



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

COMMISSION GUIDANCE DOCUMENT¹

SANCO/12184/2014 – rev. 5.1
14 July 2015

Guidance Document 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

¹ Does not necessarily represent the views of the Commission.

Introduction

The current document has been published by the European Food Safety Authority and is written for Member States and industry risk assessors and scientists involved in the authorisation and approval of plant protection products and their active substances.

The aim of the document is to provide guidance to the users on how to assess the emissions from protected crops when performing risk assessments according to Regulation EC no 1107/2009 of the European Parliament and the Council.

Implementation schedule

This document has been finalised in the Standing Committee on Plants, Animals, Food and Feed on 27 January 2015 and will apply as from 1 December 2015².

Appendix

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, 43 pp., doi:10.2903/j.efsa.2014.3615.

Available at: <http://www.efsa.europa.eu/en/efsajournal/pub/3615.htm>

Outcome of the Public Consultation on the draft 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 supporting publication 2014:EN-568. 37 pp.

Available at: <http://www.efsa.europa.eu/en/supporting/pub/568e.htm>

FINAL COMMENTS RAISED BY MEMBER STATES

Comments from United Kingdom on 15 October 2014

1. The new scenarios developed by the guidance are described as preliminary, with a recommendation that they should be developed over time. As other Member States observed in the meeting, this is not particularly helpful for those who have to implement the guidance.

If new scenarios are developed, they must first be agreed at EU level and subject to testing and validation. An appropriate lead-in time will be allowed before implementation.

2. As far as we are aware, the new Greenhouse Emission Model (GEM) has not actually been finalised and is still not available to test. We cannot run

² On 14 July 2015, the Committee agreed to postpone the date of application date from (initially) 1 May to 1 December 2015.

test substances through the guidance if one of the main new models has not been made available.

3. One of the key outcomes of the public consultation phase of the draft guidance was the identification of a number of important issues that were considered outside the remit of EFSA and that could only be addressed by risk managers. They covered a variety of issues, including whether disposal of discharge water and condensation should be part of the risk assessment scheme or handled by waste management regulations. These issues are listed in Section 3 of the report of the outcome of the public consultation. We cannot recall any such consultation with risk managers and would suggest that this needs to take place before the guidance is noted, in order that applicants and member States are clear on what routes of exposure are considered relevant.
4. EFSA introduced a tiered approach for surface water with respect to covered crops as outlined in Appendix D of the guidance. This is acceptable in principle. For most scenarios, it follows the FOCUS_{sw} Step 1, 2 and 3 approaches, which seems sensible and consistent with the tiered principles for outdoor uses. We note, however, that the Tier 1 and 2 estimates for drip irrigation in soil-less greenhouse systems can give PEC_{sw} values 10,000 times higher than would be estimated from drift in outdoor uses, so almost all uses will fail at those tiers. This is recognised in the guidance text, but seems neither helpful nor necessary. The Step 3 approach using GEM will most likely be triggered in all cases. Since we have not yet had access to GEM, we do not know how time-consuming or complex this model will be. We wonder, however, whether it would be possible to use the GEM model to develop a more realistic emission fraction for use at Step 1.
5. The EFSA guidance states on page 2 "*It is recommended that representative exposure scenarios be developed for greenhouses and walk-in tunnels with regard to groundwater and surface water and that the example scenarios be replaced by these*".

If new scenarios are developed, they must first be agreed at EU level and subject to testing and validation. An appropriate lead-in time will be allowed before implementation.

Comments from Portugal on 4 November 2014

1. The EFSA Guidance document is technically sound and applicable to a large variety of greenhouses and is therefore sufficiently applicable to different protected crop situations throughout Europe, including the most commonly found greenhouses in the southern European countries such as Portugal;
2. The approach taken is conservative with respect to estimating exposure of the different environmental compartments, and falls in most situations to

- an approach not significantly different than that taken for estimating exposure in open field situations;
3. There are still issues that need to be developed further such as the efficiency of different structures in reducing spray drift.
 4. It seems, however, that the adoption of this Guidance and underlying principles and approaches may compromise the application of article 40 of Regulation 1107/2009 as it undermines the decision making in the process of mutually recognizing an authorization issued in a MS from a different zone. In fact, under the provision a holder of an authorization granted in a particular MS of one zone may apply the mutual recognition procedure in a MS that does not belong to the same zone if the authorization was granted for use in greenhouses but if the underlying procedure for exposure and risk assessment is not fundamentally different than that taken for the use of the product in an open field, there is no point in having this exemption in the provision. As an extreme example, the approach to the use in greenhouses (except in a very small number of high tech closed structures) will not be different from that taken for uses in the field (from an environmental and ecotoxicological point of view) and therefore, open field assessments could be used as a default approach to greenhouse use.
 5. On this basis it seems that the natural consequence of the approach taken under the EFSA Guidance would cause the elimination of the use of the exemption stated in point 1 c) of article 40.
 6. Another option would be to consider the authorization of a PPP for use in a particular type (well defined) of greenhouse and the acceptance that under MR the authorization in another MS would only apply to the use in greenhouses of the exact same type but this would be extremely difficult to implement at MS level.
 7. Needless is to say that interzonal evaluation of products with greenhouse uses under Art.33(2b) is severely hindered by this GD.
 8. Our final conclusion is that we leave an open question: shall Reg.1107/2009 be amended, as a result of this GD as it stands today, or is this GD going to be amended in order to specify which conditions (which types of greenhouses) apply to interzonal evaluation (Art.33(2b)) or mutual recognition under Art.40(1c)?

Comments from Germany on 12 November 2014

We took note that residential exposure after pesticide application in greenhouses is out of the scope of this guidance. Nevertheless, we would appreciate if this topic could be addressed in a Guidance Document as well. Currently, residential exposure after greenhouse application of pesticides is assumed to be negligible when assessing the risks of plant protection products during authorisation.

Comments from Belgium on 20 November 2014

Development/selection and approval of scenarios: How and by whom?

Extract from the EFSA GD on protected crops (EFSA Journal 2014;12(3):3615):

“5. Assessments for walk-in tunnels and greenhouses

5.3.1. Soil-bound crops, leaching and drainage scenarios

The models generally used to calculate leaching and drainage from open-field cultivation can equally well be used to calculate leaching and drainage from walk-in tunnels and greenhouses if appropriate scenarios are available. As stated above, representative and generally accepted scenarios for risk assessment are lacking for soil-bound greenhouse crops, so, for the time being, scenarios have to be constructed and their parameterisation justified. For soil-bound crops, leaching can be assessed using one of the currently used FOCUS models (MACRO, PEARL, PELMO and/or PRZM). When assessing drainage to surface water, the model should be capable of handling preferential flow (MACRO or PEARL). Fate in the surface water can then be assessed using the TOXSWA model. The models and background information is available on the FOCUS website <http://focus.jrc.ec.europa.eu/>. Appropriate scenarios are to be established/selected by the notifier and the selection and parameterisation is to be justified, until methodology and scenarios are established and approved by competent bodies. Example scenarios for these are given in the appendices. [...]

A scenario requires specification of crop and soil parameters as well as soil management information and (in-system) climatic conditions. [...]

5.3.2. Soil-less crops

“The currently available model for calculating emissions from soil-less cultivations (Vermeulen et al., 2010; Van der Linden et al. 2014 in prep.) is, in fact, a combination of a model for calculating the water demand of, and water supply to, the crop (the model WATERSTREAMS; Voogt et al., 2012) and a model for calculating fate and behaviour of substances in the system and discharge (emission) from the system to surface water. The discharge can be input to a surface water simulation model in order to calculate exposure concentrations in the surface water. A software package containing GEM and TOXSWA has been established and a beta-version of the package is ready for distribution and will be made available on www.pesticidemodels.eu.[...]”

→ At this moment, the GEM Package is not yet available.

Opinion BE:

Example scenarios are given in the GD (a leaching scenario concerning soil-bound tomato crop in Italy, a drainage scenario concerning soil-bound chrysanthemum crop in the Netherlands and a soil-less rose scenario in the Netherlands). The position of the example scenarios regarding their vulnerability is unknown.

For the time being, applicants will have to construct appropriate scenarios based on the example scenarios in the EFSA Guidance and provide information on the (relative) vulnerability.

It's the BE understanding that this GD is aimed to be completed with the development of new scenarios. A clear procedure on how and by whom the scenarios will be assessed/validated and incorporated in the GD is lacking. The representativeness and vulnerability of these scenarios will have to be determined. Therefore, there's a need for a procedure GD with clear protection goals to ensure a harmonized approach through EU.

Another area of concern is the development/selection of scenarios for the extension of authorisations for minor uses and who will be charged with this work. It's the BE opinion that also for minor uses, the applicant needs to be charged with the workload.

Comments from EFSA on 8 December 2014

Question from PT:

There are still issues that need to be developed further such as the efficiency of different structures in reducing spray drift.

Answer from EFSA:

Concerning spray drift the Guidance Document refers to FOCUS air (2008) for the receptor air (see section 4.1.3 of EFSA, 2014) and to FOCUS surface water (2001) (see section 4.1.4 of EFSA, 2014) for the receptor surface water. The EFSA working group that developed this guidance decided to make reference to the existing FOCUS guidance as applicants and MS evaluators are already familiar with the approaches proposed by FOCUS.

For emissions to surface water from greenhouses the EFSA GD assumes Good Agricultural Practices (GAP) which implies closure of openings (doors and windows and ventilation systems) during application. For more open structures the open field FOCUS methodology is recommended including the recognised mitigation measures.

As stated in the responses to stakeholders on the consultation on the draft GD (See point 2.2 in EFSA, 2014) the EFSA GD does not suggest that the cover is to be seen as a risk mitigation measure. However if MSs see a need to develop guidance on the efficiency of different structures in reducing spray drift this may be brought to the attention of the EFSA Pesticide Steering Network who decides on priorities of risk assessment guidance activities.

Question from PT:

It seems, however, that the adoption of this Guidance and underlying principles and approaches may compromise the application of article 40 of Regulation 1107/2009 as it undermines the decision making in the process of mutually recognizing an authorization issued in a MS from a different zone. In fact, under the provision a holder of an authorization granted in a particular MS of one zone may apply the mutual recognition procedure in a MS that does not belong to the same zone if the authorization was granted for use in greenhouses but if the underlying procedure for exposure and risk assessment is not fundamentally different that that taken for the use of the product in an open field, there is no point in having this exemption in the provision. As an extreme example, the approach to the use in greenhouses (except

in a very small number of high tech closed structures) will not be different from that taken for uses in the field (from an environmental and ecotoxicological point of view) and therefore, open field assessments could be used as a default approach to greenhouse use.

On this basis it seems that the natural consequence of the approach taken under the EFSA Guidance would cause the elimination of the use of the exemption stated in point 1 c) of article 40.

Another option would be to consider the authorization of a PPP for use in a particular type (well defined) of greenhouse and the acceptance that under MR the authorization in another MS would only apply to the use in greenhouses of the exact same type but this would be extremely difficult to implement at MS level.

Needless is to say that interzonal evaluation of products with greenhouse uses under Art.33(2b) is severely hindered by this GD.

Our final conclusion is that we leave an open question: shall Reg.1107/2009 be amended, as a result of this GD as it stands today, or is this GD going to be amended in order to specify which conditions (which types of greenhouses) apply to interzonal evaluation (Art.33(2b)) or mutual recognition under Art.40(1c)?

Answer from EFSA:

EFSA can not comment on the interzonal evaluation of plant protection products under protected crops as this is related to risk management and is outside the remit of EFSA. The purpose of this answer is only to provide scientific and technical considerations. In the guidance a scenario requires specification of crop and soil parameters as well as soil management information and (in-system) climatic conditions. The concentrations of the active substances and the formation of metabolites from these active substances will depend on the climatic conditions outside the greenhouse ((EFSA, 2014). The weather conditions and temperature outside the greenhouse will affect the transmission of light and the temperature inside the greenhouse may result in different degradation rates through greenhouses in Europe. The difference in the temperature inside the greenhouse at outside the greenhouse can be in the range from 5 to 10 °C as can be seen in figure A1 of the EFSA GD (2014). Different climatic conditions in Europe may therefore influence the environmental fate of substances in greenhouses situated in different regions of Europe. The scientific opinion (EFSA, 2012) indicates that it is highly unlikely that a single scenario is sufficient to cover the wide ranges of environmental and cropping conditions.

Question from DE:

We took note that residential exposure after pesticide application in greenhouses is out of the scope of this guidance. Nevertheless, we would appreciate if this topic could be addressed in a Guidance Document as well. Currently, residential exposure after greenhouse application of pesticides is assumed to be negligible when assessing the risks of plant protection products during authorisation.

Answer from EFSA:

EFSA was asked by the Commission (DG SANCO) to draft an EFSA Guidance Document on clustering and ranking of emissions of active substances of PPPs and transformation products of these active substances from protected crops

(greenhouses and crops grown under cover) to relevant environmental compartments.

The EFSA Guidance Documents should respect the science proposed and methodology developed in the two adopted PPR opinions mentioned in this document (EFSA, 2010, 2012).

Residential exposure after pesticide application in greenhouses was therefore outside the scope of this guidance. However if MSs see a need to develop guidance on residential exposure after pesticide application in greenhouses, this may be brought to the attention of the EFSA Pesticide Steering Network who decides on priorities of risk assessment guidance activities.

Question/Opinion from BE:

Development/selection and approval of scenarios: How and by whom?

Extract from the EFSA GD on protected crops (EFSA Journal 2014;12(3):3615):

“5. Assessments for walk-in tunnels and greenhouses

5.3.1. Soil-bound crops, leaching and drainage scenarios

The models generally used to calculate leaching and drainage from open-field cultivation can equally well be used to calculate leaching and drainage from walk-in tunnels and greenhouses if appropriate scenarios are available. As stated above, representative and generally accepted scenarios for risk assessment are lacking for soil-bound greenhouse crops, so, for the time being, scenarios have to be constructed and their parameterisation justified. For soil-bound crops, leaching can be assessed using one of the currently used FOCUS models (MACRO, PEARL, PELMO and/or PRZM). When assessing drainage to surface water, the model should be capable of handling preferential flow (MACRO or PEARL). Fate in the surface water can then be assessed using the TOXSWA model. The models and background information is available on the FOCUS website <http://focus.jrc.ec.europa.eu/>. Appropriate scenarios are to be established/selected by the notifier and the selection and parameterisation is to be justified, until methodology and scenarios are established and approved by competent bodies. Example scenarios for these are given in the appendices. [...]

A scenario requires specification of crop and soil parameters as well as soil management information and (in-system) climatic conditions. [...]

5.3.2. Soil-less crops

“The currently available model for calculating emissions from soil-less cultivations (Vermeulen et al., 2010; Van der Linden et al. 2014 in prep.) is, in fact, a combination of a model for calculating the water demand of, and water supply to, the crop (the model WATERSTREAMS; Voogt et al., 2012) and a model for calculating fate and behaviour of substances in the system and discharge (emission) from the system to surface water. The discharge can be input to a surface water simulation model in order to calculate exposure concentrations in the surface water. A software package containing GEM and TOXSWA has been established and a beta-version of the package is ready for distribution and will be made available on www.pesticidemodels.eu. [...]”

→ At this moment, the GEM Package is not yet available.

Opinion BE:

Example scenarios are given in the GD (a leaching scenario concerning soil-bound tomato crop in Italy, a drainage scenario concerning soil-bound chrysanthemum crop in the Netherlands and a soil-less rose scenario in the Netherlands). The position of the example scenarios regarding their vulnerability is unknown.

For the time being, applicants will have to construct appropriate scenarios based on the example scenarios in the EFSA Guidance and provide information on the (relative) vulnerability.

It's the BE understanding that this GD is aimed to be completed with the development of new scenarios. A clear procedure on how and by whom the scenarios will be assessed/validated and incorporated in the GD is lacking. The representativeness and vulnerability of these scenarios will have to be determined. Therefore, there's a need for a procedure GD with clear protection goals to ensure a harmonized approach through EU.

Another area of concern is the development/selection of scenarios for the extension of authorisations for minor uses and who will be charged with this work. It's the BE opinion that also for minor uses, the applicant needs to be charged with the workload.

Answer from EFSA:

We confirm that example scenarios are given in the EFSA GD and the vulnerability of these example scenarios regarding their vulnerability is unknown. Given the timeline provided under this mandate and the lack of underlying spatial and temporal data it was not possible to derive scenarios for soil-bound and soil-less systems with known vulnerability. EFSA collected data through Europe on protected crop systems as referenced in (EFSA, 2010, 2012). Despite this extensive data-collection the EFSA Working Group preparing this guidance, found that the available data was not sufficient to develop scenarios. Therefore to develop scenarios of a given vulnerability eg 90th percentile concentration would imply an EU wide data collection through targeted surveys which would be quite resource intensive. The procedure on how to derive these scenarios is described in chapter 3 of EFSA (2012). However if MSs see a need to develop spatial and temporal scenarios assessed for vulnerability this may be brought to the attention of the EFSA Pesticide Steering Network who decides on priorities of risk assessment guidance activities.

Question from UK

We do not consider that this guidance document is in a condition for noting and it seems unlikely to be ready to be applied from 1 May 2015. In particular, we are concerned that:

- the new scenarios developed by the guidance are described as preliminary, with a recommendation that they should be developed over time. As other member States observed in the meeting, this is not particularly helpful for those who have to implement the guidance;

Answer from EFSA:

The EFSA GD on protected crops provides example scenarios for walk-in tunnels and greenhouse structures. In appendices the guidance standardised input files for leaching, drainage and surface water scenarios are provided. These input files will

provide users with standardised input files for allowing for harmonised assessment approaches through EU. As it is not known how protective the example scenarios are, the guidance recommends to further develop representative exposure scenarios for greenhouses and walk-in tunnels with regard to groundwater and surface water. In the meantime, the guidance proposes to use the example scenarios provided, but also offers notifiers opportunity to construct targeted scenarios.

Question from UK:

- as far as we are aware, the new Greenhouse Emission Model (GEM) has not actually been finalised and is still not available to test. We cannot run test substances through the guidance if one of the main new models has not been made available;

Answer from EFSA:

The guidance states that the Greenhouse Emission Model (GEM) is ready for distribution and will be made available on www.pesticidemodels.eu. It is the responsibility of the Dutch government to release the model and EFSA is not aware when this will happen. The availability of the GEM model is important to allow the use of higher tier assessments for emissions from greenhouses to surface water. The models in the GEM package are ready for distribution. However, a few problems were discovered during testing of the graphical user interface. This prevented release of the package. It is expected that the problems will be solved very shortly.

Question from UK:

- one of the key outcomes of the public consultation phase of the draft guidance was the identification of a number of important issues that were considered outside the remit of EFSA and that could only be addressed by risk managers. They covered a variety of issues, including whether disposal of discharge water and condensation should be part of the risk assessment scheme or handled by waste management regulations. These issues are listed in Section 3 of the report of the outcome of the public consultation. We cannot recall any such consultation with risk managers and would suggest that this needs to take place before the guidance is noted, in order that applicants and member States are clear on what routes of exposure are considered relevant;

Answer from EFSA:

EFSA published a technical stakeholder report on the draft EFSA GD on protected crops to collect comments and suggestions from stakeholders to improve and amend the guidance. This technical report was published in March 2014. See attachment.



In section 2.2 (General issues and considerations) of this report a number of risk management issues were identified through the public consultation. The issue concerning disposal of growing media (spent compost, etc.) was raised as an issue. In EFSA (2010) it is stated that often dedicated national legislation is in force. For this reason, no consideration on this aspect was included in the guidance.

Question from CRD:

- EFSA introduced a tiered approach for surface water with respect to covered crops as outlined in Appendix D of the guidance. This is acceptable in principle. For most scenarios, it follows the FOCUSsw Step 1, 2 and 3 approaches, which seems

sensible and consistent with the tiered principles for outdoor uses. We note, however, that the Tier 1 and 2 estimates for drip irrigation in soil-less greenhouse systems can give PEC_{sw} values 10,000 times higher than would be estimated from drift in outdoor uses, so almost all uses will fail at those tiers. This is recognised in the guidance text, but seems neither helpful nor necessary. The Step 3 approach using GEM will most likely be triggered in all cases. Since we have not yet had access to GEM, we do not know how time-consuming or complex this model will be. We wonder, however, whether it would be possible to use the GEM model to develop a more realistic emission fraction for use at Step 1.

Answer from EFSA:

The need for this EFSA GD was requested by some MSs due to monitoring studies detecting pesticides in water bodies in areas with protected crops structures. In data referenced in EFSA (2010) there is evidence that contamination is most severe in areas with high concentration of protection structures. At the moment, there is insufficient experience to propose a specific lower tier approach for substrate cultivations. This may be possible after some experience has been gained.

Reference:

EFSA PPR Panel, 2010. Scientific Opinion on emissions of plant protection products from greenhouses and crops grown under cover: outline for a new guidance. EFSA Journal 2010; 8(4)/1567. 44 pp. doi/10.2903/j.efsa.2010.1567.

EFSA Panel on Plant Protection Products and their Residues (PPR), 2012. Scientific Opinion on clustering and ranking of emissions of plant protection products from protected crops (greenhouses and crops grown under cover) to relevant environmental. EFSA Journal 2012; 10(3):2611. 87 pp. doi:10.2903/j.efsa.2012.2611. Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2014. 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, 11 pp., doi:10.2903/j.efsa.2014.3615 Available online: www.efsa.europa.eu

EFSA (European Food Safety Authority), 2014b. Outcome of the Public Consultation on 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 supporting publication. 2014:EN-568. Technical report. Available online: www.efsa.europa.eu.

FOCUS, 2003. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC Report prepared by the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2 final (May 2003), 245 pp.

FOCUS, 2008. Pesticides in air: considerations for exposure assessment. Report prepared by the FOCUS Working Group on Pesticides in Air (FOCUS Air Group), EC Document Reference SANCO/10553/2006 Rev.2 June 2008 328 pp.