



EFSA activities in the non-dietary exposure to Plant Protection Products - New EFSA-Guidance on the Exposure Assessment for Operators, Workers, Residents and Bystanders in the Risk Assessment

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OUTLINE

EFSA activities on non dietary exposure

- **Guidance document**
- **Field data collection**
- **Database on operator exposure**

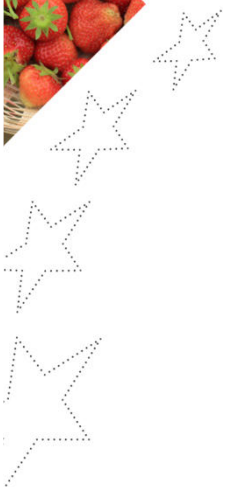
Perspectives and future activities



GUIDANCE DOCUMENT

Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents (EFSA AGREEMENT NUMBER EFSA/PPR/2007/01) - FINAL REPORT 28 NOVEMBER 2008

Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents – 2010



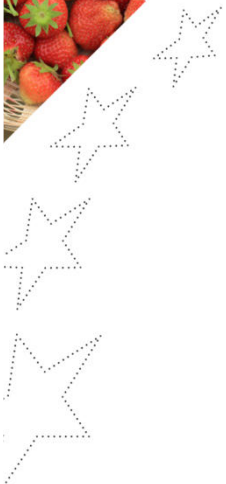
GUIDANCE DOCUMENT

EFSA was asked, in accordance with Article 31 of Regulation (EC) No 178/2002, to proceed with the preparation of a Guidance Document on the Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents

An ad hoc EFSA working group was established to prepare a GD and the related calculator

The GD had to include:

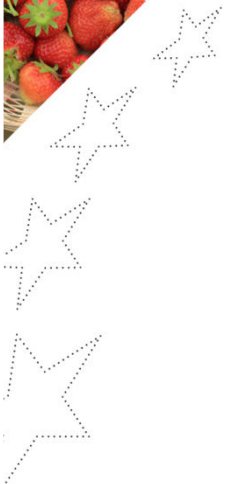
- A quality assessment of the databases made available to EFSA**
- The derivation of regulatory percentiles from the most appropriate datasets of the commonly encountered exposure scenarios**
- The preparation of an operator exposure calculator spreadsheet**





GUIDANCE DOCUMENT - ACTIVITIES

- **Assessment of the available databases**
- **Preparation of a calculator**
- **Basic principles of the Guidance and the annexed calculator are:**
 - the transparency of data,
 - the traceability of information and
 - the reproducibility of the outcomes.
- Only databases for which the working group had access to the raw data and that could be circulated, if requested by third parties, were considered.





GUIDANCE DOCUMENT - TOPICS

- **Tier approach:**
 - **Standardised first tier exposure assessment is available (most scenarios)**
 - **Scenarios not covered by standardised methods: the most appropriate *ad hoc* approach can be followed**
- **Where a non-standardised higher tier exposure assessment is adopted, the justification should be clearly documented**
- **The deterministic methods is still suggested in routine risk assessment for individual PPPs, because of the limitations of the currently available data**
- **The method of risk assessment should be refined for pesticides that are acutely toxic**



GUIDANCE DOCUMENT - TOPICS

- **Defines the exposed groups**
- **Lists and evaluates existing standard models**
- **Focuses on risk assessment for systemic toxicity (local effects not covered)**
- **Does not cover guidance on dermal absorption**
- **Does not apply to biocides/biological PPPs**
- **Proposes a tiered approach for exposure assessment**
- **Evaluates and gives recommendations for a series of default assumptions/values/parameters**

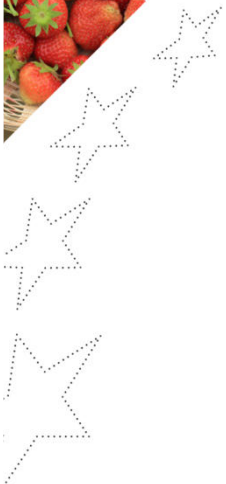


GUIDANCE DOCUMENT - TOPICS

- **Discriminates between acute and chronic assessments**
- **Introduces the concept of “Acute Acceptable Operator Exposure Level” (AAOEL) in addition to the AOEL**
- **Suggests use of 95th percentile for acute assessments**
- **Suggests use of 75th percentile for chronic assessments**
- **Introduces resident exposure assessment (limited database)**

GUIDANCE DOCUMENT - PROPOSED DEFAULTS

- **Body weights**
- **Breathing rates**
- **Average air concentrations**
- **Hectares treated per day**
- **Exposure durations**
- **Absorption values**
- **Default surface area of body parts**



GUIDANCE DOCUMENT – DEFAULT PPE

Technical control/PPE item		Protection factor (by which exposure in absence of protection should be multiplied)	Specific exposure value affected
Protective (chemical resistant) gloves ^o		Operators Liquids 10% Operators Solids 5% Workers Solids 5% (Dermal exposure – hands only
Working clothing or uncertified cotton coverall		Operators 10%	Dermal exposure – body only
Protective coverall (this is used <i>instead of working clothing/uncertified cotton coverall</i>)		Operators certified protective coverall 5%	Dermal exposure – body only
Hood and visor*		Operators 5%	Dermal exposure – head only
Hood		Operators 50%	Dermal exposure – head only
RPE mask type	Filter type		
Half and full face masks	FP1, P1 and similar	25%	Inhalation exposure
		80%	Dermal exposure – head only
	FFP2, P2 and similar	10%	Inhalation exposure
		80%	Dermal exposure – head only

^oFor manual application of granule formulations, the original exposure data were derived considering the use of PPE (gloves and coverall). For the non-PPE scenario a 100 times higher value is considered for hands and body.

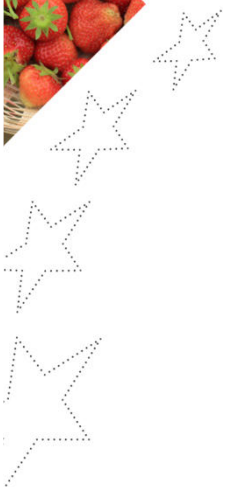
*Hood and visor are considered in alternative to the RPE



PUBLIC CONSULTATION ON THE DRAFT EFSA GUIDANCE DOCUMENT :

The public was invited to submit comments on the draft GD and the attached calculator via an online form available at www.efsa.europa.eu from 1 April 2014 to 20 May 2014. Risk assessors, risk managers, stakeholders and the scientific community were additionally informed via emails about the open public consultation.

Comments of a more general nature as well as very specific comments on the various section of the draft GD were received.



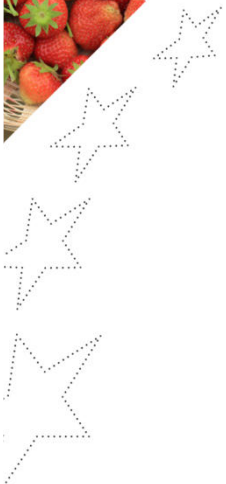


COMMENTS RECEIVED

A total of 464 comments were received on the draft GD.

Comments received on the draft GD per stakeholder category

stakeholder category	Number of Comments
authority	95
academia	222
agrochemical industry / ECPA	87
consultancy	21
farmers	3
NGOs	19
TOTAL	464





COMMENTS RECEIVED ON THE DRAFT GD PER CHAPTER

Sections of the draft GD	Number of Comments
General comments	
Abstract	8
Summary	
Table of contents	
Background as provided by the Commission	9
Terms of reference	8
Assessment	18
1. Introduction	10
2. Background Data	13
3. Definitions of exposed groups	13
4. Overall approach	32
5. Default values proposed for the assessment	10
5.1. Body weights	10
5.2. Breathing rates	6
5.3. Average air concentrations	7
5.4. Hectares treated per day	17
5.5. Exposure durations	10
5.6. Absorption values	-
5.7. Default surface area of body parts	1



COMMENTS RECEIVED ON THE DRAFT GD PER CHAPTER

Sections of the draft GD	Number of Comments
6. Methods for first tier exposure assessment	4
6.1. Operator exposure	27
6.2. Worker exposure	16
6.2.1. Dermal exposure of workers	9
6.2.2. Dislodgeable Foliar Residue (DFR)	9
6.2.3. Multiple Application Factor (MAF)	15
6.2.4. Transfer Coefficient (TC)	27
6.2.5. Inhalation exposure of workers	12
7. Resident and bystander exposure	21
7.1. Resident exposure	12
7.1.1. Spray drift	29
7.1.2. Vapour	14
7.1.3. Surface deposits	14
7.1.4. Entry into treated crops	11
7.2. Bystander exposure	8
7.2.1. Spray drift	16
7.2.2. Vapour	9
7.2.3. Surface deposits	10
7.2.4. Entry into treated crops	10



NEXT STEPS

- **With the collaboration of the WG EFSA will prepare a technical report to address all the comments received**
- **The draft guidance document and the calculator will be amended accordingly, if needed**
- **The GD and the calculator, as resulting after the discussion in the public consultation, will be sent to COM**
- **From then on, COM will decide how to deal with the available guidance (e.g. need of additional meetings with managers, etc...)**
- **In the meantime...**
 - **re-assessment of the data of the Southern Europe Greenhouse model**
 - **finalisation of BROWSE**





FIELD DATA COLLECTION

The methodologies for cumulative exposure and risk assessment are still under development for the risk assessment

The EFSA PPR Panel is currently developing a methodology for cumulative risk assessment related to dietary exposure to pesticide residues

A part of this activity will be of high relevance to also address operator, worker, bystander and resident safety regarding cumulative effects resulting from non-dietary exposure.

PPR Procurement Project "Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment" (CT/EFSA/PPR/2010/04)

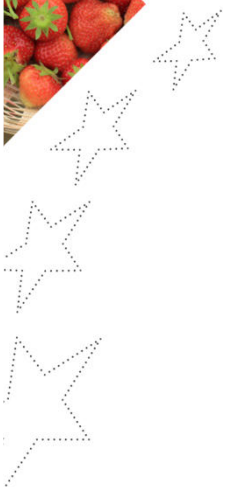
Collection of pesticide application data in view of performing Environmental Risk Assessments for pesticides (CFT/EFSA/PRAS/2012/05)

FIELD DATA COLLECTION

PPR Procurement Project “Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment” (CT/EFSA/PPR/2010/04)

The overall objective of the work was the elaboration of a data collection strategy and the initiation of data collection (pilot survey study) appropriate for non-dietary cumulative exposure and risk assessment.

The data have been recorded for the activities of individuals, so that key datasets could be constructed for operator and worker activities in developing cumulative exposure scenarios for a range of crops, regions and agronomic practices across the EU.



FIELD DATA COLLECTION

PPR Procurement Project “Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment” (CT/EFSA/PPR/2010/04)

Requirements

1. A strategy and a methodology for a collection of data regarding actual practices of operators and workers in areas treated with plant protection products meeting the specific needs of the assessment of non-dietary cumulative effects has been developed
2. Literature searches to identify existing data and the collection and review of these data at individual level and meeting the particular requirements for non-dietary cumulative exposure and risk assessment for farmers, contract applicators, amateur users and workers were carried out
3. Pilot surveys were carried out in six EU Member States
4. The data collected has been entered into a specifically designed database
5. The assessment of the collected data was performed to provide an understanding and description of the main factors influencing short and long term cumulative non-dietary exposure of operators and workers to pesticides
6. The identification of key sources of uncertainties related to the range of parameters included in the pilot survey data was performed

FILED DATA COLLECTION

PPR Procurement Project “Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment” (CT/EFSA/PPR/2010/04)

Collected information on a wide range of factors for both operators and workers such as the number of hours worked each day for specific operator and worker tasks, personal protective equipment (PPE) used etc. The risk of exposure from combined toxicity resulting from the cumulative non-dietary exposure of operators and workers to multiple active substances used for crop protection can be determined from such data.

The crops included in the pilot surveys were:

- UK Arable Crops, soft fruit
- Belgium Greenhouse ornamentals, outdoor vegetables
- Spain Greenhouse fruiting vegetables,
- Greece Greenhouse fruiting vegetables, arable (cotton/maize)
- Poland Arable (wheat), orchard (apple)
- Italy Vineyards (wine grapes)

FIELD DATA COLLECTION

PPR Procurement Project “Collection and assessment of data relevant for non-dietary cumulative exposure to pesticides and proposal for conceptual approaches for non-dietary cumulative exposure assessment” (CT/EFSA/PPR/2010/04)

A wide range of crops and EU regions were covered by the pilot surveys to include the major agronomic practices.

The pilot surveys provided an insight into the types of data recording which are carried out by growers and workers across a range of farm types and regions.

The development of assurance schemes across the EU has led to an improvement in the data recording for PPP use on farms, but farm records were not always complete with details of PPP usage.

Details on working practices, particularly on the smaller farms were often poorly recorded.

FIELD DATA COLLECTION

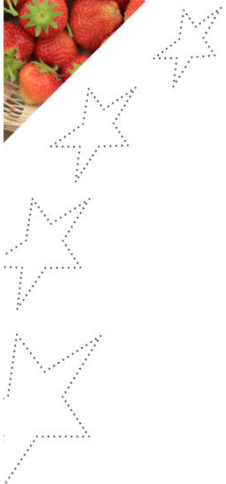
Collection of pesticide application data in view of performing Environmental Risk Assessments for pesticides (CFT/EFSA/PRAS/2012/05)

Collect data on the pesticide use on one carefully selected representative field on each farm surveyed for one year with additional data for the previous 4 years

Collect records of all activities of pesticide application operators over one year to include pesticide application related activities on the whole farm or on other farms where operators may also apply pesticides.

The surveys will therefore provide data for the exposure to pesticides for the following sampling units:

- Fields of fruit trees
- Arable crops
- Grapevines
- Potatoes and vegetables



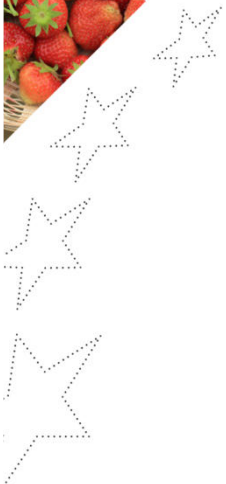
NEXT STEPS

Assessment of the available data

Check suitability and representativeness

Application of current methodology

Likely: need of more data on real scenarios



DATABASE ON OPERATOR EXPOSURE

Data collection on exposure assessment scenarios for operators exposed to pesticides - OC/EFSA/PRAS/2013/04

- The main objective is to collect technical data and to re-analyse, where necessary, the operator exposure assessments performed so far at EU level, focusing on exposure estimates/measurements and considering their outcomes with respect to the key parameters determining the exposure levels. Some of them are the following:
 - the existing scenarios proposed in the authorisation process of the peer review a.s.;
 - the methods used for the exposure assessment;
 - the application techniques;
 - the level of exposure with respect to the model/calculation applied compared to the agreed Acceptable Operator Exposure Level (AOEL) according to the final proposal made by EFSA in the EFSA conclusion on the peer review of pesticide risk assessment of specific a.s.7;
 - the use of PPE and the assigned level of exposure reduction;
 - the type of formulation;
 - the dermal absorption value(s) used.

- OPERATOR ONLY

DATABASE ON OPERATOR EXPOSURE

Specific objectives

- **Identification of the relevant a.s.(assessed by EFSA and authorised by the Commission between 1/1/2007 and 1/10/2013 (excluding microorganisms and a.s. from list 4).**
- **Identification of intended uses, application rates, application methods, etc. and of all the key relevant parameters determining the exposure to plant protection products in agriculture (as reported in the DARs and in the EFSA conclusions);**
- **Creation of an MS Excel database including all the intended use for all the a.s. as per the requirements above; the database should be interfaceable with databases and systems already present in EFSA (e.g. the possibility to submit data to EFSA's Data Collection Framework (DCF) using XML, Excel or CSV transmission formats; the possibility to include links to already existing databases).**



DATABASE ON OPERATOR EXPOSURE

Key parameters: an example

- ● **Compound:** all the active substances as per the call
- ● **AOEL** (a list is already available in EFSA)
- ● **Authorisation status**
- ● **Crop:** the representative crop for which the assessment has been performed, considering the respective GAPs (Good Agricultural Practices)
- ● **Application technique:** it is based on the information available from the proposed intended use and taking into consideration the possibilities offered by the models used to perform the exposure assessment. Need of standardisation (survey by FERA? Modelling?)
- ● **Type of formulation**
- ● **Exposure assessment method/model** (e.g. UK POEM, German model, Dutch model, PHED, Seed Tropex, EUROPOEM, others).
- ● **Use of PPE:** from "no use" to a combination of multiple possibilities (gloves during mixing/loading, gloves during application, mask during mixing/loading, etc...)
- ● **AOEL % with respect to the model/calculation applied**

DATABASE ON OPERATOR EXPOSURE

Timelines

- Provide a project outline indicating the key relevant factors of the operator exposure and a proposal for the database structure taking into account the above mentioned key parameters; a definition of the number of a.s. to be screened will also be included

March 2014

- Provide an interim report on the activity performed including the database (MS Excel) with not less than 70% of a.s. screened for all the pertaining relevant operator exposure scenarios

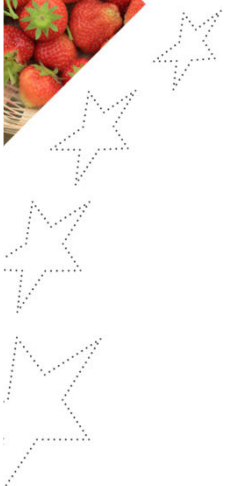
July 2014

- Provide a draft of the final report on the activity performed including the database (MS Excel) with 100% of a.s. screened for all the pertaining relevant operator exposure scenarios

Nov 2014

- Provide the final report on the activity performed and the final database (MS Excel)

Dec 2014



NEXT STEPS

Analysis of outcomes

Identification of data gaps and possible actions

Creation of a database for bystanders (and residents?)

