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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Board for the Authorisation of Plant protection products and Biocides

Chapter 7 Ecotoxicology; terrestrial; non target arthropods and plants

Category: Plant Protection Products

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).

Substances that are approved under Regulation (EC) No 1107/2009 [1] and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted after 31 December 2013 and for plant protection products submitted after 31 December 2015.

A concept guidance is available on the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1).

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

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 in Commission Implementing Regulation (EU) No 540/2011 [3] and new active substances.
A new substance is a substance not authorised in any of the Member States of the EU on the 25th of July 1993.
The plant protection product that contains such substances may be authorised if the criteria laid down in Regulation (EC) No 1107/2009 [1] are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4]. The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) 284/2013 [6] implementing Regulation (EC) No 1107/2009 [1] (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 [3] 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 Lozingenbesluit (Discharge Order).
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). 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.

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 7.

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 arthropods as elaborated in the Guidance Document on Terrestrial Ecotoxicology, which follows the recommendations of the ESCORT 2 workshop. Some NL-specific aspects (drift, natural enemies), however, are considered nationally.

Drift
National drift figures can be applied on the basis of article 8f of the Plant Protection Products and Biocides Decree (Bgb) [4].

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.

Several changes are made with regard to the Evaluation Manual 1.0 under the 91/414 Directive (January 2010) due to recent developments.
For the spray drift values in fruit, the former drift table used the database of 1998. An update is now available to include all experimental spray drift data up to and including 2005.
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 drift measurements have extended the data set of 2005 and the new data set shows higher values than the 2005 data alone. Therefore it is considered by WUR-PRI that for the moment the 1998 data should be retained for the dormant stage.
Furthermore the spray drift percentage for small fruit (berries and grapes) was set to the full-leaf values for large fruit based on a literature inventory of actual drift data in the small fruit cultivation in which it is demonstrated that the field crop drift value of 1 % is not protective. Pending actual measurements in small fruit, the full-leaf values for large fruit are taken as an approximation.

For high lane trees also new data (2010) have become available.
The changes are incorporated in the text below.

Field crops
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). This amount has for the Dutch situation been set at 10% [7]. Drift reduction measures are possible. See table 1a and 1b (without and with air assistance). The standard distance is 50 – 150 cm from the last nozzle. The standard position of the last spraying nozzle is assumed to be above the centre of the last crop row.

Tabel 1a. Spray drift deposition (% of applied dose) for different conventional spray techniques at different off-field evaluation zone distances (1m wide) from the last nozzle.

Sprayer type	Nozzle type	Nozzle spray drift reduction class	Spray drift deposition [%] at distance from last nozzle				
			37.5-137.5	50-150	75-175	100-200	150-250
Conventional	XR11004	0	10.2	9.9	8.8	7.5	4.7
Conventional	DG11004	50	7.9	7.1	5.5	4.0	1.7
Conventional	DG11004+ end nozzle	50	6.2	5.5	4.2	3.1	1.5
Conventional	ID12002	75	7.9	7.1	5.2	3.4	1.0
Conventional	ID12002+ end nozzle	75	6.2	5.5	4.0	2.6	0.9
Conventional	XLTD04-110	90	10.9	9.7	7.3	5.0	1.6
Conventional	XLTD04-110+ end nozzle	90	8.5	7.5	5.6	3.9	1.4
Low boom	DG80015+ end nozzle	50	4.4	3.1	1.6	1.0	0.9
Low boom	ID90015+ end nozzle	50	6.4	3.9	1.5	0.7	0.3
Släpduk	XR110015	0	4.7	3.4	1.7	0.9	0.6
Släpduk	AI110015	50	4.1	2.5	0.9	0.3	0.03
Tunnel	XR11004 + UB8504	0	0.26	0.26	0.26	0.25	0.21

- Conventional XR11004 = Conventionele spuit + standaard spleetdop (= standaardsituatie)
- Conventional DG11004 = Conventionele spuit + minimaal 50% driftreducerende spuitdop
- Conventional DG11004 + end nozzle = Conventionele spuit + minimaal 50% driftreducerende

spuitdop + kantdop
- Conventional ID12002 = Conventionele spuit + 75% driftreducerende spuitdop
- Conventional ID12002 + end nozzle = Conventionele spuit + 75% driftreducerende spuitdop + kantdop
- Conventional XLTD04-110 = Conventionele spuit + 90% driftreducerende spuitdop
- Conventional XLTD04-110 + end nozzle = Conventionele spuit + 90% driftreducerende spuitdop + kantdop
- Low boom DG80015 + end nozzle = Lage spuitboomhoogte (30 cm boven de top van het gewas) + minimaal 50% driftreducerende spuitdop + kantdop
- Low boom ID90015 + end nozzle = Lage spuitboomhoogte (30 cm boven de top van het gewas) + driftarme Venturidop + kantdop
- Släpduk XR110015 = Sleepdoek + standaard spleetdop
- Släpduk AI110015 = Sleepdoek + minimaal 50% driftreducerende spuitdop
- Tunnel XR11004 + UB8504 = Overkapte beddenspuit

Noot: bespuiting via een handgedragen spuitboom: driftpercentage van 3,3% op de strook 0,5 – 1,5 m.

Table 1b. Spray drift deposition (% of applied dose) for different air assisted spray techniques at different off-field evaluation zone distances (1m wide) from the last nozzle.

Sprayer type	Nozzle type	Nozzle spray drift reduction class	Spray drift deposition [%] at distance from last nozzle				
			37.5-137.5	50-150	75-175	100-200	150-250
Conventional	XR11004	0	8.8	7.9	6.2	4.5	1.9
Conventional	DG11004	50	6.1	5.7	4.6	3.4	1.2
Conventional	DG11004+ end nozzle	50	3.7	3.3	2.6	2.0	0.9
Conventional	ID12002	75	7.9	6.9	4.8	3.1	0.9
Conventional	ID12002+ end nozzle	75	4.9	4.1	2.7	1.7	0.7
Conventional	XLTD04-110	90	10.9	9.4	6.5	4.1	0.9
Conventional	XLTD04-110+ end nozzle	90	6.8	5.6	3.7	2.3	0.6
Low boom	DG80015+ end nozzle	50	2.4	1.8	1.0	0.6	0.3
Low boom	ID90015+ end nozzle	50	1.5	1.0	0.5	0.3	0.1

- Conventional XR11004 = Conventionele spuit + standaard spleetdop + luchtondersteuning
- Conventional DG11004 = Conventionele spuit + minimaal 50% driftreducerende spuitdop + luchtondersteuning
- Conventional DG11004 + end nozzle = Conventionele spuit + minimaal 50% driftreducerende spuitdop + kantdop + luchtondersteuning
- Conventional ID12002 = Conventionele spuit + 75% driftreducerende spuitdop + luchtondersteuning
- Conventional ID12002 + end nozzle = Conventionele spuit + 75% driftreducerende spuitdop + kantdop + luchtondersteuning
- Conventional XLTD04-110 = Conventionele spuit + 90% driftreducerende spuitdop + luchtondersteuning
- Conventional XLTD04-110 + end nozzle = Conventionele spuit + 90% driftreducerende spuitdop + kantdop + luchtondersteuning
- Low boom DG80015 + end nozzle = Lage spuitboomhoogte (30 cm boven de top van het gewas) + minimaal 50% driftreducerende spuitdop + kantdop + luchtondersteuning
- Low boom ID90015 + end nozzle = Lage spuitboomhoogte (30 cm boven de top van het gewas) + driftarme Venturidop + kantdop + luchtondersteuning

Recently also the following air assisted spray techniques became available:

Sprayer type	Spray drift (%) at 50 – 150 cm from last nozzle	Spray drift (%) at 150 – 250 cm from last nozzle
Conventional XR11004 Hardi TwinForce*	4.0	0.9
Conventional DG11004 + end nozzle Hardi TwinForce**	0.7	0.07

* Conventionele spuit + standaard spleetdop + Hardi Twin Force luchtondersteuning
** Conventionele spuit + minimaal 50% driftreducerende spuitdop + kantdop + Hardi TwinForce luchtondersteuning

It is possible to combine the measures mentioned in table 1a and b 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 25 cm (e.g. an additional crop-free zone of 60 cm becomes 75 cm). This choice of 25 cm is based on the smallest crop-free zone used in the LOTV (25 cm for cereals).
If an additional crop-free zone is chosen as a drift reduction measure, the total crop-free must be determined (measured from the middle of the last crop row till the border of the parcel). The standard crop-free zone is 0.5 m. Hence, in the case of an additional crop-free zone of 0.5 m the total crop-free zone is 1.0 m. For further clarity and example is given below:
- Conventionele spuit + 75% driftreducerende spuitdop + 1,0 meter teeltvrije zone (gemeten vanaf het midden van de laatste gewasrij tot aan de perceelsgrens).

Fruit crops
For fruit growing (large fruit) the percentages are 37% before 1 May (dormant) and 15.9 % after 1 May (full leaf) [7]. The latter value (15.9%) is also used for grapes and berries (irrespective of application time). This is the amount of drift at 3 m distance from the crop (standard situation; evaluation zone is 2.5 – 3.5 m)). Drift reduction measures are possible. These are presented in table 2.
Another change in comparison with the drift table in Evaluation Manual 1.0 is the introduction of a crop-free zone of 4.5 meter next to the 3 meter, to provide additional room for the specific cultivation technique (orchard lay-out) in some regions of The Netherlands. Corresponding drift values are also presented in table 2.
For *herbicide* use in fruit trees, downward spraying is applicable. New WUR-PRI values have recently become available[1]. See Table 2.

Table 2: Spray drift values for the 'off-field non-targets' for various drift-mitigation techniques in comparison with standard fruit growing situations

Drift percentage [%]				
Drift-mitigation technique top fruit	**Crop-free zone of 3 m**		**Crop-free zone of 4.5 m**	
	without leaves (dormant)	with leaves (full-leaf)	Without leaves	with leaves

[1] 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.

Standard orchard sprayer [x]	37	15.9	19.7	9.7
Standard orchard sprayer [x] + 6 m crop-free zone	12.1	7.0	n.a	n.a.
Standard orchard sprayer [x] + 9 m crop-free zone	5.5	3.9	n.a.	n.a.
Standard orchard sprayer [x] and one-sided spraying of last tree row	24	6.7	11.3	5.4
Tunnel sprayer	5.6	2.4	3.0	1.5
Sensor-controlled spraying	34	11.4	15.5	4.7
Cross flow fan sprayer with reflection shields	16.6	7.2	9.1	4.4
Venturi nozzle (90 % drift reduction)+ one-sided spraying last tree row and reduced fan setting**	6.5	1.9	1.7	0.46
Wanner equipment with reflection shield and standard nozzles [xxx]	11.8	7.2	5.8	3.8
Wanner equipment with reflection shield and 90% drift reducing nozzles (Lechler ID 90-015C) [xxx]	2.6	1.3	1.1	0.50
50% drift reducing nozzle and one-sided spraying of the last tree row	-****	7.2	-****	2.8
75% drift reducing nozzle and one-sided spraying of the last tree row	-****	6.1	-****	2.5
90% drift reducing nozzle and one-sided spraying of the last tree row	10.6	3.8	3.5	1.3
95% drift reducing nozzle and one-sided spraying of the last tree row	-****	3.2	-****	1.1
KWH k1500-3R2 VLOS 3-row sprayer with variable air support system and standard nozzles[xxxxx]	23.8	3.4	10.7	1.9
KWH k1500-3R2 VLOS 3-row sprayer with variable air support system and 90% drift reducing nozzles[xxxxx]	3.6	1.5	1.1	0.5
KWH k1500-3R2 VLOS 3-row sprayer with variable air support system and 90% drift reducing nozzles and low air setting (400 rpm pto) [xxxxx]	3.3	0.25	1.0	0.06

Herbicide use in orchards (downward spraying)			
		3 m crop free zone	**4.5 m crop free zone**
"Zwartstroken" (bare soil surface strip underneath tree)	standard nozzle	0.035	0.025
	50% drift reducing nozzle + end nozzle	0.020	0.016
	90% drift reducing nozzle + end nozzle	0.007	0.007
	shielded sprayer - standard nozzles	0.014	0.010
	Agricult LVS	0.06	0.04
"Grasstroken" (grass surface area in orchard – not black soil surface strip under trees)	standard nozzle	1.4	1.4
	50% drift reducing nozzle + end nozzle	0.13	0.13
	90% drift reducing nozzle + end nozzle	0.05	0.05

	shielded sprayer - standard nozzles	2.0	2.0
	Agricult LVS	6.4	6.4

x valid for cross-flow fan and axial fan orchard sprayer

xx fan setting off in dormant and low in full-leaf stage

xxx M. Wenneker, R. Anbergen, N. Joosten, J.C. van de Zande, 2006. Emissiereductie bij inzet van een Wannerspuit met reflectieschermen in de fruitteelt; PPO report nr. 2006-13

xxxx data not available yet

xxxxx Stallinga, H., M. Wenneker, J.C. van de Zande, J.M.G.P. Michielsen, P. van Velde, A.T. Nieuwenhuizen & L. Luckerhoff, 2012. Drift en driftreductie van de innovatieve drierijige emissiearme fruitteeltspuit van KWH. Veldmetingen 2011. Wageningen UR Plant Research International, Plant Research International Rapport 458, Wageningen

Growth of lane trees

For the growth of lane trees, separate drift percentages are used based on research by PRI, 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 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.
Recently the available PRI data set has been analysed to provide Ctgb with the following updated drift values, including drift reducing techniques[2]. See Table 3. These values are valid for fungicide and insecticide treatments.

For *herbicide* use in lane trees, downward spraying is applicable for “zwartstroken” below the trees (soil is always kept bare). New PRI values have recently become available. See Table 3.

Table 3: Drift values for various drift-mitigation techniques in comparison with standard lane trees growing situations

Drift percentage [%]			
Drift-mitigation technique lane trees	**Crop-free zone of 2 m (agronomic minimum zone)**		**Crop-free zone of 5 m (LOTV)**
High lane trees (>5 meter)	**2 m**		
Standard axial sprayer (TXB8003)	34.3		11.9
Mast sprayer (XR80015)	15.1		8.0
Mast sprayer (Venturi ID90015)	19.0		5.1
Standard axial sprayer + 5 m spray free*	3.8		1.6
Mast sprayer (XR80015) + 5 m spray free*	2.7		1.9
Mast sprayer (Venturi ID90015) + 5 m spray free*	0.13		0.12
Transplanted trees	**2 m**		
Standard axial sprayer	25.7		6.3
Standard axial sprayer + 5 m spray free*	2.7		0.65
Axial sprayer + 50 % drift reducing nozzles**	26.4		2.8
Axial sprayer + 75 % drift reducing nozzles**	24.2		3.2
Axial sprayer + 90 % drift reducing nozzles**	28.9		3.2
Axial sprayer + 95 % drift reducing nozzles**	23.5		0.88
Spindle trees	**1.5 m**	**2 m**	
Standard axial sprayer	6.5	6.1	1.8
Standard axial sprayer + 5 m spray free*	0.8	0.62	0.18
Axial sprayer + 50 % drift reducing nozzles**	8.7	6.5	0.54
Axial sprayer + 75 % drift reducing nozzles**	8.3	6.0	0.65
Axial sprayer + 90 % drift reducing nozzles**	11.2	5.9	0.05
Axial sprayer + 95 % drift reducing nozzles**	11.2	5.9	0.05
Herbicide use in tree nursery (downward spraying)			
soil surface underneath trees and up till 0,50 m from edge of surface water	standard nozzle		1.4
	50% drift reducing nozzle + end nozzle		0.13
	90% drift reducing nozzle +		0.05

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

	end nozzle	
	shielded sprayer - standard nozzles	2.0
	Agricult LVS	6.4

* in this 5 m spray 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 LOTV, Article 13: *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-aanbevelingen[1] 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.

** extrapolated from fruit

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.

Bush and hedge shrubbery
Drift percentage: as for field crops
WUR-PRI has indicated that in the LOTV this crop 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 98-31[3]) the following drift values are available:
3.46% for standard nozzle.
1.15% for 50 % 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).

If a request is made to Ctgb for individual applications, the use of this technique can be taken into consideration in the assessment for authorisation. The drift table contains the drift percentage that corresponds with the obligatory measure from the LOTV.

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. This technique is mostly used in applications by non-professional users (*particulier gebruik*).
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

[3] 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

pragmatic approach based on the approach chosen for aquatic organisms.

Natural enemies
The decision scheme and risk-mitigation measures mentioned in EU context (Guidance Document on Terrestrial Ecotoxicology [8]) 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. This warning phrase reads as follows:

'Let op: dit middel kan schadelijk zijn voor natuurlijke vijanden. Raadpleeg uw leverancier van natuurlijke vijanden 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 combination with natural enemies' .

Combination toxicity
Combination products are formulated Plant protection products that contain more than one active substance. Combinations of Plant protection products of which, in accordance with the recommendations in the directions for use, the user prepares a combination in a tank (tank mix) are also considered as combination products. When evaluating the side effects of combination products on non-target organisms the question arises whether the risk must be estimated on the basis of a toxicity test with the combination product or whether a reasonable risk estimate can be made on the basis of the toxicity data of the separate active substances. There is no European guidance as regards combination toxicology.

Toxicity data for non-target arthropods are always done with the formulation. This means that combination toxicity only needs to be determined for tank mixes. Furthermore, it is only possible to determine combination toxicity where the endpoint is expressed in a toxicity parameter (e.g., LR50). Calculation of the combination toxicity is not possible where the endpoint is an effect percentage.

Combination toxicity is determined on the basis of concentration addition.
In theory, three different effects are to be expected when two or more substances/products are used in a mixture:
- the substances/products may weaken each others' toxic effects (antagonism)
- the effects of the substances/products may be additive
- the substances/products may potentiate each others' toxic effects (synergism).

Although the effects of mixtures of active substances in Plant protection products have only been studied to a very limited extent and not for all relevant species and toxicological endpoints it is expected that active substances in a combination product or tank mix together contribute to the toxicity of that product of that tank mix. The extent to which the active substances are contributing is poorly known. The available data indicate that also in case of partial addition the extent of combination toxicity does not deviate strongly from concentration addition. In view of these considerations the evaluation of the toxicity data of combination products or tank mixes is based on concentration addition. In case of concentration addition

each substance contributes to the total toxicity of a mixture in proportion to its concentration. The calculation method is given in Appendix C to Chapter 7.

2.4 Approval

The evaluation of Plant protection products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 [3] or new substances has been laid down in Regulation (EC) No 1107/2009 [1]. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection product and Biocides Decree (Bgb) [4].

2.4.1 Criteria and trigger values

For the criteria and trigger values for non-target arthropods for the national authorisation reference is made to the EU framework (§1.4), in particular the Guidance Document on Terrestrial Ecotoxicology [8].

2.4.2 Decision making

Decision making as regards non-target arthropods for the national authorisation follows the EU part (§1.4), in particular the Guidance Document on Terrestrial Ecotoxicology [8].

2.5 Developments

In March 2010 a follow-up of ESCORT II was organised, the ESCORT III workshop. It is expected that the risk assessment will change on certain points. The report from this workshop is expected to be be input for the revision of the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002), which is taking place at this moment (by EFSA).

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 in Commission Implementing Regulation (EU) No 540/2011 [3], and new active substances.
A new substance is a substance not authorised in any of the Member States of the EU on the 25th of July 1993.
The plant protection product that contains such substances may be authorised if the criteria laid down in Regulation (EC) No 1107/2009 [1] are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4]. The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) 284/2013 [6] implementing Regulation (EC) No 1107/2009 [1] (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 evolution of a substance for approval, and consequently inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] 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 Lozingenbesluit (Discharge Order). See §2.3 for further details.

The decision tree with corresponding explanatory notes is presented in Appendix VI-1.
This decision tree summarises the evaluation as regards terrestrial non-target plants.

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.

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 7.

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 Guidance Document on Terrestrial Ecotoxicology [8]. Drift is a NL-specific aspect however, and elaborated nationally:

Drift
National drift figures can be applied on the basis of article 8f of the Plant Protection Products and Biocides Decree (Bgb) [4].

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.
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.

Field crops

A drift factor is used for estimating the ‘off-field’ exposure. 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)). 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. The amount of drift for field crops has for the Dutch situation now been set at 4.7% [7]. In table 4 the drift percentages are presented for the reference situation and drift reducing measures which are easy to realise in practice, with and without air assistance (figures from [7]).
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.

Table 4 Spray drift deposition (% of applied dose) regarding field crops for different conventional spray techniques at 150 – 250 cm distance from the centre of the last crop row, with and without air assistance.

Sprayer type	Nozzle type	Spray drift deposition (%) at 150 – 250 cm distance from the centre of the last crop row; without air assistance	Spray drift deposition (%) at 150 – 250 cm distance from the centre of the last crop row; with air assistance
Conventional	Standard flat fan	4.7	1.9
Conventional	Low drift nozzle	1.7	1.2
Conventional	Low drift nozzle + end nozzle	1.5	0.9
Conventional	75% drift reducing nozzle	1.0	0.9
Conventional	75% drift reducing nozzle + end nozzle	0.9	0.7
Conventional	90% drift reducing nozzle	1.6	0.9
Conventional	90% drift reducing nozzle + end nozzle	1.4	0.6

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
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).

Bush and hedge shrubbery
For bush and hedge shrubbery 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).

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).

Combination toxicity
Combination products are formulated plant protection products that contain more than one active substance. Combinations of plant protection products of which, in accordance with the recommendations in the directions for use, the user prepares a combination in a tank (tank mix) are also considered as combination products. When evaluating the side effects of combination products on non-target organisms the question arises whether the risk must be estimated on the basis of a toxicity test with the combination product or whether a reasonable risk estimate can be made on the basis of the toxicity data of the separate active substances. There is no European guidance as regards combination toxicology.

Toxicity tests for non-target plants are nearly always done with the formulation.
This means that combination toxicity only needs to be determined for tank mixes.

Combination toxicity is determined on the basis of concentration addition.
In theory, three different effects are to be expected when two or more substances are used in a mixture:
- the substances may weaken each others' toxic effects (antagonism)
- the effects of the substances may be additive
- the substances may potentiate each others' toxic effects (synergism).

Although the effects of mixtures of active substances in Plant protection products have only been studied to a very limited extent and not for all relevant species and toxicological endpoints it is expected that active substances in a combination product or tank mix together contribute to the toxicity of that product or that tank mix. The extent to which the active substances are contributing is poorly known. The available data indicate that also in case of partial addition the extent of combination toxicity does not deviate strongly from concentration addition.
In view of these considerations the evaluation of the toxicity data of combination products or tank mixes is based on concentration addition. In case of concentration addition each substance contributes to the total toxicity of a mixture in proportion to its concentration. The calculation method is given in Appendix C.

2.4 Approval

The evaluation of products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 [3],or new substances, has been laid down in Regulation (EC) No 1107/2009 [1]. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection product and Biocides Decree (Bgb) [4].

2.4.1 Criteria and trigger values

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 Guidance Document on Terrestrial Ecotoxicology [8].

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

Revision of the Guidance Document on Terrestrial Ecotoxicology (Sanco/10329/2002) is taking place at this moment (by EFSA).

3. APPENDICES

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

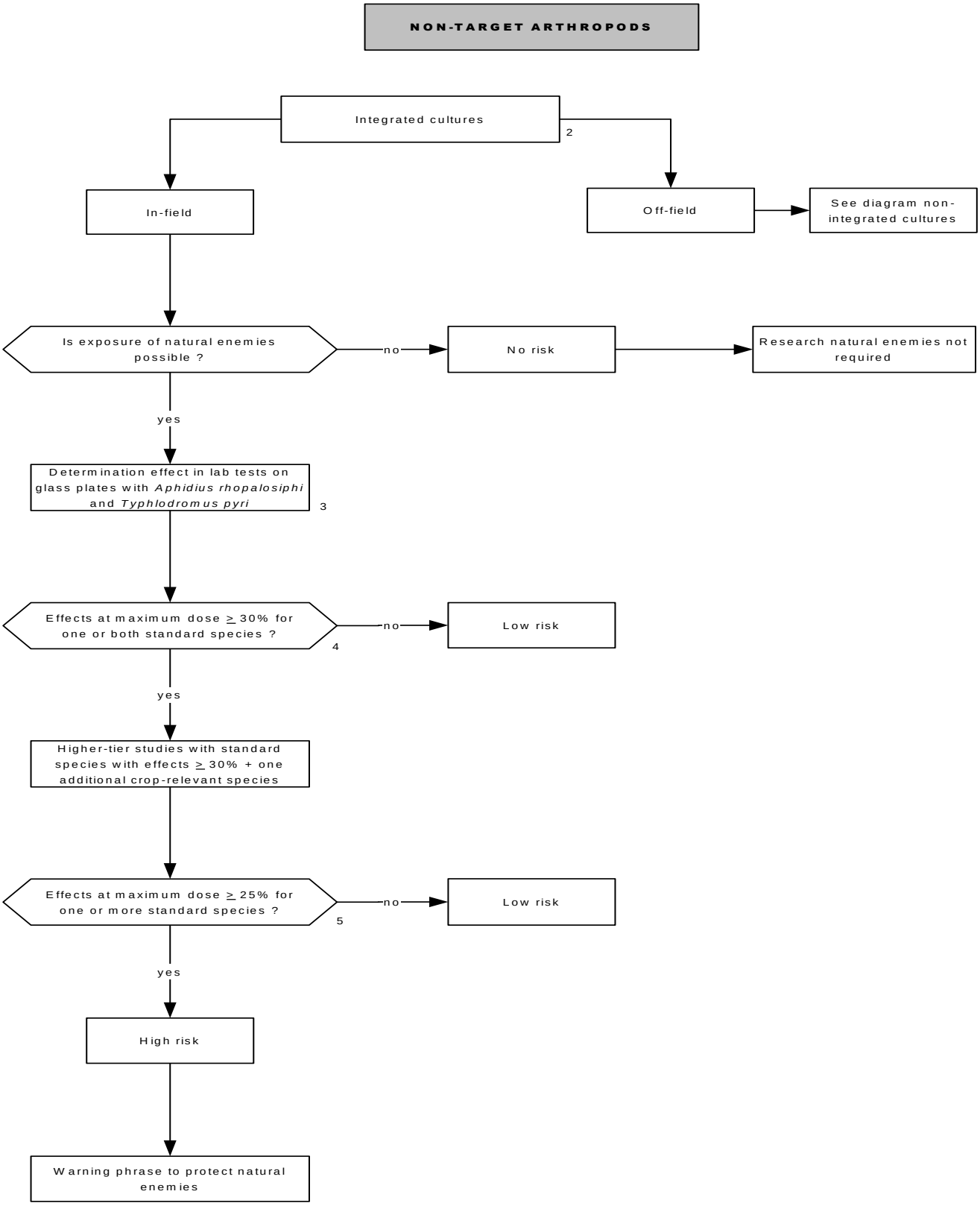
1) A distinction is made between integrated and non-integrated pest management systems because the evaluation for non-target arthropods for these two types of systems is essentially different. In the case of integrated pest management systems natural enemies are deliberately brought into the cropping 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 $\underline{\geq}$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 uw leverancier van natuurlijke vijanden 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
Integrated cultures
2
In-field
Off-field
See diagram non-integrated cultures
Is exposure of natural enemies possible ?
no
No risk
Research natural enemies not required
yes
Determination effect in lab tests on glass plates with *Aphidius rhopalosiphi* and *Typhlodromus pyri*
3
Effects at maximum dose ≥ 30% for one or both standard species ?
no
Low risk
4
yes
Higher-tier studies with standard species with effects ≥ 30% + one additional crop-relevant species
Effects at maximum dose ≥ 25% for one or more standard species ?
no
Low risk
5
yes
High risk
Warning phrase to protect natural enemies

4 REFERENCES

1 Regulation (EC) No 1107/2009, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=504604%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=1&list=504604%3Acs%2C&hwords=&action=GO&visu=%23texte
2 Directive 91/414/EEC, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=172911%3Acs&pos=3&page=1&lang=en&pgs=10&nbl=3&list=447073%3Acs%2C185439%3Acs%2C172911%3Acs%2C&hwords=&action=GO&visu=%23texte
3 Commission Implementing Regulation (EU) No 540/2011, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574460%3Acs&pos=6&page=1&lang=en&pgs=10&nbl=6&list=646199%3Acs%2C628324%3Acs%2C615541%3Acs%2C607847%3Acs%2C607130%3Acs%2C574460%3Acs%2C&hwords=&action=GO&visu=%23texte
4 Bgb: Plant protection products and Biocides Decree. See www.overheid.nl/wetten
5 Commission Regulation (EU) No 283/2013, http://eur-lex.europa.eu/Notice.do?val=724582:cs&lang=en&list=729945:cs,724582:cs,&pos=2&page=1&nbl=2&pgs=10&hwords
6 Commission Regulation (EU) No 284/2013, http://eur-lex.europa.eu/Notice.do?val=724566:cs&lang=en&list=729902:cs,724566:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=
7 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
8 European Commission (2002). Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC (SANCO/10329/2002 rev. 2 final - noted by the SCFA on 18 October 2002)