

**Date of implementation: 1st September 2024**

Interzonal working group version November 2023

[Interzonal Steering Committee/PAI –point/item 07 protected crops]

*Interim* working document on the interzonal core assessment of greenhouse uses - *environmental fate*

## **Disclaimer / Background**

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, subsequently referred to as ‘EFSA GD’] presents a categorisation of different systems of protected crops and approaches for exposure assessment for each of these systems. Among others, it covers the use of plant protection products (PPP) in greenhouses.

For the interzonal core assessment (izCA) of greenhouse uses in accordance with EU Reg. 1107/2009, Art. 33(2b) the EFSA GD should be followed. However, for this specific use a practical guidance for the exposure assessment is missing since only example exposure scenarios are presented for the receptors groundwater and surface water. This left member states (MS) with no workable approaches and complicated the harmonised assessment of greenhouse uses in the EU as most MS used alternative approaches. In the recent years, several MS initiated collaborations aiming in the development of harmonised approaches and requirements for the exposure assessment of greenhouse uses (e.g., the Southern zone requirements for the assessment of protected crops that were published on CIRCABC).

In 2021 an interzonal working group on protected crops has been established following up on a central zone predecessor to discuss the available approaches and work on a harmonisation of the assessment in all three zones. This interim working document was discussed and agreed within the interzonal working group and is meant to assist harmonisation of the exposure assessment of greenhouse uses. Currently, the target of this document is to present a comprehensive, agreed, and workable interim approach for the MS to rely on rather than to create an extensive guidance or to revise the structure definitions from the EFSA GD.

According to EU Reg.1107/2009, Art. 3 (27) a greenhouse is defined as “*a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment.*”. Therefore, implicitly, according to the regulation, only uses in structures that are in accordance with this definition are to be handled on an interzonal level. Uses in structures that do not comply with the definition should instead be dealt with on zonal level. However, this is currently not practiced in the EU, and it may likely not be practical to have separate applications for greenhouses at interzonal and zonal level. Therefore, MS from all three zones have worked together on this interim approach to give more harmonised and clear guidance to applicants and MS on the requirements for the izCA of greenhouse uses.

## **Date of implementation: 1st September 2024**

In this interim working document, only the **environmental fate risk assessment (RA) of chemical substances is addressed**. Possible interactions with the ecotoxicological RA are addressed only to some extent. The RA of PPPs of biological nature, microbial biological agents, e.g., microorganisms and the RA required for other sections than fate (e.g., residues, non-dietary exposure to workers and bystanders and efficacy) are not addressed in this working document. However, it is not expected that the procedures proposed in this working document affect these RA areas.

**Content**

- Disclaimer / Background** ..... 1
- Summary** ..... 4
- 1. Greenhouse uses and distinction from other protected structures ..... 5
- 2. Review of the methods proposed in the EFSA GD ..... 5
- 3. Proposed methods for the environmental fate RA and interactions with the ecotoxicological RA7
  - 3.1. Exposure to soil ..... 7
  - 3.2. Exposure to groundwater..... 7
  - 3.3. Exposure to surface water and sediment..... 8
  - 3.4. Exposure via air ..... 9
  - 3.5. Refinement and conclusion of the RA and applicable risk mitigation measures..... 9
- 4. General advice for applicants and reviewing MS ..... 10
- 5. Outlook/Future tasks..... 10

## Summary

### General remarks:

- A harmonised assessment is required for the izCA of greenhouse uses.
- This guidance is applicable for all professional uses falling under category ‘greenhouse’ in accordance with the EFSA GD, namely both soil-bound and soil-less uses in high- and low-tech greenhouses.
- The assessment for all other protected structures (e.g., walk-in tunnels) is performed at zonal level and not in the izCA.
- The currently available example greenhouse scenarios in the EFSA GD are not suitable for use in an izCA as those are tuned to specific conditions in some MS and are not necessarily representative for conditions in other MS.
- The development of greenhouse scenarios by the applicant is not an applicable option for the izCA because of time constraints for the assessment and as it may lead to a non-harmonised assessment. MS specific higher-tier assessments should be addressed in a national addendum.

### Requirements for the environmental fate RA for the izCA:

The following table summarises the RA required for the izCA of greenhouse uses. It is based on recommendations by the EFSA GD on protected crops (2014) and FOCUS Air (2008) using workable, agreed standard models and simple calculations. The proposed assessment is intended to cover all types of greenhouses and cultivation types. It should always be included in the izCA.

Covered uses	Soil	Groundwater	Surface water and sediment		Air
<b>All greenhouse uses (GAP category ‘G’)</b>	Standard $PEC_{soil,acc}$ for persistent a.s. and metabolites	FOCUS GW <sup>(1)</sup>	1) FOCUS SW - <i>drainage only</i> <sup>(2)</sup>	2) 0.2% dose rate entry calculation	FOCUS Air

<sup>(1)</sup> All nine FOCUS (2000b, 2009) groundwater scenarios: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva according to FOCUS groundwater scenarios in the EU review of active substances, Sanco/321/2000 rev.2 and other Sanco documents.

<sup>(2)</sup> The exposure of surface water and sediment via drainage is estimated using the standard tiered FOCUS surface water models at FOCUS Steps 1 to 3. Exposure via spray drift, runoff and erosion is excluded in the calculations as these exposure pathways are not considered relevant for greenhouse uses. See section 2.3 (1) for details.

### To be addressed in the national assessment:

Further RA or refinements may be required and acceptable at national level in accordance with Art 36(3) EG 1107/2009. The following cases are currently not covered by this working document and should be addressed at national level:

- The disposal or re-use of growing media from cultivation in pots and containers.
- Relevance of drainage/discharge to surface water.
- Restrictions to specific structures, cultivation systems or methods (e.g., soil-less, or sealed/impermeable floors, hydroponics, spraying/dripping) in the context of risk mitigation.
- Further national requirements and assessment tools or the assessment of refined experimental data.

**Date of implementation: 1st September 2024**

## 1. Greenhouse uses and distinction from other protected structures

In accordance with the agreement of the interzonal steering committee from the 21 December 2021, for PPP to be used under protected conditions applicants are required to submit 2 draft registration reports (dRR):

- 1 dRR covering high- and low-tech greenhouses, evaluated at **interzonal level**,
- 1 dRR covering walk in tunnels, open protective structures and field uses, evaluated at **zonal level**.

This working document deals only with the izCA of greenhouses.

According to EU Reg.1107/2009, Art. 3 (27), “‘greenhouse’ means a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment”. However, in practise the term ‘greenhouse’ is generally used for all permanent protected structures.

The EFSA GD gives a rough definition of ‘high-tech greenhouses’ and ‘low-tech greenhouses and provides a basis for the distinction of greenhouses from other protected structures. Some of the presented structures in the EFSA GD are very similar, e.g., ‘low-tech greenhouses’ and ‘walk-in tunnels’ which may only be differentiated by the characteristic that walk-in tunnels are “*generally ... temporary, in that they or their coverings are generally removed at the end of cultivation.*” A clear distinction between structures may, thus, in practise be complicated. Moreover, the various structure categories provided in the EFSA GD are not aligned with the currently available GAP categories.

No distinction is made in the EFSA GD regarding the RA of the two greenhouse structures ‘high-tech greenhouses’ and ‘low-tech greenhouses. Also, the interpretation of ‘high-tech’ and ‘low-tech’ greenhouse structures is likely to vary among MS. This distinction is, therefore, currently less helpful unless the criteria are clearly defined and agreed between all MS and RA areas and eventually separate GAP categories are introduced. For the exposure assessment, the distinction between different cultivations systems (e.g., soil-less, soil-bound, hydroponics) and application methods is more important and also suggested by the EFSA GD. The RA presented in this working document is intended to cover all uses falling under category ‘greenhouse’ in accordance with the EFSA GD, namely both soil-bound and soil-less uses in high- and low-tech greenhouses. **A RA in accordance with this interim working document is required in the izCA and is intended to cover all greenhouse uses. Refinements or amendments of the izCA should be applied at national level if needed to consider national requirements with regards to the national GAP (cultivation systems/methods) and specific environmental circumstances (Art 36(3) EG 1107/2009).**

## 2. Review of the methods proposed in the EFSA GD

The environmental exposure from PPP greenhouse uses is not negligible as it might be assumed from the definition of ‘greenhouses’ according to EU Reg.1107/2009, Art. 3 (27) (“...and prevents release of plant protection products into the environment.”). In accordance with the EFSA GD exposure to soil, groundwater, surface water and air need to be assessed.

## Date of implementation: 1st September 2024

### *Soil*

Concerning the compartments soil a workable approach is presented in the EFSA GD. An assessment is required for persistent substances only. A standard assessment for predicted environmental concentrations (PEC) in soil using the calculations according to FOCUS (1997<sup>1</sup>) is proposed until new guidance concerning the assessment of soil exposure has come into force.

### *Groundwater and surface water*

For the compartments groundwater and surface water no workable advice is given in the EFSA GD. For the compartment groundwater, only one example scenario, the leaching scenario concerning a soil-bound tomato crop in Italy, is presented. Likewise, for the assessment of surface water, two example scenarios from the Netherlands are presented, the drainage scenario concerning a soil-bound chrysanthemum crop and a scenario concerning a soil-less cultivation. These scenarios are tuned to very specific conditions. It is clearly stated in the EFSA GD that the representativeness of these example scenarios for other MS has not been evaluated. Many MS have, therefore, questioned whether these greenhouse scenarios are applicable for any other MS. The interzonal working group is of the opinion that new greenhouse scenarios need to be developed and validated (by EFSA) that match the conditions in all MS in order to be used in the izCA. Moreover, the EFSA GD advises applicants to construct own targeted scenarios until methodology and scenarios are established and approved by competent bodies. The working group does not agree with this advice by the EFSA GD. An interzonal rapporteur MS (iRMS) is not able to evaluate the representativeness of new scenarios for all other MS in all zones. Therefore, the working group proposes not to accept this option or if so, only for a specific higher tier refinement on national level.

Due to the complexity of the example greenhouse scenarios proposed in the EFSA GD and the challenges of developing and evaluating new greenhouse scenarios, **the example greenhouse scenarios in the EFSA GD are not to be used in the izCA. The example greenhouse scenarios or other new scenarios should only be used on national level for refinement of the RA or to address specific national conditions according to Art 36(3) EG 1107/2009.**

### *Air*

For the compartment air an assessment is required which is based on the recommendations in FOCUS Air (2008<sup>2</sup>). However, guidance is lacking on how the exposure via air to other relevant compartments, i.e., surface water, should be assessed.

---

<sup>1</sup> FOCUS, 1997. Soil Persistence Models and EU Registration, European Commission Document No. 7617/VI/96.

<sup>2</sup> PESTICIDES IN AIR: CONSIDERATIONS FOR EXPOSURE ASSESSMENT [SANCO/10553/2006 Rev 2 June 2008]

**Date of implementation: 1st September 2024**

### 3. Proposed methods for the environmental fate RA and interactions with the ecotoxicological RA

#### 3.1. Exposure to soil

**For the izCA, standard calculations in accordance with FOCUS (1997<sup>3</sup>) and a respective ecotoxicological RA for soil-organisms are required for all persistent active substances and metabolites.** 'Persistent substances' are defined as those exceeding the triggers stated in the Uniform Principles (Regulation EU no 546/2011, point 2.5.1.1):

- $DT_{90\text{field}} > 1$  year or
- $DT_{50\text{field}} > 3$  months.

It is advised to use the triggering worst-case non-normalised half-lives for the persistency assessment and PEC<sub>soil</sub> calculations. If reliable field degradation half-lives are not available substances should be considered 'persistent' if laboratory degradation half-lives exceed the persistency triggers stated above.

This requirement is in accordance with the EFSA GD. Even if this requirement is predominantly valid for soil-bound cultivation in greenhouses, it is always required in the izCA to account for all cultivation systems or methods falling under 'greenhouse uses'.

A reconsideration of this requirement might be required when the new guidance on soil assessment (including new tiered approaches and models considering zonal conditions) is updated and in force.

The disposal or re-use of growing media from cultivation in pots and containers should be addressed at national level under consideration of national disposal regulations or risk management.

#### 3.2. Exposure to groundwater

**FOCUS groundwater modelling with the nine standard EU field scenarios<sup>4</sup> should be conducted for all active substances and metabolites.** This is consistent with the current requirements in the southern zone even if it may be considered very conservative according to the EFSA GD. The representativeness of the provided scenarios for each MS is addressed at MS level as it is done in the groundwater assessment of field uses.

This groundwater assessment is only relevant for greenhouses *without* sealed floors/impermeable soil and/or recirculation systems. According to the EFSA GD "for soil-less cultivation systems leaching to groundwater can be considered not relevant". However, to account for all cultivation systems or methods falling under 'greenhouse uses' **this RA should always be included in the izCA.** The conclusion on the relevance of the assessment for the intended uses and decision on acceptable uses and applicable risk mitigation measures is left to the national level.

---

<sup>3</sup> FOCUS, 1997. Soil Persistence Models and EU Registration, European Commission Document No. 7617/VI/96.

<sup>4</sup> All nine FOCUS (2000b, 2009) groundwater scenarios: Châteaudun, Hamburg, Jokioinen, Kremsmünster, Okehampton, Piacenza, Porto, Sevilla and Thiva according to FOCUS groundwater scenarios in the EU review of active substances, Sanco/321/2000 rev.2 and other Sanco documents.

**Date of implementation: 1st September 2024**

### 3.3. Exposure to surface water and sediment

**The two following distinct approaches for calculation of predicted environmental concentrations in surface water (PEC<sub>sw</sub>) and sediment (PEC<sub>sed</sub>) are *both* to be presented in the izCA, alongside with an ecotoxicological RA for aquatic organisms for both approaches.** It is not required to add up the determined PEC from both approaches prior to the ecotoxicological RA since it is not considered likely that the predicted exposure from both approaches happens simultaneously. The assessment is required for active substances and all metabolites that are listed in the definition of residues requiring an assessment for surface water and sediment.

#### **1) Standard tiered FOCUS SW approach considering *drainage only* for entry to surface water and sediment.**

The exposure of surface water and sediment via drainage is calculated using the standard tiered FOCUS surface water models at FOCUS Steps 1 to 3. Exposure via spray drift, runoff and erosion can be excluded in the calculations as these exposure pathways are not considered relevant for greenhouse uses.

At FOCUS Step 1 and 2, an exclusion of run-off and erosion is impossible as these loadings are parameterised together with drainage. However, spray drift can easily be excluded by defining the parameter 'crop type' under application pattern as 'no drift (incorp or seed trtmt)'. It is recommended including calculations at Step 1 and 2 with the input via drift excluded. If acceptable risk can be demonstrated at Step 1 or 2, calculations at Step 3 are not required.

At FOCUS Step 3 simulation are required for drainage scenarios (D)<sup>5</sup> only, with entry by spray drift disabled if necessary. The selected application method should be kept as according to GAP, and the drift entries can be disabled setting the drift loadings to 0 via the TOXSWA interface (drift percentage) or with the SWAN tool (mass loading in mg/m<sup>2</sup>).

The representativeness of the provided scenarios for each MS is addressed at MS level as it is done in the surface water assessment of field uses. Refinements (FOCUS Step 4) of this risk assessment should not be included in the izCA.

This approach is only relevant for greenhouses *without* sealed floors/impermeable soil and/or recirculation systems. However, to account for all cultivation systems or methods falling under 'greenhouse uses' **this RA should always be included in the izCA. The conclusion on the relevance of the assessment for the intended uses and decision on acceptable uses and applicable risk mitigation measures is left to the national level.**

#### **2) Simulation of '0.2 % dose rate-entry' to surface water and sediment.**

This exposure calculation considers a '0.2% dose rate-entry' of the active substance (AS) to a standard water body (ditch of 30 cm depth and 1 m<sup>2</sup>, equivalent to 300 L water) as defined in FOCUS (2015<sup>6</sup>). Potential crop interception is not considered. Multiple applications during the cultivation period are simulated as one cumulative single load to account for condensation and for accumulation of treated waters unless 3 x DT50 in sediment/water systems (combined water + sediment, geometric mean) is less than the time between individual applications. In such a case the maximum individual application rate is used to derive the PEC. (For first order kinetics the value of 3 \* DT50 is comparable to the DT90 value.) Note, that this trigger for consideration of multiple applications is the same as applied in the FOCUS Step 1 calculations<sup>6</sup>.

---

<sup>5</sup> D1 (Lanna), D2 (Brimstone), D3 (Vredepeel), D4 (Skousbo), D5 (La Jailliere), D6 (Váyia, Thiva) according to FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC, SANCO/4802/2001-rev.2 final (May 2003).

<sup>6</sup> Generic guidance for FOCUS surface water Scenarios [May 2015]



## Date of implementation: 1st September 2024

PEC<sub>sw</sub> from '0.2% dose rate-entry' is calculated as:

$$PEC_{sw} \left( \frac{\mu\text{g}}{\text{L}} \right) = \frac{A_{AS} \times 0.002}{3}$$

with  $A_{AS}$  being the (cumulative) field application rate (g/ha).

PEC<sub>sed</sub> is calculated, considering a sediment density of 0.8 g/mL and sediment height of 5 cm, as:

$$PEC_{sed} \left( \frac{\mu\text{g}}{\text{kg}} \right) = \frac{A_{AS} \times 0.002}{0.4}$$

PEC<sub>sw</sub> and PEC<sub>sed</sub> for metabolites are calculated from the PEC<sub>sw</sub> and PEC<sub>sed</sub> of the AS as:

$$PEC_{Met} = PEC_{AS} \times \text{max. occ.} \times \frac{M_{Met}}{M_{AS}}$$

considering the molecular weight of the AS ( $M_{AS}$ ) and metabolite ( $M_{Met}$ ), respectively, and the maximum occurrence of the metabolite (max.occ) in water, soil, or sediment. Calculations are required for all metabolites that are listed in the definition of residues requiring an assessment for surface water and sediment.

Simulations with FOCUS Step2 using drift only and a 'down-factoring' should not be performed because this will result in a significantly reduced PEC<sub>sw</sub> as water/sediment distribution and time-weighted average (TWA) would be considered.

This PEC is considered to cover other exposure pathways to surface water (e.g., through condensation water or filter rinsing) and is, therefore, required for all substances, regardless of their volatility. For semi-volatile and volatile substances, it also covers the exposure via air (see section 3.4). **The conclusion on the relevance of the assessment for the intended uses and decision on acceptable uses and applicable risk mitigation measures is left to the national level.**

### 3.4. Exposure via air

In accordance with FOCUS AIR (2008<sup>7</sup>) a 0.2% deposition percentage is a conservative estimate for the exposure of adjacent areas by PPP via volatilisation after application in greenhouses. The deposition percentage of 0.2% is considered to cover semi-volatile and volatile substances with vapour pressures between  $10^{-4}$  Pa and  $10^{-2}$  Pa at 20°C, regardless of the application technique or the cultivation system. For some application techniques lower deposition percentages may apply. However, **the consideration of specific application techniques in a refined RA should be dealt with at national level only.**

Note, that the 0.2% deposition calculation agrees with the PEC<sub>sw</sub> and PEC<sub>sed</sub> approach '0.2% dose rate-entry' (approach 2). Consequently, for semi-volatile and volatile substances exposure via air is covered by the assessment of exposure to surface water and sediment.

For very volatile substances with vapour pressure  $> 10^{-2}$  Pa such a simplified assessment is considered not sufficiently protective and thus not possible. Here an assessment case by case based on expert judgement is required.

### 3.5. Refinement and conclusion of the RA and applicable risk mitigation measures

Note, that the izCA is intended to provide a comprehensive assessment but not necessarily a conclusion on acceptable uses or applicable risk mitigation measures for all MS. The requirements and approaches outlined in this working document are not necessarily considered relevant by all MS.

---

<sup>7</sup> PESTICIDES IN AIR: CONSIDERATIONS FOR EXPOSURE ASSESSMENT [SANCO/10553/2006 Rev 2 June 2008]

## Date of implementation: 1st September 2024

For instance, some MS may not consider the exposure via drainage to reflect the common practice in the MS.

If the izCA in accordance with the working document indicates a risk for the environment, refinements of the RA and/or risk mitigation may be considered. However, these refinements and risk mitigation measures (e.g., restriction to specific greenhouse structures, cultivation types, application techniques) should be considered in the subsequent national assessment in accordance with Art. 36(3) EG 1107/2009.

**Some MS have further requirements for the fate RA than specified in this working document. These national requirements should be addressed in a National Addendum.**

## 4. General advice for applicants and reviewing MS

### *Information in the GAP*

Clear information on the maximal dose rate and maximal number of applications/year/area is required in the GAP. Further information on the uses may be relevant, e.g., the max. number of crop production cycles and first and the last intended day of application. This further information should be included in the 'remarks'-column of the GAP.

### *Conclusion on the RA*

The izRMS is advised to check whether the izCA is in accordance with the requirements stated in this working document and the uses applied for (e.g., regarding the max. dose rate and max. number of applications/year/area). A clear conclusion on the acceptability of the assessment (i.e., endpoints, modelling) and generated PEC should be stated. **The izCA is intended to provide a comprehensive assessment but not necessarily a conclusion on acceptable uses or applicable risk mitigation measures for all MS. The conclusion on the relevance of the assessment for the intended uses and decision on acceptable uses and applicable risk mitigation measures is left to the national level.**

## 5. Outlook/Future tasks

This interim working document may be seen as a provisional and living working document which may be later amended and extended by the interzonal working group on protected crops or others. It may also be used by EFSA as an input for a possible revision of the EFSA GD. This document is not legally binding. However, MS encourage the applicants to follow this working document for interzonal applications.

A central zone questionnaire from the years 2018/2019 concerning the 'interzonal core assessment of protected crops' showed that the majority of the MS regards the current situation unsatisfactory and claims for a harmonised (environmental) assessment of protected crops with agreed standard methods for the izCA. This interim working document is targeted to fulfil this claim. However, almost all MS, which took part in the questionnaire, also look forward to EFSA initiating the development of specific groundwater and surface water scenarios for greenhouses and to provide further working guidance on the izCA according to the EFSA GD. Further scenarios have been developed since the publication of the EFSA GD, an evaluation and validation of these scenarios for use in an interzonal manner has, however, not been done, yet. The working group is of the opinion that this work would

## **Date of implementation: 1st September 2024**

need to be initiated and coordinated by EFSA and that the funding of the development of agreed scenarios should not be left to MS level.

Regarding the protected crop categories included in the EFSA GD a more refined and clear definition of the structures 'greenhouse' and 'walk-in tunnel' might be needed in order to avoid confusion. A further distinction between 'high-tech' and 'low-tech greenhouses' or better, between 'soil-less' and 'soil-bound' cultivation would be helpful in the GAP to allow a more differentiated RA in the future. In some MS, e.g., NL and DK, it is already compulsory to indicate in the GAP which cultivation systems are foreseen. EU agreed harmonised categories would be needed in order to apply a distinction of cultivation systems or greenhouse structures in the izCA. Discussions on these harmonised categories should involve all RA areas.

Furthermore, a critical reflection on whether a RA methodology assuming only one treated crop/culture per year reflects the practical conditions in greenhouses is suggested. In greenhouses several different cultivation cycles within one year or parallel cultivation cycles at the same time are considered common practice. Some MS already include multiple crop cycles in the national RA (e.g., NL and DK). However, this topic is rather complex and hard to address unless standardised practical information on the actual use of PPP as well as harmonised methods for the assessment of product combinations (of the same or various active substances) or mixture exposure/toxicity are developed.

For the time being, an appropriate RA approach has been determined in this working document in order to allow a sufficiently conservative RA of greenhouse uses on interzonal level which represents the minimum consensus of national conditions.