

# Non dietary exposure to plant protection products: state of the art and perspectives

This document proposes a mid-term vision on the future steps and the methodology for the collection and assessment of evidence, i.e. raw data<sup>1</sup> and related models (if developed) for the update of current approaches used to estimate non dietary (operators, workers, residents and bystanders) exposure to plant protection products.

The document analyses the available information, the constraints and the needs, recommending the engagement (e.g. through stakeholders' event(s)) of the data owners<sup>2</sup> and model developers<sup>3</sup> for the identification of the evidence that could be relevant to the update.

Partnerships<sup>4</sup> with Member States Competent Authorities, public organisations, academia, etc. (e.g. through grants) need to be implemented/improved for the assessment of the submitted evidence as well as for the development of new models. Consultation of the relevant stakeholders will be conducted, according to EFSA rules on transparency and confidentiality<sup>5</sup>.

## 1. Introduction

EFSA recently revised and published<sup>6</sup> the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (OPEX Guidance), as requested by the European Commission<sup>7</sup>. Based on new evidence, the following aspects have been addressed:

- inclusion of the greenhouse scenarios;
- revision of crop and human parameters;
- implementation of user-friendly and transparent online calculator.

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<sup>1</sup> Raw data: data that has been collected directly from a primary source and has not been processed in any way

<sup>2</sup> Defined here as owners of validated experimental data in the context of regulatory assessment of NDE

<sup>3</sup> Defined here as experts developing models in the context of regulatory assessment of NDE

<sup>4</sup> <https://www.efsa.europa.eu/en/engage>

<sup>5</sup> Decision of the Executive Director of the European Food Safety Authority Laying down practical arrangements concerning transparency and confidentiality

<sup>6</sup> <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2022.7032>

<sup>7</sup> <https://open.efsa.europa.eu/study-inventory/EFSA-Q-2018-00274>

## 2. Identified issues

According to the original mandate, EFSA should have considered for the update of the guidance document a series of open issues, as specified in the terms of reference. In order to address the terms of reference, EFSA was requested to consider all available information, as well as data received through an open call. Despite the open call and the actions undertaken by EFSA, only few raw data related to original studies were obtained. Therefore, the dedicated EFSA Working Group was only able to work on a limited number of the open issues identified in the original mandate. For the remaining issues listed in the original mandate, insufficient new information was available, and it was agreed with the Commission to address them in a subsequent revision, once related data would have been made available to EFSA. In addition, EFSA highlighted the need to reconsider the methodology for data collection, with the direct involvement of relevant stakeholders at an early stage of the preparatory work.

## 3. State of the art

EFSA undertook an internal analysis of the future of Non-Dietary Exposure (NDE) to plant protection products.

EFSA has already received some information/evidence, mainly from industry and public organisations. Also, EFSA has been informed about ongoing activities for which final results and raw data could be submitted in the near future.

Besides more general aspects concerning the development and/or implementation of cumulative risk assessment including dietary and non-dietary exposure, the common assessment of multiple active substances (e.g. in the same products), EFSA started the consideration of exposure scenarios as requested by the current legislative framework from what the needs are (for the public, the Member State Competent Authorities, European Commission). In parallel, an extensive list of data available and identified gaps was also prepared, including preliminary relevance and sensitivity assessment, to be finalised with the relevant stakeholders (Table 1).

**Table 1:** Data/information available to EFSA and gaps.  
EFSA draft analysis of need and sensitivity assessment (scoring low-medium-high).

Category	Scenario/ parameter (in grey)	Need <sup>8</sup> (frequent scenario, info often needed)	Data availability in EFSA	Work ongoing/finalised	Sensitivity <sup>9</sup> (associated concern)
Operator	Indoor post-harvest treatments	Medium	Yes	Unknown	Low
	Field applications	Low to Medium	No	Unknown	Medium
	Paintbrush	Low (chemicals); medium (basic)	No	Yes (for Biocides)	Low
	Non-professional uses	Low	No	Yes (Ref. from Member States)	Medium

<sup>8</sup> With this term we intend to capture the needs of risk assessors, i.e. how often the scenario/parameter listed is encountered in daily work

<sup>9</sup> With the term sensitivity we intend to capture the level of interest/concern of stakeholders and public at large

Category	Scenario/ parameter (in grey)	Need <sup>8</sup> (frequent scenario, info often needed)	Data availability in EFSA	Work ongoing/finalised	Sensitivity <sup>9</sup> (associated concern)
	Seed treatment	Medium to high	No	Ongoing (SeedTropex Task Force)	High
	Closed transfer system	Medium	Partially	Ongoing (field studies)	N.a.
	Drift reduction technologies	High (for refinement purposes)	No	Unknown	N.a.
	Packaging	Low	No	Unknown	N.a.
Worker	Non-professional uses	Low	No	Yes (Ref. from Member States)	Medium
	Field applications	Low to Medium	No	Unknown	Medium
	Seed treatment (handling treated seed during loading and sowing)	Medium to high	No	Ongoing (SeedTropex Task Force)	High
	Re-entry in vineyards	High	Yes	Finalised (UK HSE)	High
	DFR studies (meta-analysis)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Vapour exposure (literature + field or wind tunnel exposure data)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
Resident	Non-professional uses	Medium	No	Yes (Ref. from Member States)	Medium
	Seed treatment (dust from treated seed)	Medium	No	Ongoing (SeedTropex Task Force)	Medium
	BREAM (versions after the one included in the EFSA calculator)	High	Partially	Version 2 finalised (Silsoe Spray Applications Unit)	Medium
	Field applications	Medium to high	No	Unknown	High
	Applications in vineyards / orchards	High	Yes	Ongoing (Ref. from UK)	High
	Research on exposure of residents to pesticides in the NL	High	No	Finalised (OBO project)	High
	Overview of data and methodologies and data gap identification in	Low	Partially	Ongoing (UMIL/RIVM/BPI) <sup>10</sup>	Medium

<sup>10</sup> GP/EFSA/ENCO/2020/03

Category	Scenario/ parameter (in grey)	Need <sup>8</sup> (frequent scenario, info often needed)	Data availability in EFSA	Work ongoing/finalised	Sensitivity <sup>9</sup> (associated concern)
	exposure assessment for PPPs in residential settings				
	Drift reduction technologies	High (for refinement purposes)	No	Unknown	N.a.
	DFR studies (meta-analysis)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Vapour exposure (literature + field or wind tunnel exposure data)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Spray drift data (low crops / high crops)	High (for refinement purposes)	No	Finalised (Wageningen University)	N.a.
Bystander	Seed treatment (dust from treated seed)	Medium	No	Ongoing (SeedTropex Task Force)	Medium
	BREAM (versions after the one included in the EFSA calculator)	High	Partially	Version 2 finalised (Silsoe Spray Applications Unit)	Medium
	Field applications	Medium to high	No	Unknown	High
	Applications in vineyards / orchards	High	Yes	Ongoing (Ref. from UK)	High
	PPP exposure models for 3D orchards considering spray technologies in Southern Europe	Medium	Partially	Ongoing (UMIL/UNITO/ELGO- DIMITRA /IVIA) <sup>11</sup>	Medium
	Drift reduction technologies	High (for refinement purposes)	No	Unknown	N.a.
	DFR studies (meta-analysis)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Vapour exposure (literature + field or wind tunnel exposure data)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.

<sup>11</sup> GP/EFSA/ENCO/2020/03

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	Spray drift data (low crops / high crops)	High (for refinement purposes)	No	Finalised (Wageningen University)	N.a.

## 4. Objectives

The specific objectives are to:

1. engage data owners for raw data submission;
2. engage developers for models (and related raw data) submission;
3. build partnerships among stakeholders for submitted data/models assessment and new models development;
4. integrate the assessed raw data/models and new developed models into the OPEX Guidance and annexed calculator.

The stakeholders' workshop is aimed at defining:

- clear understanding of finalised as well as ongoing activities related to the subject matter;
- overview of available data/models;
- identification of possible cooperation among relevant stakeholders (e.g. Member States Competent Authorities, public organisations, academia, non-governmental organisations, etc.) for the assessment of submitted data/models as well as for the development of new models.

A survey, published with the event announcement, will facilitate the collection of the above-mentioned information as well as the finalisation of this 'state of the art and perspectives' document (to be published with the announcement).

Partnership agreements (e.g. tasking grants) or other outsourcing tools (e.g. <sup>12</sup>contracts<sup>[OBJ]</sup>) with art. 36 organisation or external contractors will be established for the assessment of submitted data/models as well as for the development of new models to be integrated in the OPEX Guidance and annexed calculator.

EFSA will ensure a transparent, independent and quality-driven assessment through the implementation of checkpoints (in compliance with internal Standard Operating Procedures) during the development of the draft outputs.

Any produced scientific output (new annexes and/or updated OPEX Guidance; updated calculator) will be considered for public commenting from the impacted stakeholders, including the Pesticides Steering Network (PSN) and the EC Standing Committee on Plant Animal Food & Feed (SCoPAFF).

<sup>12</sup> <https://www.efsa.europa.eu/sites/default/files/engage/Procurement/2nd-call-scientific-technical-support/Call-for-experts-preparatory-work.pdf>