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

NL part

Plant protection products

Chapter 8 Efficacy

version 2.0; January 2014

ctgb

Board for the Authorisation of Plant protection products and Biocides

Chapter 8 Efficacy

Category: Plant protection products

GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the efficacy of a plant protection product and its active substance and how reference values are derived in the NL framework (§2 - §2.5).

Substances that are approved under Regulation (EC) No 1107/2009 [1] and were approved under Directive 91/414/EEC [2] are included in Commission Implementing Regulation (EU) No 540/2011 [3].

The chapter describes the procedures following the data requirements as laid down in Commission Regulation (EU) No 283/2013 for active substances and in Commission Regulation (EU) No 284/2013 for plant protection products. These data requirements apply for active substances submitted after 31 December 2013 and for plant protection products submitted after 31 December 2015.

A concept guidance is available on the interpretation of the transitional measures for the data requirements for chemical active substances according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509/2013 – rev. 0.1).

For further information on the former data requirement as laid down in Commission Regulation (EU) No 544/2011 for active substances and in Commission Regulation (EU) No 545/2011 we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

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 [3], 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 Regulation (EC) No 1107/2009 [1] are met, also taking into account the national stipulations described in the Bgb (Plant protection products and Biocides Decree) [4].
The evaluation dossiers must meet the requirements in Commission Regulation (EU) No 283/2013 [5] and Commission Regulation (EU) 284/2013 [6] implementing Regulation (EC) No 1107/2009 [1] (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 testing framework or when the national testing framework has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 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 [3] in case no European procedure has been described.

2.1. Introduction

The efficacy must be determined to prevent that non-active products reach the market and to ensure that the products have no undesirable effects on plants or plant products.

Where a product is not or insufficiently effective there is a real risk that the user will use the product at a higher dose or frequency, which results in a higher exposure of humans and the environment to the product /the active substance, possibly with undesirable effects.

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

2.2. Data requirements

The data requirements for chemical plant protection products are in compliance 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 1 January 1998 must have been carried out under GEP.

There may be no doubt about the identity of the tested product or the purity of the tested substance for each study.

The national data requirements for efficacy fully comply with the European requirements and are as such translated in the national application form.

Data about the effects and side-effects on plants or plant products are required for each product. Data on possible resistance development strategy and, where necessary, recommendations for a resistance management strategy must be submitted as well
Draft WG (Statutory Use Instructions) must be provided.

The claimed uses must as much as possible meet the classification as given in the list for classification of Culture Groups (Appendix A, bijlage 1: Definitielijst toepassingsgebieden gewasbeschermingsmiddel, DTG list; Culture Groups, use sectors) and the names of crops and pests/diseases/weeds must correspond with nomenclature of pests and diseases as laid down by the Commissions for Terminology and Dutch nomenclature for diseases, pest and weeds of the Koninklijke Nederlandse Plantenziektenkundige Vereniging (KNPV, Royal Netherlands Plant Pathological Society).
The questions of the Application Form must be answered in full for each application (first authorisation, reregistration, prolongation, extension, change composition etc.). This can be in the form of studies, reference to earlier submitted research or by means of a scientific justification.
The Board may, when handling the application, request supplementary information (missing data in the phase of completeness check or supplementary questions in the phase of evaluation).
Where data originate from GEP studies, reporting must comply with EPPO guideline PP1/181(3), or the applicable guidelines at the time the studies were carried out.

Studies in support of an application must have been carried out by a Recognised body.
The Nederlandse Voedsel en Warenautoriteit (NVWA) (English: National Plant Protection Service) is responsible for the recognition of research organisations in the Netherlands. A list of recognised research organisations can be obtained from the NVWA. Studies carried out before 1 January 1998 can be considered as recognised if carried out by a research organisation not yet recognised at the time of the study but which is meanwhile recognised and where it can be made plausible that the study has been carried out under the principles of recognition.
Where possible, studies must be carried out in accordance with the applicable EPPO guidelines [7] (Appendix B: Listing EPPO guidelines) or –where available- the national guidelines.

2.2.1. Required efficacy research per criterion

The data requirements for the aspect efficacy are for European evaluation laid down in Commission Regulation (EU) 284/2013 [6]. These requirements apply in full for the Netherlands.
The number of trials required per culture-pest/disease/weed(group)-combination has been laid down in EPPO guideline P1/226 “Number of trials” .
The exact number (e.g. 3 to 4) depends on the risks.
No effectiveness studies need to be submitted where it is demonstrated in a different way that the product is effective against the spectrum of claimed target organisms.
It is indicated in the extrapolation document (Possibilities for extrapolation of efficacy and crop safety of Plant protection products, most recent version) in which cases extrapolation is justified.
Deviation from the guidelines is possible where carefully documented and scientifically sufficiently justified.

Further to the European requirements there is the following national elaboration for demonstrating the benefit of co-formulation.

2.2.2. Required efficacy studies co-formulation

A co-formulation (a mixture product) is defined as a product based on more than one active substance formulated as such. (NB This does not include a tank mix, the mixing of two products in the tank, with the purpose to apply this in one spray, or the combined use of two or more separately authorised products in one spray prescribed in the Wettelijk Gebruiksvoorschrift (Statutory Use Instructions) or Gebruiksaanwijzing (Directions for Use)).
In support of an application for authorisation it must be demonstrated, in addition to the data requirements above, that the claimed dose is the minimum dose to reach the desired effect, while evaluating the efficacy of the mixture. This means that the added value of the extra active substance(s) must be demonstrated besides the efficacy of the product.
This added value may be based on (a combination of) the following four points:

- strengthening of the effect;
- broadening of the effect;
- reduction of the phytotoxicity, and
- improved resistance management.

The added value may, e.g., be demonstrated by showing that a combination of active substances achieves a strengthening or broadening of the effect or that the combination reduces the chance of resistance or the extent of phytotoxicity.

Generally, in order to demonstrate the added value of the co-formulating the active substances should also be included in the trials in the form of the products as such. Deviation from this is possible in case an already authorised product, with the same composition, is included as standard product or where it can be demonstrated in another way that the active substance as such is not or less effective. As regards the added value in the context of resistance it should be made plausible that the product as such gives chance of resistance.
Where the products as such are included in the trial, and the products as such have already been authorised, the dose indicated in the directions for use of the already authorised product must be applied. Where the products as such are not authorised, the applied dose of the active substance(s) must be the same as the claimed dose of the combination product.

2.2.3. Use of experimental data obtained abroad

Experimental data obtained abroad can be used in support of the application for authorisation. A prerequisite for the use of such data is that the climatological, cropping, and phytopathological conditions are comparable.

2.3. Assessment

The evaluation methodologies for chemical Plant protection products are in compliance with the provisions in EU framework (see §1.3 of the EU part).
NL-specific evaluation methods and further elaborations of the EU methods are given in the text below.

The data submitted in the context of the application are assessed against the above-mentioned efficacy criteria. It is for each part aspect investigated whether there is an effect, and to what extent.

This extent of effect is then compared with and measured against known effects of a set of reference products (including a standard product).
Finally, the effects of the different part aspects are weighed to arrive at a final judgement about the efficacy. This weighing includes the study data as well as, if available, laboratory and field data, and, if available, literature data. In support of the evaluation of the other aspects, Appendix C contains the established spray volumes and Appendix D the uptake of dipping liquid by flower bulbs.
The established extrapolation possibilities are included in Appendix E. Appendix F contains a list of cultivation cycles for crops grown in the Netherlands.

2.4. Approval

The evaluation of products on the basis of existing active substances already included in Commission Implementing Regulation (EU) No 540/2011 [3], or new substances, has been laid down in Regulation (EC) No 1107/2009 [1]. Where no European methodology is agreed upon, a national methodology is applied as described in the Plant protection product and Biocides Decree (Bgb) [4].

All mentioned criteria are not always relevant for evaluation of the efficacy of a plant protection product. The criteria that must be evaluated in particular depend on the (method and the place of) application (field of use) of the product in question. It should be noted that the effects on beneficial and other non-target organisms are weighed in the environmental evaluation. Here, observations are only recorded under the heading efficacy.

2.4.1. Criteria and trigger values

No explicit criteria and trigger values have been laid down for the efficacy aspects.
The extent of effectiveness, extent of causing phytotoxicity, qualitative and quantitative yield reduction, extent of other undesirable side-effects, risk of resistance development are the criteria for efficacy assessment.

2.4.2. Decision making

Decisions on approval are taken on the basis of the submitted data (study results, field data, literature studies etc.): whether the product is sufficiently effective and has no unacceptable side-effects. General criteria cannot be laid down in view of the large number of possible combinations of field of use and pest/disease/weed/undesirable situations.

This assessment is carried out by competent specialists, making use of expert judgement.

2.5. Developments

- The developments in EU framework (see under 1.5 in EU part) will also affect the data

requirements and evaluation methodologies applied in NL framework because the largest possible harmonisation of data requirements and evaluation methodologies is aimed for.
- EPPO (European and Mediterranean Plant Protection Organisation) has drawn up a number of new and revised guidelines. A complete list is presented in Appendix B.
- EPPO (European and Mediterranean Plant Protection Organisation) is working on documents for the zonal evaluation of the aspect efficacy (see Eppo Website for the most updated documents).

3. REFERENCES

1 Regulation (EC) No 1107/2009, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=504604%3Acs&pos=1&page=1&lang=en&pgs=10&nbl=1&list=504604%3Acs%2C&hwords=&action=GO&visu=%23texte

2 Directive 91/414/EEC, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=172911%3Acs&pos=3&page=1&lang=en&pgs=10&nbl=3&list=447073%3Acs%2C185439%3Acs%2C172911%3Acs%2C&hwords=&action=GO&visu=%23texte

3 Commission Implementing Regulation (EU) No 540/2011, http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574460%3Acs&pos=6&page=1&lang=en&pgs=10&nbl=6&list=646199%3Acs%2C628324%3Acs%2C615541%3Acs%2C607847%3Acs%2C607130%3Acs%2C574460%3Acs%2C&hwords=&action=GO&visu=%23texte

4 Bgb: Plant protection products and Biocides Decree. See www.overheid.nl/wetten

5 Commission Regulation (EU) No 283/2011, http://eur-lex.europa.eu/Notice.do?val=724582:cs&lang=en&list=729945:cs,724582:cs,&pos=2&page=1&nbl=2&pgs=10&hwords

6 Commission Regulation (EU) No 284/2013, http://eur-lex.europa.eu/Notice.do?val=724566:cs&lang=en&list=729902:cs,724566:cs,&pos=2&page=1&nbl=2&pgs=10&hwords=

7 EPPO Standards. Guidelines for the efficacy evaluation of Plant protection products. 2e ed. Vol 1-5. 2004, see also http://www.EPPO.org\Standards\gl.htm.