



Webinar on the calculation tool annexed to the pesticides guidance document on non-dietary exposure of workers and bystanders to pesticides



19 November 2015

INTRODUCTION - GUIDE TO ATTENDEES

Webinar guide to attendees

- The meeting room
- Interaction in the event
 - Chat panel
 - EFSA Helpdesk
- Webinar outline

Speaker: Manuela Tiramani

Acting Head of Feed Unit - EFSA

Speaker: Jane Richardson

Assessment and Methodological Support Unit – EFSA

INTRODUCTION - GUIDE TO ATTENDEES

EFSA Disclaimer and data protection policy

This webinar is recorded

Before participating, please ensure you have read the EFSA disclaimer carefully (available at: http://www.efsa.europa.eu/sites/default/files/webinar_disclaimer.pdf).

If you do not agree with the EFSA policy on webinars, please disconnect yourself now.

Webinar recording and presentations will be available on the EFSA website soon after the webinar.

INTRODUCTION - GUIDE TO ATTENDEES

Virtual room

- You are automatically connected to the audio broadcast
- Check the audio panel to control your volume



- Make sure to enable the sounds on your computer and to turn on your speakers (or headphones)
- One-way audio: listen only mode

INTRODUCTION - GUIDE TO ATTENDEES

Virtual room

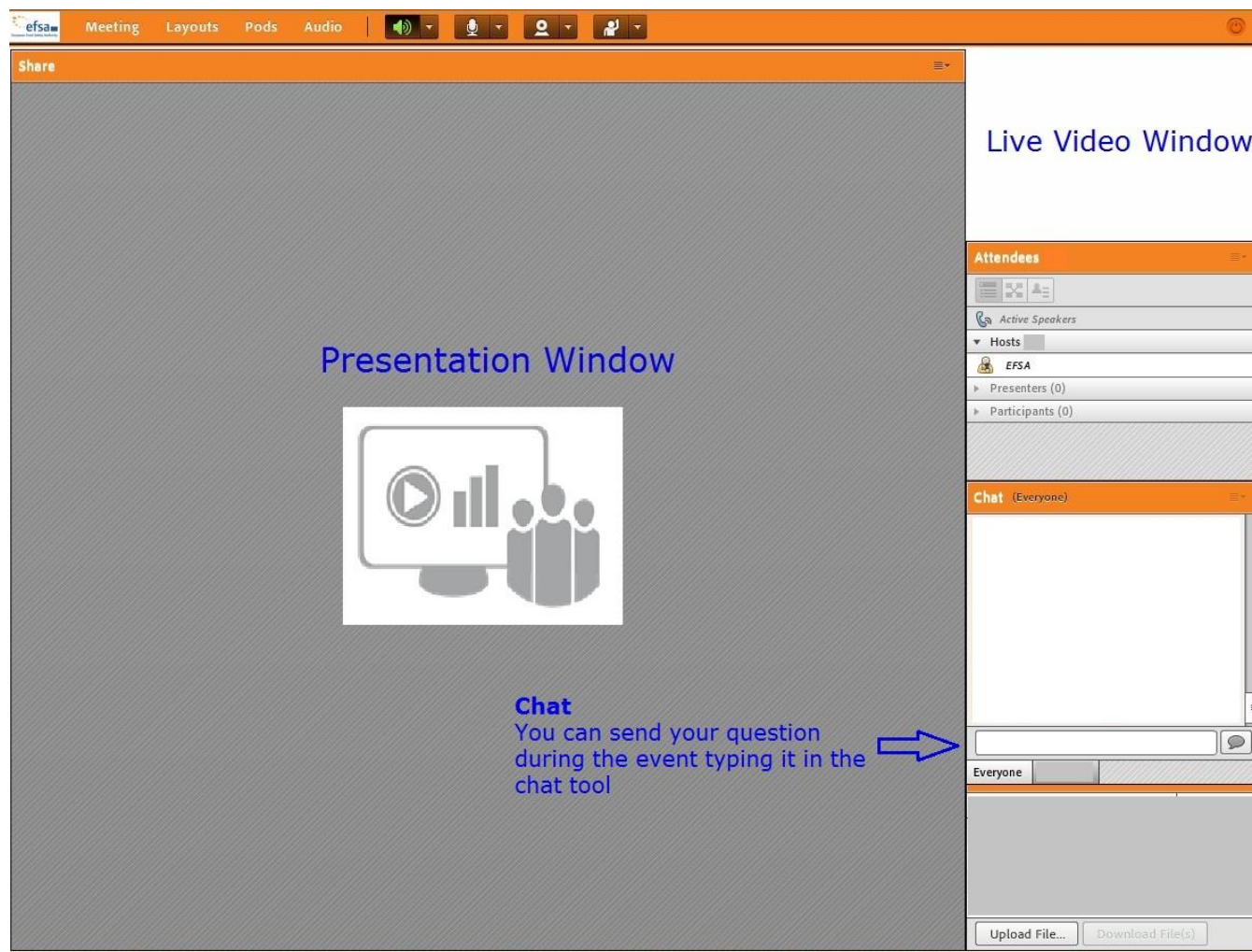


Full screen
Zoom in/out



INTRODUCTION - GUIDE TO ATTENDEES

Q&A session: two-way communication



The screenshot displays a webinar interface with the following components:

- Share**: A top bar with a dropdown menu.
- Meeting Controls**: A row of icons for Meeting, Layouts, Pods, and Audio, along with volume, microphone, and participant icons.
- Presentation Window**: A large central area with a play button icon and a bar chart, labeled "Presentation Window".
- Live Video Window**: A panel on the right side labeled "Live Video Window".
- Attendees**: A panel on the right side showing a list of participants, including "Active Speakers", "Hosts" (EFSA), "Presenters (0)", and "Participants (0)".
- Chat (Everyone)**: A panel on the right side with a text input field and a send button, labeled "Chat (Everyone)".
- File Management**: Buttons for "Upload File..." and "Download File(s)" at the bottom right.

Chat
You can send your question during the event typing it in the chat tool

→

INTRODUCTION - GUIDE TO ATTENDEES

Sending questions – Q&A sessions

- Please submit your questions only once
- We will address them during the Q&A sessions
- If you do not receive answers to your questions during the webinar, you can submit them through the **EFSA APDESK** web form:

[http://www.efsa.europa.eu/en/applicationsh
elpdesk/askaquestion?ScientificArea=zero](http://www.efsa.europa.eu/en/applicationsh
elpdesk/askaquestion?ScientificArea=zero)

INTRODUCTION - GUIDE TO ATTENDEES

Objective

- Present the **calculation tool** annexed to the guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products.
- Demonstrate to **Member States** and to **companies** the use of the excel calculator to quantify potential non-dietary, systemic exposure to pesticides.
- Illustrate the application of the tool via practical scenarios on **operators** and **workers**.

INTRODUCTION - GUIDE TO ATTENDEES

Webinar outline

Overview of guidance document

Speaker: Manuela Tiramani - EFSA

Guidance document: <http://www.efsa.europa.eu/en/efsajournal/pub/3874>

Overview of the Excel calculator

Speaker: Jane Richardson - EFSA

Excel calculator:

http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/3874Ax1.zip

Q&A session

Speakers: Manuela Tiramani and Jane Richardson - EFSA

INTRODUCTION - GUIDE TO ATTENDEES

Webinar outline

The workbook through different scenarios

Speaker: Jane Richardson - EFSA

Q&A session

Speakers: Manuela Tiramani and Jane Richardson - EFSA

Conclusions

Speakers: Manuela Tiramani and Jane Richardson - EFSA





Webinar on the calculation tool annexed to the pesticides guidance document on non-dietary exposure of workers and bystanders to pesticides.



The EFSA calculator

Speaker: Manuela Tiramani - EFSA



GUIDANCE OF EFSA

Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

Regulation (EC) No 1107/2009 ensures that the residues of plant protection products (PPPs), consequent to application consistent with good plant protection practice and having regard to realistic conditions of use, shall not have any harmful effects on human health. In 2010, the EFSA Panel on Plant Protection Products and their Residues (PPR) prepared a Scientific Opinion on "Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Residents and Bystanders", which highlighted some inconsistencies between the approaches adopted by regulatory authorities. Therefore, the PPR Panel proposed a number of changes to those practices in use (e.g. routine risk assessment for individual PPPs should continue to use deterministic methods, and a tiered approach to exposure assessment remains appropriate; there is a need to introduce an acute risk assessment for operators, workers and bystanders where PPPs are acutely toxic; for acute risk assessments, exposure estimates should normally be based on 95th percentiles of relevant datasets, whereas, for longer term risk assessments, the starting point should be a 75th percentile). To prepare a Guidance Document, an *ad hoc* working group was established to revise all available data and procedures to perform the operator, worker, resident and bystander risk assessment. In addition to the data reported in the PPR opinion, further data were made available to the working group which were analysed and considered. The opinion also identifies those scenarios for which exposure estimates are least satisfactory, and makes recommendations for further research that would reduce current uncertainties. An exposure calculation spreadsheet, reflecting the Guidance content, is annexed to this Guidance Document, to support stakeholders in performing the assessment of exposure and risk.

© European Food Safety Authority, 2014

KEY WORDS

exposure, operator, worker, bystander, resident, plant protection products, estimation, guidance, calculator

¹ On request from European Commission, Question No EFSA-Q-2011-01062, approved on 17 October 2014.

² Correspondence: pesticides.ppr@efsa.europa.eu

³ Acknowledgement: EFSA wishes to thank the members of the Working Group on the operator, worker, resident and bystander exposure assessment: Claudia Grosskopf (as of September 2013), Paul Y Hamey, Kyriaki Macheri, Sabine Martin, Walter Steurbaut for the preparatory work on this scientific output, the hearing expert: Georgina Downs, and EFSA staff: Lena Elisabeth Jacobi (until October 2012), Jane Richardson, Istvan Sebestyen (until May 2012), Hans Steinkellner (until April 2014) and Manuela Tiramani for the support provided to this scientific output.

Suggested citation: EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014;12(10):3874, 55 pp., doi:10.2903/j.efsa.2014.3874

Available online: www.efsa.europa.eu/efsajournal

COMMISSION ENDORSEMENT

What: Operator and worker exposure assessment

When: as of Jan 2016

Why no resident and bystander exposure assessment endorsement?



THE GD ON NON-DIETARY EXPOSURE: THE WAY SO FAR

2007

EFSA "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") <http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf>

2010

EFSA Scientific Opinion on preparation of a guidance document on pesticide exposure assessment for workers, operators, bystanders and residents. EFSA Journal 2010;8(2):1501

2011

Request from European Commission (*A working group of risk managers was set up and a meeting took place in Brussels on 11 May 2011 to discuss about the specific questions raised by EFSA opinion*)

2013

First draft of the GD circulated to MSs for commenting

2013

Finalisation of a new model developed by BfR (AOEM)

2013-2014

Revision of the first draft (inclusion of new data)


2014 (April-May)

Public consultation


2014 (October)

PUBLICATION

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

MAIN CONTENTS

- 
- 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

MAIN CONTENTS

- Amount and quality of data?
- Availability of data?
- Selection of scenarios based on?
- Driven by scenarios of concern or data availability?

Exposed category	Database/model
Operator (field)	German model
Operator (field)	UK POEM
Operator (field)	Agricultural operator exposure model (AOEM)
Operator (field)	EUROPOEM II
Operator (field)	PHED
Operator (field)	TNSG Biocides
Amateur	ConsExpo
Amateur	French data
Operator (greenhouse)	Industrieverband Agrar (IVA)–Germany
Operator (greenhouse)	Southern Europe
Operator (greenhouse)	Dutch
Operator (seed treatment)	SeedTropex
Worker	EUROPOEM II
Worker	German
Worker (fork lift driver, sowing)	SeedTropex
Worker	Transfer coefficient
Residents and bystanders	EUROPOEM II
Residents and bystanders	BREAM (Resident and Bystander Exposure Assessment Model)
Residents and bystanders	ConsExpo
Residents and bystanders	Lloyd and Bell 1983 and 1987 (spray drift values)
Residents and bystanders	CRD 2008
Residents and bystanders	California EPA
Residents and bystanders	Ganzelmeier spray drift data
Residents and bystanders	BfR 2008



MAIN CONTENTS

A further challenge was the analysis and harmonisation of default values to be used in the calculator

In particular for:

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

CHALLENGES: 5

Finally, everything had to be included in a user-friendly calculator!

Substance name	<input type="text"/>	
Product name	<input type="text"/>	
Reference value non acutely toxic active substance (RVNAS)	<input type="text"/>	mg/kg bw/day
Reference value acutely toxic active substance (RVAAS)	<input type="text"/>	mg/kg bw/day
Crop type	<input type="text"/>	
Substance properties		
Formulation type	<input type="text"/>	
Minimum volume water for application (liquids)	<input type="text"/>	L/ha
Maximum application rate of active substance	<input type="text"/>	kg a.s. /ha
50% Dissipation Time DT50	<input type="text" value="30"/>	days
Initial Dislodgeable Foliar Residue	<input type="text" value="3"/>	µg/cm ² of foliage/kg a.s. applied/ha
Dermal absorption of product	<input type="text" value="100.00%"/>	
Dermal absorption of in-use dilution	<input type="text" value="100.00%"/>	
Oral absorption of active substance	<input type="text" value="100.00%"/>	
Inhalation absorption of active substance	<input type="text" value="100.00%"/>	
Vapour pressure of active substance	low volatile substances having a vapour pressure of <math><5 \cdot 10^{-3}</math>Pa	
Scenario		
Indoor or Outdoor application	<input type="text"/>	
Application method	<input type="text"/>	
Application equipment	<input type="text"/>	
Buffer strip	<input type="text" value="2-3"/>	m
Number of applications	<input type="text" value="1"/>	
Interval between multiple applications	<input type="text" value="365"/>	days
Season (upward spraying orchards only)	<input type="text" value="not relevant"/>	



TECHNICAL REPORT

Outcome of the Public Consultation on the draft EFSA Guidance Document on the Assessment of Exposure for Operators, Workers, Residents and Bystanders in Risk Assessment for Plant Protection Products¹

European Food Safety Authority^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA was asked by the Commission, 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 Operators, Workers, Residents and Bystanders. This Guidance is designed to assist risk assessors and applicants when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products.

© European Food Safety Authority, 2014

KEY WORDS

exposure, operator, worker, bystander, resident, plant protection products, estimation, guidance, calculator

¹ On request from European Commission, Question No EFSA-Q-2014-00081, approved on 17 October 2014.

² Correspondence: pesticides.ppr@efsa.europa.eu


³ Acknowledgement: EFSA wishes to thank the members of the Working Group on the operator, worker, resident and bystander exposure assessment: Claudia Grosskopf (as of September 2013), Paul Y Hamey, Kyriaki Machera, Sabine Martin, Walter Steurbaut for the preparatory work on this scientific output, the hearing expert: Georgina Downs, and EFSA staff: Lena Elisabeth Jacobi (until October 2012), Jane Richardson, Istvan Sebestyén (until May 2012), Hans Steinkellner (until April 2014) and Manuela Tiramani for the support provided to this scientific output.



MAIN CONTENTS

- 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)

OPERATOR EXPOSURE

- 
- So far, models established over 20 years ago (e.g. UK POEM, German model) have been the standards
 - A new predictive model for the estimation of agricultural operator exposure has been developed (AOEM, Großkopf 2012) on the basis of new exposure data to improve the current agricultural operator exposure and risk assessment in the EU
 - For the assessment of operator exposure, the 75th percentile was considered appropriate (in addition, a model based on the 95th percentile was developed for future use). The model includes application techniques and scenarios for outdoor treatment of low and high crops, by vehicle-mounted/trailed or self-propelled sprayers or by hand-held spray guns and knapsack sprayers
 - Further models are available (adapted from EFSA PPR Panel, 2010) covering partly additional scenarios (e.g. granular application)

HECTARES PER DAY

Crops	Area treated per day (ha)	
	Hand-held equipment ^(a)	Vehicle-mounted equipment
Bare soil ^(b)	4/1	50
Berries and other small fruits (low)	4/1	50
Brassica vegetables	4/1	50
Bulb vegetables	4/1	50
Cane fruit	4/1	10
Cereals	4/1	50
Citrus fruit	4/1	10
Fruiting vegetables	4/1	50
Golf course turf or other sports lawns	4/1	50
Grassland and lawns	4/1	50
Grapes	4/1	10
Hops	4/1	10
Leaf vegetables and fresh herbs	4/1	50
Legume vegetables	4/1	50
Oilfruits (high crops)	4/1	10
Oilseeds	4/1	50
Ornamentals	4/1	10
Pome fruit	4/1	10
Root and tuber vegetables	4/1	50
Stone fruit	4/1	10
Tree nuts	4/1	10

•Hectares treated per day:

(a): The first value should be used for hand-held application using tank sprayers with lances and the second value for other equipment (e.g. knapsack sprayers in low or high crops); for upwards spraying with hand-held equipment on dense foliage (late season), the area treated is 1 ha.

(b): In the exposure calculator (see Appendix E) there are no specific data on bare soil; however, it was considered that for spraying application downwards on soil (e.g. herbicides in pre-emergence) the same data as for application in low crops, tractor mounted, can be used, with the exception that no relevant re-entry exposure is foreseen. Planting activities in a bare soil are not covered by the present Guidance.


DEFAULT PERSONAL PROTECTIVE EQUIPMENT (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

WORKER EXPOSURE

- 
- Exposure of workers must be estimated for activities that involve contact with treated crops. Such contact may occur when workers re-enter treated areas after application of a PPP
 - The underlying studies for the worker exposure model show a high level of uncertainties in terms of quality and reliability of data
 - For the exposure calculator, the longer term exposure was only considered
 - The main routes of exposure during post-application activities are dermal and inhalation, and the sources of exposure are contact with foliage, soil and possibly dust.
 - Oral exposure may occur secondarily to dermal exposure, through hand to mouth transfer. It is generally assumed to be negligible in comparison with that via skin and inhalation
 - The level of resultant exposure (for a given activity) depends on:
 - the amount of residue on foliage
 - the intensity of contact with the foliage
 - the overall duration of contact

WORKER EXPOSURE


- 
- Inhalation exposure may be to vapour and/or airborne aerosols (including dust)
 - After outdoor application of PPPs and after the spray solution has dried, there will be more rapid dissipation of vapour and aerosols, leading to lower inhalation potential than from indoor treatments (where the inhalation route is a relevant route for re-entry workers), such as those made to crops grown in glasshouses
 - Worker exposure estimates for the inhalation route after outdoor applications are only necessary in exceptional cases (e.g. for volatile substances)
 - The default value for time of exposure should be taken as eight hours for harvesting and maintenance type activities and two hours for crop inspection and irrigation-type activities
 - The initial DFR in a first tier assessment should assume 3 μg active substance/cm² of foliage/kg a.s. applied/ha
 - If no data are available on the degree of dissipation, it may be assumed that active substances will dissipate with a half-life of 30 days


Table 1: Transfer coefficients (TCs) (modified from EUROPOEM II (2002) considering US EPA, 2012; for both outdoor and indoor scenarios)

Crop	Nature of task ^(a)	Main body parts in contact with foliage	TC (cm ² /h), total potential exposure	TC (cm ² /h) assuming arms, body and legs covered (workwear; bare hands)	TC (cm ² /h), covered body (workwear) and gloves (PPE)	Applicable for the following crops
Vegetables	Reach/pick	Hand and body	5 800	2 500	580	Brassica vegetables, fruiting vegetables, leaf vegetables and fresh herbs, legume vegetables, bulb vegetables
Tree fruits	Search/reach/pick	Hand and body	22 500	4 500	2 250	Citrus, cane fruits, oilfruits, pome fruits, stone fruits, tree nuts
Grapes ^(b)	Harvesting and other activities (e.g. leaf pulling and tying)	Hand and body	30 000	10 100	No justified proposal possible (data missing)	n.a.
Strawberries	Reach/pick	Hand and forearm	5 800 ^(c)	3 000	750	Berries and other small fruit, low
Ornamentals	Cut/sort/bundle/carry	Hand and body	14 000	5 000	1 400	Ornamentals and nursery
Golf course, turf or other sports lawns	Maintenance	Hand and body	5 800	2 500	580	n.a.
General ^(c)	Inspection, irrigation	Hand and body	12 500 ^(d) 7 500 ^(e)	1 400 ^(d)	No justified proposal possible	Cereals, grassland and lawns, hops, oilseeds, root and tuber vegetables, sugar beets, etc.

- The transfer of residues from the plant surface to the clothes or skin of the worker has to be taken into account
- It is determined by the nature and duration of the activity during re-entry. Therefore, it is possible to group various crop habitats and re-entry activities.
- $TC (cm^2/h) = PDE (mg/h) / DFR (mg/cm^2)$



RESIDENT AND BYSTANDER EXPOSURE

- 
- Limited dataset
 - Four pathways of exposure are considered (EFSA PPR Panel, 2010):
 - spray drift (at the time of application)
 - vapour (may occur after the PPP has been applied)
 - surface deposits
 - entry into treated crops
 - Summing all the exposure pathways, each one being conservative (considering high percentiles of exposure), would result in an overly conservative and unrealistic result. This is particularly true for bystanders, considering that it is extremely unlikely that all exposures occur together. However, for residents, it might be appropriate to sum up the mean exposures from each pathway, where available.
 - For estimating exposure from surface deposits, ground sediments based on drift for application in orchards are taken from Rautmann/Ganzelmeier; for arable crops, respective data are from the BREAM project.
 - Dermal and oral absorption percentages should be taken from the toxicological evaluation. For the dermal absorption percentage (resulting from contact with the spray solution) used for resident and bystander exposure assessment, the value for the in-use dilution should be used, and, for contact with drift deposits, the higher of the two values should be used.

PERSPECTIVES

Data gaps

The WoG highlights the following specific data gaps:

■ Operator:

Seed treatment exposure scenarios, greenhouse exposure scenarios, home and allotment garden exposure scenarios and other minor scenarios are not covered by the Guidance.

Water-soluble bags: the exposure deriving from ML activities is assumed to be 10 % of the corresponding formulation; however further data are needed.

Less experienced operators: no data are available to model these cases (but operators and workers have to be trained)

■ Use of PPE:

A lot still needs to be done for an appropriate application of the proposed factors at the post-marketing level.

PERSPECTIVES

Data gaps

■ Workers:

Available data are not reliable enough to proceed with the acute exposure assessment (in particular with regard to the TC and DFR values); further collection/production of data on specific TC and DFR values is needed to produce more realistic exposure assessments.



PERSPECTIVES

Data gaps

- Residents/bystanders:

Limited dataset!!

No AAOEL derivation methodology yet in place

PERSPECTIVES

EU Projects: e.g. BROWSE


EU organisations: EFSA (e.g. surveys to define representative scenarios, literature search for relevant published papers)

MSs: national initiatives to address specific scenarios (on exposure, on the use of PPE, etc...)

Industry: field studies to address specific scenarios, to refine the current ones

Academia: field studies integrating exposure and health data (see EFSA activity on epidemiology)

Greenhouse: BfR activity



Webinar on the calculation tool annexed to the pesticides guidance document on non-dietary exposure of workers and bystanders to pesticides.

Practical scenarios and Q&A sessions

(no slides available for this part, please refer to the recording)

Speakers: Jane Richardson and Manuela Tiramani - EFSA




Webinar on the calculation tool annexed to the pesticides guidance document on non-dietary exposure of workers and bystanders to pesticides.



Conclusions

Speakers: Jane Richardson and Manuela Tiramani - EFSA

CONCLUSIONS

- 
- The calculator provides a user-friendly tool to run the first tier exposure assessment for operators and workers
 - A large number of scenario is covered however it is not exhaustive: need of new data (missing scenarios)
 - All the existing scenarios can be further refined based on new valid data/specificities
 - Deviations from the model have to be duly and scientifically justified
 - Dataset is more solid for operator and workers

CONCLUSIONS

EFSA APDESK

- If you have not received answer to your question during the webinar, please contact the **EFSA APDESK** through the web form here:

<http://www.efsa.europa.eu/en/applicationshelpdesk/askaquestion?ScientificArea=zero>

- **Pesticides webpage**

<http://www.efsa.europa.eu/en/panels/pesticides>

Thank you very much for attending our webinar!

Please fill out our evaluation form that you will receive at the end of the webinar!



We are looking forward to welcoming you at a future EFSA event!