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

NL part

Plant protection products

Chapter 7 Ecotoxicology: non-professional uses

version 1.0; October 2022

ctgb

Board for the Authorisation of Plant protection products and Biocides

Chapter 7 Ecotoxicology; non-professional uses

Category: Plant Protection Products

Changes in the Evaluation Manual

Evaluation manual PPP NL part Chapter 7 Non-professional uses			
Version	**Date**	**Paragraph**	**Changes**
1.0	October 2022		New EM part

GENERAL INTRODUCTION
This chapter describes the estimation of the effects of non-professional spray uses on terrestrial and aquatic organisms of a Plant protection product and its active substance in the NL framework (§2 - §2.5).

This chapter consists of two parts: first tier (I) and higher tier (II).

I NON-PROFESSIONAL (SPRAY) USES

2 NL FRAMEWORK

The NL framework (§2 - §2.5) describes the authorisation procedure for plant protection products based on existing substances, included 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 25 July 1993.

The plant protection product that contains such substances may be authorised if the criteria laid down in the 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.

2.1 Introduction

This chapter describes the estimation of effects of non-professional spray uses on terrestrial and aquatic organisms. Specific rules apply in the national approval framework when the national framework has been elaborated in more detail than the EU framework.

From directive (2009/128/EG) L_2009309EN.01007101.xml (europa.eu):

- Member States shall take all necessary measures regarding pesticides authorised for non-professional users to avoid dangerous handling operations. These measures may include use of pesticides of low toxicity, ready to use formulations and limits on sizes of containers or packaging.
- For non-professional users who in general do not have the same level of education and training, recommendations should be given, in particular on safe handling and storage of pesticides as well as on disposal of the packaging.

Non-professional uses are defined as a separate group, according to 1107/2009 and it has to be specifically stated on the label. In the Netherlands:

Uitsluitend bestemd voor particulier gebruik in huis en/of (volks)tuin en/of kas.

In addition, the packaging may contain the amount of Plant protection products (after dilution) to apply for a **maximum** of 500 m^2 (Bgb art 32aa (Plant protection product and Biocides Decree))\:

Het formaat van de verpakking van een gewasbeschermingsmiddel bedoeld voor niet-professioneel gebruik is beperkt voor toepassing op een oppervlakte van ten hoogste 500 m^2.

The aspect of Ecotoxicology assesses non-professional uses, for mainly in -and around- the house, in the first tier according to the professional guidance documents and evaluation manuals for their respective sections (namely, birds and mammals, aquatic organisms, bees, arthropods other than bees, micro- and macro- soil organisms and non-target terrestrial plants).

Since non-professional users cannot be assumed to have professional greenhouses, the array of protected use by non-professional users may be wide (varying from a simple, non-permanent low-tech plastic coverage to actual glass greenhouses). Therefore, as a first step non-professional protected uses are assessed as field uses.

A NL-specific methodology deviating from the EU evaluation methodology, is followed for Plant protection products containing only pheromones or micro-organisms and for the higher tier for the aspects birds and mammals, aquatic organisms, bees, arthropods other that bees, soil micro- and macro-organisms, non-target plants.

A decision tree with corresponding explanatory notes is presented in Appendix 1.

This decision tree shows the decision scheme for all non-professional spray uses applied for in the Netherlands.

2.2 Data requirements

All first tier data requirements for chemical Plant protection products are in agreement with the provisions in EU frameworks (for birds and mammals, aquatic organisms, bees, arthropods other than bees, micro- and macro- soil organisms and non-target terrestrial plants).

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 .

Some NL-specific aspects (drift, natural enemies), however, are considered nationally if relevant for the section under assessment, for instance. Please refer to the relevant, individual evaluation manuals (chapter 7).

7. Ecotoxicology | Assessment framework PPP | Board for the Authorisation of Plant Protection Products and Biocides (ctgb.nl)

For non-professional spray uses the decision tree in appendix 1 has to be followed. Applicants are requested to indicate in the new application for non-professional use(s) which steps from the decision tree are considered relevant and whether the criteria of limited exposure apply.

However, if the GAP needs to be adjusted to meet the criteria for limited exposure (step C), the applicant shall ensure that efficacy remains or is sufficiently substantiated. An additional

assessment of efficacy may be necessary.

For other non-professional applications, an assessment in accordance with the current framework will be carried out. This applies, for example, to applications based on granulates, pour treatments or sticks.

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 Trigger values, criteria and decision on approval

For the criteria and trigger values for non-target organisms for the national authorisation reference is made to the EU framework.

2.5 Developments

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3 REFERENCES

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4 APPENDICES

Appendix 1 Explanatory notes decision tree non-professional spray uses

A) A distinction is made between Plant protection products containing only pheromones and/or micro-organisms and all other active ingredients. Given the expected low toxicity of pheromones and micro-organisms, for formulations containing only those substances as active ingredients assessment is deemed unnecessary. Authorisation can be granted without assessment for the aspect of ecotoxicology.
For all other active ingredients, got to step B.

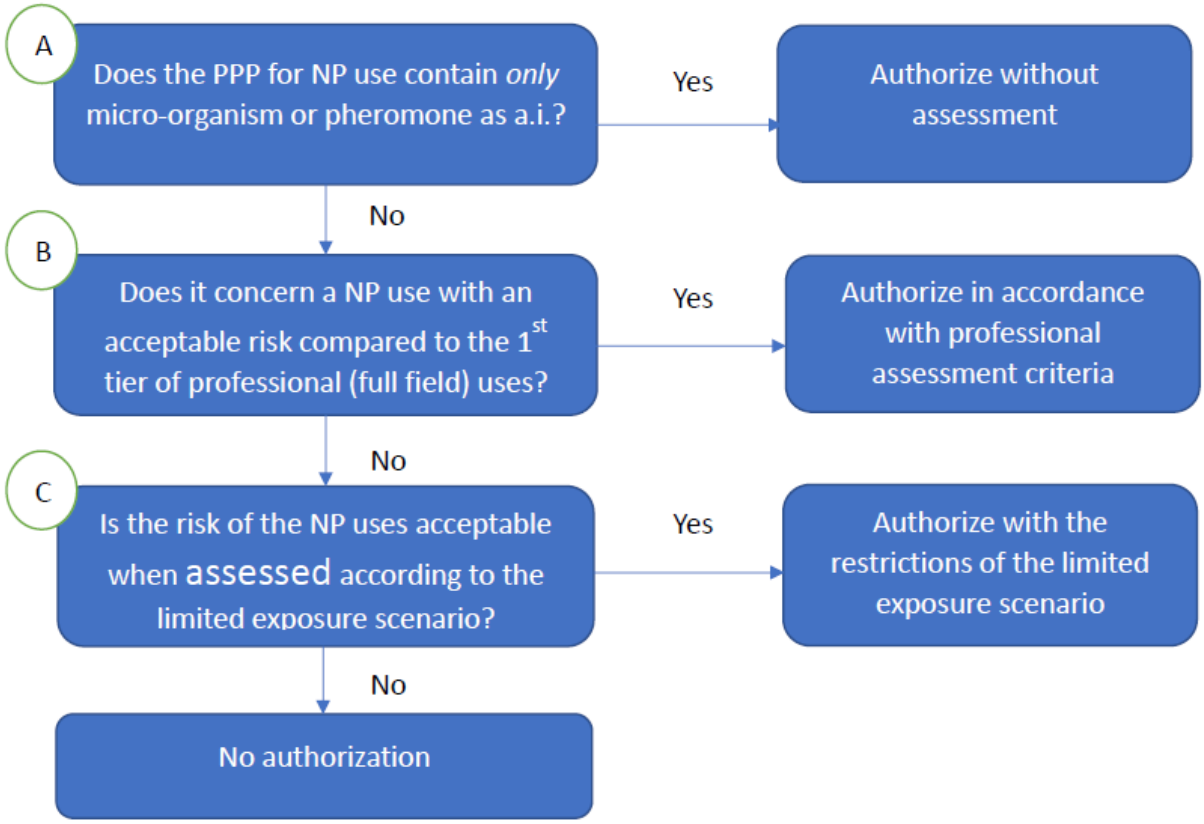
B) A standard 1st tier risk assessment is performed for all relevant sections (birds and mammals, aquatic organisms, bees, arthropods other than bees, micro- and macro-soil organisms and non-target terrestrial plants) based on the professional assessment framework (NL guidances and evaluation manuals). If no unaccepted risk are identified at 1st tier, the product can be authorized according to the applied for GAP. However, if not all sections passed the 1st tier, go to step C.
In case professional uses are applied for alongside the non-professional uses, the necessity of step C can be made based on expert judgement of the risk assessor.

C) The sections that indicate unacceptable risk(s) at the standard 1st tier, will be assessed as a 'higher tier' according to the limited exposure scenario. This scenario entails the following measures, that *all have to be fulfilled*:

- GAP with a single application; or a maximum of two *if* the interval can be considered as two separate applications during risk assessment (taking into account the chemical properties of the a.i.)
- The packing has to be Ready to Use (RTU), containing the amount of product to apply a maximum of 50 m^2 (per treatment).

Again a risk assessment is performed (1st tier) based upon all above mentioned limitations. The risk is found to be acceptable when the limited exposure scenario indicates no unacceptable risk for the relevant triggers/sections. The product can be authorized in accordance with the limited exposure measures.
Is the risk is found still to be unacceptable, no authorization can be granted.

Decision tree for all non-professional spray uses



a.i.= active ingredient
NP= Non-Professional
PPP= Plant Protection Product