DRAFT REGISTRATION REPORT
Part B

Section 8
Environmental Fate

Detailed summary of the risk assessment

Product code: <xxx>

Product name(s): <xxx>

Active substance(s):

<active_substance_1>, <conc1> g/L or g/kg
<active_substance_2>, <conc2> g/L or g/kg
<active_substance_3>, <conc3> g/L or g/kg
<active_substance_4>, <conc4> g/L or g/kg

Central Zone

Zonal Rapporteur Member State: <zRMS>

NATIONAL ADDENDUM The Netherlands

(authorisation/extension of use/<…>)

Applicant: <company name>
Submission date: <dd/mm/yyyy>

MS finalisation date: <dd/mm/yyyy>

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8 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KCP 9)

This document is to be used by the applicant of a plant protection product for registration at Member State level. It has been designed to provide guidance on the preparation of Part B Section 8 (Environmental Fate) of the draft registration report (dRR) and on the information required specifically for this section. This guidance is applicable to the national addendum (if submitted) for the Netherlands.

Notes: Text shaded turquoise provides general information/support and should be deleted when the document is finalized. Texts 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: tables can be added or deleted.

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

Critical GAP and overall conclusions

Table 8-1 Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
					Application				**Application rate**					**Conclusion**	
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)	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	PHI (days)	Remarks: e.g. g saf-ener/ synergist per ha	Groundwater	Drinking water
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 “Conclusion”

A	Safe use
Afr	Further refinement and/or risk mitigation measures required
N	No safe use

Metabolites considered in the assessment

Table 8-2 Metabolites of <active substance 1> potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
			Soil/Water/Sediment: > 10 % of a.s. or > 5 % of as in 2 sequential measurements or > 5 % of a.s. and maximum of formation not yet reached at the end of the study	PEC_{GW}: leaching potential to groundwater $PEC_{sw/sed}$: if not covered by EU assessment

If metabolites are covered by the EU assessment (e.g. lead formulation,…) no further risk assessment will be necessary.

8.1 RATE OF DEGRADATION IN SOIL (KCP 9.1.1)

The rate of degradation in soil is considered as core data since there are no specific national requirements. All studies are presented in the core assessment for the formulation.

8.2 FIELD STUDIES (KCP 9.1.1.2)

The field studies in soil are considered as core data since there are no specific national requirements. All studies are presented in the core assessment for the formulation.

8.3 MOBILITY IN SOIL (KCP 9.1.2)

The studies on mobility in soil are considered as core data since there are no specific national requirements. All studies (with the possible exception of 8.3.1) are presented in the core assessment for the formulation.

8.3.1 LYSIMETER STUDIES (KCP 9.1.2.2)

For a general description of the study and optionally a standardisation according to guidance[1] please refer to the core assessment.

If a Dutch specific evaluation of the study is necessary –e.g., if standardisation is not carried out in the core assessment - the following text is suggested:
In a lysimeter experiment with dose rate once or twice x g a.i./ha average yearly concentration of the a.s. [name] and its metabolites [name] in the percolate was [xx] µg/L. Average concentration of the a.s. [name] and its metabolites [name] was [xx] µg/L. A standardisation of the lysimeter study was presented by the applicant. This standardisation has been summarised and evaluated.

When the method of Verschoor is applied the following text is suggested:
Simulation errors for the a.s. [name] and its metabolites [name] were calculated based on average relative formation rate of the metabolites for [number] soil types of the soil degradation studies.
Simulation errors of lysimeters X and Y can be used for the risk assessment. According to Van der Linden et al., the adjustment factor for leaching estimations in the authorisation procedure is x (x experiments, x number of lysimeter soils, x degree of freedom, t-value = x).

If only a single lysimeter experiment is available the adjustment factor becomes:

$$f_{adj} = \exp(0.5457 \cdot SE) = SE^{0.5457}$$

where SE is the simulation error of the single lysimeter experiment. From the available studies a simulation error of [xxx] is derived. This SE is used in 8.6 to refine the modelling results.

8.4 DEGRADATION IN THE WATER/SEDIMENT SYSTEMS (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

The degradation in water-sediment system is considered as core data since there are no specific national requirements. All studies are presented in the core assessment for the formulation.

[1] Report of the FOCUS Ground Water Work Group, Version 3 of 10 October 2014. EC Document Reference Sanco/13144/2010 version 3, 613pp.

8.5 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC_{SOIL}) (KCP 9.1.3)

This is not an NL specific aspect.
In the case where it is not possible to define a critical GAP (risk envelope) that covers all the uses in the zone and results in an acceptable PEC soil calculation then PEC calculations will need to be performed to national GAPs and to national requirements. Then, the template for the core assessment can be adopted.
In all other cases, reference to the core assessment should be made.

Please refer to the core assessment.

8.6 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN GROUNDWATER (PEC_{GW}) (KCP 9.2.4)

This is an NL specific aspect.
The first tier can be taken from the core (FOCUS-PEARL 4.4.4 or higher, Kremsmünster scenario). However please note that The Netherlands apply an additional threshold of 0.01 µg/L for groundwater protection areas. When this trigger is exceeded either a (generic) restriction sentence should be placed on the label or higher tier modelling should be performed. Furthermore, in specific cases The Netherlands requests an additional assessment (see Evaluation Manual NL part, Chapter 6 Leaching).
As a higher tier the GeoPEARL 3.3.3 national model should be used (only applicable to field uses). The higher tier can also take into account the adjustment factor based on the standardisation of available lysimeter studies, if available. The adjustment factors may be used on the Tier 1 results from the core based on the appropriate FOCUS-PEARL version and scenario and/or on the Tier 2 GeoPEARL results. See below for example lay-out.

In the case where it is not possible to define a critical GAP (risk envelope) that covers all the uses in the zone and results in an acceptable PEC groundwater calculation then PEC calculations will need to be performed to national GAPs and to national requirements.

8.6.1 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).

8.6.2 ACTIVE SUBSTANCE(S) AND RELEVANT METABOLITE(S) (KCP 9.2.4.1)

Provide reference to study by applicant or recalculation by zRMS

Table 8.6-1 Input parameters related to application for PEC_{GW} calculations

Crop		
Application rate (g as/ha)	<active substance 1>: <active substance 2>:	
Number of applications/interval (d)		
Crop interception (%)		
Frequency of application	annual, biennial, triennial	
Models used for calculation	FOCUS PEARL v4.4.4,	

Table below only required if absolute application dates used. Otherwise delete table. Please note that for the Dutch national assessment default dates for spring applications (May 25th) and autumn applications (November 1st) are used, unless the GAP clearly indicates that other dates should be chosen.

Table 8.6-2 Application dates used for groundwater risk assessment

Crop	Scenario	Application dates (absolute)
	Kremsmünster	

Table 8.6-3 Input parameters related to active substance <active substance 1> and metabolite(s) for PEC_{GW} calculations

Compound	<active substance 1>	<metabolite 1>	<metabolite 2>	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)				
Water solubility (g/mol):				
Saturated vapour pressure (Pa):				
DT_{50} in soil (d)	(geomean/median, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58/2.2, n =<x>)			
DT_{50} in soil (d) lab/field	acidic soil: neutral/alkaline soils:			delete row in case of no pH dependency
K_{foc} (mL/g)/K_{fom}	… (arithmetic mean/median, n = <x>) … (pH …) … (pH …)			
1/n	… (arithmetic mean/median, n = <x>)			
Plant uptake factor	0			Default value is 0, unless there is experimental or other adequate proof that another value is justified
Formation fraction	-	… from	… from	

PEC_{GW} for <active substance 1>, <metabolite 1>, <metabolite 2>

Table 8.6-4 PEC_{GW} for <active substance 1> and <metabolite(s)> on <crop> with FOCUS PEARL 4.4.4 and the Kremsmünster scenario (taken from core)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)		
		<active substance 1>	<metabolite 1>	<metabolite 2>
	<insert scenario crop choice used for assessment>			

In case of higher tier modelling the following text is suggested.

In the second tier, leaching in potential area of use is evaluated using the spatial distribution model GeoPEARL 3.3.3.

If no standardised lysimeters are available:
The leaching potential of substances to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL model. The same input data as used in the first tier with Pearl 4.4.4 is employed. Additional input is the crop and the number of plots (minimum 250). For results see Table 8.6-5.

Table 8.6-5 PEC_{GW} for <active substance 1> and <metabolite(s)> on <crop> (with GeoPEARL 3.3.3)

Crop	Scenario	90th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)		
		<active substance 1>	<metabolite 1>	<metabolite 2>
	<insert scenario crop choice used for assessment>			

GeoPEARL calculations show that the predicted leachate concentrations for [name] are smaller than 0.1 µg/L.

If predicted leaching is between 0.01 and 0.1 µg/L:
However, as the predicted concentration for [substance] is larger than 0.01 µg/L, a restriction on the use in groundwater protection areas should be placed on the label.
Om het grondwater te beschermen mag dit product niet worden gebruikt in grondwaterbeschermingsgebieden.

If predicted leaching is above 0.1 µg/L:
GeoPEARL calculations show that the predicted leachate concentrations are larger than 0.1 µg/L. Therefore, the proposed use of the active substance is not permissible.

When standardised lysimeters are available:

The leaching potential of substances to the shallow groundwater in the potential area of use within The Netherlands is calculated using the GeoPEARL model. The same input data as used in the first tier with Pearl 4.4.4 is employed. Additional input is the crop [crop] and the number of plots (minimum 250).

In case of standardisation according to Verschoor:
Correction of the GeoPEARL results is performed with the adjustment factor derived from the simulation errors of the available lysimeter studies. These are derived in section 8.3.1.
For results see Table 8.6-6.

Table 8.6-6 Leaching of a.s. [name] and metabolites [name] as predicted by (Geo)PEARL including correction based on lysimeter studies.

Crop	Scenario	Adjusted 80th/90th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)		
		<active substance 1> (f_{adj}=xxx)	<metabolite 1> (f_{adj}=xxx)	<metabolite 2> (f_{adj}=xxx)
	<insert scenario crop choice used for assessment>			

GeoPEARL calculations show that the predicted leachate concentrations for [name] are smaller than 0.1 µg/L. Hence, the active substance meets the standards laid down in the BGB for the proposed applications.

If predicted leaching is between 0.01 and 0.1 µg/L:
However, as the predicted concentration for [substance] is larger than 0.01 µg/L, a restriction on the use in groundwater protection areas should be placed on the label.
Om het grondwater te beschermen mag dit product niet worden gebruikt in grondwaterbeschermingsgebieden.

If predicted leaching is above 0.1 µg/L:
GeoPEARL calculations show that the predicted leachate concentrations are larger than 0.1 µg/L.
Therefore, the proposed use of the active substance is not permissible.

8.7 PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER (PECSW) (KCP 9.2.5)

This is an NL specific aspect. The Dutch drift values are to be used, and simulations should be performed with the TOXSWA 1.2 model (GUI version 1.0).
The drift values are presented in the Evaluation Manual of the Ctgb, Chapter 6, surface water, NL part, Appendix 2. See www.ctgb.nl for the most recent version of the Evaluation Manual. Describe the required drift mitigation techniques to meet the ecotoxicological threshold below the tables presenting the PEC values.

8.7.1 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).

8.7.2 ACTIVE SUBSTANCE(S), RELEVANT METABOLITE(S) AND THE FORMULATION (KCP 9.2.5)

Provide reference to study by applicant or recalculation by zRMS.

The following tables are intended for the situation when a Dutch specific assessment is required.

Table 8.7-1 Input parameters related to application for $PEC_{sw/sed}$ calculations

Crop		
Application rate (kg as/ha)	<active substance 1>: <active substance 2>:	
Number of applications/interval (d)		
Models used for calculation	TOXSWA 1.2 (GUI 1.0)	

Table 8.7-2 Input parameters related to active substance <active substance 1> and metabolite(s) for $PEC_{sw/sed}$ calculations

Compound	<active substance 1>	<metabolite 1>	<metabolite 2>	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)				
Saturated vapour pressure (Pa) at <20/25> °C				
Water solubility (mg/L) at <20/25> °C				
Diffusion coefficient in water (mm^2/d)	40			Default TOXSWA
Exchange coefficient pesticide in liquid phase (m/d)				Default 1.7 or calculated value
Exchange coefficient pesticide in gas phase (m/d)				Default 163.1 or calculated value
K_{foc} (mL/g)	… (arithmetic mean/median, n = <no>)			
K_{om} (mL/g)				K_{foc} / 1.724
Freundlich Exponent 1/n	… (arithmetic mean/median, n = <no>)			
$DT_{50,water}$ (d) at 20 °C	[$DT_{50,system}$ or default 1000, if no level PII $DegT_{50,water}$ is available]			
$DT_{50,sed}$ (d) at 20 °C	[$DT_{50,system}$ or default 1000, if no level PII $DegT_{50,sediment}$ is available]			
Activation energy (J/mol)	55000			Default

Compound	<active substance 1>	<metabolite 1>	<metabolite 2>	Value in accordance to EU endpoint y/n/ Reference
				TOXSWA-NL
Maximum occurrence observed (% molar basis with respect to the parent)	-	Water: Sediment:	Water: Sediment:	

$PEC_{SW/SED}$ of <active substance 1>

If PECsediment is needed to complete the assessment (*i.e.*, when the ecotoxicological studies are performed with spiked sediment) the results for PECsed can be retrieved from the EC080.out file.

Table 8.7-3 PEC_{SW} and PEC_{SED} for <active substance 1> in the edge-of-field ditch following spring/autumn application

Scenario (spring/autumn) (drift reduction)	Drift value*	Max PEC_{SW} (µg/L)	xx d- $PEC_{sw,twa}$ (µg/L) (twa-time as required by ecotox)	Max PEC_{SED} (µg/kg)** (if required by ecotox)
Crop				
Crop				

* <indicate % drift and drift reducing technique>
** calculated as (PECsed in g/m^3 / 80 kg/m^3)*10^6 (conversion of g/kg to µg/kg)

Metabolite(s) of <active substance 1> (if not covered by the EU active substance approval)

$PEC_{SW/SED}$ of <metabolite 1>

Table 8.7-6 PEC_{SW} and PEC_{SED} for <metabolite 1> in the edge-of-field ditch following spring/autumn application

Scenario (spring/autumn) (drift reduction)	Drift value*	Max PEC_{SW} (µg/L)	xx d- $PEC_{sw,twa}$ (µg/L) (twa-time as required by ecotox)	Max PEC_{SED} (µg/kg)** (if required by ecotox)
Crop				
Crop				

*<indicate % drift and drift reducing technique>
** calculated as (PECsed in g/m^3 / 80 kg/m^3)*10^6 (conversion of g/kg to µg/kg)

8.7.3 Additional data

In this section national monitoring data are presented. Furthermore also the drinking water assessment is presented. This is not an NL specific aspect, however, in the EU no assessment methodology is developed. Therefore the Netherlands uses their own assessment methodology.

8.7.3.1 Monitoring data groundwater

There are no data available regarding the presence of the substance [name] in groundwater.
Or:

The active substance xxxx was observed in groundwater (Ground Water Atlas). There are x results available in the Ground Water Atlas, from x sites (screen depth x to xx meter below soil surface) sampled from xxxx to xxxx. Descriptive statistics are presented in Table 8.7.3.1-1, drinking water limit is 0.1 µg/l.

Table 8.7.3.1-1: Monitoring data in Dutch groundwater for [name substance] from Ground Water Atlas

	<LOD	<LOQ	<LOR	≤ drinking water limit	> drinking water limit
Number of measurement result per category					
Minimum value per category (µg/l)					
Maximum value per category (µg/l)					
P50/median per category (µg/l)					
P90 per category (µg/l)					

Insert short conclusion regarding groundwater monitoring data.

The groundwater monitoring data show that…

It must be noted that the quality of the data in the Ground Water Atlas still needs to be assessed (please refer to page 7 of the manual of the Ground Water Atlas). Work on establishing criteria to assess the quality and to set the values of the quality labels in the Ground Water Atlas is ongoing. In addition, a methodology for implementing the Ground Water Atlas in the national decision tree for leaching is lacking. A scientific working group is working on such a methodology.
Therefore currently no consequences can be drawn for the proposed uses of the product based on the data in the Ground Water Atlas.

8.7.3.2 Monitoring data surface water

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (EQS, MKN in Dutch, data source http://www.rivm.nl/rvs/Normen). These environmental quality standards consist either of the harmonised WFD thresholds derived according to the Fraunhofer methodology[2] (AA-EQS and MAC-EQS) or of an MPC value (which is usually derived on the basis of outdated guidance).
The Pesticide Atlas includes a statistical correlation analysis between concentrations, threshold exceedance and land use, which may indicate probable relationships.

[2] P.L.A. van Vlaardingen and E.M.J. Verbruggen, Guidance for the derivation of environmental risk limits within the framework of 'International and national environmental quality standards for substances in the Netherlands' (INS). Revision 2007'. RIVM report 601782001.

Data can be derived from www.bestrijdingsmiddelenatlas.nl.

Number and size of exceedance (if any) of the authorisation threshold, ad hoc/indicative MPC and/or MAC-EQS & AA-EQS can be accessed via the main entrance `stoffen` > `stoffen individueel`. Maps and histograms regarding the threshold exceedance can also be directly accessed.
At the right hand side the substance, the monitoring year and the required threshold can be selected.

Please note that the Pesticide Atlas is in Dutch. The following abbreviations for threshold values are used.

KRW (kader richtlijn water) = WFD (Water Framework Directive)
JG-MKN (jaargemiddelde-milieukwaliteitsnorm) = AA-EQS (annual average environmental quality standard)
MAC-MKN (maximale acceptabele concentratie-milieukwaliteitsnorm) = MAC-EQS (maximum acceptable concentration- environmental quality standard)
MTR (maximaal toelaatbaar risico) = MPC (maximum permissible concentration)
toelatingscriterium = authorisation threshold (based on the Uniform Principles according to EU plant protection products legislation 91/414 and 1107/2009)

[substance 1]
There are no data available in the Pesticide Atlas regarding the presence of the substance in surface water.
OR
The active substance /metabolite [name] was measured in the surface water (most recent data from [year]). In Table 8.7.3.2-1 the number of observations in the surface water are presented.
The authorisation threshold equals [xx] µg a.s./L (consisting of first or higher tier acute or chronic ecotoxicological threshold value, including relevant safety factors, which is used for risk assessment, in this case [fill out relevant threshold type as indicated in the factsheet of the Pesticide Atlas]).

The relevant Environmental Quality Standard (EQS) for this substance are/is [the WFD thresholds/the MPC] and equal(s) [xx] µg/L.

- ➔ Threshold values and their basis can be found in the factsheet (in Dutch). This information can also be accessed via the menu `stoffen` > `stoffen individueel` or via the information button (i) at the right hand side of the selected substance.
- ➔ Please note: once WFD-EQS values are available for a substance, the MPC is not reported in the Pesticide Atlas. If no WFD-EQS values are available, the MPC value is presented.

Table 8.7.3.2-1 Monitoring data in Dutch surface water for [name] (from www.pesticidesatlas.nl, version 3)

Total no of locations	***n* > authorisation threshold**	***n* > EQS**		
		MAC-EQS	**AA-EQS**	**MPC (ad-hoc/indicative)**
[number of locations]*	Value	Value or n.a.	Value or n.a.	Value or n.r.

* total number of measurements is [xx].

** n.a. not available (in case of no EQS) or n.r. not relevant (in case of MPC when there are EQS values)

- ➔ The map with exceedance `mate van overschrijding per stof` shows the locations where the substance is monitored and whether an exceedance of the selected threshold is observed.
- ➔ In order to present how many locations show an exceedance of a certain threshold the histogram `Verdeling mate van overschrijding per stof` should be checked. Only the number for exceedance classes orange and red should be reported (values above the selected threshold ánd above analytical reporting limit). Report the number of exceedances in the available classes (values exceeding threshold, values exceeding threshold with a factor 5 or more) in the table above for each threshold.
- ➔ The number of locations `Trend (jaren) aantal meetpunten per stof` and the number of measurements per substance `Trend (jaren) aantal metingen per stof` can be selected and recorded in the table/footnote to the table for the most recent year. This information can also be accessed via the menu `Thema's` > `meetintensiteit`.

- ➔ with regard to exceedance of the water quality thresholds in the Pesticide Atlas, the following section applies:

The exceedance of the WFD water quality standards AA-EQS and MAC-EQS (and MPC in case no EQS have been derived), is from 2016 onwards addressed by the ERP (Emission Reduction Plan), which is carried out under responsibility of the Ministry of Infrastructure and Environment (I&M). Ctgb has no active role in this process. The outcome of the ERP may lead to label changes on request of the applicant.

However, Ctgb is the responsible authority to address exceedance of the authorisation threshold.

- ➔ In case no exceedance of the authorisation threshold is recorded in the Pesticide Atlas: provide the following default sentence indicating no problems are expected.

As there is no exceedance of the authorisation threshold, the monitoring data have no consequences for the proposed use(s) of the product.

OR:

- ➔ In case exceedance of the authorisation threshold has been recorded in the Pesticide Atlas, the table indicating a potential correlation of exceedance with land use types `Correlatie: Overschrijdingen per stof - Landgebruik` should be selected for the most recent period of 3 years. This information can also be accessed via the menu `Landgebruik`.

Please note: moving on to the correlation sheet Land use/Exceedings does not make sense in case of applied non-professional use, as this use has not been included among the land uses in the Pesticide Atlas. Non-professional uses have to be dealt with on a case-by-case basis (using qualitative arguments).

Several locations show an exceedance of the authorisation threshold. Therefore it is assessed whether there is a correlation between the observed exceedances and land use types. The correlation analysis as included in the Pesticide Atlas uses a progressive three-year period to assess whether there is a relation. The last three available years, in this case [201x-201x] are used to establish the relation.

The observed exceedance of the authorisation threshold is [not] significantly correlated to the proposed uses.

➔ In case no significant correlation can be established.

Therefore, no consequences can be drawn from the observed exceedance.

➔ In case a significant correlation can be established for the use applied for and the authorisation threshold exceedance: please indicate the relevant use(s) for with a correlation was established including the significance of the correlation. Furthermore, please provide an adequate risk assessment in which it is shown that the observed exceedance measured in surface water is not related to the applied use(s) or in which adequate mitigating measures are proposed.

It cannot be excluded that the observed exceedance of the authorisation threshold is related to the use in [name crop(s)]. Therefore, an adequate risk assessment is needed to show that the observed exceedance of [name substance] of the authorisation threshold measured in surface water is not related to the applied for use in [name crops].

➔ applicant to provide an adequate assessment and an emission reduction proposal, when required

[substance 2]
Repeat the procedure.

8.7.3.3 Drinking water criterion

The assessment methodology followed is developed by the WG implementation drinking water criterion and outlined in Alterra report 1635[3] and described in the Ctgb Evaluation Manual, NL part, Chapter 6 surface water.

Substances are categorized as new substances on the Dutch market (less than 3 years authorisation) or existing substances on the Dutch market (authorised for more than 3 years).

- For new substances, a pre-registration calculation is performed.
- For existing substances, the assessment is based on monitoring data of VEWIN (drinking water board).
    - If for an existing substance based on monitoring data no problems are expected by VEWIN, Ctgb follows this VEWIN assessment.
    - If for an existing substance based on monitoring data a potential problem is identified by VEWIN, Ctgb assesses whether the 90th percentile of the monitoring data meet the drinking water criterion at each individual drinking water abstraction point.

The list of potentially problematic substances is updated yearly and presented on the site of Vewin.

[3] Adriaanse et al. (2008). Development of an assessment methodology to evaluate agricultural use of plant protection products for drinking water production from surface waters - A proposal for the registration procedure in the Netherlands. Alterra-Report 1635

Existing non-problematic substance

[substance] has been on the Dutch market for > 3 years (authorised since xx-xx-xxxx). This period is sufficiently large to consider the market share to be established. From the general scientific knowledge collected by the Ctgb about the product and its active substance, the Ctgb concludes that there are in this case no concrete indications for concern about the consequences of this product for surface water from which drinking water is produced, when used in compliance with the directions for use. The Ctgb does under this approach expect no exceeding of the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

Existing problematic substance

- ➔ In case of an existing problematic substance: please calculate the overall 90-percentile for the drinking water abstraction points, and add the values to Table 8.7.3-3. For more information on the calculation of the 90-percentile: see the work instruction **Calculation of the 90th Percentile at the Ctgb website**.
- ➔ The relevant data set needed to calculate the 90-percentile are available upon request at Vewin.

[substance] has been on the Dutch market for > 3 years (authorised since xx-xx-xxxx). This period is sufficiently large to consider the market share to be established. The existing active substance [name] is included in the list of substances of concern due to its presence in surface water at drinking water abstraction points as established by VEWIN/Ctgb. Therefore, an adequate risk assessment is needed based on the highest tier data. There are monitoring data concerning the presence of [name] at drinking water abstraction points. The most recent 5 years are used for the assessment.
See Table 8.7.3.3-1.

Table 8.7.3.3-1 Monitoring data for [name] at drinking water abstraction points from surface water in the period [e.g., *2014 – 2018*]

Abstraction point	Number of measurements above detection limit/ Number of measurements [n/N]	Number of measurements above drinking water limit/ Number of measurements [n/N]	Overall 90-percentile [µg/L]
Amsterdam-Rijnkanaal (Nieuwersluis)			
Nieuwegein			
Andijk			
Brakel			
Heel			
Petrusplaat/Keizersveer			
Scheelhoek/Stellendam			
Drentsche Aa (De Punt)			

The relevant monitoring data (data set VEWIN, 20xx-20xx) indicate that…

Therefore, the application of [name] is

…..not expected to exceed the drinking water criterion.

……expected to exceed the drinking water criterion.

Further studies are required/submitted…
OR

The standards for surface water destined for the production of drinking water are not met.

New substance on Dutch market

➔ In case of a new substance on the Dutch market: please provide DROPLET calculations (available via https://www.pesticidemodels.eu/droplet/droplet-download; version 1.4.2 should be used, which is compatible with FOCUS SWASH 5.3 and Windows 11). On this webpage also a document on the changes compared to the previous version is provided and a separate document "Getting started instruction". The manual for the software tool DROPLET (Alterra report 2020, 2010) can be downloaded from https://www.pesticidemodels.eu/droplet/references).

As [name] is a new active substance, there are no data available regarding its presence in surface water at drinking water abstraction points.
The decision tree as outlined in Alterra report 1635 (2010) should be followed. The tool DROPLET (described in Alterra report 2020, 2010) to calculate concentrations on drinking water abstraction points is used for the assessment.

The following data are used for the assessment:

Input in SWASH:

Substance input parameters:

Molecular mass:	g/mol
Saturated vapour pressure:	Pa (20 °C)
Solubility in water:	mg/L (20 °C)
Arithmetic mean/median Kom:	L/kg
Arithmetic mean/median 1/n:	
Factor plant uptake:	0.0 (default, 0.5 only for systemic substances)
Geometric mean/median DT50 water (DT50 system or default):	xx days
Geometric mean/median DT50 sediment (DT50 system or default):	xx days
Geometric mean/median field/lab DT50 soil:	xx days
DT50 Crop:	10 days (default)

Scenario (Focus wizard):
Selected crop: xx
Selected scenario: D3
Input in FOCUS-TOXSWA: NL Drift value xx% (see Evaluation Manual for actual drift values)

Input in DROPLET:
Selected crop: xx
f_{market}: 0.4 (default)
$f_{additional\ dilution}$: 1 for all abstraction points, except for Andijk: 0.17 (default)

Other parameters: standard settings SWASH and DROPLET

See Table 8.7.3.3-[x] for the predicted concentrations for each drinking water abstraction point.

Table 8.7.3.3-[x] Predicted concentrations at drinking water abstraction points in The Netherlands as calculated by DROPLET 1.4.2

Drinking water abstraction point	FOCUS D3 crop	$f_{useintensity}$ (-)	Relative Cropped Area (-)	$PEC_{drinking\ water\ abstraction\ point}$ (µg/L)
De Punt				
Andijk				
Nieuwegein				
Heel				
A'dam Rijnkanaal				
Brakel				
Petrusplaat				
Twentekanaal				
Scheelhoek				
Bommelerwaard (subarea of Brakel)				

Results show that for all drinking water abstraction points the predicted concentrations are below 0.1 µg/L. Therefore, the application of [name formulation] is not expected to exceed the drinking water criterion. The standards for surface water destined for the production of drinking water are met.

If outcome is 0.1 – 0.5 µg/L, the following refinements can be made:

- drift reducing measurements
- refinements of the DROPLET calculation.

If outcome is above 0.5 µg/L, it should be discussed with (zR/c)MS The Netherlands what adequate risk assessment might be possible. When this fails:

Therefore, the application of [name formulation] is not permissible as the drinking water criterion is exceeded.

8.8 FATE AND BEHAVIOUR IN AIR (KCP 9.3, KCP 9.3.1)

The fate and behaviour in air is considered as core data since there are no specific national requirements.

Appendix 1 – List of data considered in support of the evaluation

The following list should include all product data considered in support of the evaluation, independently 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 name of authors

Tables considered not relevant can be deleted by MS 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 N°> <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 and 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 ANNEX II STUDIES

Present the authority's comment on the study in a box above each individual study. If there is more than one fate study available, list them separately, i.e., A.7.1.1 Study 1, A.7.1.2 Study 2 etc.

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:	**<OECD Dossier No.>, <Study Title>**
Author(s), year:	<Author>, <Year>
Report/Doc number:	
Guidelines:	<Yes/No (If yes, give guidelines; If no, give justification, e.g., " no guidelines available" or " methods used comparable to guideline(s) <xxx>")>
GLP:	<Yes/No (If no, give justification, e.g., state that GLP was not compulsory at the time the study was performed)>
Deviations:	<Yes/No (If yes, describe deviations from test guidelines)>
Validity:	<Yes/No/Supplementary>

APPENDIX 3: ADDITIONAL INFORMATION PROVIDED BY THE APPLICANT (E.G. DETAILED MODELLING DATA)

- Additional appendices may be added to include further information such as the table of metabolites
- This appendix can be deleted if not needed.