

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

NL part

Plant protection products

Chapter 5 Residues; risk to consumers

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ctgb

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

Chapter 5: Residues; risk to consumers

Category: Plant protection products

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GENERAL INTRODUCTION

This chapter describes the way in which the risk for consumers is estimated for 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 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 [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 dossier requirements (§2.2), evaluation methodologies (§2.3), criteria and trigger values (§2.4) for which specific rules apply in the national approval framework or where the national framework has been elaborated in more detail than the EU framework.

The NL procedure described in §2 - §2.5 of this chapter can be used for evaluation of a substance for approval, and consequently inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] where no EU procedure has been described.

2.1. Introduction

A statistical model for assessing acute and chronic exposure for adults, children and general

populations in which all available EU Member State diets are included was created by EFSA: PRIMo (Pesticide Residue Intake Model rev. 2).

Since PRIMo is applied in the European risk assessments performed by EFSA, all national diets are included. This also holds true for the Dutch general population and the Dutch children 1-6y. In 2013, EFSA will be working on an update to incorporate more recent dietary data (e.g. for the Netherlands).

2.2. Data requirements

For chemical plant protection products the Ctgb has fully adopted the European data requirements in Regulation (EC) No 1107/2009 [1] as far as residues are concerned.

For inclusion of a substance in Commission Implementing Regulation (EU) No 540/2011 [3] of Regulation (EC) No 1107/2009 [1] often only one use is defended. Additional uses are often requested at Member State level. This means that for such authorisations residue data are required for national evaluation (at 'Member State level'). With regard to the consumer risk assessment, the integrated European PRIMo in which the Dutch consumer groups are integrated is used.

2.3 Risk assessment

The evaluation methodology for chemical Plant protection products complies with the provisions in EU part of the Evaluation Manual (PPP) (see §1.3 of the EU part).

2.4 Approval

The evaluation of Plant protection 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].

Criteria and trigger values

In the Netherlands, consumer risk is tested against the most critical limit value, the ADI or ARfD. This complies with the criteria and trigger values applied in EU framework.

Assessment consumer risk

The assessment methods for EU and NL evaluations are the same.

2.5 Developments

There are developments in the following areas:

- Results from a new national food consumption survey (VCP-4) have been submitted to EFSA to be included in PRIMo.
- There are in EU context far-reaching developments as regards the probabilistic approach for the risk evaluation of acutely toxic substances.
- The developments in EU framework (see 1.5 in EU framework) will also affect the applied dossier requirements and evaluation methodologies in NL framework in view against the aim for the largest possible harmonisation of data requirements and evaluation methodologies.

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.wetten.overheid.nl
- 5 Commission Regulation (EU) No 283/2013, <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=>