

**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; bees

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**Board
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of Plant protection products and Biocides**

Chapter 7 Ecotoxicology; terrestrial; bees

Category: Plant protection products

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GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the effects on bees 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

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 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 on the basis of agricultural, phytosanitary and ecological, including climatological, conditions deviate from the EU evaluation methodology which are specific to 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

The assessment as regards the risk to bees follows the EU framework; for the NL assessment reference is therefore made to the EU assessment.

The decision tree with corresponding explanatory notes is presented in Appendix II-1. This decision tree summarises the evaluation as regards bees.

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.

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).

Combination toxicity is not part of the EU data requirements. This aspect is, however, given attention in the national evaluations (see below).

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 recommendation 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.

It is possible to base the risk assessment of a combination product on toxicity tests with the formulation. The *acute* toxicity test may lead to variable results because quantity and quality of the co-formulants may not be constant and the formulation may alter the availability of the active substances. For the acute risk assessment, the combination toxicity on the basis of the tests with the product are compared with the combination toxicity based on the toxicity research with the separate active substances. The lowest combination toxicity value is then used in the risk assessment.

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 to Chapter 7.

Off-field risk

In the case that an in-field risk to bees has been determined (see §1.3 of the EU part), an off-field risk should be calculated using the drift values as used for non-target arthropods (see §1.3 of the NL part).

Crop attractiveness for honey bees

On national level, an overview is given of the attractiveness of agricultural crops for honeybees for the collection of nectar and/or pollen (in Dutch, appendix II-1). This document is used for identification of relevant crops for honeybee risk assessment. Moreover, this document is valuable for the understanding of risk mitigation sentences in which the phrase 'bee-attractive crops' is mentioned.

The document also contains definitions of flower and flowering crop (in Dutch). These are translated below.

Definitions for terminology flower and flowering crop with respect to bee risks:

Definition flowering (bloom):

Flowers in which the stamen or pistils are visible.

Definition flowering crop – flower bulbs/bulb flowers:

A crop is in flower when more than 1% of the plants in a field is flowering. In Dutch agricultural practice this means that a crop is considered to be flowering when more than two plants per linear metre of a field are flowering.

Definition flowering crop - orchard:

An orchard is considered a flowering crop when more than 1% of the flowers in an orchard are flowering.

Definition flowering crop - field crops:

The crop is considered a flowering crop when more than two plants (crop and/or weed plants) per square meter are flowering.

Dust drift

The use of coated seeds in combination with certain seeding processes can lead to dust drift which can be hazardous for bees. The matrix 'Relevance of dust for pesticide treated seeds' shows in which circumstances (crops in combination with coated seeds or certain seeding processes) protective actions must be taken to prevent dust drift (appendix II-2).

In case dust drift can not be excluded applicants are requested to submit relevant risk assessments.

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 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 bees for the national authorisation reference is made to the EU part (§1.4.1).

2.4.2 *Decision making*

For decision making as regards the risk to bees for the national authorisation reference is made to the EU part (§1.4.2).

2.5 *Developments*

See EU part §1.5.

3. APPENDICES

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Appendix II-1 List of attractiveness of agricultural crops for honeybees for the collection of nectar and/or pollen (in Dutch)



LIST
JAANTREKELIJKE GEWASSEN

Appendix II-2 Relevance of dust for treated seeds

MATRIX 'RELEVANCE OF DUST FOR PESTICIDE TREATED SEEDS'

version 15 September 2010

Sources: Plantum NL (seed companies and seed treatment companies); information checked and complemented by pesticides manufacturers (Bayer CropScience, Syngenta Crop Protection, BASF), contractors (Cumela), growers (LTO Netherlands)

crop	Direct sowing, or transplanting?	If direct sowing outdoors, pneumatic? ¹	seed treatment technology ²	Conclusion on dust <i>formation</i> (and potential risk for non-target organisms) ³
arable crops				
beet (sugar and fodder)	Direct sowing	No, mechanical seed drill equipment	pelleting, with active ingredient not on the outside of the seed but closed in by an inert layer; new development: filmcoating on top of the pellet	not relevant, due to pelleting and filmcoating (and mechanical drilling)
corn	Direct sowing	Yes, 90% vacuum principle (but nowadays modified machines with airflows directed downwards)	basis seed treatment direct on the seed (active ingredient can be present on the outside surface of the seed)	Relevant
sweetcorn	Direct sowing	Yes, 90% vacuum principle (but nowadays modified machines with airflows directed downwards)	basic seed treatment / basic coating	Relevant
cereals	Direct sowing	mostly mechanical seed drill equipment, pneumatic with vacuum principle upcoming	basic seed treatment / basic coating	Relevant
flax	Direct sowing	mostly mechanical seed drill equipment, pneumatic with vacuum principle	basic seed treatment / basic coating	Relevant

		upcoming		
oilseed rape	Direct sowing	mostly mechanical seed drill equipment, pneumatic with vacuum principle upcoming	basic seed treatment / basic coating	Relevant
poppy seed	Direct sowing	mostly mechanical seed drill equipment, pneumatic (both with vacuum and gauge pressure principle) is possible as well	basic seed treatment / basic coating	Relevant
grasses, grasseed	Direct sowing	both mechanical and pneumatic (vacuum) are possible	basic seed treatment / basic coating	Relevant
caraway	Direct sowing	both mechanical and pneumatic (vacuum) are possible	This crop has no seed treatments.	not relevant, since no seed treatments
alfalfa	Direct sowing	both mechanical and pneumatic (vacuum) are possible	This crop has no seed treatments.	not relevant, since no seed treatments
green manure crops	Direct sowing	both mechanical and pneumatic (vacuum) are possible	This crop has no seed treatments.	not relevant, since no seed treatments
outdoor vegetables				
onion	Direct sowing	yes, for 90% of the seed (vacuum, but exhaust air not deflected upwards)	filmcoating/rotostat; part of the market extra top layer	not relevant due to high quality coating

leek	Most sowing in seed beds and transplanting later, approximately 10% direct sowing. Mostly sowing outdoors, some sowing indoors in trays.	yes (vacuum, but exhaust air not deflected upwards)	filmcoating/rotostat; part of the market extra top layer	not relevant due to high quality coating
carrot	Direct sowing	yes (vacuum, but exhaust air not deflected upwards)	filmcoating/rotostat; part of the market extra top layer	not relevant
chicory, endive	Direct sowing	mainly coated seed, pneumatic (vacuum but exhaust air not deflected upwards); also pelleted seeds, sown mechanically	filmcoating/rotostat	not relevant
beetroot	Direct sowing, small percentage indoors.	yes (vacuum, but exhaust air not deflected upwards)	basic coating	relevant
spinach	Direct sowing	mainly mechanically drilled, pneumatic equipment upcoming (both vacuum and gauge pressure principle)	basic coating, partly filmcoating, and sometimes toplayer	relevant
beans, peas	Direct sowing	both mechanical and pneumatic (vacuum but exhaust air not deflected upwards) are possible	basic seed treatment / basic coating	relevant
asparagus	Sowing in seed beds, later transplanted.	yes (vacuum, but exhaust air not deflected upwards)	filmcoating/rotostat	Not relevant
greenhouse vegetables				
radish	Direct sowing, partly indoors, small percentage outdoors.	yes (vacuum, but exhaust air not deflected upwards)	filmcoating/rotosat	not relevant
lettuce, including lettuce-like (radichio rosso, endive,	All these crops are only sown and raised to young plants indoors; later transplanted	not applicable	pelleting, with active ingredient not on the outside of the seed but closed in by an inert layer	not relevant

etcetera)	indoors or outdoors.			
corn salad	Direct sowing, in the Netherlands only grown indoors.	not applicable		not relevant
brassica, including head cabbages, Brussels sprouts, cauliflower, broccoli, Chinese cabbage, kale	All these crops are only sown and raised to young plants indoors; later transplanted indoors or outdoors.	not applicable	filmcoating/rotostat, and sometimes top layer	not relevant
celeriac	Sown indoors, later transplanted outdoors.	not applicable		not relevant
fruiting vegetables (tomatoes, cucumber, weet pepper, eggplant, etcetera)	Plant raising and cultivation only indoors.	not applicable	sometimes fungicide treatments, no insecticide treatments	not relevant
ornamentals				
several ornamental crops from seed	Cultivation both indoors and outdoors; many crops through plant raising indoors; limited crops directly sown outdoors.		sometimes fungicide treatments, no insecticide treatments yet; if used: filmcoating (high value seeds)	not relevant

1: Mechanical seed drill equipment does not work with air and therefore can not release air flows. With pneumatic seed drill equipment there are two principles: using the vacuum principle and using the gauge pressure principle. When using the gauge pressure principle there is no more air replacement (with potential dust) than with mechanical seed drill equipment. When using the vacuum principle seeds are put in the sowing row by vacuum and the excess air will come free. At conventional corn sowing machines, this exhaust air was directed upwards. Meanwhile, these machines (mostly) are modified: they have deflectors directing the exhaust air downwards to the soil. For vegetable vacuum seed drilling machines the airflows already always were directed towards the soil.

2: There is no complete one-on-one relationship crop - seed treatment: which method is used also depends on e.g. the type of pesticide used, the composition of that pesticide and whether multiple pesticides are used, seed type (smooth, rough, etc.), to a certain extent for which market the seed is treated, etc. Also, various terms are used. This table presents an indication. In general, the more valuable the seed is, the higher quality (and more expensive) seed treatment technology can be used. Furthermore: coating means stickers (polymers) are used; in basic coating the pesticide can irregularly be distributed over the seed, in film coating a regular layer is spread over the seed (used for somewhat higher valuable seeds); a part of the market has on top of that a top layer (without active ingredient). And in any case, insecticide-treated seeds are generally coloured, so this colour layer is on top of the layer with active substance, on the outside surface.

3: dust *distribution* (depending on type of seed drill equipment used) is not yet taken into account here: so risks can still be 'not relevant' due to the sowing method, and whether dust is spread by this method.

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=>