

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

EU part

Plant protection products

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

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**Board
for the Authorisation
of plant protection products and biocides**

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

Category: Plant Protection Products

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Changes in the Evaluation Manual

Evaluation manual PPP EU part Chapter 6 Behaviour in air			
Version	Date	Paragraph	Changes
2.1	October 2016		No major changes from the previous version (EM 2.0, 2014).
2.2	January 2020	1.	Sentence included on the administrative EFSA guidance

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 EU framework (§1 - §1.5) under [Regulation \(EC\) No 107/2009](#). The described risk assessment in this chapter can be used for both the approval procedure for active substances as well as for (inter)zonal applications for the authorization of plant protection products (i.e. core registration reports).

1. EU FRAMEWORK

In this document, the procedures for the evaluation and re-evaluation of active substances as laid down in the EU are described; the NL procedure for evaluation of a substance is reverted to when no EU procedure has been laid down. The NL-procedure for the evaluation of a substance is described in §2 - §2.5 of part 2 of the Evaluation Manual (plant protection products). This document aims to give procedures for the approval of active substances and inclusion in Commission Implementing [Regulation \(EU\) No 540/2011](#).

Notifiers preparing an assessment report for active substances need to comply with the relevant guidance, instructions and format laid down in the EFSA [Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances](#).

1.1. Introduction

Plant protection products may volatilise after use in accordance with the proposed instructions for use. The environment is exposed via this route: volatilisation from crop and/or soil. Distribution of volatile plant protection products via air will be evaluated in compliance with a risk assessment scheme developed by the Working Group FOCUS AIR. This chapter has a link with Chapter 2, Physical-chemical properties where the determination of the volatility of substances is described.

Decision trees with corresponding explanatory notes are given in Appendix 1 and 2. These decision trees summarise the draft testing framework for behaviour in air.

Data requirements, evaluation methodologies, criteria and trigger values that deviate from, or further elaborate, the provisions under EU framework (§1), are described in the NL part (§2 - §2.5). The national further provisions can also be used for inclusion of an active substance in Commission Implementing [Regulation \(EU\) No 540/2011](#).

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing [Regulation \(EU\) No 540/2011](#) a dossier that meets the provisions laid down in Commission [Regulation \(EU\) No 283/2013](#) and Commission [Regulation \(EU\) No 284/2013](#) of [Regulation \(EC\) No 1107/2009](#) must be submitted for the active substance as well as for the product.

Generally, EU and OECD guidelines for the execution of experiments are mentioned in [Commission Communications 2013/C 95/01](#) and [Commission Communications 2013/C 95/02](#).

When according to the applicant a certain study is not necessary, a relevant scientific justification needs to be provided for the non-submission of the particular study.

1.2.1. Data requirements for the active substance

The data requirements regarding the fate and behaviour of the active substance in air are described in part A of Commission [Regulation \(EU\) No 283/2013](#), point 7.3 (fate and

behaviour in air) and 7.5 (monitoring data).

The fate and behaviour in air section comprises requirements regarding Route and rate of degradation in air (7.3.1), Transport via air (7.3.2) and Local and global effects (7.3.3).

The monitoring data section decrees the reporting of available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, breakdown and reaction products in (among others) air (7.5).

1.2.2. Data requirements for the product

The data requirements regarding the behaviour of the plant protection product in air are described in part A of Commission [Regulation \(EU\) No 284/2013](#), point 9.3 (fate and behaviour in air).

Section 9.3 deals with the Route and rate of degradation in air and transport via air (9.3.1).

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission [Communications 2013/C 95/02](#). The relevant section regarding air is 9.3, in which it is referred to the [FOCUS Air Group Report Pesticides in air: considerations for exposure assessment \(Rev. 2, June 2008\)](#).

1.3. Risk assessment

Each study is summarised and analysed separately. The final conclusion and the endpoint per aspect (such as vapour pressure of a substance) are presented in a list of endpoints. Risk is assessed by comparison with the endpoints.

Guidelines for evaluation of the contribution of the distribution via air to environmental loading by plant protection products are available in the [FOCUS Air Group Report Pesticides in air: considerations for exposure assessment \(Rev. 2, June 2008\)](#). The report was commented by the PPR Panel in a PPR opinion that is added to the report. The output of the group is summarised in the following points (including PPR panel comments) :

- A Tiered risk assessment scheme for the deposition of volatilised residues at a distance <1 km from the source of application (short-range). Guidance is given on how this exposure scheme fits into the existing schemes for exposure assessment for soil and surface water under [Regulation \(EC\) No 546/2011](#).
- A trigger to identify substances that are unlikely to show significant long-range transport (defined as >1000 km from the source) behaviour and guidance on how to identify substances that are identified as being of potential concern.
- An inventory of suitable models to estimate exposure from long- and short-range transport of pesticides in air.

In line with the Panel opinion, generally the FOCUS Air report provides guidance to assess deposition after volatilisation for substances that comply with identified vapour pressure trigger and require drift reducing measures in the first tier assessment. Furthermore, in line with the UNECE trigger value, a trigger value for substances that need further assessment of long range transport is defined.

No adjustments from the current approaches addressing long-range transport according to FOCUS Air were proposed in the EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover)

to relevant environmental compartments ([EFSA Journal 2014; 12\(3\):3615](#)) for all protection structures.

1.4. Approval

This section describes the approval criteria for active substances (section 1.4.1) and plant protection products (section 1.4.2 and 1.4.3). For the EU approval procedure of active substances a representative formulation has to be included in the dossier. Therefore section 1.4.1 to 1.4.3 apply. For the zonal applications of plant protection products only section 1.4.2 and 1.4.3 apply.

1.4.1. Approval of the active substance

[Regulation \(EC\) No 1107/2009 Annex II](#) provides the procedure and criteria for the approval of an active substances, safeners and synergists pursuant to Chapter II of [Regulation \(EC\) No 1107/2009](#).

Point 3 of Annex II of [Regulation \(EC\) No 1107/2009](#) gives the criteria for the approval of an active substance. The texts specifically applicable to the aspect behaviour in air concern the estimation of the fate and distribution of the active substance in the environment and its impact on non-target species (3.1) and relevance of metabolites (3.3).

1.4.2. Evaluation of plant protection products

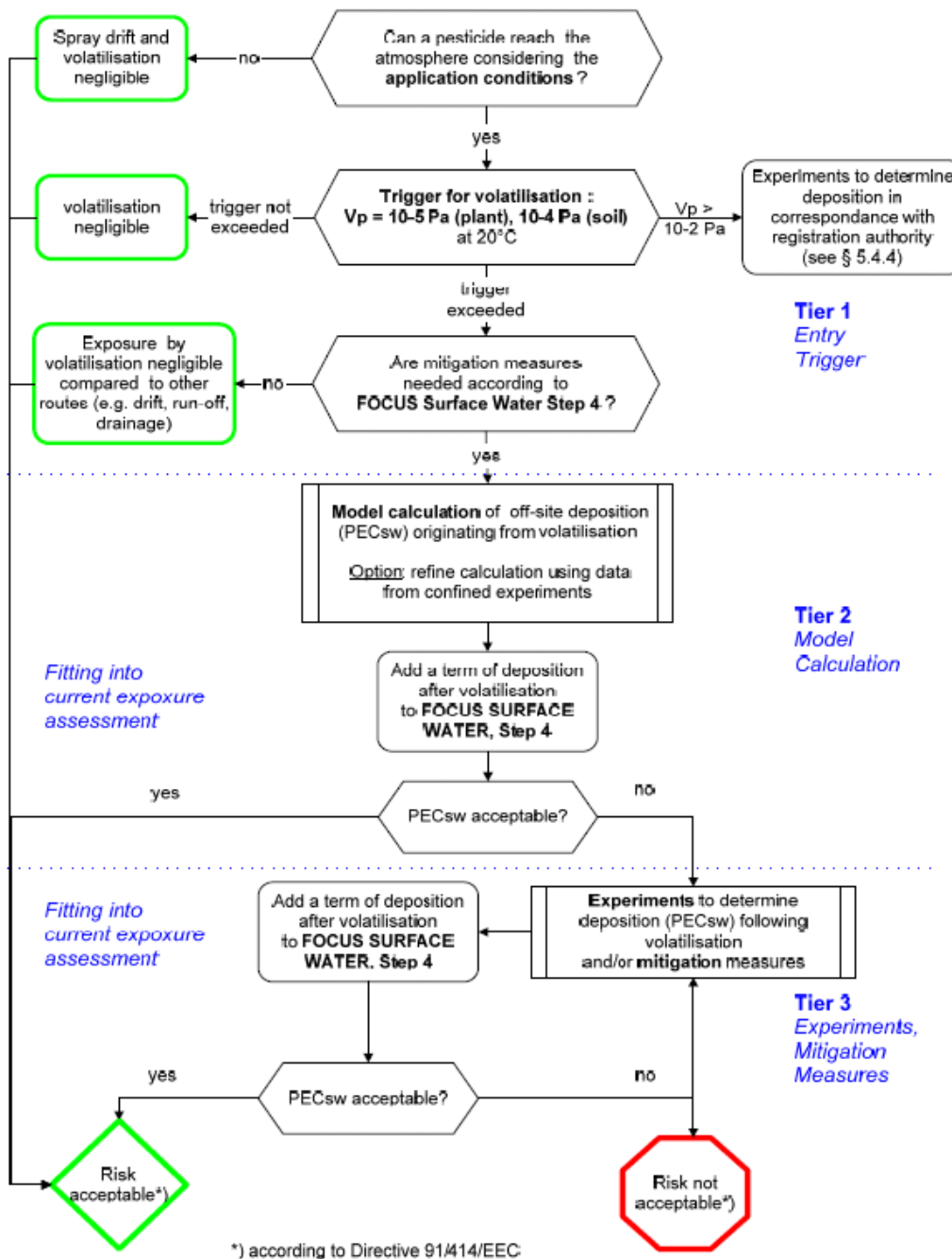
The principles for the evaluation (the Uniform Principles) of the effects on the environment are presented in are presented in Commission [Regulation \(EU\) No 546/2011](#). These concern the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.

In [section 2.5.1.4](#), reference has been made towards the information considered relevant regarding the evaluation of the possible dissipation in air of plant protection products.

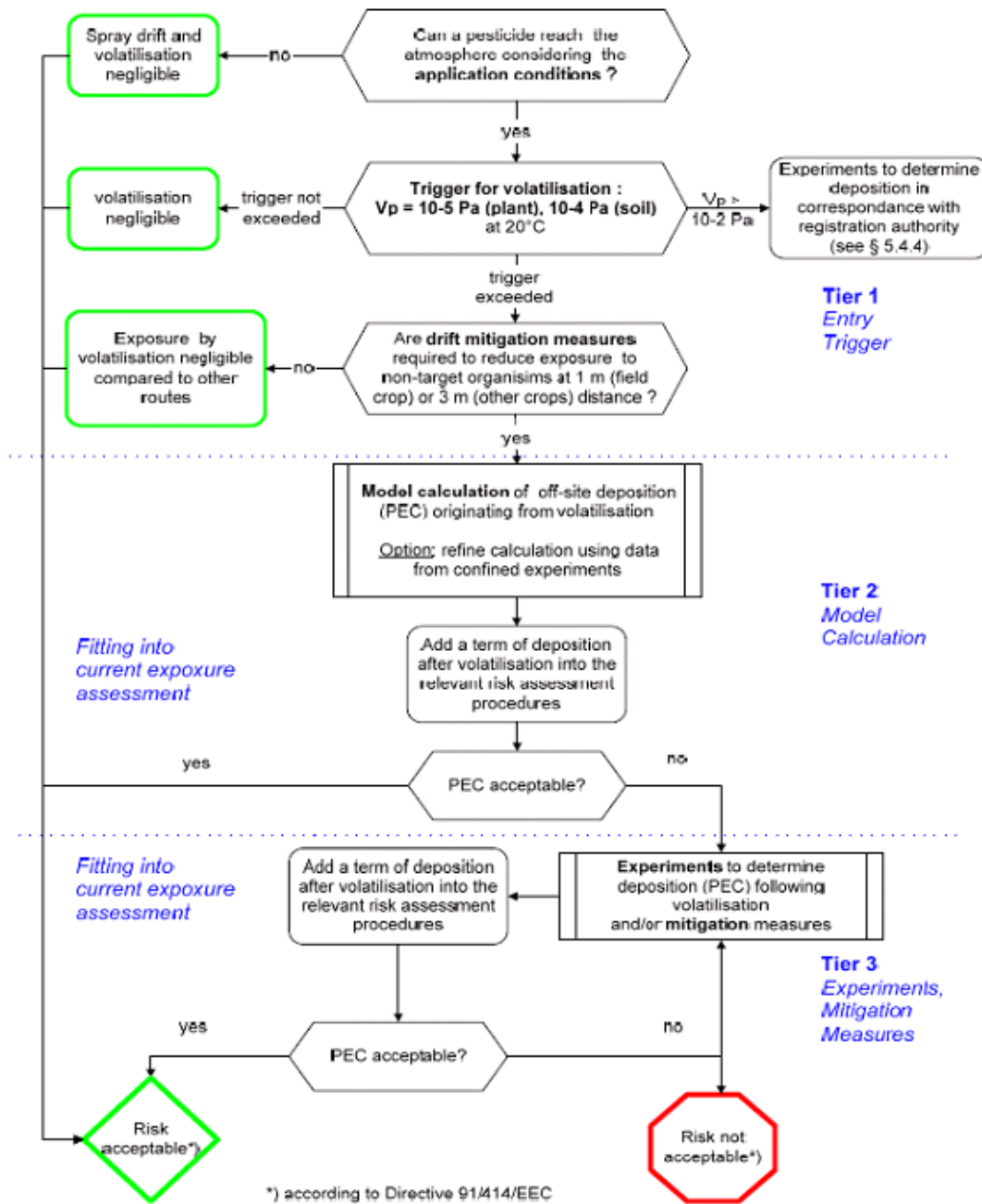
2. APPENDICES

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Appendix 1: Decision tree Behaviour in air; Aquatic Deposition



Appendix 2: Decision tree Behaviour in air; Terrestrial Deposition



Green rectangle No further action required with regard to volatilisation