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

NL part

Plant protection products

Chapter 7 Ecotoxicology: terrestrial; non target arthropods and plants

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For the Authorisation of Plant protection products and Biocides

Chapter 7 Ecotoxicology; terrestrial; non target arthropods and

Category: Plant Protection Products

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Changes in the Evaluation Manual

Evaluation manual PPP NL part			
			arthropods and plants
Version	Date	Paragraph	Changes
2.0	January 2014		
2.1	October 2016	2.3 NTA/NTP	A number of changes in the Dutch drift figures; see section 2.3 in both Chapters.
2.2	January 2018	2.3 NTA/NTP	Consequences of change in Activity Decree (entry into force January 2018) have been implemented:
			Drift values for individual techniques have been replaced with drift values per DRT class, conform the <i>DRT klassenlijst</i> and using the deposition values that are derived using the reference techniques per class as established by WUR-WPR. During the transitional period laid down in the Activity Decree concerning some techniques in fruit and lane tree cultivation, Ctgb will take the drift deposition values for these techniques into account when

			performing the risk assessment.
		2.3 NTA/NTP	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.
		2.3 NTP	Use of a MAF in the risk assessment for non-target terrestrial plants in case of a seedling emergence test and of a vegetative vigour test.
		2.3 NTP	Use of the Lower Limit of the HR5 value in the risk assessment for non-target terrestrial plants in certain cases.
2.3	March 2019	2	Bgb link updated
		ToC	Page numbers update
		All paragraphs	Links updated

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the effects on terrestrial organisms of a Plant protection product and its active substance in the NL framework (§2 - §2.5).

This chapter consists of two parts: a part about non-target arthropods (I) and a part about non-target plants (II).

I NON TARGET ARTHROPODS

2 NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for plant protection products based on existing substances, included <u>Commission Implementing Regulation (EU) No 540/2011</u> and new active substances. A new substance is a substance not authorised in any of the Member States of the EU on 25 July 1993.

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

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

The NL procedure described in §2 - §2.5 of this chapter can also be used for evaluation of a substance for approval, and consequently inclusion in Commission Implementing Regulation (EU) No 540/2011 in case no European procedure has been described.

2.1 Introduction

This chapter describes the data for arthropods 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.

A NL-specific methodology deviating from the EU evaluation methodology, is followed for the aspect arthropods as regards the estimation of off-field exposure. This concerns the use of national drift percentages as well as a national system of drift-reducing measures. This serves to meet the specific NL conditions (climatological conditions; specific standard drift-reducing measures packages from the Activity Decree (expected January 2017). This is elaborated in §2.3.

The other points described in this chapter concern further elaborations of the EU procedure. This in particular concerns the risk assessment for arthropods that are used as natural enemies in integrated pest management (IPM) (see §2.3).

A decision tree with corresponding explanatory notes is presented in Appendix 1. This decision tree shows the decision scheme for arthropods in integrated pest management systems.

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).

Experiments carried out after the 25th of July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

2.3 Risk assessment

The evaluation methodologies for chemical Plant protection products comply with the description under EU framework (see §1.3 of the EU part).

Some NL-specific aspects (drift, natural enemies), however, are considered nationally:

Drift

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

Artikel 8f. Driftcijfers

Bij de risicobeoordeling voor waterorganismen, vogels, zoogdieren, niet-doelwitarthropoden, niet-doelwitplanten of oppervlaktewater bestemd voor de bereiding van drinkwater, hanteert het college specifieke driftcijfers. Het college stelt deze cijfers vast en maakt hen bekend op zijn website.

General

The proposed spray drift percentages are derived from research by the Wageningen UR division Plant Research (WUR-PRI).

On an individual basis an applicant/registration holder can request Ctgb to consider additional spray drift-mitigation measures 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.

Change in Activity Decree and introduction of DRT classes

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 new Activity Decree (Activiteitenbesluit), per January 2018, including the introduction of drift reducing technology (DRT) classes. Individual techniques will be classified into groups of techniques with a minimum drift reduction. The list of these DRT classes and techniques that fall into these classes is available at Helpdesk Water (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. 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 Eenduidige 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 2.2, NL part, chapter 7 Ecotoxicology; terrestrial; non target arthropods and plants.

Explanation per crop/application

<u>Downward sprayed field crops</u> (including downward sprayed forest trees and hedging plants, and flower bulbs)

A drift factor is used for estimating the 'off-field' exposure. This is the amount of drift at 1 m from the centre of the last crop row (evaluation zone is 0.5 – 1.5 m). With the entry into force of the new Activiteitenbesluit (Activity degree) a <u>75% drift reducing technique on the</u> whole field has to be applied.

For dossiers in which no drift reduction is requested in principle the boundary conditions defined by the Activity Decree apply. The aim laid down in the Activity Decree for downward sprayed crops is 75% spray drift reduction. 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 (Technische Commissie Techniekbeoordeling) in collaboration with WPR (Wageningen Plant Research) 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 for downward spraying are defined in WPR report 419¹.

The absolute spray <u>drift deposition values</u> for the DRT classes are used for the exposure assessment and are presented in table 1.

Table 1. Spray drift values for DRT classes for downward spraying based on the Activity Decree; non-target arthropods

Spray drift percentage [%] on evaluation zone NTA			
DRT classes			
Drift deposition values for DRT classes meeting	the aim laid down in the Activity Decree		
DRT75	5.5		
DRT90	5.5		
DRT95	5.5		
DRT97.5	1.6		
DRT99	1.6		

For the assessment for downwards sprayed crops this means that the drift percentage of 5.5% belonging to the reference spray technique of the DRT class 75, will be used. Please note that the drift reduction percentage was established on the basis of the drift deposition at the evaluation zone for surface water. Therefore the DRTclassification does not always correspond to the reduction that is achieved at the evaluation zone for non-target arthropods, which is much closer to the crop.

The drift percentages mentioned in table 1 are not all the exact values for the different reference techniques for the DRT classes. Some pragmatic choices have been made.

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¹ 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 . <u>WUR-WPR Report 419</u>, Wageningen. Table 4, page 18.

Regarding the DRT90 class, the drift percentage of the reference technique is 3.3% and for DRT97.5 the drift is 0.69 for the reference technique. However, since in the DRT90 class another technique is mentioned with a drift percentage higher than 5.5% and since it is not logical that the drift for the DRT90 class is lower than the drift for the DRT95 class (which is also 5.5%), the same percentage as for the DRT75 and DRT95 class is chosen for risk assessment. The same applies to the choice for the drift percentage for the DRT97.5 class.

Within the classes the drift percentage differs quite a lot between the different techniques in a class. Hence, if more drift reduction is needed than what is possible based on the DRT classes, separate drift reduction techniques may be mentioned on the label.

It is possible to combine DRT classes with an additional crop-free zone. If for example the evaluation zone lies at 50 - 150 cm and drift reduction measures are only sufficient at a distance of 100 - 200 cm, an additional crop-free zone of 0.5 m may be added. Keep in mind that crop-free zones are rounded to multitudes of 25 cm (e.g. an additional crop-free zone of 60 cm becomes 75 cm).

If an additional crop-free zone is chosen as a drift reduction measure, the total crop-free zone must be determined (measured from the middle of the last crop row till the edge of the parcel). The standard crop-free zone is 1.0 m. Hence, in the case of an additional crop-free zone of 0.5 m the total crop-free zone is 1.5 m. For further clarity, an example for text on the label is given below:

- Een techniek uit de klasse DRT75 in combinatie met een totale teeltvrije zone van minimaal 1,5 m (gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij tot aan de perceelgrens) op het gehele perceel.

Deviating spray drift values for specific crop related techniques

WPR has indicated that the crops forest trees and hedging plants (downward sprayed) are 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 98-31²) the following spray drift values are available:

- 3.46% for standard nozzle.
- 1.15% for 50% spray drift reducing nozzle or a shielded standard spray nozzle. These values can also be applied for non-professional applications with a knapsack (assuming a crop-free zone of 0.50 m).

Fruit crops (including soft fruit and hop cultivation)

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

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 WUR-WPR report 564 (draft)³.

² 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

³ Zande, J.C. van de, H.J. Holterman, J.F.M. Huijsmans & M. Wenneker. 2017. Spray drift for the assessment of exposure of

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

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 for these measures. The measures are also mentioned in table 2.

For dossiers in which no drift reduction is requested in principle the boundary conditions defined by the Activity Decree apply. For the non-target arthropods assessment for fruit this comes down to the use of the spray drift deposition values (dormant/full-leaf stage) of DRT90 in combination with 3 m crop free, as this covers for the spray drift deposition when using DRT75 in combination with a crop free zone of 4.5 meter and also the measures allowed during the transitional period. This means that for the dormant crop stage the value of 10.6% and for the full-leaf stage the value of 3.8% will be used as starting point for the risk assessment.

An exception to the rules of the Activity Decree is the biological cultivation, which may 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.

The drift values for the full-leaf stage have been updated based on the extension of the WUR-PRI drift database⁴. Results of spray drift measurements up to 2005 are included. 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 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 (unpublished) 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.

For *herbicide* use in fruit trees, downward spraying is applicable. Drift values from WUR-WPR are available⁵. See Table 3.

Soft fruit (berries and grapes)

Based on an inventory report by WUR-WPR⁶ it was decided in 2014 that for sideways or

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.

⁴ Van de Zande J.C. & Huijsmans J. 2012 Notitie update driftcijfers fruit voor een nieuwe Ctgb drifttabel. Intern WUR-WPR report 07-03-2012

⁵ Stallinga, H., J.C. van de Zande, A.M. van der Lans, P. van Velde & J.M.G.P. Michielsen, 2012. Drift en driftreducerende spuittechnieken voor onkruidbestrijding in de boomteelt. Referentie techniek en driftreducerende spuitdoppen, Veldmetingen 2010-2011. Wageningen UR Plant Research International, Plant Research International Rapport 454, Wageningen.

⁶ Van de Zande J.C., M. Wenneker, A. de Bruine. 2011. Inventarisatie kleinfruitteelten en afleiden driftdepositie en maatregelpakketten. WPR report 398.

upwards sprayed soft fruit (grapes and berries) the large fruit spray drift values are used. For all application periods, only the full-leaf values are used. 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 WUR-WPR 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% techniques 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.

Spray drift mitigation techniques and spray drift deposition values
See Table 2 and 3 for a description of the spray drift deposition values belonging to the various DRT classes for large fruit (upwards/sideways spraying and downward spraying).

Upwards/sideways spraying

Table 2: Spray drift values for DRT classes (and separate techniques on the basis of transitional measures laid down in the Activity Decree) for upwards/sideways spraying in fruit crops for non-target arthropods

Spray drift percentage [%]				
Individual techniques/DRT classes Crop-free zone of 3 m Crop-free zone of 4.5				zone of 4.5
			m	
	Without	with	Without	with leaves
	leaves	leaves	leaves	
	(dormant)	(full-leaf)		
Standard orchard sprayer*	37.7	15.9	19.7	9.7
Drift deposition values for techniques accepted to be used during the transitional period until				

2021 as indicated i	in the Activity L	Decree		
Tunnel sprayer at 3 m crop free (allowed till 2021)	5.6	2.4	-	-
Windbreak (in combination with 75DRT) at 3 m crop free (allowed till 2021)	7.0	0.9	-	-
Drift deposition values for DRT classes me	eting the aim la	aid down in	the Activity	Decree
DRT75	23.8**	6.1**	10.7	2.5
DRT90	10.6	3.8	3.5	1.3
DRT95	6.5	1.9	1.7	0.46
DRT97.5	6.5	0.41	1.7	0.17
DRT99	3.3	0.25	1.0	0.06

^{*} relevant for non-professional use in the absence of drift values for knapsack/ready to use upwardsideways spraying

Downward spraying (herbicides)

Table 3: Spray drift values for DRT classes for downward spraying in fruit crops for non-target arthropods

Herbicide use in orchards (downward spraying)			
		3 m crop free zone	4.5 m crop free zone
"Zwartstroken" (bare soil surface strip underneath tree)	DRT75	0.014	0.010
	DRT90	0.007	0.007
"Grasstroken" (grass surface area in orchard)	DRT75	2.0	2.0
	DRT90	0.05	0.05

There are no specific drift rates for non-professional use in fruit crops.

Growth of lane trees

For the growth of lane trees, separate drift percentages are used based on research by WUR-WPR, A distinction is made between high lane trees, 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 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.

^{**} only relevant for biological production (see Activity Decree, article 3.80, 4c, sub 3, will be used when relevant)

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 WUR-WPR report 564 (draft).

The absolute spray <u>drift deposition values</u> for those reference techniques are used for the exposure assessment and are presented in table 4.

Please note that the reduction percentage was established on the basis of the drift deposition at the evaluation zone for surface water. Therefore the DRTclassification does not always correspond to the reduction that is achieved at the evaluation zone for non-target arthropods and non-target plants. Which is clearly demonstrated by the drift figures for the 1,5/2m distances in table 4.

The Activity Decree allows during a transitional period 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.

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, 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 for applications made between now and 2021.

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 included in the below drift table (table 4).

In this table also a distinction is made between drift percentages corresponding with a crop-free zone of 5 meter (according to the Activity Decree) and a crop-free zone of 1.5/2 meter, which is the agronomic minimum. This has been done, since a crop-free zone of 5 meter is only obliged in the case of field edges bordering surface water. Hence, on all edges of the field not bordering surface water only a crop-free zone of 1.5 (spindle trees) or 2 meter (transplanted trees and high lane trees) is necessary. This means that in practice in risk assessments the drift percentages at 1.5 or 2 meter must be used, because in the great majority of cases not all edges of a field will border surface water.

If then 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 a 1,5/2m crop-free zone) will be assessed. If this leads to an acceptable risk, a 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 niet tot de doelsoorten behorende insecten/geleedpotigen/terrestrische planten te beschermen is toepassing van dit middel 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 niet tot de doelsoorten behorende insecten/geleedpotigen/terrestrische planten te beschermen is toepassing van dit middel 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 distance as stated by the Activity Decree)].

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 is applicable for "zwartstroken" below the trees. See Table 5.

Upwards/sideways spraying

Table 4: Spray drift values for DRT classes (and separate techniques on the basis of transitional measures laid down in the Activity Decree) for upwards/sideways spraying in lane trees for non-target arthropods

Spray drift-mitigation technique lane trees	Crop-free zone of 5 m (Activity Decree)	Crop-free zone of 1.5/2 m (agronomic minimum
	(Addivity Doorso)	zone)*
Type of lane trees (stage)	NTA/NTP: field borders	NTA/NTP: field borders
	adjacent to surface water	not adjacent to surface water
Hig	h lane trees (>5 meter)	•
Spray drift deposition values for tech	niques accepted to be used	during the transitional
period until 2021 as indicated in the A	ctivity Decree	
DRT0 (standard situation)	12	34
DRT0 (standard equipment) + 5 meter	1.6	3.8
crop free**		
DRT50	5.1	19
DRT50 + 5 meter crop free**	0.12	0.13
Drift deposition values for DRT cla	sses meeting the aim laid do	own in the Activity Decree
DRT75	2.9	4.9
DRT90	-	-
DRT95	0.7	2.1
Transplanted trees		
Drift deposition values for techniques	accepted to be used during	g the transitional period until
2021 as indicated in the Activity Decre	ee	
DRT0	6.3	26
DRT0 (standard equipment) + 5 meter	0.65	2.7
crop free**		
DRT50	2.8	26
Drift deposition values for DRT cla	sses meeting the aim laid de	own in the Activity Decree
DRT75	-	-
DRT90	0.88	24
	Spindle trees	
Drift deposition values for techniques	accepted to be used during	g the transitional period until
2021 as in	dicated in the Activity Decre	ee

DRT0 (standard equipment)	1.8	6.5	
DRT0 (standard equipment) + 5 m crop	0.18	0.8	
free**			
DRT50	0.54	8.7	
Drift deposition values for DRT classes meeting the aim laid down in the Activity Decree			
DRT75	-	-	
DRT90	0.05	11	

^{* 1.5} m for spindle trees and 2 m for transplanted trees and high lane trees

NB: 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 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, in which non-sprayed trees of the same height may be grown. Hence the total crop free zone is 10 m when using this mitigation technique.

It will be difficult to apply DRT classes for NTA/NTP, especially with a crop-free zone of 1.5/2m, since a higher DRT class has a similar or higher drift percentage. Therefore, if more drift reduction is needed than possible based on DRT classes, separate drift reduction techniques may be mentioned on the label. As already indicated above reference is made to Evaluation Manual version 2.2, NL part, chapter 7 Ecotoxicology; terrestrial; non target arthropods and plants for these techniques.

Downward spraying (herbicides)

Table 5: Spray drift values for DRT classes for downward spraying in lane trees for non-target arthropods

Herbicide use in tree nursery (downward spraying)		NDA/NDP
soil surface underneath trees and up till 0.50 m from edge of surface water		2.0
	DRT90	0.05

When it concerns a handheld spraying boom a drift percentage of 3.3% is used.

In case crop-free zones have been introduced which are larger than standard distances from the centre of the last crop row given here, the 'off-field' area only starts after the crop-free zone and the drift percentage should be determined at a distance as large as the crop-free zone. In case natural objects have been placed to reduce the amount of drift (e.g., wind hedge) this object should not be considered as part of the off-field area that needs to be protected. It must be kept in mind that those crop-free zones and natural objects in many cases are only applied on those parts of parcels which borders watercourses. Protection of non-target arthropods is needed for all sides of a parcel.

There are no specific drift rates for non-professional use in tree nursery.

^{**} in this 5 m crop free zone only non-sprayed crops of the same height can be grown. These crops are eligible from 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.*

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

Special applications (field)

Knapsack (handheld equipment)

For hand held equipment (*rugspuit/spuitlans*) a drift percentage of 1.15 % is assumed when a protection shield or 50 % nozzle is used (without mitigation a value of 3.46 % applies) based on a crop free zone of 0.50 m.

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 1.73% is used. This value is half of the value used for hand held equipment without mitigation (see above). This is a pragmatic approach based on the approach chosen for aquatic organisms.

Please note that these values for handheld equipment are only to be used 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 4 above.

Applications without drift

A drift percentage of 0% applies for:

- 1) Enclosed spaces (not greenhouses):
 - 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.

Natural enemies

The decision scheme and risk-mitigation measures mentioned in EU context (<u>Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final)</u>) apply for non-target arthropods in general. Other 'in-field' criteria apply where natural enemies ('beneficials') in integrated pest management systems (such as greenhouse crops, fruit growing, tree nursery crops) are concerned.

Effects on beneficials higher than or equal to 30% in the first tier and higher than or equal to 25% for higher tiers are in that case not acceptable, even if recovery occurs at short term. This means that in case of exceedance of the criteria a warning phrase must be included in the WG (Statutory Use Instructions), to avoid damage to natural enemies when used by the grower.

Combination toxicity

Combination toxicity must be determined when plant protection products contain several active substances. The issue of combined toxicity is further described in Appendix A.

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 Bgb (Plant protection product and Biocides Decree).

2.4.1 Trigger values, criteria and decision on approval

For the criteria and trigger values for non-target arthropods for the national authorisation reference is made to the EU framework (see §1.4 EU-chapter).

2.5 Developments

See EU-chapter (§1.5).

II NON TARGET PLANTS

2 NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for plant protection products based on existing substances, included <u>Commission Implementing Regulation (EU) No 540/2011</u> and new active substances. A new substance is a substance not authorised in any of the Member States of the EU on 25 July 1993.

The plant protection product that contains such substances may be authorised if the criteria laid down in the 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 Commission Regulation (EU) No 283/2013 and Commission Regulation (EU) No 284/2013 implementing Regulation (EC) No 1107/2009 (see Application Form and corresponding instructions).

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

The NL procedure described in §2 - §2.5 of this chapter can also be used for evaluation of a substance for approval, and consequently inclusion in Commission Implementing Regulation (EU) No 540/2011 in case no European procedure has been described

2.1 Introduction

This chapter describes the data for non-target plants 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.

There is for the aspect non-target plants a deviation from the EU evaluation methodology as regards estimation of the off-field exposure, for which an NL specific methodology is followed. This concerns the use of national drift percentages as well as a national system of drift-reducing measures to do justice to the specific NL conditions (climatological conditions; specific standard drift-reducing measures packages from the Activity Decree. See §2.3 for further details.

2.2 Data requirements

The data requirements for chemical Plant protection products comply with the provisions in EU framework (see §1.2 of the EU part). The question numbering of the NL Application Form has also been included in §1.2 of the EU part.

Experiments carried out after the 25th of July 1993 must have been carried out under GLP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

2.3 Risk assessment

The evaluation methodologies for chemical Plant protection products comply with the description under EU framework (see §1.3 of the EU part).

The national evaluation is in line with the European risk assessment methodology for non target plants as elaborated in the <u>Guidance Document on Terrestrial Ecotoxicology</u> (Sanco/10329/2002 rev 2 final).

There are a few further interpretations on the following issues:

Use of a MAF in the risk assessment for non-target terrestrial plants

Seedling-emergence test

In case of a seedling-emergence test a fate-MAF as given in the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002 rev 2 final) (see ESCORT 2 document (Appendix III)) may be used, because the exposure is by the soil. The DT50 in soil can be taken into account. In case no soil DT50 is available the default values can be taken ((T1/2: spray interval = 6:1).

Vegetative vigour test

In case of a vegetative vigour test the exposure is not via an external medium, but directly on the leaves of the plants. The effect values from the study are determined by the behaviour of the substance on the plants and the toxicokinetics in the plants. In this case an effect-MAF is preferred.

In the EFSA Scientific opinion on NTTP (2014) a way to calculate such an effect-MAF is described. However, this approach is not taken up in a Guidance Document and is also not used by EFSA or Member States. Hence, it is too early to apply this approach in national/zonal assessments.

Therefore it is proposed from a pragmatic point of view to keep using the default values presented in Appendix III from the ESCORT 2 document (T1/2: spray interval = 2.3 : 1). However, because it concerns surrogate effect-MAF values and no fate-MAF values, refinements based on refinement of the DT50 on vegetation are not possible.

<u>Use of the Lower Limit of the HR5 value in the risk assessment for non-target terrestrial</u> plants in certain cases

In quite some cases the SSD-approach is applied in the risk assessment for NTTPs as a refinement of the risk. In most cases the HR5 value is below the lowest ER50 value. However, in cases that the lowest ER50 value is a lot lower than the other values, the HR5 may be higher than the lowest ER50 value. Because normally no additional safety factor is applied on the HC5 for NTTPs, the RA based on the HR5 is in these cases underprotective for at least the most sensitive species. To avoid this situation it is proposed to use the lower limit of the HR5 in these cases.

In addition, drift is a NL-specific aspect and elaborated nationally:

Drift

National drift figures can be applied on the basis of <u>article 8f</u> of the <u>Bgb</u> (Plant protection product and Biocides Decree). Ctgb bases the exposure assessment on average spray drift

values determined by WPR (Wageningen Plant Research, formerly WUR-WPR).

Artikel 8f. Driftcijfers

Bij de risicobeoordeling voor waterorganismen, vogels, zoogdieren, niet-doelwitarthropoden, niet-doelwitplanten of oppervlaktewater bestemd voor de bereiding van drinkwater, hanteert het college specifieke driftcijfers. Het college stelt deze cijfers vast en maakt hen bekend op zijn website.

For field crops the drift percentages are different from the percentages used for non-target arthropods because the evaluation zone is different. The drift percentages are presented below.

Change in Activity Decree and introduction of DRT classes

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 new Activity Decree (Activiteitenbesluit), per January 2018, including the introduction of drift reducing technology (DRT) classes. Individual techniques will be classified into groups of techniques with a minimum drift reduction. The list of these DRT classes and techniques that fall into these classes is available at Helpdesk Water (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. 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 Eenduidige 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 2.2, NL part, chapter 7 Ecotoxicology; terrestrial; non target arthropods and plants.

For the other crops (large and small fruit, lane trees) reference is made to the corresponding section for non-target arthropods, because the same evaluation zone and thus the same drift percentages are used for risk assessment.

<u>Field crops</u> (including downward sprayed forest trees and hedging plants, and flower bulbs)

A drift factor is used for estimating the 'off-field' exposure for non-target plants. For field crops this is now defined as the amount of drift at 1 m from the edge of the parcel. The drift percentage is determined by taking the mean drift percentage of the zone 0.5-1.5 m from the edge of the parcel (off-field evaluation zone for non-target plants)). The edge of the parcel is defined as 1 meter from the centre of the last crop row. Hence, the total distance of the evaluation zone is 1.5-2.5 m from the centre of the last crop row. The standard position of the last spraying nozzle is assumed to be above the centre of the last crop row. With the entry into force of the new Activity Decree 75% drift reduction on the whole field has to be applied.

For dossiers in which no drift reduction is requested in principle the boundary conditions defined by the Activity Decree apply. The aim laid down in the Activity Decree for downward sprayed crops is 75% spray drift reduction. This drift reduction can be achieved by applying spray techniques of a certain drift reduction class (DRT class). 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 for downward spraying are defined in WPR report 419⁷.

The absolute spray <u>drift deposition values</u> for those reference techniques are used for the exposure assessment and are presented in table 6.

For the assessment of non-target plants for downwards sprayed crops this means that the drift percentage of 0.9% belonging to the reference spray technique of the DRT class 75, will be used. Please note that the drift reduction percentage was established on the basis of the drift deposition at the evaluation zone for surface water. Therefore the DRT classification does not always correspond to the reduction that is achieved at the evaluation zone for non-target plants, which is closer to the crop.

Table 6. Spray drift values for DRT classes for downward spraying based on the Activity Decree; non-target plants

Activity Decree, non-target plants			
Spray drift percentage [%]			
DRT classes			
Drift deposition values for DRT classes meeting the aim laid down in the Activity Decree			
DRT75	0.90		
DRT90	0.89		
DRT95	0.62		
DRT97.5	0.068		
DRT99	0.023		

If necessary, also additional crop-free zones may be applied (with steps of at least 25 cm). When additional crop-free zones are proposed, the amount of drift reduction of these zones must be determined separately. Since no drift percentages are available for evaluation zones greater than 1.5 - 2.5 meter from the middle of the last crop row, the spray drift percentage belonging to the additional crop free zone should be underpinned by specific spray drift research by WUR-WPR submitted by the applicant.

If an additional crop-free zone is chosen as a drift reduction measure, the total crop-free zone must be determined (measured from the middle of the last crop row till the edge of the parcel). The standard crop-free zone is 1.0 m. Hence, in the case of an additional crop-free zone of 0.5 m the total crop-free zone is 1.5 m. For further clarity and example is given below:

- een techniek uit de klasse DRT75 in combinatie met een totale teeltvrije zone van minimaal 1,5 m (gemeten vanaf het midden van de laatste gewasrij of de laatste plant in de rij tot aan de perceelgrens) op het gehele perceel.

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 drift value based on conventional spraying techniques should be used (4.7%).

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

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 . <u>WUR-PRI Report 419</u>, Wageningen. Table 4, page 18.

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:

- 3.46 % for standard nozzle.
- 1.15 % for 50 % spray drift reducing nozzle or a shielded standard spray nozzle. These values can also be applied for non-professional applications with a knapsack (assuming a crop-free zone of 0.50 m).

In case crop-free zones have been introduced which are larger than standard distances from the centre of the last crop row given here, the 'off-field' area only starts after the crop-free zone and the drift percentage should be determined at a distance as large as the crop-free zone. In case natural objects have been placed to reduce the amount of drift (e.g., wind hedge) this object should not be considered as part of the off-field area that needs to be protected. It must be kept in mind that those crop-free zones and natural objects in many cases are only applied on those parts of parcels which borders watercourses. Protection of non-target terrestrial plants is needed for all sides of a parcel.

Fruit crops (including soft fruit)

For fruit crops the drift percentages for non-target plants are the same as for the non-target arthropods. Therefore reference is made to the chapter regarding non-target arthropods (section 2.3).

Growth of lane trees

For the growth of lane trees the drift percentages for non-target plants are the same as for the non-target arthropods. Therefore reference is made to the chapter regarding non-target arthropods (section 2.3).

Special applications (field)

Knapsack (handheld equipment)

For the knapsack (handheld equipment) the drift percentages for non-target plants are the same as for the non-target arthropods. Therefore reference is made to the chapter regarding non-target arthropods (section 2.3).

Applications without drift

Reference is made to the chapter regarding non-target arthropods (section 2.3).

Combination toxicity

Combination products are formulated plant protection products that contain more than one active substance. The issue of combined toxicity is further described in Appendix A.

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 Bgb (Plant protection product and Biocides Decree).

2.4.1 Criteria and trigger values

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

For the criteria and trigger values for non-target plants for the national authorisation reference is made to the EU framework (§1.4), in particular the <u>Guidance Document on Terrestrial</u> <u>Ecotoxicology (Sanco/10329/2002 rev 2 final)</u>.

2.4.2 Decision on approval

For decision-making as regards non-target plants for the national authorisation reference is made to the EU framework (§1.4).

2.5 Developments

See EU-chapter (§1.5).

3 REFERENCES

1. Van de Zande, J.C., J.M.G.P. Michielsen & H. Stallinga., Spray drift and off-field evaluation of agrochemicals in the Netherlands, Report 149, July 2007

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Plant protection products

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Appendix 1 Explanatory notes decision tree risk to non-target arthropods

- A distinction is made between integrated and non-integrated pest management systems because the evaluation for non-target arthropods for these two types of systems is essentially different. In the case of integrated pest management systems natural enemies are deliberately brought into the cropping system to control pests. In the case of non-integrated pest management systems the risk is estimated for non-target arthropods that are present by nature. The scheme for integrated pest management systems is included in this chapter. The scheme for non-integrated systems is dealt with in Appendix 1 to the EU-part of this chapter. The numbering below starts with 2 due to the interconnectedness between these two decision trees.
- 2) For integrated pest management systems the 'in-field' risk to effects on natural enemies is evaluated. Examples of integrated pest management are: fruit vegeTables under glass, fruit cultures, tree cultures. There is a tendency that more and more cultures are grown under integrated pest management. Evaluation of the 'off-field' situation for integrated pest management does not differ from non-integrated pest management. This then again concerns the naturally occurring non-target arthropods (see EU-part of this chapter).
- 3) Also in this case, the first step consists of the performance of glass plate tests with the standard test organisms *Aphidius rhopalosiphi and Typhlodromus pyri*. The evaluation criterion, however, differs from the criterion applied for non-integrated pest management in view of the fact that significant acute effects on populations of natural enemies are not accepted because these lead to a reduction of the controlling effect of these organisms.
- 4) The criterion is as follows: if the effects at the maximum dose are ≥ 30% for one or both standard species, the risk is unacceptable and higher-tier tests are required with the species for which a risk has been established and at least one additional crop-relevant species.
- 5) A high risk exists when the effects in the higher-tier tests at the maximum dose are ≥25% for one or more species. In that case a warning phrase must be included in the label to prevent unacceptable effects on natural enemies. This phrase reads: 'Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg deskundigen (uw leverancier van natuurlijke vijanden, de producent van dit middel, uw adviseur) over het gebruik van dit middel in combinatie met het gebruik van natuurlijke vijanden.' In English: 'Attention: this product can be harmful for natural enemies. Seek consultation with your supplier of natural enemies about the use of this product in combnation with natural enemies'.

NON-TARGET ARTHROPODS

