

**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; aquatic  
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general introduction.....	3
I Aquatic and sediment dwelling organisms.....	3
2. NL framework.....	3
2.1. Introduction.....	4
2.2. Data requirements.....	4
2.3. Risk assessment.....	4
2.4. Approval.....	6
2.4.1. Criteria and trigger values.....	6
2.4.2. Decision making.....	6
2.5. Developments.....	6
II Effects on a sewage treatment plant (STP).....	7
2. NL framework.....	7
2.1. Introduction.....	7
2.2. Data requirements.....	8
2.3. Risk assessment.....	8
2.4. Approval.....	8
2.4.1. Criteria and trigger values.....	8
2.4.2. Decision making.....	8
2.5. Developments.....	8
3. References.....	9

## GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the effects of a plant protection product and its active substance on the aquatic environment and STP, and how reference values are derived in the NL framework (§2 - §2.5).

This chapter consists of two parts: a part about effects on aquatic and sediment dwelling organisms (I), and a part about effects on sewage treatment plants (STPs) (II),

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

## I AQUATIC AND SEDIMENT DWELLING ORGANISMS

### 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 25<sup>th</sup> 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 dossier 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 is 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 aspects for aquatic and sediment dwelling organisms for which specific rules apply in the national approval framework .

NL-specific drift percentages, deviating from the EU evaluation methodology, are used as input for calculation of the PEC for aquatic and sediment dwelling organisms. There is a national system of drift-reducing measures as well. 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.

This chapter is related to Chapter 6 Fate and Behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP) where the estimated or measured concentrations in water and sediment are determined.

## 2.2. Data requirements

The data requirements for chemical Plant protection products are in compliance with the provisions in EU framework (see §1.2 of this chapter).

NL-specific data requirements and further elaborations of the EU data requirements are given in the text below.

Experiments carried out after the 25<sup>th</sup> 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. An overview of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 7.

For animal welfare reasons it is recommended to limit the vertebrate tests with formulations and also metabolites as much as possible. In some cases it is even not allowed to submit fish studies with formulations, i.e. in the case that already fish studies are available with a comparable formulation. In Appendix D to chapter 7 is indicated in which cases it is not necessary to submit fish studies with the formulation or metabolites.

## 2.3. Risk assessment

The evaluation methodologies for chemical plant crop protection products are in compliance with the provisions in EU framework (see §1.3 of the EU part).

The national evaluation is in line with the risk evaluation methodology for aquatic and sediment dwelling organisms as elaborated in the European Guidance Document on Aquatic Ecotoxicology [7], with the exception of the drift percentages used for the calculation of the concentration in surface water; the used drift percentages are NL-specific, to meet the NL-specific climatological conditions and the specific standard drift-reducing measures packages from the Lozingenbesluit (Discharge Order).

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 the drift percentages reference is made to chapter 6: Fate and Behaviour in the environment; behaviour in surface water and sediment .

Furthermore, a national method has been elaborated for determination of combination toxicity (see below). Combination toxicity is not relevant in the EU framework because active substances are evaluated instead of products.

### **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.

It is possible to base the risk assessment of a combination product on toxicity tests with the formulation. The *acute* toxicity test can lead to varying results because the quantity and the quality of the co-formulants may not be constant and the formulation may change 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. In the assessment the risk of the combination products is determined on the basis of the lowest TER value, as calculated by the toxicity of the separate active substances or the toxicity of the product.

The fact that the ratio between the active substances changes by differences in sorption and degradation rate plays a role in determining *chronic* toxicity. This means that the concentration of the combination product in the environment (the PEC) cannot be predicted because the separate active substances may behave differently after application. For chronic risk assessment it is therefore preferred to determine the toxicity of the combination product on the basis of toxicity research with the separate active substances.

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 toxicological endpoints have not been studied for all relevant species 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 aquatic and sediment dwelling organisms for the national authorisation reference is made to the EU part (§ 1.4.2).

### 2.4.2. Decision making

The risk to aquatic and sediment dwelling organisms is determined as follows: Where the criteria mentioned in the UP are not exceeded, the product is permissible. Where one of the mentioned criteria is exceeded, the product cannot be authorised unless an (adequate) risk evaluation clearly demonstrates that under field conditions no unacceptable effects occur after application of the plant protection product in accordance with the directions for use. If relevant monitoring data, carried out in surface water and/or sediment, show that the criterion for aquatic and/or sediment dwelling organisms is exceeded, there is a possible risk.

Criteria to be met by monitoring data are given in Chapter 6 Fate and Behaviour in the environment; behaviour in surface water and sediment.

## 2.5. Developments

- In the framework of the WG Water, the Effects assessment working group has produced a draft report (Brock et.al. 2011)[8]. In this report new proposals for the aquatic effects assessment of plant protection products in the Netherlands are described for edge-of-field surface waters (drainage ditches) falling under the domain of the Plant protection Product Regulation (pre-registration) and for water bodies falling under the domain of the Water Framework Directive (post-registration). This report is not officially handed yet to Ctgb.
- Multiple stress and mixture toxicity  
In many crops during the growing season more than one compound will be used. In some crops this can add up to more than 50 applications and some of these compounds will be applied together, e.g. an herbicide together with an insecticide and/or fungicide. Sometimes even two or three herbicides or two or three fungicides or two insecticides may be applied simultaneously, up to 5 or 6 compounds at the same time. When these combinations (e.g. tank mixes) are not sold as a formulation the legislative process does not take account for the potential combined effects of the use of these tank mixes. Neither does the legislative process take into account that different compounds of the same group (e.g. insecticides) or of different groups (e.g. insecticides, herbicides, fungicides) are used over time in the same growing season.  
When a compound is allowed on the market this decision is sometimes based on the potential of recovery. Whether under different crop scenarios the recovery option is appropriate to use in the derivation of the RAC needs to be evaluated from an ecological point of view, since during the growing season drainage ditches may be affected multiple times by the use of plant protection products. Research on multiple stress of pesticides

on aquatic communities representative for Dutch drainage ditches, and how to deal with mixture toxicity of pesticides, has already been initiated in the past (Hartgers *et al.*, 1998[9]); Deneer, 2000 [10]; De Zwart, 2005 [11]; Van Wijngaarden *et al.*, 2004 [12]; Arts *et al.*, 2006 [13]; Van den Brink *et al.*, 2002b[14] & 2009 [15]). In 2009 a literature research was started to update the knowledge on mixture toxicity (Verbruggen & Van den Brink, 2010) [16]. In addition, a working group has been installed to look into the problem of multiple stress caused by pesticides in Dutch drainage ditches. This group will analyze some of the more realistic worst cases of pesticide use in crops (e.g. potatoes and fruit). A report is expected early 2013.

## II EFFECTS ON A SEWAGE TREATMENT PLANT (STP)

### 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 25<sup>th</sup> 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 taken into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4] The evaluation dossiers must meet 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 methodology on the basis of agricultural, phytosanitary and ecological, including climatological, conditions which are specific for the Netherlands.

The NL framework describes the dossier requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national decision scheme or when the national decision scheme has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter is used for evaluation of a substance for approval, and consequently inclusion 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 effects on an STP for which specific rules apply in the national decision scheme or when the national decision scheme has been elaborated in more detail than the EU framework.

Methods for exposure estimation for an STP have not been laid down in EU framework. Criteria for this aspect have neither been described. This aspect has therefore been elaborated nationally (see §2.3. and 2.4.1). For the methods for exposure estimation of an STP we refer to Chapter 6 Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP). The national elaboration of criteria setting is described in §2.4.1.

This chapter deals with substances which, in view of the nature of their use, may reach a sewage or waste water treatment plant. This category includes plant protection

products that are used in mushroom growing, chicory forcing, greenhouse cultures, and for pre-treatment of cut flowers. Use on hard surfaces (pavements) by municipalities, private organisations, companies and households may also contribute to Plant protection products reaching STPs via runoff [17].

## **2.2. Data requirements**

The data requirements for chemical plant protection products are in compliance with the provisions in EU framework (see §1.2 of the EU part).

Experiments carried out after the 25<sup>th</sup> 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.

The data requirements for the NL evaluation are identical to the data requirements for the EU; reference is therefore made to the EU part §1.2, where the NL question codes are given as well.

## **2.3. Risk assessment**

Methods for exposure estimation of an STP are given in Chapter 6, Fate and behaviour in the environment; behaviour in surface water, sediment and sewage treatment plant (STP). The exposure is compared with a criterion derived on the basis of the toxicity to micro-organisms in an STP.

## **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**

The criteria and trigger values are in compliance with the European regulations, see §1.4 of the EU part of the Evaluation Manual PPP.

### **2.4.2. Decision making**

Decisions on approval are taken in compliance with the European regulations, see §1.4 of the EU part of the Evaluation Manual PPP.

## **2.5. Developments**

There is a draft new EFSA guidance document for aquatic organisms: Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7):3290. This guidance document has to be implemented still. The implementation is expected somewhere in the second half of 2014.



### 3. REFERENCES

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