EU level or in the core 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 cRMS and must therefore be attached to each study summary.

A 2.1 KCP 10.1 Effects on birds and other terrestrial vertebrates

A 2.1.1 KCP 10.1.1 Effects on birds

A 2.1.1.1 KCP 10.1.1.1 Acute oral toxicity

A 2.1.1.1.1 Study 1

Comments of cRMS:	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

A 2.1.1.2 KCP 10.1.1.2 Higher tier data on birds

A 2.1.2 KCP 10.1.2 Effects on terrestrial vertebrates other than birds

A 2.1.2.1 KCP 10.1.2.1 Acute oral toxicity to mammals

A 2.1.2.2 KCP 10.1.2.2 Higher tier data on mammals

A 2.1.3 KCP 10.1.3 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians)

A 2.2 KCP 10.2Effects on aquatic organisms

A 2.2.1 KCP 10.2.1 Acute toxicity to fish, aquatic invertebrates, or effects on aquatic algae and macrophytes

A 2.2.2 KCP 10.2.2 Additional long-term and chronic toxicity studies on fish, aquatic invertebrates and sediment dwelling organisms

A 2.2.3 KCP 10.2.3 Further testing on aquatic organisms

A 2.3 KCP 10.3 Effects on arthropods

A 2.3.1 KCP 10.3.1 Effects on bees

A 2.3.1.1 KCP 10.3.1.1 Acute toxicity to bees

A 2.3.1.1.1 KCP 10.3.1.1.1 Acute oral toxicity to bees

A 2.3.1.1.2 KCP 10.3.1.1.2 Acute contact toxicity to bees

A 2.3.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.3.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A 2.3.1.4 KCP 10.3.1.4 Sub-lethal effects

A 2.3.1.5 KCP 10.3.1.5 Cage and tunnel tests

A 2.3.1.6 KCP 10.3.1.6 Field tests with honeybees

A 2.4 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.4.1 KCP 10.4.1 Earthworms

A 2.4.1.1 KCP 10.4.1.1 Earthworms - sub-lethal effects

A 2.4.1.2 KCP 10.4.1.2 Earthworms - field studies

A 2.4.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

A 2.4.2.1 KCP 10.4.2.1 Species level testing

A 2.4.2.2 KCP 10.4.2.2 Higher tier testing

A 2.5 KCP 10.5 Effects on soil nitrogen transformation

A 2.6 KCP 10.6 Effects on terrestrial non-target higher plants

A 2.6.1 KCP 10.6.1 Summary of screening data

A 2.6.2 KCP 10.6.2 Testing on non-target plants

A 2.6.3 KCP 10.6.3 Extended laboratory studies on non-target plants

A 2.7 KCP 10.7 Effects on other terrestrial organisms (flora and fauna)

A 2.8 KCP 10.8 Monitoring data