

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

NL part

Plant protection products

**Chapter 6 Ecotoxicology; terrestrial; birds and
mammals**

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**Board
for the Authorisation
of Plant protection products and Biocides**

Chapter 6 Ecotoxicology; terrestrial; birds and mammals

Category: Plant Protection Products

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Important changes in the Evaluation Manual

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| 2.0 | January 2014 | | |
| 2.1 | October 2016 | | |
| 2.2 | March 2019 | 2 | Bgb link updated |
| | | All paragraphs | Links updated |
| 2.3 | July 2020 | | Potato-eating mammals added |
| 2.4 | October 2025 | 2.3, 2.4 | Update to EFSA 2023. Relevant for submissions after 30-09-2025 |
| 2.5 | May 2026 | 2.3.2 | Removal of a small outdated section |

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.

The major part of the risk assessment for birds and mammals is not based on national specific conditions. In appendix A of the zonal EM a translation of the Dutch crop definitions (DTG-list) to relevant EFSA 2023 GD crop groups or scenarios is given.

Screening and tier 1 assessment for direct exposure should be included in the core dossier. No extra tier 1 scenarios will be included in the NL addendum, except for scenarios linked to spray drift (see 2.3.1).

For higher tier, only refinements specific to Dutch conditions may be discussed specifically in the NL addendum. Field effect and field monitoring studies are expected to be relevant for more countries than NL and these should therefore be included in the core, barring exceptional situations which are justified to be relevant for NL only. On the other hand, statements for extrapolation of higher tier data from other countries should always be included in the Dutch addendum.

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 Drift

Valid for submissions under EFSA 2023 (from October 2025 onward).

In the guidance 'Risk assessment for birds and mammals' ([EFSA 2023](#)), a terrestrial area of interest (TAI) has been identified, which is similar to other terms such as 'off- crop', or 'off-field' risk assessment. This area has been specified for situations in which the in-field or in-crop risk assessment is lacking critical focal species that can still be found outside the treated field. To cover those species an additional risk assessment has to be performed using relevant spray drift rates. The guidance also states (section 6.2.1): *'Given that the Tier 1 exposure assessment provides information to the Tier 3 (if required), it was agreed that it would be preferable to perform such assessment for all growth stages in the Tier 1 assessment to provide clarity on whether any higher tier assessment should consider exposure in the TAI. It is emphasized that a risk assessment in the TAI is only needed for small mammals (herbivorous, granivorous and insectivorous), in all crops, as the in-crop risk assessment for all other generic model species covers exposure from the TAI.'*

In the EM-EU short-cut values have been calculated for mammal scenarios in TAI.

Note that drift values can be adapted manually in the EFSA calculator tool.

National drift figures can be applied on the basis of article 8f of the Plant protection products and Biocides Decree (Bgb). Ctgb bases the exposure assessment on average spray drift values determined by WPR (Wageningen Plant Research, formerly WUR-PRI).

Art. 8f :

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

As spray drift is Dutch specific, this part of the birds and mammal risk assessment should also use Dutch specific drift rates. For the description of the relevant drift rates and methods, a reference is made to the evaluation manual chapter 6, NL part for non-target arthropods and plants. The specifications and drift values that are described for non-target arthropods are also considered relevant for birds and mammals.

2.3.2 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 \(2009\)](#) for submissions prior to 01-10-2025 and to risk assessment for birds and mammals' ([EFSA 2023](#)) for submissions after 1-10-2025 onward. However it should be noted that PECwater (based on

drift) is a Dutch specific aspect and that the Dutch value should be used in risk assessment for secondary poisoning via fish (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 birds, mammals and 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.