



28 March 2022
Stakeholder workshop on the
next update of the EFSA
Guidance on Non-Dietary
Exposure to Pesticides

First update of the OPEX Guidance: overview

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Trusted science for safe food



- First Guidance: need of an update
- Second Guidance: what was updated ?
 - Greenhouse scenarios
 - Crop parameters
 - Human parameters
 - New online calculator
- Second Guidance: recommendations for future update

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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}

- scenarios for outdoor uses
- annexed calculator
- recommendations for further research



- **EC Mandate** in 2017 asking EFSA to update the EFSA Guidance and annexed calculator considering new available information



- Open call in 2018 to gather relevant available data



- Limited raw data related to original studies



- Limited topics from EC Mandate could be addressed (revised Terms of Reference)



Open call

General principles:

- ❖ identification of data sources
- ❖ traceability of information
- ❖ criteria for use: including validity and relevance
- ❖ reproducibility of outcomes

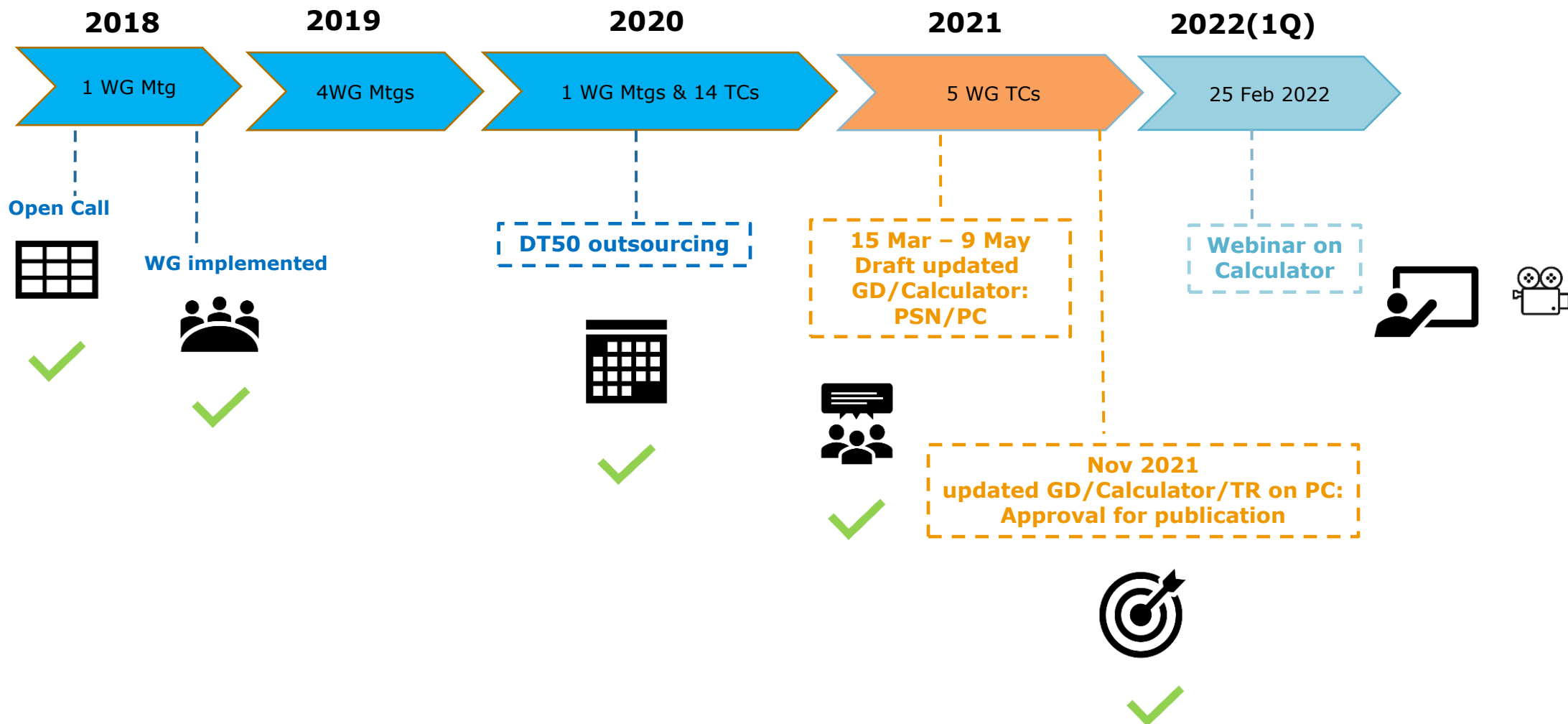


Use of validated databases with supporting raw data



Use of peer reviewed information if indications that a more protective approach was appropriate

First Guidance: need of an update (4)



GUIDANCE DOCUMENT

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

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Second Guidance: what was updated ? (2)

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- Greenhouse scenarios
- Crop parameters
- Human parameters

Second Guidance: what was updated ? (3)

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OPEX

Non-dietary exposure estimation related to the use of plant protection products

Annex E with link to the online **Calculator**

Greenhouse scenarios

OPERATORS

- Data: 10 exposure studies in protected crops
 - (BfR 2015 and 2020)
- Assessment in [Appendix A](#):
 - Quality check
 - Statistical analysis

- Results: 4 models for greenhouse scenarios
 - Hand-held application in low crops
 - Hand-held application in high crops (also trolley)
 - Tank mixing/loading (indoor + outdoor)
 - Knapsack mixing/loading (indoor + outdoor)
- Distinction between dense and normal scenario

WORKERS in greenhouses

- Dermal exposure route based outdoor uses data
- Estimates for exposure by inhalation from 2014 and amended approaches

RESIDENTS / BYSTANDERS close to greenhouses

- Default based on outdoor uses data ([Appendix B](#))
- Estimates for re-entry exposure not relevant

Crop parameters (DFR – DT₅₀)

- **DFR**: analysis of literature reviews ([Appendix C](#) and [Annex B](#))

➔ Default value of 3 µg a.s./cm² foliage/kg a.s. applied/ha is kept

- **DT₅₀** : analysis of literature review (outsourced data extraction based on protocol developed by the WG) ([Appendix D](#) and [Annexes C and D](#))

➔ Default value of 30 days is kept

Crop parameters (TCs)

- Experimental data for removing bolting beet ([Appendix G](#))
- Experimental data for harvesting activities in orchards (peaches) ([Appendix H](#))
 - ➔ New TC values
- Review of EU surveys on worker activities ([Appendix E](#)):
 - ➔ No impact
- Review of US data ([Appendix F](#)):
 - ➔ adoption of more protective values for a few crops (sweet corn, cabbage, turf)

Human parameters

- Inhalation rates
 - ➔ based on recent ECHA & US EPA approaches
- Default surface area of body parts
 - ➔ based on recent ECHA & US EPA approaches
- Personal protective equipment
 - ➔ with reference to certified PPE according to regulatory requirements

Second Guidance: what was updated ? (10)

Safe Use per Crop

The worst case for all substances and all application equipments is selected with minimum necessary protection level to reach an exposure level below the (A)AOEL in the listed scenarios

Generate Report Download Report

Crop









- Low vegetables
 Low vegetables
 Low vegetables
 Low vegetables
 Low berries
 Low ornamentals
 Low vegetables
 Oil fruits
 High vegetables
 Low ornamentals
 Low ornamentals

Season

- Not relevant

Operator

Low vegetables - Short term exposure

Mixing/Loading	Application	Active WPHerb1		
		normal & Vehicle-mounted	normal & Manual-Hand held	normal & Manual-Knapsack
		757	298	160
		287	92.8	26.4
  		46.4	31.4	18.1

Output at d0

Single Scenario

Possibility to select a different scenario (row) from the table above.

PPE	Dermal exposure (mg a.s./day)	Inhalation exposure (mg a.s./day)	Total exposure (mg a.s./day)	Total exposure (mg/kg bw/day)	% of AOEL at day 0	Safe re-entry interval (days)
Total potential exposure	4.2	NA	4.2	0.07	69.6	0
Arm, body and legs covered	1.8	NA	1.8	0.03	30	0
Hands, arm, body and legs covered	0.4	NA	0.4	0.007	7	0
Hands covered, no workwear	NA	NA	NA	NA	NA	NA

- **New calculator** with improved functionalities:
 - Inclusion of GH scenarios
 - Update of mixing/loading data
 - Rounding of coefficients in formulas
 - Inclusion of inhalation exposure
 - Optional calculation of air concentration
 - Inclusion of soil-borne residue approach
 - Pro-rata calculation of dermal absorption
 - Inclusion of safe re-entry period calculation
 - Combined exposure for different active substances in one product
 - Generation of a report with detailed results
 - Including an info-sheet and info bullets for the users

- **Operator** - seed treatments, post-harvest uses, single plant use, paintbrush, home garden uses, and minor scenarios
- **Workers** - data required for acute exposure, vineyard re-entry, sowing treated seed, DBR for cotton harvesting, further data to improve dermal TC database, data for inhalation in greenhouses, good quality DFR & DT50 for evaluation of possible extrapolation between crops and formulations
- **Risk mitigation measures** - data on protection by PPE, technical and engineering controls

- **Bystanders and residents** - updated data/models still required for exposure from use on high crops and sowing treated seed, qualitative and quantitative information on pathways of exposure, and data on human parameters eg inhalation rates and activities for age categories
- **General** - data/information on hand-to-mouth transfer for occupational and other exposures, aggregate and additional combined exposures (multiple products), statistical analysis of small datasets (≥ 10) for acute exposure assessment

- **New calculator**
 - Detailed testing by the WG prior to November publication
 - Wider community extended the range of scenarios, combinations and options tested and provided additional feedback
 - Minor issues that can be easily fixed - intention these will be addressed soon
 - More substantial requests for additional functionality that require more significant input - these will be considered during the next update