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

NL part

Plant protection products

Chapter 8 Efficacy

version 2.6; September 2023

ctgb

Board
for the Authorisation
of Plant protection products and Biocides

Chapter 8 Efficacy

Category: Plant protection products

Changes in the Evaluation Manual

Evaluation manual PPP NL part Chapter 8 Efficacy			
Version	**Date**	**Paragraph**	**Changes**
2.0	January 2014	entire document	major revision needed.
		appendices	Some of the appendices were no longer relevant Numbering of appendices was confusing and outdated.
2.1	October 2016	entire document	There are no major changes regarding requirements for the efficacy dossier, but the document has been rewritten for clarity.
		appendices	irrelevant appendices removed. Added links to appendices instead of refering 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 apendices.
2.2	November 2017		Added: paragraph 2.4. Table for Dutch seed sowing and planting densities
2.3	March 2019		New version of Dutch extrapolation tables. Updated broken links.
2.4	June 2019		New version of the DTG list
2.5	July 2021		New version of the DTW list
2.6	September 2023		Added: paragraph 2.11. Considerations for Mutual recognition

GENERAL INTRODUCTION

No national specific data requirements exist for 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 (this is the Dutch label, and is referred to as “WG” (Wettelijk gebruiksvoorschrift) in this document).

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 (version 3.0) and English. The definitions are numbered in both lists to facilitate translation of the Dutch terms to English, as numbers for the same definition correspond. The Dutch list is sorted alphabetically.

2.2. Crop definitions

The Dutch definition list for crops is the DTG list; the current version number of the list is 2.2 and can be found on the CTGB website as one of the appendices to the evaluation manual (link). A guidance document for converting labels that were made using earlier versions of the DTG list to version 2.2 is also available under the same link.

The DTG list includes translated English names for each crop and crop group and includes EPPO codes for crops when available. The primary language of the reading guide in the document is however in Dutch as some understanding of the Dutch language is required when writing a WG.
The uses claimed for the Netherlands on the WG should follow the terminology and order given in the DTG list, if possible.

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 version 2.1. 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. Seed sowing rates and planting density

The seed sowing table provides data on seed sowing rates and planting densities commonly used in Dutch agriculture. Data (if known) are arranged per crop according to the DTG list and can be used to determine maximum amount of product applied per hectare from planting treated seeds and starting materials. It should be noted that this list is specific for the Netherlands, and that sowing and planting densitites in other countries may differ from these values.

2.5. 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.

2.6. 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.

2.7. 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 adressed 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. In 2018 an updated Dutch extrapolation table was written for ornamental crops.

Dutch extrapolations for crops other than ornamentals can be found in the general Dutch extrapolation document. Currently both documents are only available in Dutch.

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.

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

2.9. 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 at the page with application forms. This page also provides templates and instructions for other required documents such as the table of uses (GAP).

The WG should be drafted in Dutch.

2.10. Information on GEP certification.
Supporting studies submitted with an application must be 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).

2.11 Considerations for Mutual recognition
According to 1107/2009 (Article 29), authorisations granted by one Member State should be accepted by other Member States where agricultural, plant health and environmental (including climatic) conditions are comparable. Although there are no national specific data requirements for the aspect efficacy in the Netherlands, there are several situations that require special attention and need adaptation to the Dutch situation, taking into account the agricultural practices described by the appendices explained under national elements point 2.1 till 2.8 (e.g. crop cycles, seed sowing rates and planting density, water spray volumes, dipping of flower bulbs and extrapolation tables for efficacy and phytotoxicity).

Climatological conditions
Climate is an important factor that can influence the efficacy of a product. Therefore, zones with comparable climates have been defined, as explained in EPPO Standard PP 1/241 *Guidance on comparable climates*. It should be noted that these zones differ from the EU registration zones. Hence, it is possible that an authorization from a member state belonging to the central registration zone, is based on efficacy data conducted in an EPPO climate zone, which is not comparable to the Dutch climate zone. Therefore, during mutual recognition it will be checked in which climate zones the efficacy trials had been conducted in the core dossier underlying the authorization in the member state from which mutual recognition is received (henceforth indicated as the reference member state). This is especially relevant for claims of control against diseases for which high disease pressure is expected under the climatological conditions of the Netherlands. For example, for the control of *Phytophthora infestans* a low dose rate and/or number of applications may not be sufficient for the control of this disease in the Netherlands compared to other regions, even

within the Maritime EPPO climate zone. EPPO Standard PP 1/241 states that differences in e.g. edaphic conditions, agronomic conditions, and differences in biology and pressure of target pests, if relevant, should be taken into account, even within an EPPO climate zone. When these conditions are sufficiently similar between NL and the reference member state or sufficient support is presented for NL in the core dossier, Ctgb will take over the evaluation of the core dossier, while staying within what is authorized in the reference member state, as indicated by the GAP and label of the reference member state.

It happens that the zRMS shifts the decision of a core-specific point to the member state level (e.g. when only a limited number of trials had been submitted in a specific climate zone, or extrapolation based on national situations like disease pressure). In this case Ctgb will assess if the decision made by the member state from which mutual recognition is received is also applicable for the Dutch situation. For instance, for member states located at borders between EPPO climate zones, it may be acceptable to permit efficacy trials from other EPPO climatic zones as supportive information than would be the case for the Netherlands.
For interzonal dossiers, EPPO climate zones are of lesser relevance. Nonetheless, placement of efficacy trials should represent potential variation in pest biology, light conditions, agronomy, growing practices, etc., as explained in EPPO standard PP1/226 *Number of efficacy trials*. It will be checked, whether the evaluation of the member state or the zRMS of the underlying core dossier from which mutual recognition is received, is likewise applicable for the Dutch agricultural practices. Phytotoxicity may for instance be more pronounced under greenhouse conditions in Northern regions. Also water spray volumes differ between member states. In the Netherlands often high water spray volumes are needed to ensure coverage of crops that may grow particularly tall under high technology greenhouse situations. In those cases, Ctgb will check whether the tested conditions (e.g. location of trials, water spray volumes) assessed in the core dossier are still suitable for Dutch agricultural practices. If this is not the case, claims and/or restriction sentences may be adapted to the Dutch situation (while staying within what has been authorized in the member state from which the mutual recognition was received).
In some exceptional cases, additional trials may be asked to cover relevant conditions, when these have not been covered by the core dossier. These can then be submitted in an Efficacy NL-addendum (Part B section 3). However, the necessity of submitting additional trial(s) should preferably be prevented. Accepting additional efficacy studies or not always needs to be addressed in a case-by-case manner. A mutual recognition based on a core dossier where (also) studies from the Maritime EPPO climate zone have been fully evaluated is preferred above hybrid dossiers supplemented with a national addendum for efficacy. Submitting additional studies will likely always represent additional work.

Bridging
When the efficacy section of the core dossier underlying the mutual recognition is based on bridging data, a special (often complex) situation arises. In case of demonstrated comparability of the product to that of the bridging partner (following EPPO PP1/307, *Efficacy considerations and data generation when making changes to the chemical composition or formulation type of plant protection products*), individual member states will take over the label claims of the bridging partner, under the condition that this product is out of data protection. If the bridging product is not out of data protection in the Netherlands, a LoA from the registration holder of the bridging partner is required. During mutual recognition Ctgb is required to stay both within the authorization of the member state from which mutual recognition is received and within the Dutch label claims of the bridging partner. This is because the supporting efficacy data on which the authorization will be based are evaluated in the dossier of the bridging partner and may therefore differ from those originally evaluated nationally by the reference member state from which the mutual recognition is received. In an application for mutual recognition only the comparability between the product and the bridging partner will be evaluated.

Drafting a label

How a label is drafted, differs per member state (for drafting Dutch labels refer to Opstellen wettelijk gebruiksvoorschrift | Instructie gewasbeschermingsmiddelen | College voor de toelating van gewasbeschermingsmiddelen en biociden (ctgb.nl). Firstly, the DTG and DTW lists need to be taken into account for the Dutch label (point 2.1 and 2.2 under national elements), which may result in deviations between the labels due to the placement of crop(groups) on the label. Another example between member states is differences in how minor and major uses are reflected on the label. In the Netherlands for instance some ornamental crops are major crops and need more attention than in other member states.
In some member states for herbicides all tested weeds will be placed individually on the label, often accompanied by the control levels obtained in the trials. While in the Netherlands the entire group of weeds can be claimed if sufficient control against several representative weed species has been demonstrated. This kind of extrapolations need to be made on a national level and can result in deviations between the label of the reference member state and the Dutch label. Although it should be stated once more that during mutual recognition the claims on Dutch label can never be broader than those on the reference member state.
Deviation in label claims may also exist due to the level of effectiveness. While some member states also placed target pests to which only moderate control/reduction is observed on the label, this is not common practice in the Netherlands (with the exception of low-risk products and/or products based on micro-organisms, in line with EPPO standards PP1/296, *Principles of efficacy evaluation for low-risk plant protection products* and PP1/276*, Principles of efficacy evaluation for microbial plant protection products*). This may result in label deviations from the label of the reference member state regarding the claims that will be put on the label.

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.