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

NL part

Plant protection products

Chapter 7 Ecotoxicology; terrestrial; birds and mammals

version 2.2; March 2019

ctgb

Board for the Authorisation of Plant protection products and Biocides

Chapter 7 Ecotoxicology; terrestrial; birds and mammals

Category: Plant Protection Products

Important changes in the Evaluation Manual

Evaluation manual PPP NL part Chapter 7 Ecotoxicology; terrestrial; birds and mammals			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014		
2.1	October 2016		
2.2	March 2019	2	Bgb link updated
		All paragraphs	Links updated

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).

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, 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 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) No 284/2013 implementing Regulation (EC) No 1107/2009 (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 - §2.4 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 in case no European procedure has been described.

2.1 Introduction

This chapter describes the data for birds and mammals for which specific rules apply in the national approval framework.

The other points in this chapter concern further elaborations of the EU procedure.

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

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.

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).
NL-specific evaluation methodologies and further elaborations of the EU procedure are presented in the text below.

2.3.1 Exposure via sprayed crops/plants/(insects) and secondary poisoning

The NL evaluation is in line with the risk assessment methodology for birds and mammals as elaborated in the EFSA guidance on risk assessment for birds and mammals (2009). However it should be noted that PECwater (based on drift) is considered to be a Dutch specific aspect and that the Dutch value should be used in risk assessment for secondary poisoning (see also § 2.4.1)

The risk for drinking water in the EFSA guidance on risk assessment for birds and mammals (2009) is not depending on drift and is therefore not Dutch specific.

2.4 Approval

The evaluation of products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 , or new 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 Bgb (Plant protection product and Biocides Decree).

2.4.1 Criteria and trigger values

The criteria as described in the Commission Regulation (EU) No 546/2011 (i.e. the Uniform Principles) are applied for the acute, sub-acute and semi-chronic toxicity to birds and mammals (see the EU part §1.4).

For the Dutch specific criteria and trigger values as applied in the evaluation of surface water reference is made to the Bgb (Plant protection product and Biocides Decree) .
Article 8f (new and existing substances) of the Plant Protection Products and Biocides Decree (Bgb) describes the authorisation criterion applicable for birds and mammals.

This concerns drift-values.

2.4.2 Decision making

Decisions making on approval proceeds as follows:
The product is permissible in case the criteria mentioned under 2.4.1 are not exceeded (see EU part §1.4).

Where one of the mentioned UP criteria is exceeded, the product is not permissible unless a further (adequate) risk assessment clearly demonstrates that there are under field conditions no unacceptable effects after application of the Plant protection product in accordance with the directions for use.