

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

NL part

Plant protection products

**Chapter 6 Fate and behaviour in the environment:
behaviour in air**

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Chapter 6 Fate and behaviour in the environment; behaviour in air

Category: Plant protection products

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GENERAL INTRODUCTION

This chapter describes the data requirements for estimation of the fate and behaviour in the compartment air 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 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 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 is 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

There is as regards behaviour in air no deviation from the EU evaluation methodology for any of the aspects and no NL-specific methodology is followed.

2.2. Data requirements

The data requirements for chemical Plant protection products are in agreement with the provisions in EU framework (see §1.2 of the EU part). The question numbering of the NL Application Form has also been included in §1.2 of the EU part.

NL-specific data requirements and further elaborations of the EU data requirements are given in the text below.

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

The studies must be carried out in compliance with the applicable guidelines. A review of the guidelines and whether or not these are required for particular fields of use is given in Appendix A to Chapter 6

2.3. Risk assessment

The national evaluation will be in line with the European risk assessment methodology for behaviour in air as presented in the in the FOCUS Air report [7].

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].

Decision making regarding the compartment air is in line with the EU framework. This concerns the parts B Evaluation and C Decision making as for behaviour in air included in §1.4. Testing for permissibility as regards environmental criteria was developed in the Working group FOCUS AIR [7].

2.4.1. *Criteria, trigger values and decisions on approval*

For the criteria, trigger values and decisions on approval for the national authorisation we refer to the EU part (§1.4.1 and §1.4.2).

2.5. Developments

PESTICIDE EMISSIONS FROM PROTECTED CROP SYSTEMS PPR Working Group on the Development of a new Guidance Document on Emissions of Plant protection products from Protected Crops Opinion on the development of guidance has been published: Scientific Opinion on clustering and ranking of emissions of plant protection products from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2012;10(3):2611 [87 pp.].

3. APPENDICES

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Appendix 2 Decision tree Behaviour in air; Terrestrial Deposition	7

4. 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>
- 7 FOCUS (2008). "Pesticides in Air: Considerations for Exposure Assessment". Report of the FOCUS Working Group on Pesticides in Air, EC Document Reference SANCO/10553/2006 Rev 2 June 2008. 327 pp.;