

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

EU part

Plant protection products

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

version 2.0; January 2014

ctgb

**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

General introduction	3
1. EU framework.....	3
1.1. Introduction	3
1.2. Data requirements	4
1.2.1. Data requirements for the active substance	4
1.2.2. Data requirements for the product.....	5
1.3. Risk assessment.....	7
1.4. Approval.....	7
1.4.1. Evaluation	8
1.4.2. Decision making.....	8
1.5. Developments	9
2. Appendices.....	9
3. References	12

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 1107/2009 [1]. The described risk assessment in this chapter can be used for both the approval procedure for active substances as well as for zonal applications for the authorization of plant protection products (i.e. core registration reports).

Substances that are approved under Regulation (EC) No 1107/2009 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 [4] for active substances and in Commission Regulation (EU) No 284/2013 [5] 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 [6] for active substances and in Commission Regulation (EU) No 545/2011 [7] we refer to the Evaluation Manual for Authorisation of plant protection products according to Regulation (EC) No 1107/2009 version 1.0

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 [3].

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 [2].

1.2. Data requirements

In order to qualify for inclusion in Commission Implementing Regulation (EU) No 540/2011 [3] a dossier that meets the provisions laid down in Commission Regulation (EU) No 283/2013 [4] and Commission Regulation (EU) No 284/2013 [5] of Regulation (EC) No 1107/2009 [1] 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 [8] .

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

Experiments carried out after 25 July 1993 should have been carried out under GLP.

The data requirements, and the fact whether or not they are required for certain fields of use, and the corresponding guidelines are summarised in the overview table; see Appendix A to Chapter 6.

1.2.1. Data requirements for the active substance

The text below in grey frames has been taken from Commission Regulation (EU) No 283/2013 [4]. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given above the headings. Any relevant results of the study are given as well.

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 [4], point 7.3 (fate and behaviour in air) and 7.4 (monitoring data).

Fate and behaviour in air
(283/2013; 7.3)

Route and rate of degradation in air

7.3.1 Route and rate of degradation in air

The vapour pressure of purified active substance, as provided under point 2.2, shall be reported. An estimate of the half-life in the upper atmosphere of the active substance and any volatile metabolites, breakdown and reaction products, formed in soil or natural water systems, shall be calculated and reported.

Estimates of active substance upper atmospheric half-lives, based on monitoring data shall also be calculated, when monitoring data that enable this to be done, are available.

Transport via air
(283/2013; 7.3.2)

7.3.2 Transport via air

The type and conditions of the study to be performed shall be discussed with the national competent authorities.

Circumstances in which required

If the trigger for volatilisation, $V_p = 10^{-5}$ Pa (plant) or 10^{-4} Pa (soil) at a temperature of

20 °C, is exceeded and (drift) mitigation measures are required, data from confined experiments may be reported.

If needed, experiments to determine deposition following volatilisation may be provided.

The national competent authorities shall be consulted to decide whether this information is necessary.

Local and global effects

(283/2013; 7.3.3)

7.3.3 Local and global effect

For substances that are applied in high amounts, the following effects shall be considered:

- global warming potential (GWP);
- ozone depleting potential (ODP);
- photochemical ozone creation potential (POCP);
- accumulation in the troposphere;
- acidification potential (AP);
- eutrophication potential (EP).

Monitoring data

(283/2013; 7.5.)

7.5. Monitoring data

Available monitoring data concerning fate and behaviour of the active substance and relevant metabolites, breakdown and reaction products in soil, groundwater, surface water, sediment and air shall be reported.

1.2.2. Data requirements for the product

The text below in grey frames has been taken from Commission Regulation (EU) No 284/2013 [5]. The numbering in these grey frames follows the section numbering in this Commission Regulation. Any necessary additions to the text have been added below the grey frames. Question numbers (NL as well as EU) are given below the headings. Any relevant results of the study are given as well.

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 [5], point 9.3 (fate and behaviour in air).

Generally, EU and OECD guidelines for the execution of experiments are mentioned in Commission Communications 2013/C 95/02 [6].

Introduction

1. Predicted environmental concentrations (PEC).

1.1. A realistic worst-case estimation shall be made of the expected concentrations of the active substance and metabolites, breakdown and reaction products:

- which account for more than 10 % of the amount of active substance added,
- which account for more than 5 % of the amount of active substance added, in at least two sequential measurements,
- for whose individual components (> 5 %) the maximum of formation is not yet reached

at the end of the study, in soil, surface in soil, groundwater, surface water, sediment and air, following use as proposed or already occurring.

1.2. For the purposes of the estimation of such concentrations the following definitions apply:

(a) Predicted environmental concentration in soil (PEC S): the level of residues in the top layer of the soil and to which non-target soil organisms may be exposed (acute and chronic exposure).

(b) Predicted environmental concentration in surface water (PEC SW): the level of residues, in surface water to which non-target organisms may be exposed (acute and chronic exposure).

(c) Predicted environmental concentration in sediment (PEC SED): the level of residues, in sediment to which non-target benthic organisms may be exposed (acute and chronic exposure).

(d) Predicted environmental concentration in groundwater (PEC GW): the level of residues in groundwater.

(e) Predicted environmental concentration in air (PEC A): the level of residues in air, to which man, animals and other non-target organisms may be exposed (acute and chronic exposure).

1.3. For the estimation of these concentrations all relevant information on the plant protection product and on the active substance shall be taken into account. Where relevant the parameters set out in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013 [4] shall be used.

1.4. When models are used for estimation of predicted environmental concentrations they shall:

- make a best-possible estimation of all relevant processes involved taking into account realistic parameters and assumptions,
- where possible be reliably validated with measurements carried out under circumstances relevant for the use of the model,
- be relevant to the conditions in the area of use.

1.5. The information provided shall, where relevant, include that referred to in Section 7 of Part A of the Annex to Regulation (EU) No 283/2013 [4].

2. For solid plant protection products, treated and coated seeds there shall be an assessment of the risk from dust drift on to non-target species during application or sowing. Until agreed dust dissipation rates are available, then likely exposure levels shall be determined using a range of application techniques, suitable dust measurement methodology and, where appropriate, mitigation measures.

Fate and behaviour in air
(284/2013; 9.3)

Route and rate of degradation in air and transport via air
(284/2013; 9.3.1)

9.3. Fate and behaviour in air

9.3.1 Route and rate of degradation in air and transport via air

If the trigger for volatilisation, $V_p = 10^{-5}$ Pa (for volatilisation from plant) or 10^{-4} Pa (for volatilisation from soil) at a temperature of 20 °C is exceeded and (drift) mitigation measures are required to reduce exposure to non-target organisms, model calculations of off-site deposition (PEC) originating from volatilisation shall be provided. The volatilisation term (PEC) shall be added into the relevant risk assessment procedures for PECs and PECsw. The calculation may be refined using data from confined experiments. Where relevant, laboratory, wind-tunnel or field experiments to determine PECs from deposition following volatilisation and mitigation measures shall be provided.

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 (see Appendix B to Chapter 6 and 7). 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 final FOCUS Air report [7]. 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 <1km 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 [8].
- A trigger to identify substances that are unlikely to show significant long-range transport (defined as >1000km from the source) behaviour and guidance on how to identify substances that are identified as being of potential concern.

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.

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 [1] 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 [1].

Point 3 of Annex II of Regulation (EC) No 1107/2009 [1] gives the criteria for the approval of an active substance. The texts specifically applicable to the aspect behaviour in air are presented below.

3. Criteria for the approval of an active substance

3.1. Dossier

The dossier submitted pursuant to Article 7(1) shall be sufficient to permit, where relevant, an estimate of the fate and distribution of the active substance in the environment, and its impact on non-target species.

3.3. Relevance of metabolites

Where applicable the documentation submitted shall be sufficient to permit the establishment of the toxicological, ecotoxicological or environmental relevance of metabolites.

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 Commission Regulation (EU) No 546/2011 [10]. These concern the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.

The specific principles Environmental effects, part Behaviour and distribution in the environment as regards behaviour in air are in the text below printed in a grey frame. This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011 [10].

2.5.1.4. Member States shall evaluate the possibility of the plant protection product being dissipated in the air under the proposed conditions of use; if this possibility exists they shall make the best possible estimation, using where appropriate a suitable, validated calculation model, of the concentration of the active substance and of relevant metabolites, degradation and reaction products that could be expected in the air after use of the plant protection product according to the proposed conditions of use.

This evaluation will take into consideration the following information:

- (i) the specific information on fate and behaviour in soil, water and air as provided for in the Annex to Regulation (EU) No 544/2011 [6] (now repealed by 283/2013 [4]) and the results of the evaluation thereof;
- (ii) other relevant information on the active substance such as:
 - vapour pressure,
 - solubility in water,
 - hydrolysis rate in relation to pH and identity of breakdown products,
 - photochemical degradation in water and air and identity of breakdown products,
 - octanol/water partition coefficient;
- (iii) all relevant information on the plant protection product as provided for in the Annex to Regulation (EU) No 545/2011 [7] (now repealed by 284/2013 [5]), including the information on distribution and dissipation in air.

1.4.3. Decision making for plant protection products

The principles for evaluation of the effects on the environment are presented in Commission Regulation (EU) No 546/2011 [10]. These concern the relevant sections of the introductory principles, the general principles and the specific principles Environmental effects.

The specific principles Environmental effects, part Behaviour and distribution in the environment as regards behaviour in air are in the text below printed in a grey frame.

This text, including numbering, is the literal text from Commission Regulation (EU) No 546/2011 [10].

2.5.1.4. No authorisation shall be granted if the airborne concentration of the active substance under the proposed conditions of use is such that either the AOEL or the limit values for operators, bystanders or workers as referred to in point 2.4.1 are exceeded

1.5. Developments

Pesticide emissions from protected crop systems;

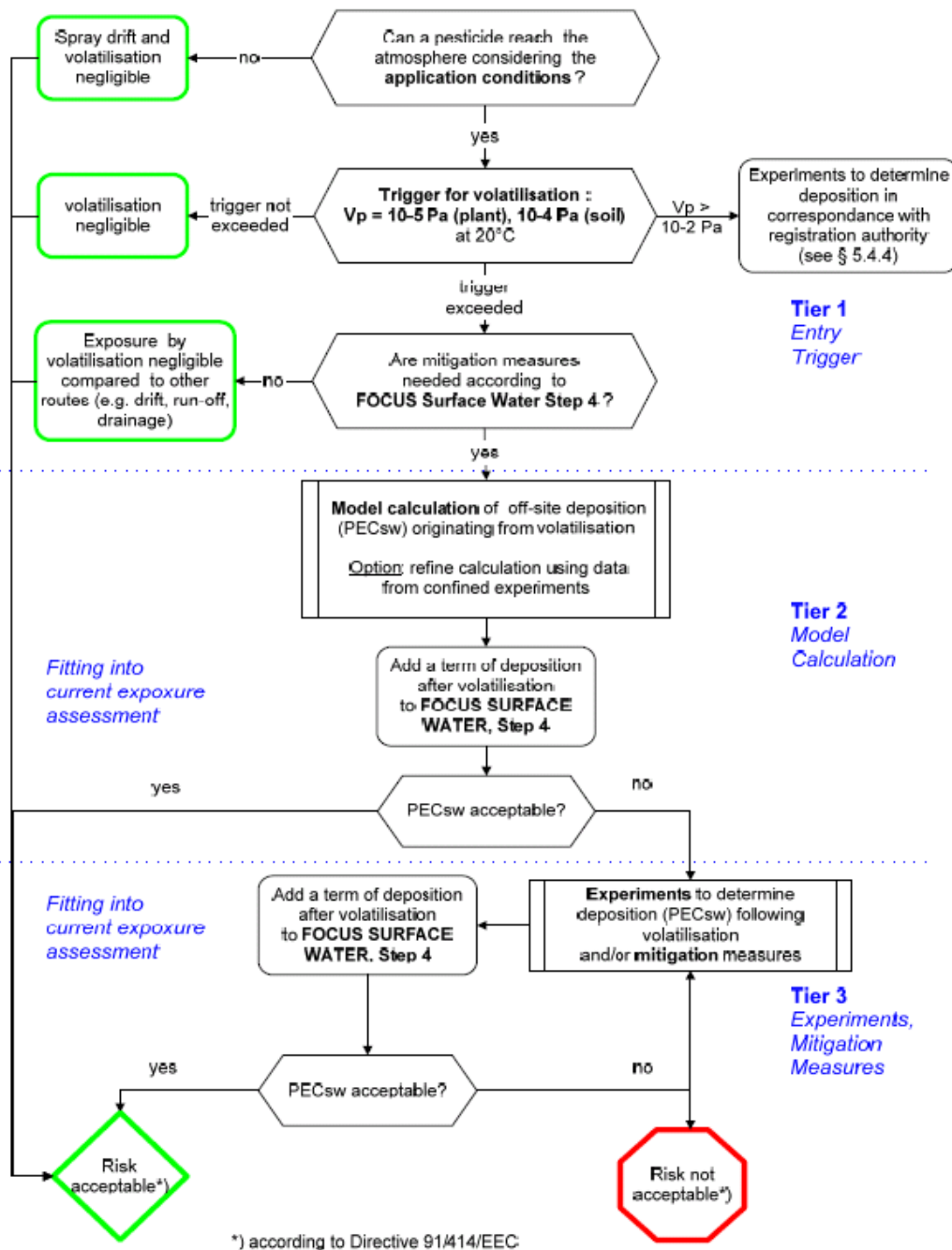
European Food Safety Authority, 2013. Guidance of EFSA on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal in prep ([to be published on the EFSA website first quarter of 2014](#)).

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.].

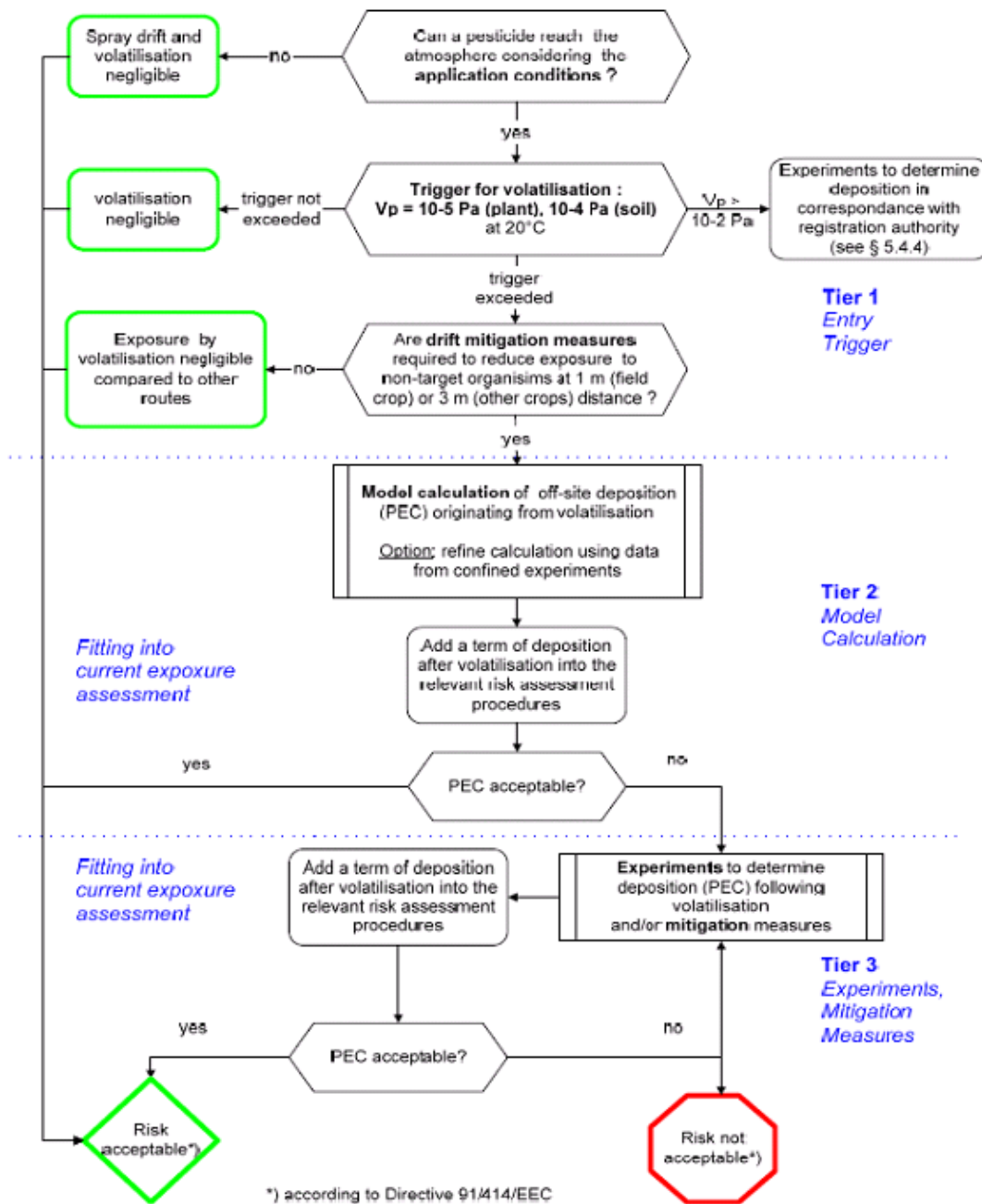
2. APPENDICES

Appendix 1 Decision tree Behaviour in air; Aquatic Deposition	10
Appendix 2 Decision tree Behaviour in air; Terrestrial Deposition	11

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

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 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=>
- 5 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=>
6. Commission regulation (EU) No 544/2011, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:155:0067:0126:EN:PDF>
7. Commission regulation (EU) No 545/2011, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:155:0001:0066:EN:PDF>
8. Commission Communication 2013/C 95/02
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:095:0021:0037:EN:PDF>
- 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.;
- 8 Commission Regulation (EU) No 546/2011, <http://eur-lex.europa.eu/Notice.do?checktexts=checkbox&val=574598%3Acs&pos=2&page=1&lang=en&pgs=10&nbl=2&list=607713%3Acs%2C574598%3Acs%2C&hwords=&action=GO&visu=%23texte>