Evaluation Manual for the Authorisation of Plant protection products and Biocides according to Regulation (EC) No 1107/2009

NL part

Plant protection products

Chapter 6 Fate and behaviour in the environment: behaviour in surface water and sediment

version 2.2; January 2018



Board for the Authorisation of Plant protection products and Biocides

Chapter 6 Fate and behaviour in the environment; behaviour in surface water and sediment

Category: Plant protection products

General introduction	5
Behaviour in surface water and sediment	5
2. NL framework	5
2.1. Introduction	5
2.2. Data requirements	6
2.3. Risk assessment	6
2.3.1. Edge-of-field ditch	6
2.3.2. Drinking water abstraction points	10
2.3.3. Refinement options for PEC calculations	11
2.3.4. Use of monitoring data	12
2.4. Approval	14
2.4.1. Criteria and reference values	14
2.4.2. Decision making	15
2.5. Developments	
3. APPENDICES	

Changes in the Evaluation Manual

	Evaluation manual PPP NL part				
	Chapter 6 Behaviour in surface water and sediment				
Version	Date	Paragraph	Changes		
2.0	January 2014				
2.1	October 2016	2.1-2.4	Throughout a division between the assessment for field uses and protected crops is given		
			The Dutch Hoofdlijnenakkoord Zuivering Glastuinbouw has been added		
		2.3.3	Procedure for non-standard TWA concentrations added.		
		2.3.4.2	New format text concerning monitoring data from pesticidesatlas.nl, new correlation analysis.		
			Additional information concerning WFD versus authorisation threshold added. Role of Ctgb in Emission Reduction Plans specified.		
		2.4.1	Non-relevance assessment for surface water metabolites in surface water intended for drinking water is added based on extrapolation of the guidance document on non-relevance of groundwater metabolites.		

	1		version 2.2
			Decision tree has been updated to reflect
			changes in data requirements and changes in
			assessment framework
			Consequences of change in Activity Decree
			(expected entry into force date January 2017)
			have been announced.
			 For downward spraying spray drift
			reducing <u>nozzles</u> are replaced with
			spray drift reducing techniques in order
			to facilitate the transition to the use of
			drift reducing technology (DRT)
			classes.
			- Requirement of minimum reduction of
			75% on the whole field has been
			added (Activity Decree). The
			procedure and conditions for the use of
			95% spray drift reduction techniques
			are added
			- For fruit cultivation it is stressed that
			the Activity decree requires 75%
			reduction + 4.5 m crop free zone or
			90% spray drift reduction in
			combination with a 3 m crop free zone
			- The use in hop will be assessed on the
			basis of the drift values for dormant
			trees.
			Activity Decree change is expected to enter
			into force in January 2017.
			One dition a condense de la CEO/ anno de det
			Conditions under which 95% spray drift
			reduction can be requested are specified.
			For the first tier assessment of crops not
			included in the Activity decree a value of 5.4%
			is used representing a conventional spraying
			technique.
			Application in reed added (100% spray drift)
		Appendix 3	Section added on drinking water assessment
		11	for protected crops.
2.2	January 2018	Main text,	Greenhouse uses
		section 2.3.1	A purification level of 95% of the waste water
			will be the basis of the risk assessment for all
			organic chemical substances.
			NB This purification requirement is not
			relevant for plant protection products with
			active substances belonging to the inorganic
			compounds (e.g., metals, salts) and micro-
			organisms.
			-
			Closed buildings
			Specified that discharge of PPPs and biocides

1	Version 2.2
	from crop cultivations or treatments in closed buildings is not allowed according to the Activity Decree.
Appendix 2	Consequences of change in Activity Decree (entry into force January 2018) have been implemented:
	Field uses - Drift values for individual techniques have been replaced with drift values per DRT class, using the deposition values that are derived using the reference techniques per class as established by WPR. During the transitional period laid down in the Activity Decree concerning fruit (some techniques) and lane tree cultivation, Ctgb will take the drift deposition values for these techniques into account when performing the risk assessment.
	Greenhouse uses - the use of 0.1% emission modelled as spray drift is not used anymore for organic substances in greenhouses.
Appendix 2	Other changes with regard to drift values: - clarification that for non-professional use by manual spraying in lane trees and fruit trees the default values for the professional use are used in the absence of spray drift data for hand-held equipment used in upward and
	sideways spraying.

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the behaviour of an active substance in a plant protection product and its metabolites, degradation products and reaction products in surface water and sediment and how reference values are derived in the NL framework (§2 - §2.5).

I BEHAVIOUR IN SURFACE WATER AND SEDIMENT

2. NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for plant protection products based on active substances, included in Commission Implementing Regulation (EU) No 540/2011.

The plant protection product that contains such substances may be authorised if the criteria laid down in Regulation (EC) No 1107/2009 are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree). The evaluation dossiers must meet the requirements in Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 of Regulation (EC) No 1107/2009 (see Type of application).

A Member State may deviate from the EU evaluation on the basis of agricultural, phytosanitary and ecological, including climatological, conditions which are specific for that Member State, in this case the Netherlands.

The NL framework describes the data requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national approval framework or when the national framework has been elaborated in more detail than the EU framework.

2.1. Introduction

This chapter describes the procedure to determine estimated or measured concentrations in surface water and sediment following normal agricultural applications (field uses and protected uses (e.g., greenhouse and walk-in tunnels)). Evaluation of the aspect behaviour in surface water and sediment with regard to emission routes to surface water deviates from the EU evaluation methodology for field uses, and a NL-specific methodology is followed. This is because the Netherlands have their own NL-specific spray drift values data base, based on the geographical and climatological circumstances. A NL-specific scenario for emission to surface water via drainage pipes is not yet available (see section developments). Emission to surface water via atmospheric deposition is described in *Chapter 6 fate and behaviour in the environment: behaviour in air.*

The following water systems are distinguished in the national risk assessment:

- edge-of-field ditch: relevant for the risk assessment for organisms that depend on surface
 water and/or sediment (aquatic and sediment organisms, and birds and mammals (through
 consumption of surface water and secondary poisoning), see also Chapter 7
 Ecotoxicology; aquatic organisms, and 7. Ecotoxicology; terrestrial organisms; birds and
 mammals. The following further subdivision is relevant for the exposure assessment:
 - o Field uses
 - Protected uses (specifically greenhouse uses, for which some national specific choices and options are described)
- Drinking water abstraction points: relevant for the assessment of the drinking water criterion for surface water intended for the production of drinking water (this Chapter).

For the assessment of the emission to the edge-of-field ditch, a decision tree with corresponding explanatory notes is presented in Appendix 1 to this chapter. This decision tree summarises the approval framework for the behaviour in surface water and sediment (edge-of-field ditch).

For the assessment of the drinking water criterion for surface water intended for the production of drinking water, the schematic decision trees are presented in Appendix 3.

The other points described in this chapter are further elaborations of the EU procedure.

2.2. Data requirements

The data requirements for chemical Plant protection products are in agreement with the provisions in EU framework (see §1.2 of the EU part). NL-specific data requirements and further interpretations of the EU data requirements are given in the text below. For the other general chemical parameters of a substance that are required as model input data reference is made to Chapter 2 Physical-chemical properties.

2.3. Risk assessment

The evaluation methodologies for chemical Plant protection products are in agreement with the provisions described in EU framework (see §1.3 of the EU part). NL-specific evaluation methodologies and further elaborations of the EU procedures are given in the text below.

Please note that for non-professional use the dose rate in kg/ha may be corrected to match a maximum acreage of 500 m2.

2.3.1. Edge-of-field ditch

The exposure concentration (Predicted Environmental Concentration (PEC)) is the model-calculated concentration in surface water and sediment. The calculations are based on the maximum specified frequency and the minimum specified interval for the use in question.

The risk assessment procedure differs for the field uses and protected uses.

Field uses

The exposure concentration as result of spray drift is calculated with the TOXSWA programme according to the <u>Plant protection products and Biocides Decree (Bgb)</u> (Appendix I). The spray drift values used for exposure assessment used in NL framework are described in various spray drift tables (standard values for risk assessment, based on the aims of the Activity Decree, and values with further mitigation). These tables are included in Appendix 2 to this chapter.

The TOXSWA model (v1.2, GUI 1.0) is used for determination of the concentration of an active substance in a standard ditch by emission via spray drift. All processes and process parameters considered in TOXSWA, including spray drift percentage, are based on research relevant for the Netherlands. This means that the model is tailored to the NL situation. For determination of the PEC, agricultural use in compliance with the prescribed method of application (GAP) is assumed. Loading of surface water and sediment by agricultural use of Plant protection products is only based on drift of spray mist (spray drift).

The most important substance-related input parameters of the TOXSWA model are:

• Geometric mean DT50 for degradation rate in surface water at 20°C (days)

- Geometric mean DT50 for degradation rate in sediment at 20°C (days)
- Arithmetic mean K_{om} and corresponding arithmetic mean 1/n for suspended organic matter (L/kg) (if not available use K_{om} soil)
- Arithmetic mean K_{om} and corresponding arithmetic mean 1/n for sediment (L/kg) (if not available use K_{om} soil)
- Saturated vapour pressure (Pa) usually available at 20 or 25 °C
- Solubility in water (mg/L) usually available at 20 or 25 °C
- Molecular mass (g/mol)

A conversion factor of 1.724 is used to translate K_{oc} into K_{om} .

The degradation parameters should be derived in line with FOCUS Guidance Document on Degradation Kinetics (SFO or pseudo-SFO). When no separate degradation half-lives (DegT50 values) are available for the water and sediment compartment (accepted level P-II values), the system degradation half-life (DegT50-system, level P-I) is used as input for the degrading compartment and a default value of 1000 days is to be used for the compartment in which no degradation is assumed. This is in line with the recommendations in the FOCUS Guidance Document on Degradation Kinetics. The other model parameters are applied in accordance with the standard settings of the TOXSWA model.

For a summary of the risk assessment methodology for water and sediment we refer to the decision tree with explanatory notes, presented in Appendix 1 to this chapter. National spray drift values can be applied on the basis of article.8f of the Plant protection products and Biocides Decree (Bgb). The loading of surface water and sediment is calculated on the basis of the spray drift percentage values as presented in Appendix 2 to this chapter.

Protected crops

The "EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments" (in short: EFSA Guidance Document on Protected crops) has entered into force in the Netherlands as of March 2016.

For a description of the risk assessment on EU level (substance approval or (inter)zonal authorisation assessment) refer to the EU part of the Evaluation Manual. In principle emission from greenhouses is not a Dutch specific issue. However the GEM model contains several scenarios that are specifically tuned to conditions in The Netherlands. Furthermore several policy choices are made in The Netherlands that may not be the same as requirements of other member states. Hence in this Chapter national deviations from or additions to the guidance document are further elaborated upon.

In the guidance document a subdivision between non-permanent covers, walk-in tunnels, greenhouses and closed buildings is made, each with a different (tiered) exposure assessment.

Non-permanent covers

Use under non-permanent covers is assessed as field use. This means that for the Dutch assessment a TOXSWA 1.2 simulation is required. See field uses for the assessment methodology.

Walk-in tunnels

Walk-in tunnels are to be assessed via EU methodology (see Chapter 6 surface water, EU part). No specific NL scenarios are available.

Greenhouse uses

For the estimation of exposure to surface water resulting from greenhouse uses the <u>Greenhouse Emission Model</u> (GEM) is developed. The Guidance Document on Protected crops mentions two example scenarios ("soil bound chrysanthemum in the Netherlands" and "non-soil bound rose in the Netherlands", both available in GEM).

In the Dutch decision tree and the resulting simulation model GEM several scenarios were developed that are representative for the Dutch situation.

Soil-bound uses (see Wipfler et al., WUR-Alterra report 2388, 2015)

The Guidance Document on Protected crops states that "the models generally used to calculate leaching and drainage from open-field cultivation can equally well be used to calculate leaching and drainage from walk-in tunnels and greenhouses <u>if appropriate</u> <u>scenarios are available</u>. [...]

Appropriate scenarios are to be established/selected by the notifier and the selection and parameterisation is to be justified, until methodology and scenarios are established and approved by competent bodies. However currently there are no such models available and only example scenarios have been presented in the guidance."

As a tiered approach the walk-in tunnel assessment i.e. up to FOCUS Step 3 Drainage scenarios may be used as a first tier, as is also proposed in the EFSA Guidance Document Appendix D. Refer to the EU part of the Evaluation Manual.

In the second tier the chrysanthemum scenario available in GEM can be used (as also indicated in Table 1 of the Guidance Document), using conservative input parameters.

The most important substance-related input parameters of the GEM model for the soil-bound scenario are:

- First tier: Longest hydrolysis DT50 for degradation rate in water at 20°C within the greenhouse (days), refinement possible in higher tier (e.g., OECD 309, outdoor mesocosms)
- Geometric mean DT50 for degradation rate in soil at 20°C (days).
 - Please note that in the scenario report it is recommended to adjust the DT50 values obtained in open field soils by a default factor of 10 in the absence of a thorough dataset to account for the presumably slower degradation in greenhouse soils. The Dutch ministries have decided that this adjustment factor will not be used until more experience has been gained with the model.
- Geometric mean DT50 for degradation rate in surface water at 20°C (days)
- Geometric mean DT50 for degradation rate in sediment at 20°C (days)
- Arithmetic mean K_{om} and corresponding arithmetic mean 1/n for suspended organic matter (L/kg) (if not available use K_{om} soil)
- Arithmetic mean K_{om} and corresponding arithmetic mean 1/n for sediment (L/kg) (if not available use K_{om} soil)
- Saturated vapour pressure (Pa) usually available at 20 or 25 °C
- Solubility in water (mg/L) usually available at 20 or 25 °C
- Molecular mass (g/mol)

Further refinement can be made in Tier 3 (substance data and time window) and Tier 4 (crop management i.e. realistic scenarios for other crops than chrysanthemum). The report states that although the soil-bound scenario is based on application by spraying, it can also be used for soil applied plant protection products (PPP) e.g. fungicides.

Non-soil bound uses (see Van der Linden et al, RIVM report 2015-0128)

For soilless cultivation a simple tiered approach is described in the guidance document - (Appendix D). For the drip irrigation, two simple calculation methods are provided as a conservative approach. For spray applications it is suggested to take into account the amount of condensation water as a total dose per season applied at once (step 1). The model GEM with the soil-less scenario in rose is given as highest tier in the EFSA Guidance Document. Refer to the EU part of the Evaluation Manual.

The model GEM also contains additional scenarios to the rose scenario that is mentioned as example scenario in the guidance document. In total there are four available crop scenarios: rose, tomato, sweet pepper and ficus, which were discerned based on the leading emission factors sodium tolerance and transpiration. All greenhouse grown crops of the Dutch DTG list can be chosen in the model and the model will then use the most appropriate crop scenario.

Depending on the applied for use the most appropriate scenario needs to be used. As various application methods can be used in a greenhouse several substance fate models are available within GEM:

Model A: application by drip irrigation/in nutrient solution.

Model B: spray/fog application to crop grown on shielded slabs (drip irrigation system.

Model C: spray/fog application to crops grown in pots in an ebb/flow system.

The non-soil bound scenario was developed with the possibility to choose between two temporal percentiles: the 50th and the 90th percentile (see scenario description). This percentile is largely governed by the flow velocity of the receiving ditch. The Dutch Ministries of Economic Affairs and Infrastructure and Environment have chosen to use the 50th temporal percentile and the 90th temporal percentile factor will not be used for national authorisations until more experience has been gained with the model.

The most important substance-related input parameters of the GEM model for the substrate scenarios are:

- The equilibrium sorption coefficient K_{OM} (L kg-1) to substrate (specific for pot plants). In case no specific information is available it is suggested to use the sorption coefficient for soil here.
- Half-life in recirculation water (d) and the temperature at which it was measured. In case no specific information is available it is suggested to use the DegT50 for hydrolysis.
- Molar activation energy (kJ mol-1) for the degradation in recirculation water. It is suggested to
 use a molar activation energy of 75 kJ mol-1.
- Half-life in the disinfection tank (d) and the temperature at which it was measured. In case no specific information is available it is suggested to use the DegT50 for hydrolysis.
- Half-life on the greenhouse floor (d). In case no specific information is available it is suggested to use 100 d.
- Half-life in substrate (d). In case no specific information is available it is suggested to use the DegT50 for degradation in soil.
- Geometric mean DT50 for degradation rate in surface water at 20°C (days).
- Geometric mean DT50 for degradation rate in sediment at 20°C (days).
- Half-life in greenhouse air (d) and the temperature at which it was measured. It is suggested to use the half-life in air here, when available, otherwise a half-life of 100 d could be used.
- Molar activation energy (kJ mol-1) for the degradation in greenhouse air. It is suggested to use a molar activation energy in air of 45 kJ mol-1.

Due to the implementation of the changed Activity Decree as per January 2018, in which it is laid down that the wastewater of greenhouses should be purified with at least a reduction of 95%, the assessment for organic chemical substances will take into account the use of 95% mitigation. A list with all purification techniques that comply with this 95% mitigation can be

found on the Helpdesk Water (BZG list).

If more than 95% purification is needed to achieve an acceptable aquatic risk, the applicant can submit an adequate risk assessment with refinements of substance properties (e.g., realistic degradation or sorption in recirculation systems) and management properties (e.g., waiting periods, recycling of filter rinse water, which should be based on quantitative effects of such management options) using GEM to demonstrate that in combination with 95% reduction this results in an acceptable risk for aquatic organisms.

If more than 95% purification is still required after substance parameter or management refinement Ctgb will judge on a case by case basis whether a more restricted use can be granted.

For further guidance on the use of the model refer to the <u>GEM manual</u> and further information on the Ctgb website.

Please note that the obligation for 95% purification of waste water is not applicable to inorganic substances such as metals and salts, nor to micro-organisms, according to the Activity Decree.

Closed buildings

For cultivations and treatments in closed buildings, emission to surface water is not assessed on an EU level since there is no established methodology. The Guidance Document on Protected crops does not fill in this data gap. In the absence of an EU harmonised approach, some national approaches for exposure assessment to STP and/or surface water are described in the EU part of the Evaluation Manual. Please note that the Activity Decree specifically prohibits certain emissions of waste water containing plant protection products or biocides to surface water and/or STP for certain closed building types (see e.g., § 3.5.2, Article 3.75-3.77 for cultivation in closed buildings, and § 3.5.6, Article 3.96-3.105 for other treatments in closed buildings). Therefore no exposure assessment on a national level is required for such uses.

2.3.2. Drinking water abstraction points

Surface water destined for the production of drinking water should meet the drinking water criterion. For most active substances in plant protection products this drinking water limit is 0.1 μ g/L.

Field uses

Agricultural use (professional use)

For the assessment of surface water destined for the production of drinking water at **agricultural use** the methodology developed in the WG "Implementatie drinkwatercriterium" is followed (<u>Adriaanse et al, 2008, Alterra report 1635</u>). The methodology exists of 2 tiers: pre-registration modelling and post-registration monitoring.

The pre-registration modelling tier (first tier) is based on the model <u>DROPLET</u> that starts with a FOCUS D3 edge-of-field scenario cf. <u>FOCUS 2001</u> but with Dutch spray drift values. From the edge-of-field concentration the concentration at the abstraction point is calculated by multiplying with factors accounting for e.g. (i) the relative crop area, i.e. the ratio of the area of the crop and the entire intake area, (ii) market share, reflecting that the active substance is not used on the entire area of a crop, (iii) difference in timing of applications within the area of use, (iv) degradation and volatilisation from the edge-of-field watercourse to the abstraction point and (v) (in very specific case) additional dilution by a lake or incoming river.

The post-registration monitoring tier (highest tier) for the relevant substances, see below for interpretation) consists of an analysis of monitoring data on all abstraction points. A 90th percentile value is calculated for each individual abstraction point.

In fact, for all substances pre-registration modelling is the first tier. However jumping in tiers is possible.

The interpretation of Ctgb of the WG report/decision tree is therefore as follows:

- The analysis of post-registration monitoring data is only relevant for substances that have been indicated (on a yearly basis) as substances of concern by the VEWIN.
- For substances that have been on the market for over 3 years at the time of the assessment and are not included on the list of substances of concern, there is no need to analyse monitoring data or perform model calculations (a standard paragraph is added to the assessment)
- For new substances on the Dutch market (< 3 years) pre-registration modelling is needed.
 If modelled concentrations exceed the drinking water criterion, first, (spray drift) reducing
 measures should be proposed. If then the use of the substance is still predicted to exceed
 the drinking water criterion but with a factor < 5, authorisation could be granted under
 condition of post-registration monitoring.

For the full text please refer to <u>Alterra report 1635</u> and the user manual of DROPLET (<u>Van Leerdam et al, 2010</u>, <u>Alterra 2020</u>). A decision tree is presented in Appendix 3.

Agricultural use (non-professional use)

The developed decision trees and models are not suitable for non-professional (agricultural) use since the area of use cannot be described adequately. Therefore as an approximation a more qualitative assessment following the interim decision tree or RAT factor approach should be used (see Appendix 3) based on the PECsw as calculated with TOXSWA. Alternatively, a DROPLET assessment based on the corresponding professional use may be submitted as a conservative approach.

Non-agricultural use

For the pre-registration assessment of surface water destined for the production of drinking water after **application to hardened surfaces** a separate methodology was developed by the WG "Implementatie drinkwatercriterium" (<u>Linders et al., 2010, RIVM report 601450021</u> together with <u>Addendum and calculation tool, Van der Linden, 2016).</u>
See Appendix 3 for a short description.

Protected crop uses

The developed decision trees and models are not suitable for protected use since the area of use (greenhouses) is not taken into account in DROPLET. Therefore as an approximation a more qualitative assessment following the interim decision tree should be used (see Appendix 3), based on the PECsw calculated with GEM (or one of the lower tier calculation methodologies for protected crops).

2.3.3. Refinement options for PEC calculations

Options to refine the risk assessment on the exposure side by decreasing the exposure concentrations are:

- Higher tier data on the fate of a substance in the aquatic environment (including sediment) or within the greenhouse,
- Mitigation of the exposure by spray drift reducing technologies (field use) and end-of-pipe water purification measures or management refinements (greenhouse).

Supplementary research to establish the fate of the active substance(s) in representative aquatic (model) ecosystems (including sediment) should be in accordance with the requested use of the product and relevant for the Dutch agricultural and climatologic situation.

Another way to adjust (predicted) exposure concentrations is the prescription of the use of emission mitigating measures/techniques (spray drift for field uses, purification for greenhouses). The spray drift mitigation options are described in Appendix 2 (Drift Tables) for the field uses.

Please note that Ctgb considers that in view of the changed definition in the Activity Decree (drift reduction on the whole field instead of only in the 14 meter bordering the surface water body) any additional drift reduction resulting from the authorisation assessment also applies to the whole field (see Appendix 2 for more details on the change in the Activity Decree).

Refined exposure calculations might be combined with a refined adequate risk assessment for aquatic organisms, as included in *Chapter 7. Ecotoxicology; aquatic*.

This may include argumentation that a time-weighted average (TWA) concentration is relevant for risk assessment. For the calculation of TWA concentrations for another time window than standard available in the TOXSWA output (i.e., 4, 21 and 28 days) please refer to the <u>working instruction on the Ctgb website</u>.

2.3.4. Use of monitoring data

2.3.4.1. Introduction

Monitoring data are taking into account in the risk assessment, provided that these meet qualitative and quantitative requirements as described below.

An essential condition for the application of monitoring data in the evaluation of the permissibility of Plant protection products is that it must with reasonable certainty be possible to establish a plausible causal relationship between the use in compliance with legal instructions for use and the monitoring concentration of a Plant Protection Product in the environment.

When such a relationship is lacking, monitoring data can have a warning function, making a study into the possible risks desirable. This also means that monitoring data in the context of the evaluation of the permissibility will have to meet a number of quality criteria such as, e.g., regarding the number of measurements, set-up of measurements etc.

Currently two existing types of data sets are taken into account:

- Surface water quality monitoring from an eco(toxico)logical perspective (water boards, gathered in Pesticide atlas, paragraph 2.3.4.2)
- 2. monitoring data for surface water destined for the production of drinking water (Vewin data, paragraph 2.3.4.3).

Furthermore, general criteria were set up to assess the acceptability of other/additional monitoring data sets not described below (a reference to these criteria is made in paragraph 2.3.4.4).

2.3.4.2. Monitoring data for surface water (ecotoxicological quality)

In principle, monitoring data are higher tier data in the context of a tiered risk assessment. However, monitoring data in surface water are of limited use as refinement for registration

purposes, as monitoring may not adequately capture the initial exposure relevant for the aquatic risk assessment. Therefore, the absence of exceedance based on monitoring data cannot be used as such to overrule the predicted concentrations. Furthermore monitoring in surface water is often performed in other waterbodies than in the edge-of-field ditch which is the relevant waterbody for the registration. If however monitoring data show that there is threshold exceedance further assessment is triggered.

Regular screening monitoring data of the various water boards are gathered in the Pesticide Atlas, maintained by CML, part of Leiden University). It is verified that the data in this Atlas comply with the criteria set below for Category 1 data. On a yearly basis Ctgb provides an update of the relevant aquatic thresholds for authorisation to CML. The Pesticide Atlas includes a statistical correlation analysis between concentrations, threshold exceedance and land use that may indicate probable relationships. In this version also the correlation analysis of land use with the environmental quality standards (EQS) of the Water Framework Directive (WFD) is included.

Data from the Pesticide Atlas are used to evaluate potential exceedances of the authorisation threshold and environmental quality standards (MKN in Dutch, data source http://www.rivm.nl/rvs/Normen). These environmental quality standards consist either of the harmonised WFD thresholds (AA-EQS and MAC-EQS) derived according to the Fraunhofer methodology as laid down in RIVM report 601782001 or of an MPC value (which is usually derived on the basis of outdated guidance).

If an exceeding of the authorisation threshold is observed, first an analysis of land use with the exceeding is made by reviewing the correlation analysis on www.bestrijdingsmiddelenatlas.nl. The applicant is requested to submit a further adequate risk assessment when the authorisation threshold is exceeded and a relation with the proposed use is plausible (*i.e.*, when a statistically significant correlation between threshold exceedance and land use is found).

The applicant should then substantiate that the proposed use does not contribute to the exceeding, or submit a proposal for emission reduction. If there is a correlation of exceeding with already authorised uses, this will be mentioned as a signal for future (re-)registrations of the product.

Ctgb is not the responsible authority for the examination of the WFD threshold. WFD thresholds are essentially identical to the MPC-INS which is laid down in the RGB in the way that these thresholds are derived (*i.e.* following the earlier mentioned Fraunhofer methodology). However there has been a status change with regard to the role of this MPC-INS in the authorisation procedure for plant protection products. Until 2011 the MPC-INS was included as an authorisation criterion in the RGB (article 2.10). In 2011 an adaptation of the RGB was made due to the implementation of 1107/2009 EC. It is now laid down in the RGB that Ctgb can calculate the MTR-INS on request (article 8.11).

In the project Decision Tree Water "Terugkoppeling monitoring naar toelating" a plausible cause analysis protocol (<u>De Werd & Kruijne, 2013</u>) was developed that also uses the Pesticide Atlas as data source for monitoring data. As a transitional measure, awaiting the implementation of the work of the working group *Terugkoppeling Monitoring naar Toelating*, Ctgb has until now considered monitoring data in relation to exceedance of EQS values(MPC-INS).

The result of the Working Group has been implemented in the Emission Reduction Plan

(ERP) approach. This implementation of the Emission Reduction Plan is steered by the Ministry of Infrastructure and Environment and aims at reduction of the threshold exceedance with regard to the WFD thresholds. Ctgb is not the responsible authority to address any potential exceedance of the WFD thresholds.

When the applicant concludes that the authorisation conditions need to be amended, an application for label change can be proposed. Ctgb will judge whether the proposed emission reduction will be adequate and amend the label accordingly.

Hence, Ctgb continues to report monitoring data in relation to ecological threshold exceedance but will only draw consequences when the authorisation threshold is exceeded and a plausible relation with the relevant land use is present (statistically significant correlation as defined by the Pesticide Atlas).

2.3.4.3. Monitoring data at Drinking water abstraction points (drinking water quality)

The Vewin assembles the monitoring data of all drinking water companies into a data set comprising all drinking water abstraction points in surface water and supplies these data to Ctgb on a yearly basis. It is verified that the data of the Vewin comply with the criteria set below for Category 1 data. Furthermore, the Vewin data are designated by the WG drinking water criterion to be used in the authorisation procedure.

A causal or statistical correlation with land use cannot be made because of the more diffuse source of the surface water reaching the drinking water abstraction points. Therefore the criterion of a plausible causal relation up to specific crops or applications is not applicable to this assessment. However, it should be clear that a substantial part of the source of the substance is agricultural before the monitoring data will affect authorisations of PPP.

2.3.4.4. Additional monitoring data

When an applicant wishes additional monitoring data to be considered in the evaluation, these should meet certain criteria and the monitoring protocol should be discussed with the Ctgb on beforehand. The Ctgb criteria for taking additional monitoring data into account are described in Evaluation Manual version 1.0, G6 water, NL part, 2.3.5.4 (2010).

2.4. Approval

The evaluation of products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 or new substances has been laid down in Regulation (EC) No 1107/2009. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection product and Biocides Decree (Bgb).

2.4.1. Criteria and reference values

The concentration in surface water and sediment as determined according to the methods in this chapter are primarily used for assessment of the risk to aquatic organisms. The ecotoxicological criteria and reference values have been laid down in the section Ecotoxicology; aquatic organisms. Furthermore, the concentration in surface water is relevant with regard to the secondary poisoning assessment for fish-eating birds and mammals, see section Ecotoxicology; birds and mammals.

The criterion laid down for surface water intended for drinking water production is that the concentration of any active substance and the metabolites formed from that active substance must be lower than $0.1 \, \mu g/L$. A separate decision tree is available for this assessment (see

Appendix 3).

In the case of metabolites that are declared non-relevant with regard to groundwater this non-relevance can be extrapolated to surface water intended for the abstraction of drinking water. This is sustained by the <u>Guidance Document (GD) on non-relevant metabolites</u> where it is stated in the introduction that: "This guidance document focuses on groundwater, though the general approach may also be applicable for the <u>regional management of surface water</u> resources intended for the abstraction of drinking water in Member States."

2.4.2. Decision making

The procedure for taking a decision on approval regarding the risk to aquatic organisms has been elaborated in chapter 7 Ecotoxicology; aquatic.

The criterion laid down for surface water intended for drinking water production is that the concentration of any active substance and the metabolites formed from that active substance must be lower than the drinking water threshold laid down in the Drinking Water Directive (0.1 µg/L for organic substances).

2.5. Developments

The following developments will be implemented in the coming years. For the moment, assessment is based on either the old situation or on interim methodologies as described in this Chapter.

- Introduction of the new model DRAINBOW (Working group Water, "blootstelling waterorganismen"). Expected in 2019. Aspects that will (or might) change as a result of the Working Group's progress:
 - spray drift differentiation for field crops (edge-of-field) based on minimum agronomic crop-free zone
 - spray drift data tall fruit dormant and full leaf distinction based on BBCH code instead of fixed date
 - introduction of emission route via drainage from adjacent field
 - · Guidance for the input parameters for degradation in water
- Some of the above aspects will also be affected by the project "Eénduidige voorschriften". The policy advice was finalised at the end of 2015. Up to date there is no clear effectuation of this advice. A number of the recommendations of this project is implemented as a result of the transition from individual techniques towards DRT classes, as effectuated in this Evaluation Manual version.
- Dust drift from seed treatments (not NL specific, see EU part of the Evaluation Manual for details)

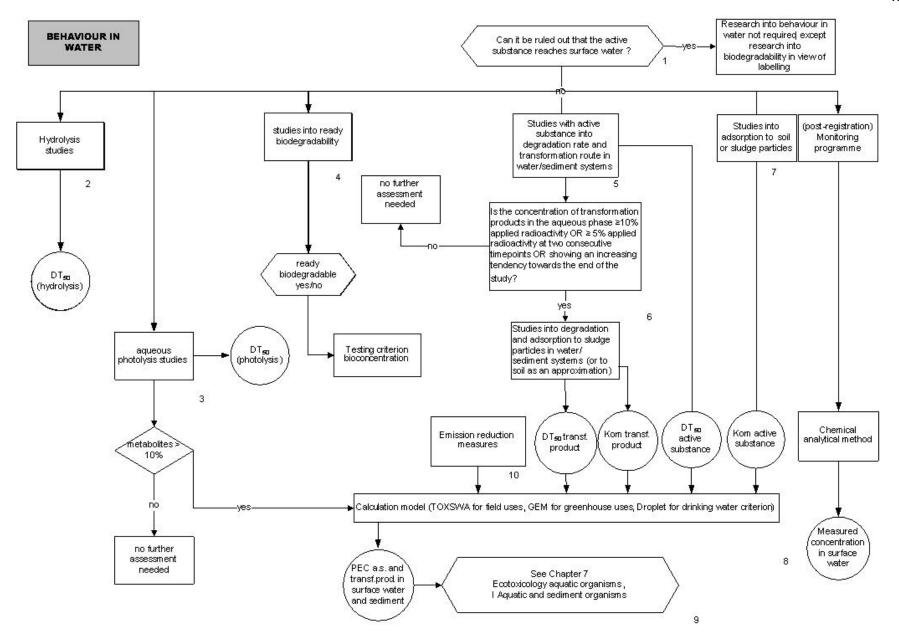
3. APPENDICES

Appendix 1 Explanatory notes decision tree behaviour in surface water and	I sediment17
Appendix 2 Spray drift and emission percentages	20
Appendix 3 Decision tree Drinking Water Criterion	32

Appendix 1 Explanatory notes decision tree behaviour in surface water and sediment

- 1) For each active substance, information concerning behaviour in surface water and sediment (283/2013 7.2) must be provided, unless it can be demonstrated that it can be ruled out that the substance reaches surface water and sediment during good (agricultural) use of the product, according to the WG/GA (Statutory Use Instructions/Directions For Use).
- 2) For the performance of the hydrolysis study, reference is made to question 283/2013 A2.09.1a and 7.2.1.1. This information is used as background information during the assessment.
- 3) Data on the photochemical degradation (283/2013 A2.09.2a/A2.09.3a and 283/2013 7.2.1.2 and 7.2.1.3) are used as background information in the assessment. Any photolysis metabolites exceeding the trigger of 10% should be assessed.
- 4) Data on "ready biodegradability" are required for testing the bioconcentration factor. The criterion for bio-concentration is associated with the degree of biodegradability 'ready biodegradable' / 'not ready biodegradable' of a substance.
- 5) A study in water must be conducted into the dissipation (disappearance) of the active substance, and the transformation of the active substance into its degradation products (283/2013 7.2.2.). The routes through which the transformation processes take place, and the rates of the transformations must, where possible, be determined.
- 6) Toxicologically or ecologically relevant degradation products in the <u>aqueous phase</u> are degradation products formed in the aqueous phase of which the laboratory research into the degradation in a water/sediment system at any point in time showed an amount higher than or equal to 10% or 2x5% or increasing towards the study end of the added amount of active substance. For these metabolites, data on the rate of degradation and sorption are required.
 - NB For toxicologically or ecologically relevant degradation products in the <u>sediment phase</u> formed in the sediment phase in a water/sediment system after 14 days the trigger for further assessment remains to be 10% of the added amount of active substance. For these metabolites, data on the toxicity for sediment organisms are required.

- 7) The data obtained on adsorption to soil can be used (see 283/2013 7.1.3) for evaluation of the adsorption of the test substance to suspended solids and sediment..
- 8) The exposure (Predicted Environmental Concentration (PEC)) is the value calculated by a calculation model, taking into consideration the frequency of application. When calculating the concentration of a Plant Protection Product in surface water and sediment, the relevant emission routes of the product to surface water and sediment should be determined, and the concentration must then be calculated with the appropriate module. For the current Dutch assessment of Plant protection products, the emission route spray drift is considered for field uses (TOXSWA) and emission from greenhouses is addressed in GEM.
- 9) In the assessment diagram concerning the risk to aquatic organisms, the PEC is related to toxicity data of the different tested aquatic organisms, for which reference is made to the next Chapter 7 Ecotoxicology; aquatic.
- 10) In a refined exposure assessment, emission reducing measured can be applied to decrease the PEC. Another option for refinement of the exposure assessment is the generation of supplementary data about the fate of the substance in the aquatic environment (including sediment) which may lead to adjustment of the calculated exposure concentration.



Appendix 2 Spray drift and emission percentages

Framework

National spray drift values can be applied on the basis of Article 8f of the Plant protection products and Biocides Decree (Bgb). Ctgb bases the exposure assessment on average spray drift values determined by WPR (Wageningen Plant Research, formerly WUR-PRI).

Change in Activity Decree and introduction of DRT classes (January 2018).

A major general change affecting the use of spray drift values in the assessment of plant protection products is the Entry into force of the <u>revision of the Activity Decree</u> (Activiteitenbesluit), per January 2018, including the introduction of drift reducing technology (DRT) classes. Individual techniques are classified into groups of techniques that comply with a minimum drift reduction. The list of these DRT classes and techniques that fall into these classes is available at <u>Helpdesk Water</u> (Dutch version only).

The standard requirement for field applications (downward sprayed crops, fruit culture and lane tree cultivation) is the use of a 75% reducing technique on the whole field irrespective whether these fields are adjacent to surface water.

Furthermore the minimum crop free zone changes from 25 cm to 50 cm for downward sprayed crops (relevant for cereals and grassland).

For fruit culture this standard requirement of 75% reduction should be applied in combination with 4.5 m crop free zone. If a crop free zone of 3 meter is used then techniques with 90% reduction should be applied.

For lane tree cultivation the policy aim is a reduction of 75% of the emission, at a crop free zone of 5 meter.

Users of plant protection products should always comply to the rules of the Activity Decree.

For fruit culture and lane tree cultivation a number of transitional measures are described in the Activity Decree. This allows farmers to use certain techniques that do not completely meet the policy aims laid down in the Activity Decree for a limited period of time.

However, for the authorisation assessment of plant protection products the potential risk that may occur due to the use of these techniques will be taken into account. See the specific sections for fruit culture and lane tree cultivation for details.

Please note that Ctgb considers that in view of the changed definition in the Activity Decree any additional drift reduction resulting from the authorisation assessment also applies to the whole field, in line with the recommendations of the working group Eénduidige voorschriften. When additional drift reduction on top of the obligated reduction as laid down in the Activity Decree is required to achieve an acceptable risk for aquatic organisms, this drift reduction will in principle be expressed in DRT classes. In exceptional cases, individual techniques may be acceptable. For drift deposition values for individual techniques please refer to Evaluation Manual version 2.1, NL part, chapter 6 surface water, appendix 2.

Spray drift values

In Table 1 a general overview of the default spray drift percentages used by Ctgb under the new Activity Decree for all crop types is presented. Spray drift values are different for downward sprayed crops (arable crops) and for upward or sideways sprayed crops (fruit and lane trees).

Upward and sideways spraying

For the spray drift values in fruit, all experimental spray drift data up to and including 2005 are used. For the dormant stage data from 1998 are maintained. Furthermore the <u>spray drift percentage for soft fruit was set to the full-leaf values for large fruit based on a literature inventory of actual spray drift data in small fruit cultivation in which it is demonstrated that the field crop spray drift value of 1 % is not protective.</u>

In the absence of actual measurements in small fruit, the full-leaf values for large fruit are taken as an approximation.

For the cultivation of lane trees updated spray drift data (2010) were added during the Evaluation Manual update of January 2014.

See Table 2 for a more detailed description for the situation for fruit trees and Table 3 for lane trees.

Downward spraying

Spray drift values based on 75% reduction are only valid for crops covered by the Activity Decree. If applicants wish to apply for other uses (e.g. amenity use and field edges), the spray drift value based on conventional spraying techniques should be used, and mitigation can be proposed as required. See explanatory notes for more detail.

Table 1 Spray drift percentages on surface water for standard situations*

drift %	
Upward and sideways spraying techniques	
	1000 11
' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '	l on 1998 data
fruit**) – minimum crop free (dormant)	
zone 3 meter	
	l on 2005 data
(full leaf)	
·	l on 1998 data
free zone 5 m closely spaced)	
Transplanted trees 2.8 Based	l on 1998 data
("opzetters",	
widely spaced)	
High lane trees 5.8 Based	l on 2010 data
Downward spraying techniques	
Field crops (including For Based	I on report IMAG 97-04 in
downward sprayed forest crops combin	nation with a 75% spray
trees and hedging plants and covered drift re	educing technique as per
flower bulbs/bulb flowers) by the the Ac	ctivity Decree (from
Activity Janua	ry 2018)
Decree:	
0.5 Differe	entiation of the spray drift
	s to cover different crop-
	ones is under development
crops:	
	on report IMAG 97-04,
	ntional technique
Special applications -mud-bank 100 see ex	xplanatory notes

	-dry ditch	100	
	-reed	100	
	-Knapsack	1.2	
Applications without spray	See explanatory	0	
drift	notes		

- * Spray drift-mitigation measures will be discussed in more detail in the explanatory notes below.
- ** for small fruit (grapes, berries, ...) only the **full leaf situation** is used for the exposure assessment, since
 - the use of spray drift values from downward directed spraying is too best-case (inventory report Van de Zande J.C., M. Wenneker, A. de Bruine. 2011. Inventarisatie kleinfruitteelten en afleiden driftdepositie en maatregelpakketten. *PRI report 398*.)
 - the full leaf values are comparable in order of magnitude with the EU spray drift values for vines (Rautmann)

Explanatory notes spray drift percentages

General

The proposed spray drift percentages are derived from research by Wageningen Plant Research (WPR).

On an individual basis an applicant/registration holder can request Ctgb to consider additional spray drift-mitigation technique/crop free zone combinations and corresponding spray drift percentages for a particular application. These spray drift percentages must be supported by reliable scientific data.

The additional measures should be realistic and enforceable. Below, specific mitigation options are described per crop/application type.

Explanation per crop/application

Upward and sideward spraying

Fruit crops (including soft fruit and hop cultivation)

Large fruit (pome- and stone fruit/top fruit)

Standard spray drift percentages are based on a crop-free zone of 3 meter (standard situation, see Table 1). However, the Activity Decree prescribes that in large fruit a 75% drift reducing technique is compulsory, in combination with a crop free zone of 4.5 m. A crop free zone of 3 meter is only allowed when a drift reducing technique of at least 90% is used. These DRT classes have been defined on the basis of the reduction in the full leaf stage as compared to the conventional standard technique at the evaluation zone relevant for the position of the edge-of-field ditch.

An exception to this is the biological cultivation, for which it is allowed to use a crop free zone of 3 meter with a spray drift reduction of 75%. If for a product for which an application for authorisation is made it is clearly indicated on the label (instructions for use) to be applicable for biological cultivation, Ctgb will use the spray drift values relevant for this situation. Any required additional mitigation should then be stated on the label.

See Table 2 for a description of the spray drift deposition values for fruit culture. For completeness (and for the use of default values for non-professional users) also the old standard situation is included. A distinction is made between spray drift values in the dormant stage and in the full-leaf stage. This distinction is now fixed to the date of May 1st. In future, the spray drift curves will be based on BBCH codes (see section on developments in main text).

The spray drift values for the full-leaf stage are based on the WPR spray drift database up to 2005 ¹. For the dormant stage, values from 1998 are retained (these values were not based on experiments but extrapolated based on an estimated factor with regard to the spray drift data set in full-leaf). The limited data set of experimental values in the dormant stages up to 2005 are lower than the 1998 extrapolated values. However, newer (still unpublished) spray drift measurements have extended the data set of 2005 and the new data set shows higher values than the 2005 data alone. Therefore the 1998 data are retained for the dormant stage. These values are valid for *fungicide* and *insecticide* treatments. See Table 2.

Soft fruit (berries and grapes)

Based on an inventory report by WPR² it was decided in 2014 that for sideways or upwards sprayed soft fruit (grapes and berries) the large fruit spray drift values are used. For all application periods, <u>only the full-leaf values are used</u>. This is done to acknowledge the difference between large fruit and small fruit as established by Rautmann and Ganzelmeier (basis for EU spray drift values) to some extent.

With regard to the crop-free zone it is concluded in the PRI 398 report that although according to the Activity Decree the obligatory distance to the ditch for small fruit is only 0.5 m, in practice the distance is about 3 meter. This is in line with the minimum distance set for large fruit. Therefore the use of the spray drift values of large fruit (minimal crop-free zone 3 m) is defensible at this stage.

Please note that with regard to spray drift mitigation not all techniques are realistic for application in soft fruit, which is often cultivated under certain types of coverage. Applicants should take this into account when proposing the use of certain DRT classes and make sure that an appropriate technique for soft fruit is available in that class. For instance, the use of KWH 3-row sprayers is not feasible for soft fruit like berries. On the basis of the current DRT list (December 2017) it appears that DRT97.5% or DRT99% technique are not practically feasible for soft fruit at this moment.

The use of the full-leaf spray drift values for large fruit also for small fruit must be seen as a transition phase until sufficient actual measurements leading to separate spray drift values for soft fruit are available.

Hop cultivation

For the sideways and upward application in hop no spray drift deposition values are available. Hop cultivation in The Netherlands is usually 3-4 meter high (Limburg) For the assessment the values applicable to tall fruit in the dormant stage are used, based on expert judgement of WPR (personal communication, 2014).

Please note that with regard to spray drift mitigation not all techniques are realistic for application in hop. For instance the use of drift reducing nozzles that lead to very coarse droplets is not recommended, since they will not reach the top of the crop. Applicants should take this into account when proposing the use of certain DRT classes and make sure that an appropriate technique for hop cultivation is available in that class. On the basis of the current DRT list (December 2017) it appears that in each class a feasible technique for hop is available.

¹ Van de Zande J.C. & Huijsmans J. 2012 Notitie update driftcijfers fruit voor een nieuwe Ctgb drifttabel. Intern PRI report 07-

² Van de Zande J.C., M. Wenneker, A. de Bruine. 2011. Inventarisatie kleinfruitteelten en afleiden driftdepositie en maatregelpakketten. PRI report 398.

Spray drift mitigation techniques and spray drift deposition values

See Table 2 for a description of the spray drift deposition values belonging to the various

DRT classes for large fruit.

The aim laid down in the Activity Decree for fruit culture is 75% spray drift reduction when applying a crop free zone of 4.5 meter, or a 90% spray drift reduction when applying a crop free zone of 3 meter.

This drift reduction can be achieved by applying spray techniques of a certain drift reduction class (DRT class). These DRT classes have been established by the TCT in collaboration with WPR within the framework of the Activity Decree.

For each DRT class a benchmark (reference) technique has been assigned on the basis of their spray <u>drift reduction percentage</u>. Reference techniques are defined in WPR report 564³.

The absolute spray <u>drift deposition values</u> for those reference techniques are used for the exposure assessment and are presented in the Table 2.

For dossiers in which no drift reduction is requested in principle the boundary conditions defined by the Activity Decree apply. For the assessment for fruit culture this means the use of the spray drift deposition values (dormant/full-leaf stage) of **DRT75 in combination with 4.5 m crop free**, as this covers for the spray drift deposition when using DRT90 in combination with a crop free zone of 3 meter.

However, the Activity Decree (see Article 3.80a) allows during a transitional period until 2021 the use of a tunnel sprayer at 3 meter (classified in DRT75), and the use of a windbreak at 3 meter (in combination with an application technique from the class DRT75). For the purpose of risk assessment it is assumed that the effect of a windbreak will be (at least) maintained, also when used in combination with a DRT75, for which up to date no drift deposition values are available. Hence the existing drift deposition values as were included in the previous Evaluation Manual will be maintained.

Hence, as until 2021 also other options are still allowed that may lead to higher spray drift deposition Ctgb considers that this additional risk should be taken into account in the risk assessment.

This means that for the <u>dormant crop stage the value of 7%</u> (from the windbreak) and for the <u>full-leaf crop stage the value of 1.3%</u> (tunnel sprayer) will be used as starting point for the assessment for those dossiers.

If this does not lead to an acceptable risk then the defined final boundary conditions of the Activity Decree (i.e. drift values at DRT75 and 4.5 m crop free zone) will be assessed. If this leads to an acceptable risk the following restriction sentence is needed to exclude the possibility that users will use the equipment/measures allowed in the transitional period for the product in question.

Om in het water levende organismen te beschermen is toepassing van dit middel in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRT75 in combinatie met een teeltvrije zone van 4,5 meter of een techniek uit tenminste de klasse DRT90 in combinatie met een teeltvrije zone van 3 meter.

-

³ Zande, J.C. van de, H.J. Holterman, J.F.M. Huijsmans & M. Wenneker. 2017. Spray drift for the assessment of exposure of aquatic organisms to plant protection products in the Netherlands. Part 2: Sideways and upward sprayed fruit and tree crops. Wageningen UR, WPR Report 564, Wageningen. 2017.

If further drift mitigation is required to achieve an acceptable risk, this will always lead to a restriction sentence, in which the DRT class and the minimum required crop free zone should be specified, if more than 3 meter:

Om in het water levende organismen te beschermen is toepassing van dit middel in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRTxx [in combinatie met een totale teeltvrije zone van xx meter (specify only when larger than the minimum of 3 meter)].

Spray drift deposition values for the different drift reducing technique classes are presented in the table below. If a combination of a DRT class and an additional crop free zone is needed to achieve a safe use then a specific drift report (e.g., by WPR) should be submitted by the applicant.

For *herbicide* use in fruit cultivation, downward spraying –complying to a minimum drift reduction of 75%- is applicable. See Table 2.

Please note that with the entry into force of the new Activity Decree Ctgb considers that all additional mitigation measures should also apply to the whole field.

Table 2: Spray drift values for DRT classes and separate techniques on the basis of transitional measures laid down in the Activity Decree

Spray drift	percentage [%	6]		
Individual techniques/DRT classes	Crop-free zone of 3 m		Crop-free zone of 4.5	
		1	m	_
	Without	with	Without	with leaves
	leaves	leaves	leaves	
	(dormant)	(full-leaf)		
Standard orchard sprayer*	16.6	8.6	10.3	6.3
Spray drift deposition values for techniques	accepted to be	e used durin	g the transiti	ional period
until 2021 as indica	ted in the Acti	vity Decree		
Tunnel sprayer at 3 m crop free (allowed till 2021)	2.5	1.3	-	-
Windbreak (in combination with 75DRT) at 3 m	7.0	0.9	-	-
crop free (allowed till 2021)				
Spray drift deposition values for DRT classes	s meeting the	aim laid dow	n in the Acti	ivity Decree
DRT75	8.3**	2.0**	5.0	1.2
DRT90	2.5	1.0	1.0	0.7
DRT95	1.3	0.36	0.6	0.26
DRT97.5	1.3	0.13	0.6	0.10
DRT99	0.65	0.05	0.23	0.04
Herbicide use in orch	ards (downwa	rd spraying)		
			3 m crop free zone	4.5 m crop free zone
"Zwartstroken" (bare soil surface strip underneath tree)	DRT75		0.010	0.010
	DRT90		0.007	0.007
"Grasstroken" (grass surface area in orchard)	DRT75		0.014	0.014
	DRT90		0.008	0.008

- * relevant for non-professional use in the absence of drift values for knapsack/ready to use upward-sideways spraying.
- ** only relevant for biological production (see Activity Decree, article 3.80, 4c, sub 3, will be used when relevant)

Lane trees

For the growth of lane trees, separate spray drift percentages are used based on research by WPR. A distinction is made between the growth of "spillen" (spindles; closely spaced trees) and "opzetters" (transplanted trees; widely spaced trees) because of the differences in tree shape, and the resulting differences in spray drift emission. Spindles form dense rows (plant distance 30 cm), whilst transplanted trees are planted further apart (1 m plant distance), are taller, and often have bare lower trunk.

Based on the available data set including spray drift reducing techniques⁴, spray drift deposition values are presented in Table 3. These values are valid for fungicide and insecticide treatments (sideways and upwards).

The aim laid down in the Activity Decree for lane tree cultivation is 75% spray drift reduction. This drift reduction can be achieved by applying techniques of a certain spray drift reduction class (DRT class). These DRT classes have been established by the TCT in collaboration with WPR within the framework of the Activity Decree.

For each DRT class a benchmark (reference) technique has been assigned on the basis of their spray <u>drift reduction percentage</u>. Reference techniques are defined in WPR report 564⁵.

The absolute spray <u>drift deposition values</u> for those reference techniques are used for the exposure assessment and are presented in the below table.

For dossiers in which no spray drift reduction is requested in principle the boundary conditions defined by the Activity Decree apply. For the assessment for lane trees this comes down to the use of the spray drift deposition values of DRT75 (not available for all lane tree stages).

However, the Activity Decree (see Article 3.80a) allows during a transitional period until 2021 the use of the standard techniques for lane trees to allow the sector to develop spray drift reduction techniques as insufficient techniques are available at the moment. Hence, as until 2021 also other options are still allowed that may lead to higher spray drift deposition Ctgb considers that this additional risk should be taken into account. This means that the standard technique (no spray drift reduction) will be used as starting point for the assessment for those dossiers. Also the use of a 50% spray drift reducing technique is still allowed under the transitional conditions given in the Activity Decree. The use of a conventional or DRT50 technique in combination with an additional crop free zone in which a non-sprayed crop of the same height can be grown is also still possible until 2021 and is therefore maintained in Table 3⁶.

If the use of a standard technique does not lead to an acceptable risk then the defined final boundary conditions of the Activity Decree (i.e. minimum DRT75 and 5 m crop free zone) will be assessed. If this leads to an acceptable risk a restriction sentence is needed to exclude

⁴ Van de Zande J. & Huijsmans J. 2012 Notitie update driftcijfers laanbomenteelt voor Ctgb. Intern PRI report 07-03-2012

⁵ Zande, J.C. van de, H.J. Holterman, J.F.M. Huijsmans & M. Wenneker. 2017. Spray drift for the assessment of exposure of aquatic organisms to plant protection products in the Netherlands. Part 2: Sideways and upward sprayed fruit and tree crops. Wageningen UR, WPR Report 564, Wageningen. 2017.

⁶ Please note that from 2021 onwards the use of DRT75 is obligatory. For authorisations based on DRT0 or DRT50 in combination with the additional crop free zone it is essential that after 2021 the additional crop free zone is maintained as requirement.

the possibility that users will use the equipment/measures allowed in the transitional period for the product in question.

Om in het water levende organismen te beschermen is toepassing van dit middel in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRT75 (please note this may come down to the use of DRT90 or higher in the case that a technique in DRT75 is not available).

If more than 75% drift mitigation is required to achieve an acceptable risk, this will always lead to a restriction sentence:

Om in het water levende organismen te beschermen is toepassing van dit middel in percelen die grenzen aan oppervlaktewater uitsluitend toegestaan indien op het gehele perceel gebruikt gemaakt wordt van een techniek uit tenminste de klasse DRTxx [in combinatie met een totale teeltvrije zone van xx meter (specify only when larger than the minimum of 5 meter)].

Spray drift deposition values for the different drift reducing technique classes are presented in the table below, when available. If a combination of a DRT class and an additional crop free zone is needed to achieve a safe use then a specific drift report is needed.

For *herbicide* use in lane trees, downward spraying –complying to a minimum drift reduction of 75%- is applicable. See Table 3.

Please note that with the entry into force of the new Activity Decree Ctgb considers that all additional mitigation measures should also apply to the whole field.

Table 3: Spray drift values on surface for various spray drift-mitigation techniques in comparison with standard lane trees growing situations

Spray drift percentage [%]				
DRT classes	Crop-free zone of 5 m (as obligated by the Activity Decree)			
Type of lane trees (stage) – upward and sideways spraying				
High lane trees (>5 meter)				
Spray drift deposition values for techniques accepted to be used during the transitional period until 2021 as indicated in the Activity Decree				
DRT0 (standard situation)	5.8			
DRT0 (standard equipment) + 5 meter crop free*	0.9			
DRT50	1.6			
DRT50 + 5 meter crop free*	0.09			
Spray drift deposition values for DRT clas	ses meeting the aim laid down in the Activity Decree			
DRT75	1.4			
DRT90	-			
DRT95 0.3				
Transplanted trees				
Spray drift deposition values for techniques accepted to be used during the transitional period				
until 2021 as indicated in the Activity Decree				
RT0 2.8				
DRT0 (standard equipment) + 5 meter crop 0.33 free*				
DRT50	1.1			

Spray drift deposition values for DRT classes meeting the aim laid down in the Activity Decree			
DRT75		-	
DRT90	0.19		
Spindle trees			
Spray drift deposition values for techniques accepted to be used during the transitional period			
until 2021 as indicated in the Activity Decree			
DRT0 (standard equipment)	0.76		
DRT0 (standard equipment) + 5 m crop free*	0.09		
DRT50	0.32		
Spray drift deposition values for DRT classes meeting the aim laid down in the Activity Decree			
DRT75	-		
DRT90	0.05		
Herbicide use in lane trees (downward spraying)			
soil surface underneath trees and up till 0.50 m from edge of surface water	DRT75	0.014	
	DRT90	0.008	

^{*} in this 5 m crop free zone only non-sprayed crops of the same height can be grown. These crops are eligible from the CIW report referred to in the explanatory notes of the Activity Decree, Artikel 3.80: *Op grond van het vijfde lid moet voor de opwaarts bespoten boomkwekerijgewassen, zoals laan- en parkbomen, een teeltvrije zone van tenminste 500 cm worden aangehouden. In de teeltvrije zone mogen gewassen geteeld worden waarin geen gewasbeschermingsmiddelen worden gespoten. Dit komt overeen met de CIW-aanbevelingen¹ voor de vergunningverlening, waarin bovendien een lijst van gewassen is opgenomen die niet bespoten worden.*

Please note that this option is not originally intended as spray drift reducing measure, but as a means to use the crop free zone space for non-sprayed trees. Furthermore Article 3.80 of the explanatory notes of the Activity Decree states that non-sprayed crops of the same height MAY be grown but does not say SHOULD be grown. If this is not done, there is no spray drift mitigating effect. Therefore Ctgb interprets this measure as: an ADDITIONAL crop free zone of 5 m should be used. Hence when using this mitigation technique the total crop free zone is 10 m, in which non-sprayed trees of the same height may be grown. This will be stated explicitly on the label.

Downward spraying

Field Crops (including downward sprayed forest trees and hedging plants, and flower bulbs

Spray drift percentage: 0.5%.

With the entry into force of the revision of the Activity Decree the use of a <u>75% spray drift</u> reducing technique on the whole field will be obligatory. Individual techniques are classified into groups of techniques that comply with a minimum drift reduction. For each DRT class a benchmark (reference) technique has been assigned on the basis of their spray <u>drift</u> reduction percentage. Reference techniques for downward spraying are defined in WPR report 419⁷.

Spray drift reducing techniques, classified according to drift reduction classes by the TCT (Technische Commissie Techniekbeoordeling), are listed on <u>Helpdesk Water</u>.

The first tier assessment is based on the obligatory use of a 75% spray drift-reducing technique on the whole field. For this situation, a spray drift emission of 0.5 % is available,

¹ Commissie Integraal Waterbeheer, 1998, Protocol opwaarts spuiten (laan)bomen.

⁷ Zande, J.C van de, H.J Holterman & J.F.M Huijsmans. 2012. Spray drift for the assessment of exposure of aquatic organisms to plant protection products in the Netherlands. Part 1: field crops and downward spraying. WUR-PRI Report 419, Wageningen. Table 4, page 18.

based on spray drift data of WPR for potatoes with a crop-free buffer zone of 1.5 m. Currently this spray drift value is also used for <u>all other field crops with downward spraying</u>, irrespective of the specific (agronomic) crop-free buffer zone.

In practice, crops are separated in the Activity Decree into two main groups based on their minimal obligatory crop-free zone: 150 cm for the intensively sprayed crops as described in Article 3.80 of the Activity Decree, and 50 cm for both cereals, grassland and remaining crops.

In the decision tree currently under development by the WG Water, spray drift differentiation between crops on the basis of crop-free buffer zones will be implemented on the basis of WPR data. These differentiated spray drift values will be implemented in the new exposure model for the Dutch edge-of-field ditch (implementation expected in 2017/2018), or sooner depending on developments in other projects (e.g., Eénduidige voorschriften, WPR drift calculator).

Refined assessment

If further spray drift reduction than 75% is necessary to meet the ecotoxicological threshold values, the use of 90 % spray drift reducing techniques can be requested by the applicant. The corresponding spray drift values used for the assessment is 0.2 % (90 % spray drift reducing technique) for all field crops.

Furthermore, it is possible to consider additional measures with accompanying spray drift percentages on an individual basis for each application and crop combination on the basis of specific spray drift research (e.g., by WPR) submitted by the applicant.

The Ctgb does not accept the generic use of additional mitigation measures beyond the use of 90% DRT because the actual national assessment framework does not take into account the differentiation of crop free zones for different crops. This could lead to severe underestimation of the real spray drift values, especially for crops that are grown with a small crop free zone. If the level of spray drift reduction is higher, this effect will become more pronounced. For the current use of 75% and 90% spray drift reduction this is not taken into account due to historic insights, but Ctgb is of the opinion that this historic situation should not be extrapolated to higher levels of spray drift reduction.

Hence, Ctgb only accepts the use of additional spray drift mitigation on a case by case basis if this is substantiated with a spray drift deposition calculation that takes into account the specific crop-free zone and nozzle position to last crop row for the specific use under consideration. At this moment 95% spray drift reducing techniques may be accepted for use in the authorisation process. The use of 97.5 and 99% reducing techniques in downward spraying may be technically feasible but from a policy perspective these are still under discussion and is therefore not recommended for use in the surface water assessment.

Please note that if the use of 90% or higher spray drift reduction techniques is necessary to achieve an acceptable risk to aquatic organisms in the authorisation procedure for <u>intensively sprayed crops</u>, the label should explicitly state that this is to be used in combination with a 1.50 meter crop free zone.

This is to prevent confusion for the user, since on the basis of equivalence ('gelijkwaardigheidsbepaling') currently drift reducing techniques of 90% or more can also be used to decrease the minimum crop free zone from 1.50 meter to 1 meter (on the basis of granting by the competent authority for law enforcement). This is however not allowed when on the basis of the risk assessment DRT90 is needed in combination with the default value of 1.5 meter crop free zone. See Article 3.80 sub 1 and 2 of the Activity Decree for a listing

of the intensively sprayed crops for which a standard crop free zone of 1.50 m applies.

Please note that with the entry into force of the new Activity Decree Ctgb considers that all additional mitigation measures should also apply to the whole field.

Deviating spray drift values for specific crop related techniques

WPR has indicated that the crops forest trees and hedging plants (downward sprayed) is considered to be sprayed with boom sprayers like a common field crop, and that the same percentage can be used based on the same assumptions as described above. In practice, however, a specific spraying technique is often used in specific regions (i.e. on small parcels in the Boskoop region), *i.e.*, a hand-held spray boom. From field experiments (IMAG Nota 98-31⁸) the following spray drift values are available:

- 1.2 % for standard nozzle.
- 0.6 % for 50 % spray drift reducing nozzle or a shielded standard spray nozzle. As these values are also applied for non-professional applications with a knapsack (assuming a crop-free zone of 0.50 m), they are maintained in the Evaluation Manual.

Greenhouse Applications

For all greenhouse uses a pseudo-spray drift value of 0.1% was used in the past to account for all types of emission. From March 2016 onwards the Greenhouse Emission Model (GEM) should be used instead for organic substances. See main text of this chapter. *NB* The use of the 0.1% overall emission, modelled as spray drift, has therefore become obsolete, but it may still be used for the assessment of emission for e.g., micro-organisms (see Evaluation Manual for Biopesticides).

Special Applications (field)

For mud-banks and dry-ditch beds, a default spray drift value of 100 % applies. This is also valid for reed as a worst case estimate, taking into account the wet environment of the crop applied for.

- Knapsack (handheld equipment)

For hand held equipment (*rugspuit/spuitlans*) a spray drift percentage of 0.6 % is assumed when a 50 % spray drift reducing nozzle or a shielded standard spray nozzle is used. For knapsack application without mitigation a value of 1.2 % applies. These values are based on a crop free zone of 0.50 m (extrapolated from the forest trees and hedging plants spraying technique).

These spray drift values will particularly be relevant for applications by non-professional users. For non-professional application with small spraying cans a value of 0.5 % is used.

Please note that these values for handheld equipment are only to be used for non-professional use in downward sprayed crops. If application is made sideways or upward e.g. in fruit trees or lane trees, these values do not apply. In the absence of estimates for drift deposition values in fruit and lane trees for the use of a knapsack or small spraying cans a conservative value is used on the basis of the standard techniques for these crops. Refer to Tables 2 and 3 above.

Applications without spray drift

A spray drift percentage of 0% applies for:

⁸ Driftreductie in de lage boomteelt bij een bespuiting met een handgeduwde spuitboom, een afgeschermde spuitboom en een dichte afscherming op de perceelsrand, IMAG nota 98-31

- 1) Enclosed spaces (indoor uses, not greenhouses and walk-in tunnels):
 - a. storage cells and
 - b. shower rooms and comparable enclosed spaces;
- 2) witloof/chicory (forcing)
- 3) Specific field applications:
 - a. application of granules using a specially mounted granule sprinkler,
 - b. drenching,
 - c. dipping,
 - d. foaming,
 - e. placing of bait,
 - f. injection of soil/plant,
 - g. treatment of plant base
 - h. smearing,
 - i. jointing,
 - j. treatment of furrow,
 - k. dosing pistol or comparable apparatus, and
 - I. seed treatment.

Developments

Differentiated spray drift percentages for downward sprayed crops

As mentioned above, it is anticipated that Ctgb will switch to differentiated percentages for each crop tuned to the minimum agronomic crop-free zone based on a spray drift matrix that is properly substantiated by new scientific insights. Implementation of these differentiated percentages will be upon instruction from the ministries to use the new Dutch exposure surface water model DRAINBOW or sooner depending on developments in other projects (e.g., Eénduidige voorschriften, WPR drift calculator).

Distinction bare-full leaf situation in fruit

Change of date distinction to BBCH/growth stage distinction for fruit (WG water). This will be implemented upon instruction from the ministries to use the new Dutch exposure surface water model DRAINBOW.

Appendix 3 Decision tree Drinking Water Criterion

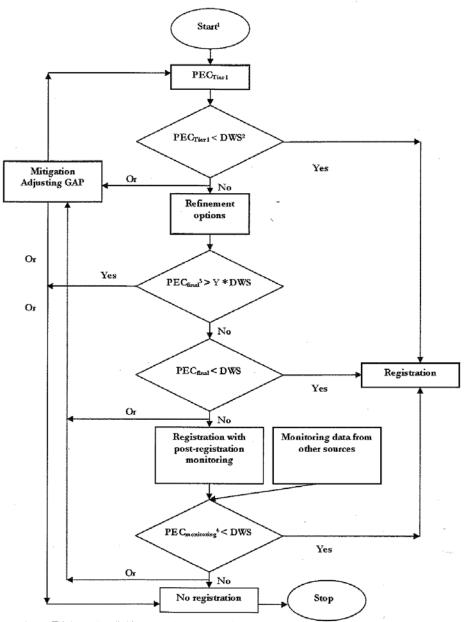
FIELD USES

PROFESSIONAL USE

1. AGRICULTURAL CROP TREATMENTS

For the assessment of the drinking water criterion, Ctgb uses the decision tree as developed by the Working Group Implementation Drinking Water Criterion (see Alterra report 1635) from January 2010 onwards.

The decision tree from the report is presented below.



- This is as well applicable to new substances as to substances already allowed on the market
- DWS is the Drinking Water Standard, in the Netherlands this is 0.1 µg/L at the moment when the report was issued
- In case no refined assessment has been applied the PECfinal is PECTime.1
 Before making a decision it has to be analysed whether the substance is of Dutch origin or not

Tier I calculation:

The equation to calculate the substance concentration in the surface water at the abstraction points $(PEC_{Tier\,I})$ reads:

$$PEC_{\textit{TierI}} = \sum_{\textit{all}}^{\textit{crops}} \; ((PEC_{\textit{FOCUS_NL},D3} \cdot f_{\textit{corrFOCUSscen}}) f_{\textit{use_intensity}}) \cdot f_{\textit{ti min g}} \cdot f_{\textit{dissipation}} \cdot f_{\textit{add_dilution}}) \cdot f_{\textit{ti min g}} \cdot f_{\textit{dissipation}} \cdot f_{\textit{add_dilution}} \cdot f_{\textit{dissipation}} \cdot f_{$$

With:

PEC_{Tier I} PEC in surface water at location where it is abstracted for drinking water

preparation (µg/L)

 $\mbox{PEC}_{\mbox{\tiny FOCUS_NL,D3}} \mbox{ global maximum PEC edge-of-field for the FOCUS D3 scenario based upon}$

Dutch spray drift deposition data (µg/L)

f_{corrFOCUSscen} correction factor for implicit choices concerning contributing areas made in

FOCUS D3 scenario (-)

 $f_{use_intensity}$ factor considering the use of the substance (-)

f_{timing} factor considering the difference in timing of application within the area of use

(-)

f_{dissipation} factor considering the dissipation from the edge-of-field watercourse to the

abstraction point (-)

 $f_{\text{add_dilution}}$ factor considering additional dilution, e.g. by considerable water flows

entering the intake area, or by lakes via which water travels to the abstraction

point

Further detailed explanation of these terms is given in <u>Adriaanse et al, 2008, Alterra report</u> <u>1635</u>.

Tier II evaluation of monitoring data:

The quality criteria to which monitoring data should comply are elaborated in paragraph 5.2.6 of Alterra report 1635. The procedure of evaluation of monitoring data described applies to post-registration monitoring data but can be extrapolated to the evaluation of existing (VEWIN) monitoring data (paragraph 5.3) since no clear guidance is given there.

In short, the procedure is as follows (for details see Alterra report 1635). Ideally the monitoring data should comply with the following criteria (set up for post-registration monitoring purposes for new substances):

- -13 measurements should be available for each drinking water abstraction point each year for the calculation of a 90-percentile value for each calendar year.
- if (due to exceptional circumstances) less than 13 measurements per year are available, the maximum value should be taken and should be below 0.1 µg/L
- if 12 measurements are available per year, the maximum value should also be taken and should be below 0.15 μg/L (explained in note *b* on page 68 of the report)

However, Ctgb considers that it is the responsibility of the water quality managers to decide whether to monitor a specific substance. Hence, any missing data for one or more specific abstraction point(s) for a potentially problematic substance cannot lead to a request for additional information from the applicant.

The 90-percentile value over a 5-year period is to be calculated for each abstraction point. If the 90-percentile over the 5-year period exceeds the threshold, an adequate risk assessment should be provided.

Next to the 90-percentile for 5 years, an analysis per year can be done if sufficient data are available. If the 90-percentile value for one year exceeds the threshold, a problem analysis should be provided.

No overall 90-percentile over the various drinking water abstraction points is calculated. Each individual abstraction point should meet the drinking water limit.

The Ctgb uses the possibility of jumping to higher tiers for the assessment of the drinking water. This means that in practice three categories of substances are distinguished:

- 1. New substances on the Dutch market (< 3 years authorised in NL): A Tier I PEC is calculated according to the methodology in Alterra report 1635. A Tier II cannot be performed yet as there are no monitoring data for new substances. If Tier I fails (with less than a factor 5 exceeding), post-registration obligation will be imposed in order to collect Tier II data for future evaluations of the substance. (if the VEWIN during the authorisation period indicates that the substance is regarded as a substance of concern on the basis of new, adequate and sufficient monitoring data the substance will move to the third category)</p>
- 2. Old (> 3 years authorised in NL) **substances of no concern**: if there are no indications from the VEWIN that the substance is a potential problem for drinking water production, then no Tier I calculations are deemed necessary. The substance meets the drinking water criterion based on the Tier II information (as the available VEWIN monitoring data indicate no problems). (if the VEWIN during the authorisation period indicates that the substance is regarded as a substance of concern on the basis of new, adequate and sufficient monitoring data the substance will move to the third category)
- 3. Old (> 3 years authorised in NL) **substances of concern**: the VEWIN indicated that the substance is a potential problem for drinking water production by including it on a yearly updated list on the basis of monitoring data. In this case, Tier II is used directly (jumping of Tier I) the available monitoring data of the VEWIN of the most recent 5 years at all drinking water abstraction points will be analysed on the basis of the criteria set out in the Alterra report.

The list of substances of concern is yearly updated by VEWIN and published on the VEWIN website (http://www.vewin.nl/probleemstoffen).

For further details refer to Alterra report 1635.

2. NON-AGRICULTURAL USE (USE ON HARDENED SURFACES)

Alterra report 1635 only provides guidance for agricultural applications (direct emission to edge-of-field ditches). For the specific use on hardened surfaces, an assessment methodology is provided to the Ctgb (<u>Linders et al., 2010, RIVM report 601450021</u> together with <u>Addendum and calculation tool, Van der Linden, 2016</u>.

This methodology takes into account, among other parameters, the ratio of hardened surfaces and total area, the fraction treated area, and flow velocity in the catchment area. This methodology is used for new substances (< 3 years on the Dutch market, in analogy with the agricultural use) with proposed uses on hardened surfaces.

For substances that have been on the Dutch market for more than 3 years the above described procedure in Alterra report 1635 is followed, i.e. evaluation of monitoring data.

NON-PROFESSIONAL USE

1. AGRICULTURAL CROP TREATMENTS

The developed decision trees and models described above are not suitable for non-professional (agricultural) use since the area of use cannot be described adequately.

Therefore the interim decision tree of the Ctgb, as laid down in C-163.5, still applies as a first tier in those situations for new substances (< 3 years on the Dutch market). For full text of C-163.5 see Evaluation Manual version 1.0.

In the interim decision tree, in short, the PIEC in the edge-of-field ditch according to TOXSWA is used as a basis for further calculations. A dilution factor of 10 and a travelling time of 14 days is taken into account to predict the concentration at the drinking water abstraction point. The applicant may also submit a RAT factor approach.

2. NON-AGRICULTURAL USE (USE ON HARDENED SURFACES)

For non-professional use <u>on hardened surfaces</u>, the above approach for non-professional agricultural crop treatments is not entirely applicable. Therefore a qualitative assessment is performed on a case-by-case basis.

For substances that have been on the Dutch market for more than 3 years the above described procedure in Alterra report 1635 is followed, i.e. evaluation of monitoring data.

PROTECTED CROPS

PROFESSIONAL USE

The developed decision trees and models described above are not suitable for greenhouse uses since the area of use is not available in DROPLET. Therefore the assessment is made analogously to the interim decision tree.

The PIEC in the edge-of-field ditch <u>according to GEM</u> (or a lower tier result) is used as a basis for further calculations. A dilution factor of 10 and a travelling time of 14 days is taken into account to predict the concentration at the drinking water abstraction point.

NON-PROFESSIONAL USE

A qualitative assessment is performed on a case-by-case basis.