

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

NL part

Plant protection products

Chapter 8 Efficacy

version 2.1; October 2016

ctgb

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

Chapter 8 Efficacy

Category: Plant protection products

General introduction	3
Information on Dutch agricultural practice and terminology for the legal conditions for use....	3
2.1. Definitions of terminology	3
2.2. Crop definitions	3
2.3. Crop cycles	3
2.4. Dutch spray volumes	4
2.5. Dipping of flower bulbs.....	4
2.6. Extrapolation tables	4
2.7. Minor uses.	4
2.8. Legal conditions for use in the Netherlands	4
2.9. Information on GEP certification.	5
3. Developments.....	5

Important changes with the last version of the E.M.

Evaluation manual PPP NL part Chapter 8 Efficacy Version 2.0; January 2014		Evaluation manual PPP NL part Chapter 8 Efficacy Version 2.1; October 2016	
Paragraph and page number	Short explanation of old EM situation	Paragraph and page number	New situation in the updated E.M.
entire document	major revision needed.	entire document	There are no major changes regarding requirements for the efficacy dossier, but the document has been rewritten for clarity.
appendices	Some of the appendices were no longer relevant Numbering of appendices was confusing and outdated.	appendices	irrelevant appendices removed. Added links to appendices instead of referring to appendix numbers. English translations added for “dipping fluid for flower bulbs appendix”, and “spray volumes list”. Formatting and text edited in other appendices but no major updates to content of the appendices.

GENERAL INTRODUCTION

No specific data requirements exist for the evaluation of the aspect efficacy in the Netherlands. [EU Evaluation manual chapter 8 on Efficacy](#) describes the data requirements and how they should be evaluated under [Regulation \(EC\) no 1107/2009](#).

Although data requirements are the same for all member states, differences in agricultural practices exist between countries (such as different application equipment, spray volumes etc.), while this may lead to differences in the table of uses *this should not lead to additional evaluations on a national level*. It is preferable that the core dossier covers all uses for all concerned member states (CMS) taking into account the agricultural practices in all relevant countries.

The table of uses in the core dossier should cover the risk envelope of all the CMS.

This manual gives an overview of the documents that are relevant for writing the table of uses for the Netherlands, and for writing the legal conditions for use in the Netherlands (referred to as “WG” (Wettelijk gebruiksvoorschrift) in this document, this is the Dutch label).

More information on the composition of the core dossier and the national addendum for efficacy can be found in [SANCO/10055/2013 Rev. 4](#) (*Guidance document on the efficacy composition of core dossier and national addenda submitted to support the authorization of plant protection products under regulation (EC) No 1107/2009 of the EU parliament and council on placing of plant protection products on the market*)

In general, as much as possible of the evaluation should be performed in the core dossier.

INFORMATION ON DUTCH AGRICULTURAL PRACTICE AND TERMINOLOGY FOR THE LEGAL CONDITIONS FOR USE.

A number of appendices are available that either describe Dutch agricultural practices, or can be used for translation of the claims and restrictions between the dossier and the Dutch label (which is to be written in Dutch)

2.1. Definitions of terminology

A list is available for the definitions of terminology used in the WG. This “DTW” list is available in [Dutch](#) and [English](#). The definitions are numbered in both lists to facilitate translation of the Dutch terms. The Dutch list is sorted alphabetically.

2.2. Crop definitions

The Dutch definition list for crops can be found here: [DTG list version 2.1](#). The list is available in both Dutch and English, and includes [EPPO codes](#) for crops when available. The uses claimed for the Netherlands on the WG should follow the terminology and order given in the DTG list, if possible.

A guidance document for converting labels made using an earlier version of the crop list (DTG 2.0) is available here: [conversion list from DTG 2.0 to 2.1 document](#).

Even older versions of crop lists including relevant conversion tables may be found in previous versions of the evaluation manual.

2.3. Crop cycles

[The crop cycle list](#) provides the number of crop cycles per year and in which conditions (protected and/or unprotected) the crop is grown. The crop cycles list is based on the crop definition list. Certain crops are cultivated for several crop cycles in the Netherlands, which can influence the risk envelope. The table of uses (GAP) should, where relevant, clearly state how many applications are claimed per crop cycle and per year.

The number of crop cycles per year depends on climatic influences and agricultural practices. The crop cycle list is therefore specific to the Netherlands and may not reflect the situation in other countries.

2.4. Dutch spray volumes

The Dutch spray volumes list includes an overview of spray volumes that are commonly used under Dutch agricultural practices. Both [Dutch](#) and [English](#) versions are available. These values should preferably be used for the GAP. When submitting a dossier to a ZRMS other than the Netherlands, it is advisable to make sure that the core GAP covers the Dutch spray volumes. It is possible to deviate from these values, in which case the required spray volume should be indicated on the WG.

Spray volumes depend on agricultural practices, such as cultivation methods, spray equipment etc. The volumes used in the Dutch list may therefore not reflect the situation in other countries.

2.5. Dipping of flower bulbs

An appendix is available listing the amounts of dipping fluid absorbed by flower bulbs or flower tubers during a dipping treatment. This appendix also lists the resulting amount of product applied per hectare from planting the treated bulbs. The values from this appendix should be used if an application is made for a product intended for dipping of flower bulbs or tubers. Both [Dutch](#) and [English](#) versions are available.

2.6. Extrapolation tables

Extrapolations in the core dossier based on expert judgement or the [EPPO extrapolation tables](#) are sometimes left open by the ZRMS because these may depend on crop acreages on a national level. In such cases a decision should be taken on a national level based on the evaluation presented in the core dossier. For example; on the EU level EPPO extrapolations can only be used for extrapolation from a major to a minor crop. Because the ZRMS does not have an overview of the crop status as major or minor in all countries, this needs to be addressed on a national level.

In the Netherlands restrictions on crop acreage for extrapolation do not apply and extrapolation may be granted from major to major crops, if the original crop is supported by sufficient trials. In addition, the Netherlands have national extrapolation tables that can be used for extrapolations that are not addressed in the EPPO tables. These extrapolation tables are available in [Dutch](#) and [English](#).

It is possible to submit extrapolation requests not based on EPPO or Dutch extrapolation tables but on expert judgement alone. Similarly it is possible to submit extrapolations based on the Dutch extrapolation for a zonal dossier. In both cases a valid scientific justification needs to be submitted.

Further harmonisation of extrapolation tables is ongoing, The Netherlands aims to have more extrapolations from national tables recognized in the EPPO extrapolation tables.

2.7. Minor uses.

For more information on applications for minor uses (article 51) please refer to the CTGB website on this subject.

2.8. Legal conditions for use in the Netherlands

More information about the legal conditions for use (WG) including templates and instructions for drafting can be found in the application forms and the attachments; such as the table of uses (GAP).

The WG should be drafted in Dutch.

2.9. Information on GEP certification.

Supporting studies submitted with an application must have been carried out by a Recognised (GEP certified) body.

The [NVWA](#) (Nederlandse Voedsel en Warenautoriteit) is responsible for the recognition of research organisations in the Netherlands. A list of recognised research organisations can be obtained from the NVWA (The NPPO or National Plant Protection Organisation is part of the NVWA).

3. DEVELOPMENTS

- Development of EPPO codes for crops (cultivated and wild), pests and pathogens including crop and pest groups is ongoing, and should facilitate translation between national crop lists.
- Harmonisation of extrapolation tables is ongoing. An effort is made to have more of the extrapolation possibilities transferred from the Dutch extrapolation tables to EPPO extrapolation tables.