

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

**NL part**

**Plant protection products**

**Chapter 4 Human toxicology; risk operator, worker  
and bystander**

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## Chapter 4 Human toxicology; risk operator, worker and bystander

Category: Plant protection products

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## 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 all other Dutch approval procedure of plant protection products. 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.

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 substances included in Commission Implementing Regulation (EU) No 540/2011 [3].

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].

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.

Furthermore, 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 Regulations (EU) No 540/2011 [3] in case no EU procedure has been described.

## 2.1. Introduction

Specific evaluation methodologies are available for the aspect operator, worker, bystander and resident risk assessment which differ from those described under the EU part of the Evaluation Manual (§1.2).

There is a deviation from the EU evaluation methodology for the aspect operator, worker, bystander and resident exposure regarding the models used for exposure estimation; an NL-specific methodology is followed. This is because there is no European consensus about the model to calculate operator exposure. In addition, specific national aspects, such as acreage play a role.

The other evaluation methodologies do not differ from the EU part of the Evaluation Manual (PPP) (§1.2). The NL procedure is only described where no EU procedure has been described.

## 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 evaluation methodologies and further elaborations of the EU procedures are given in the text below. The other evaluation methodologies for chemical Plant protection products are as described in the EU framework (see §1.3 in the EU part of the Evaluation Manual).

### 2.3.1 Estimation of operator exposure

A harmonised exposure model has not yet been approved by the Commission. Therefore suitable modules from mainly EUROPOEM I [7] or –where appropriate– the NL model and NL greenhouse model are used, before as well as after inclusion (in accordance with the text below). This is a deviation from the EU evaluation methodology. Calculation with EUROPOEM is in many cases more conservative than calculation with the DE model. This is in particular caused by the choice of the statistical starting point of both models and by the variation that may exist in the application practice between Member States, which is included in EUROPOEM I.

In addition, the EUROPOEM modules that are used are based on the best quality data base. The English or German model are not preferred for exposure estimation under Dutch field conditions because:

- the underlying data bases are too different due to local differences in application techniques, acreage etc.
- the exposure reduction by personal protection equipment assumed in the DE model is too high.
- the choices of the percentile in both models (UK 75/ DE 50) is considered less suitable in view of the fact that exposure may vary strongly as result of differences in labour conditions, climatological conditions etc. In addition, the underlying data base is of lower quality than that of EUROPOEM.

However, for manual upward and manual downward spraying in the field, the modules from the DE and UK model, respectively, are currently the best available (but for the DE model

the 90<sup>th</sup> percentile has been chosen).

*Models that are used for the Dutch evaluation (application).*

The text from the Bgb [4] specifically referring to the exposure estimation of the professional operator is given below (in Dutch):

**Artikel 8b Blootstelling als gevolg van professioneel gebruik**

1. Het college schat de kwantitatieve blootstelling aan het gewasbeschermingsmiddel, bedoeld in uitvoeringsverordening (EU) 545/2011, bijlage, deel A, punt 7.2.1.1, zonder rekening te houden met het effect van persoonlijke beschermingsmaatregelen en met gebruikmaking van de volgende modellen voor blootstellingssituaties:

- a. voor mengen en vullen van apparatuur voor de toepassing van gewasbeschermingsmiddelen met een:
  1. niet-vast gewasbeschermingsmiddel bij tractortoepassingen: model EUROPOEM I, bedoeld in bijlage 1 onder 1;
  2. niet-vast middel bij handmatige toepassing: model EUROPOEM I, bedoeld in bijlage 1 onder 1, voor huidblootstelling en NL model, bedoeld in bijlage 1 onder 4,5 en 7, voor inhalatoire blootstelling;
  3. poedervormig middel: NL-model bedoeld in bijlage 1 onder 4, 5 en 7;
  4. granulaatvormig middel: NL-model, bedoeld in bijlage 1 onder 4, 5 en 7, rekening houdend met de poederfractie in het middel;
- b. voor toepassen van het gewasbeschermingsmiddel:
  1. buiten opwaarts en neerwaarts met grote spuitapparatuur; model EUROPOEM I, bedoeld in bijlage 1 onder 1;
  2. buiten neerwaarts met handapparatuur: model UK POEM, bedoeld in bijlage 1 onder 9;
  3. buiten opwaarts met handapparatuur: de 90-percentiel waarde volgens het Duitse blootstellingsmodel, bedoeld in bijlage 1 onder 6;
  4. binnen met handapparatuur: NL-kasmodel, bedoeld in bijlage 1 onder 4, 5 en 7;

2. Het college gaat bij de beoordeling van de voorgestelde beschermende kleding en apparatuur volgens de uniforme beginselen, bedoeld in uitvoeringsverordening (EU) 546/2011, bijlage, deel I, onderdeel B Evaluatie, punt 2.4.1.3., uit van beschermingsfactoren voor deze kleding en apparatuur volgens de tabel, bedoeld in bijlage 2.

Where field studies under Dutch field conditions are lacking, exposure is first estimated with generic models. The EUROPOEM I model is currently required for those applications for which sufficient observations (50-100) are present (see table below for the applications). The 75<sup>th</sup> percentile of the exposure values has been chosen as surrogate value for these applications. The studies included in EUROPOEM I have been subjected to a strict screening for suitability and quality. For the other applications for which fewer observations are included in EUROPOEM I, the Dutch model is considered as most suitable for the Dutch application situation. The 90<sup>th</sup> percentile of the exposure values in the Dutch model has been chosen to take into account the variation in exposure which occurs in practice.

The following summary shows which models are required by the Bgb, for which type of application for estimating the dermal and respiratory exposure [7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17]. A qualitative exposure estimation, based on expert judgement, is made for applications that are not mentioned. The models are available on the Ctgb website.

Activity / Formulation		Scenario	Preferred generic model	
			<i>dermal</i>	<i>respiratory</i>
mixing and loading	Liquid	mechanical	EUROPOEM I	EUROPOEM I
		manual	EUROPOEM I	NL model
	Powder <sup>1</sup>	mechanical	NL model	NL model
		manual	NL model	NL model

	Granule <sup>2</sup>	mechanical	NL model	NL model
		manual	NL model	NL model
Spraying in the field		mechanical upward	EUROPOEM I	EUROPOEM I
		mechanical downward	EUROPOEM I	EUROPOEM I
		manual upward	German model <sup>4</sup>	German model <sup>4</sup>
		manual downward	UK model	UK model
Spraying in greenhouses, including mixing & loading		manual upward and downward <sup>3</sup>	NL greenhouse model	NL greenhouse model

<sup>1</sup> Where the product is a water-soluble foil formulation, the calculated default exposure is a factor 100 lower than for a powder.

<sup>2</sup> Where the data about particle size distribution and attrition of the granule are lacking, the model for powder formulations is used with an assumed 10% powder in the granules. Where the granule meets the EU criteria for granules a 1% powder fraction is assumed. The determination of the powder fraction is based on the data submitted under AIII 2.8.6.3 (determination of the dust percentage of granules) and on data submitted under AIII 2.8.6.5 (determination of the attrition of granules (attrition behaviour)).

<sup>3</sup> In the Dutch greenhouse model, the exposures estimated for mixing/loading and application are combined (in case a value is known for dermal absorption of the concentrate as well as the spray solution, the highest value for dermal absorption is taken to calculate the systemic exposure).

<sup>4</sup> The 90-percentile of the German model is used for manual upward spraying.

Application by means of LVM equipment (Low Volume Misters) is also used in greenhouses. Application is then automated and nobody is present in the greenhouse at the time of application. In that case no exposure estimate during application is calculated. An operator risk assessment for mixing/loading and for the worker, however, should be prepared, based on the amount of active substance applied per hectare.

Furthermore, the list of spray volumes (see Chapter 8 of the NL part of the Evaluation Manual (PPP) (Efficacy, Appendix C S spuitvolumina) and default values for the treated area per day, duration of mixing/loading, and duration of application are used in the exposure estimation [7]:

Activity	Treated area per day (ha)	Duration mixing/loading (hours)	Duration application (hours)
Mechanical downward spraying	10	1	6
Mechanical upward spraying	6	1	6
Manual application, upward and downward, overall or in greenhouses	1	0.5	6

For plant protection products in spray cans the exposure of operators is estimated with the model CONSEXPO [18].

#### *Non-professional use*

For the non-professional operators reference is made to the Plant protection products and Biocides Decree (Bgb) article 8 and 8c [4], which is given below (in Dutch).

#### **Artikel 8. Toelating niet-professioneel gebruik**

Het college verleent geen toelating voor niet-professioneel gebruik van een gewasbeschermingsmiddel dat overeenkomstig richtlijn 1999/45/EG is ingedeeld als giftig, zeer giftig, kankerverwekkend, mutageen of vergiftig voor de voortplanting.

#### **Artikel 8c. Blootstelling als gevolg van niet-professioneel gebruik**

Het college schat de kwantitatieve blootstelling aan het gewasbeschermingsmiddel voor de toepasser van een middel bestemd voor niet-professioneel gebruik, bedoeld in uitvoeringsverordening (EU) 545/2011, bijlage, deel A, punt 7.2.1.1, zonder rekening te houden met het effect van persoonlijke beschermingsmaatregelen. Het college gebruikt voor de inschatting van de blootstelling een van de methoden, bedoeld in artikel 8b.

The Ctgb does not grant authorization of plant protection products for non-professional use that are classified in line with Directive 1999/45/EC as toxic, very toxic, carcinogenic, mutagenic or toxic for reproduction.

Where possible the Ctgb will use a similar method as described for professional operators. Study data on the exposure of non-professional operators of plant protection products are not available. Models for professional application are therefore used, with a number of assumptions.

These are:

- Application is always manual
- Use of PPE is not taken into account
- A body weight of 63 kg
- The default value for the treated area is set at 500 m<sup>2</sup>/day, as agreed after discussions with the ministries.

#### *Protective measures for operator/worker*

Exposure is firstly estimated for the unprotected operator wearing normal working clothes. The effect of protective measures will, where necessary, be included at a later stage of the assessment for professional use. This effect will not be taken into account for non-professional use. PPE is not prescribed or non-professional use based on the risk assessment, but only based on formulation hazard, e.g. in case the formulation is classified for sensitisation. NL uses the default values described in Appendix 2 of the Bgb for the effectiveness of protective measures (see below).

The text from the Bgb specifically referring to the protection factors of personal protective equipment (bijlage 2, behorend bij artikel 8b, tweede lid) is given below (translated from Dutch):

#### **Protection factors for personal protection equipment**

Personal Protection Equipment	Protection factor
Half- and full-face masks with filter type 2	10
Powered full-face filtering devices with filter type 2	20
Powered full-face filtering devices with filter type 3	40
Protective clothing operator material-type CEN 3 or 4 (hands, head and neck excluded)	10

Personal Protection Equipment	Protection factor
Protective clothing workers in / on crops / treated area (hands, head and neck excluded)	5
Gloves, non-solid preparations	10
Gloves, solid preparations	20
Boots (chemical resistant)	10
Closed cabins	10

A protection factor of more than 10 may only be used in certain circumstances:

- for gaseous preparations inside closed areas,
- for gaseous preparations outside closed areas,
- for soil fumigants,
- for gloves when mixing, loading or applying solid preparations.

### 2.3.2 Estimation of worker exposure (re-entry)

A harmonised exposure model has not yet been approved by the Commission. The text from the Bgb specifically referring to the estimation of the professional worker exposure is given below (in Dutch):

#### Artikel 8b. Blootstelling als gevolg van professioneel gebruik

1. Het college schat de kwantitatieve blootstelling aan het gewasbeschermingsmiddel, bedoeld in uitvoeringsverordening (EU) 545/2011, bijlage, deel A, punt 7.2.1.1, zonder rekening te houden met het effect van persoonlijke beschermingsmaatregelen en met gebruikmaking van de volgende modellen voor blootstellingssituaties:
  - c. voor degenen die werkzaamheden uitvoeren in ruimten die behandeld zijn met gewasbeschermingsmiddelen of werkzaamheden uitvoeren met of aan gewassen die behandeld zijn met middelen: model model EUROPOEM II, bedoeld in bijlage 1 onder 2, voor dermale blootstelling;
  - d. voor degenen die werkzaamheden uitvoeren in ruimten die behandeld zijn met middelen of in ruimten werkzaamheden uitvoeren met of aan gewassen die behandeld zijn met middelen: NL model voor inhalatoire blootstelling, bedoeld in bijlage 1 onder 5 en 7.
2. Het college gaat bij de beoordeling van de voorgestelde beschermende kleding en apparatuur volgens de uniforme beginselen, bedoeld in uitvoeringsverordening (EU) 546/2011, bijlage, deel I, onderdeel B Evaluatie, punt 2.4.1.3., uit van beschermingsfactoren voor deze kleding en apparatuur volgens de tabel, bedoeld in bijlage 2.

The table below summarises which models are required by the Bgb for which type of application to estimate dermal and respiratory exposure in case of re-entry activities [7, 19, 20, 21, 22, 23].

Activity	Preferred generic model	
	<i>dermal</i>	<i>respiratory</i>
Re-entry in greenhouses	EUROPOEM II, module DFR model	NL model
Other re-entry work where relevant	EUROPOEM II, module DFR model	No model available



Even in crops where worker exposure during harvesting activities does not take place, crop inspection may occur shortly after application. Therefore, worker exposure should always be calculated, unless it can be justified that no crop inspection will take place. A work period of 2 hours/day is considered appropriate for crop inspection.

#### *Dermal absorption*

Where two values are known for dermal absorption (for the concentrate as well as for the spray solution), in principle the value for dermal absorption of the spray solution is chosen for the worker. Starting point here is that the skin is in principle wet and that the exposure expressed as area dose shows most similarity with the spraying situation.

For protective measures the same procedure is followed as for the operator, see §2.3.1 Estimation of operator exposure; subsection 'Protective measures for operator/worker'.

#### *Non-professional use*

For the non-professional worker reference is made to the Plant protection products and Biocides Decree (Bgb) article 8 and 8c. Where possible the Ctgb will use a similar method as described for professional workers.

Study data on the exposure of non-professional users of Plant protection products are not available. Models for professional application are therefore used, with the assumption of a body weight of 63 kg. In addition, use of PPE is not taken into account.

### **2.3.3 Estimation of bystander and resident exposure**

A harmonised exposure model has not yet been approved by the Commission. The text from the Bgb specifically referring to the estimation of the professional bystander exposure is given below (in Dutch):

#### **Artikel 8d. Omstander beroepshalve aanwezig**

Het college schat de kwantitatieve blootstelling aan het gewasbeschermingsmiddel voor de omstander, bedoeld in uitvoeringsverordening (EU) 545/2011, bijlage, deel A, punt 7.2.1.1., zonder rekening te houden met het effect van persoonlijke beschermingsmaatregelen. Het college gebruikt voor de inschatting van de blootstelling het model EUROPOEM II, bedoeld in bijlage 1 onder 3.

Professional bystander exposure is estimated with the relevant module from EUROPOEM II in case of field application while assuming that the bystander is present at the border of the treated field.

In reality, however, the distance to the field will usually be larger which means that this is a reasonable worst case situation. For applications in greenhouses it is assumed that – in accordance with good agricultural practice – no other persons are present in the greenhouse.

It is assumed that the body weight of a professional bystander is 70 kg.

For non-professional bystanders and residents, including children, no specific requirements are mentioned in the Bgb, except for residents near glasshouses (see 2.3.4) and secondary exposure on treated lawns (see 2.3.5). It is expected that further procedures for the exposure estimation of these groups will be implemented shortly.

### **2.3.4 Estimation of exposure of residents near glasshouses**

For residents near glasshouses the exposure is estimated with the 'Lee side turbulence

model' (in Dutch: 'lijwervel' model).

The emission of plant protection products out of the greenhouses will lead to transiently increased concentrations of the active substance(s) in the air in the vicinity of the greenhouse. The concentration of the active substance(s) outside the greenhouse during and after application is dependent on several factors, such as physical chemical properties of the active substance(s), the application method used, specific characteristics of the greenhouse, the position of the greenhouse to other buildings and climatological conditions. At the request of the Ministry of Infrastructure and the Environment, the Lee Side Turbulence model (lijwervel model) should be used to assess the risk of residents living nearby greenhouses.

The Lee side turbulence model estimates the acute exposure of persons outside a greenhouse at a distance of 20m over 24 hours. The concentration at the lee side of the greenhouse will decrease only very slightly over the first 20-30 meters.

The Lee side turbulence model is available on the Ctgb website.

### **2.3.5 Estimation of secondary human exposure on treated lawns**

Adults and children who recreate or sport on lawns or sports fields, treated with PPPs, can be exposed to these compounds. The BgB states that the Secondary exposure to lawn pesticides methodology described by the RIVM should be used to estimate this exposure [24].

## **2.4. Approval**

The evaluation of products on the basis of active 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].

## **2.5. Developments**

The developments at EU level will also affect the applied data requirements and evaluation methods in NL framework in view of the aim of the largest possible harmonisation of data requirements and evaluation methodologies.

It is to be expected that the methodology for risk assessment of residents will be developed at some later stage.

#### 4. REFERENCES

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- 4 Bgb: Plant protection products and Biocides Decree. See [www.wetten.overheid.nl](http://www.wetten.overheid.nl)
- 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>
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