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

NL part

Plant protection products

Chapter 3 Human toxicology; risk operator, worker and bystander

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ctgb

Board for the authorisation of Plant protection products and Biocides

Chapter 3 Human toxicology; risk operator, worker and bystander

Category: Plant protection products

GENERAL INTRODUCTION 3
2. NL framework 3
2.1. Introduction 3
2.2. Data requirements 4
2.3. Risk assessment 4
2.3.1 Estimation of operator, bystander/resident and worker exposure 4
2.4. Approval 7
2.5. Developments 7
3. References 8

Important changes in the Evaluation Manual

Evaluation manual PPP NL part Chapter 3 Human toxicology; risk operator, worker and bystander			
Version	**Date**	**Paragraph**	**Changes**
2.0	Janaury 2014	2.3	This section described the Dutch specific exposure models.
2.1	October 2016	2.3	Complete change due to the adoption of the EFSA OPEX model.
2.2	March 2017	2.3.1	The section on the reference values has been updated to include the AAOEL.
		2.3.1	Information on how to address operator exposure for bulb dipping has been included.
2.3	March 2018	2	Bgb link updated
		All paragraphs	Links updated
2.4	January 2023	2.3.1	Updated according to working document ICZS on non-prof use.
		2.3.1 and 2.5	From January 1st 2022, the EFSA OPEX online calculator will be used for all exposure scenarios included in this model (EFSA Journal 2022;20(1):7032).
2.5	October 2025	2.3.1	Consistency with implementation of the ECJ judgment (C-308/22)
2.6	October 2026	GENERAL INTRODUCTION	Addition of a note to align this evaluation manual chapter with the effects of Reg. (EU) 2024/1487.

GENERAL INTRODUCTION

This chapter describes the methodology for estimation of the risk to the operator, worker and bystander for the authorisation evaluation of plant protection products within the NL framework (§2 - §2.5). The chapter describes the requirement for the Dutch national addendum of the registration report for zonal applications and for other Dutch approval procedures of plant protection products submitted from January 1st 2016 that fall under the Bgb (Plant protection products and Biocides Decree) assessment framework. For the core registration report as well as for the EU approval procedure of active substances the methodology as described in the EU part of the evaluation manual is used.

Note added in the version 2.6 update to align this evaluation manual chapter with the effects of Reg. (EU) 2024/1487 (entry into force on 19 June 2024) defining data requirements for the approval of safeners and synergists and establishing a work programme for the gradual review of safeners and synergists on the market in accordance with Regulation (EC) No 1107/2009:

Data requirements for active substances as described in this chapter likewise apply to safeners and synergists, pursuant to Regulation (EU) 2024/1487 (amended by Regulation (EU) 2025/2274). For the purposes of this evaluation manual, references to active substance shall be understood as referring collectively to active substances, synergists and safeners.

In accordance with (EC) No 1107/2009, Art.81(1), a derogation applies for plant protection products that contain yet non-approved safeners and synergists that have been included in the work programme; until 3 December 2030, such products are subject to the data requirements as they were before the entry into force of (EU) 2024/1487.

2. NL FRAMEWORK

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

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

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 where the national framework has been elaborated in more detail than the EU framework.

2.1. Introduction

Specific evaluation methodologies used in the Netherlands are the same as those described under the EU part of the Evaluation Manual (§1.2).

Therefore, in principle no national assessment is required. There are however a few national specific points which are not always taken into account in the core assessment and therefore require an assessment at a national level. These points are described in section 2.3.

2.2. Data requirements

The EU data requirements regarding operator, worker, bystander and resident exposure are described in Chapter 4 Human toxicology, mammalian toxicity dossier of the EU part of the Evaluation Manual, §1.2.2.

2.3. Risk assessment

NL-specific elements of the risk assessment are given in the text below.

2.3.1 Estimation of operator, bystander/resident and worker exposure

To estimate the operator, bystander/resident and worker exposure the same models are used as those described in the Evaluation manual, Chapter 4: human toxicology; risk operator, worker, bystander and resident (EU part). However, some specific points should be taken into account.

Reference values:

The reference values as set during the approval of the active substance should be used. Only in cases where the proposed use in the Netherlands is not covered by the semi-chronic EU-AOEL, it is possible to deviate from the EU-AOEL. For example chronic exposure can occur in continuous systems in greenhouses, and certain applications in the Netherlands are performed by contract workers. A TNO report with the results of a survey among contract workers was published in 2001 [1].

This survey was performed by the sector organisation of contract workers in the Netherlands, Cumela. Cumela conducted a new survey in 2004. The results show that contract workers may operate in the following crops (with a proportion contract labour >10%): maize, cereals, beet, potatoes, onions, grassland, asparagus, vegetables for processing, and other field vegetables, other vegetable crops (e.g., oilseed rape, flax,
oil-containing crops), tree nursery stock, public parks and gardens, recreation grasses and uncultivated land.

The expected exposure duration will be evaluated per application, on the basis of which a decision will be taken whether a semi-chronic or chronic AOEL needs to be derived.

With the adoption of the revised Guidance document on the assessment of exposure of operator, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7) an acute risk assessment will be required for operator and bystanders. This will only be required when an Acute AOEL (AAOEL) has been derived at EU level. An AAOEL will not be derived at a national level and therefore if an AAOEL has not been derived yet at EU level, then no acute risk assessment is needed. The revised Guidance document applies to all applications submitted from the 1st of March 2017.

Application scenario for field crops:

Crops can be sprayed by using a tractor or hand-held equipment, and depending on the crops height up/side or downward spraying is used. Ctgb will assess the appropriate application method for each field crop. A list (field use scenario list TOX) is available on the Ctgb website which describes for each crop which exposure scenario should be taken into account, such as handheld versus mechanical (tractor mounted) application and downward versus upward application. The list is included in Appendix 1 of this evaluation manual. If for

a zonal application the specific exposure scenario is not taken into account for a certain crop than this exposure scenario will have to be addressed in a national assessment.

Spray volume:
For zonal application in which the Netherlands was a concerned Member State there have been cases where the spray volume in the intended use table in the core assessment does not correspond to the spray volume in the final NL-GAP. If the spray volume in the NL-GAP is lower this would affect the exposure assessment in particular for bystanders and resident. In cases where the spray volume is higher in NL-GAP it may affect the dermal absorption value if the tested spray dilution in the dermal absorption study no longer covers the intended spray dilution. Therefore, differences between the NL-GAP and EU-GAP in terms of the spray volume may trigger the need for a re-evaluation of the exposure assessment at a national level.

Combination toxicity:
If combination toxicity of 2 or more active substances in one plant protection product has not been addressed in the core assessment than this should be done on a national level. As a first tier additivity is assumed. If the added exposure exceeds 100% than based on the mode of action and critical targets of the active substances it will be determined if combination toxicity is indeed likely. Further refinement may be possible in the use of additional PPE compared to the core assessment.

Operator assessment bulb dipping:
For bulb dipping exposure will only take place during mixing and loading. The exposure can be estimated using the EFSA OPEX model. Please note that the EFSA OPEX online calculator will be used (EFSA Journal 2022;20(1):7032). However, some adjustment have to be made to the model to make it suitable for the intended use since in this case the amount of kg active substance/ha is not relevant for the operator exposure. In the Netherlands a maximum dipping volume of 5000 L is assumed. The applicant should calculate the amount of product needed to make 5000 L dipping volume and the amount of active substance needed for this (in kg). For crop type ‘bare soil’ can be selected in the model which assumes an application of 50 hectare a day. By dividing the amount of active substance needed to create 5000 L dipping fluid by 50 ha a day you will get the kg as/ha that needs to be filled in the model. In the results sheet for the operator only the exposure during mixing and loading should be used for the risk assessment.

Worker assessment bulb dipping:
After dipping of bulbs for the forcing cultivation, exposure of the worker due to contact with treated bulbs cannot be excluded as these will be manually planted in crates. For the exposure assessment of workers handling wet flower bulbs after dipping, there is no suitable model available. The available re-entry model (EFSA OPEX) is based on the use of a crop specific transfer coefficient to calculate the dermal load of a daily task. These models assume that residues are transferred continuously from crops to the workers skin, starting at zero to a maximum load at the end of the shift, thus a continuously constant increase of the dermal load. These models are developed to estimate the transfer of dry residues. Exposure from handling of wet bulbs after dipping is in fact a different process and requires a different approach. The worker has contact with a concentration of the active substance equal to the concentration of the bulb treatment solution. The first contact with wet bulbs surface immediately leads to a maximal dermal load which is maintained throughout the shift as a liquid layer of bulb dip solution is continuously transferred from the wet bulbs to the hands.

In the Technical Notes for Guidance for the exposure assessment of biocidal products

(TNSG 2002) several models are available for estimating the exposure when handling wet surfaces. The TNsG 'Handling contact with wet surfaces model 1' seems most appropriate to estimate the worker exposure resulting from planting tasks after bulb dipping. This model describes hand contact with wet or moist wood over an average period of 3 hours (cycle). As a realistic worst-case exposure value the 75th percentile hands default inside gloves (1080 mg/cycle; n=43 data points) may be used and three cycles per day may be assumed, i.e. 3240 mg/day.

In addition, according to the HEEG opinion on the assessment of Potential & Actual Hand Exposure (agreed at TMI08, 2008), the exposure without gloves may be estimated by using a multiplication factor of 100 for the conversion of actual to potential hand exposure (thus 3240 mg/day x 100 = 324000 mg dipping fluid/day). These exposure values equals to 324 mL dipping fluid/day without gloves and 3.24 mL dipping fluid/day with the use of gloves. For the risk assessment, these exposure estimates are recalculated to mg a.s./day based on the concentration active substance used in the dipping fluid. Then the predicted systemic exposure is calculated by correcting for dermal absorption and compared with the AOEL.

An example of the exposure calculation is given below:

Worker exposure - contact with wet bulbs after the dipping process						
Biociden handling model 1						
	actual (inside gloves)			**potential (without gloves)**		
	3240	mg dipping fluid/working day		324000	mg dipping fluid/working day	
	3,24	g dipping fluid/working day		324	g dipping fluid/working day	
Exposure dipping fluid	3,24	mL dipping fluid/working day		324	mL dipping fluid/working day	
EU-AOEL	0,1	mg/kg bw/day				
Dermal absorption	10%					
a.s. in product	250	mg/mL				
dosage of product	2	%				
external exposure	0,06480	mL product/day		6,48000	mL product/day	
external exposure	16,20000	mg a.s./day		1620,00000	mg a.s./day	
internal systemic exposure	1,62000	mg a.s./dag		162,00000	mg a.s./dag	
internal systemic exposure	0,02700	mg a.s./kg bw/dag		2,70000	mg a.s./kg bw/dag	
	27,0	%-EU-AOEL		2700,0	%-EU-AOEL	

Bystanders/residents assessment:
The EFSA OPEX model provides several options for the distance between the application and the bystander/resident. Please note that the EFSA OPEX online calculator will be used for all exposure scenarios included in this model (EFSA Journal 2022;20(1):7032). This model should also be applied to assess bystanders/residents following application in greenhouses.
For downward spraying this ranges from 2 meter to 10 meter. For upward spraying this ranges between 5-10 meter. In the Netherlands the lowest buffer strip is used in the risk assessment as this is considered to be the most appropriate for the Dutch situation. If no safe use has been shown at this distance refinement may be possible, e.g. with a specific DT50 value or refined dermal absorption values. Every proposed higher tier refinement should be scientifically justified.

Non-professional use
For the non-professional operators reference is made to the Plant protection products and Biocides Decree (Bgb) article 8 and 8c

The Ctgb does not grant authorization of plant protection products for non-professional use that are classified in line with Regulation (EC) No 1272/2008 as toxic, very toxic, carcinogenic, mutagenic or toxic for reproduction.

For the assessment, reference is made to the working document published by the ICZS (See EU part of the evaluation manual chapter 4, for more details). For the evaluations in the Netherlands, the following assumptions are made:

These are:
- Application is always manual
- Use of PPE is not taken into account
- The default value for the treated area is set at 500 m^2/day, as agreed after discussions with the ministries.

The Ctgb does not grant authorization of plant protection products for non-professional use if personal protective equipment (PPE) is required to ensure safe use. PPE can be on the label only based on formulation hazard, e.g. in case the formulation is classified for sensitisation.

2.4. Approval
The evaluation of products on the basis of active substances has been laid down in Regulation (EC) No 1107/2009. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection product and Biocides Decree (Bgb).

2.5. Developments
he EFSA model is expected to undergo further development (e.g. for scenarios currently not included).

3. REFERENCES

1 Drooge, H.L. van, Huijbers, R.F., Kerkman, M., Groeneveld, C.N., Schipper, H.J. Pesticide application patterns of contract workers in agriculture. TNO report V3680 (2001).