Webinar | 20 February 2025

UPDATE OF THE OPEX CALCULATOR FOR NON-DIETARY EXPOSURE TO PLANT PROTECTION PRODUCTS

STARTING AT 15:00 CET

efsa
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The event is in **English**

This event is **being recorded** and the recording will be published on EFSA's website

After the event, attendees will receive a **link to a survey** to evaluate the EFSA's event & services

TODAY'S SPEAKERS & CONTRIBUTORS

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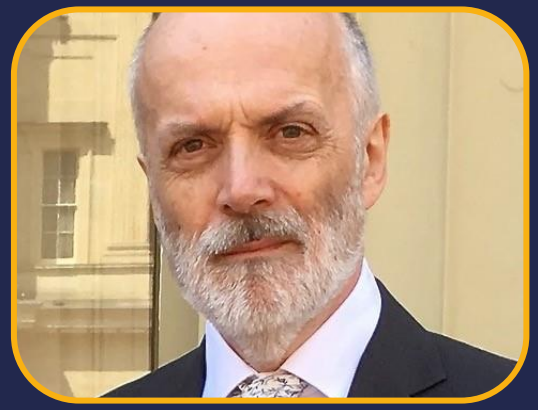
Open Analytics



Paul Hamey
OPEX WG member

AGENDA

Introductory remarks
Arianna Chiusolo

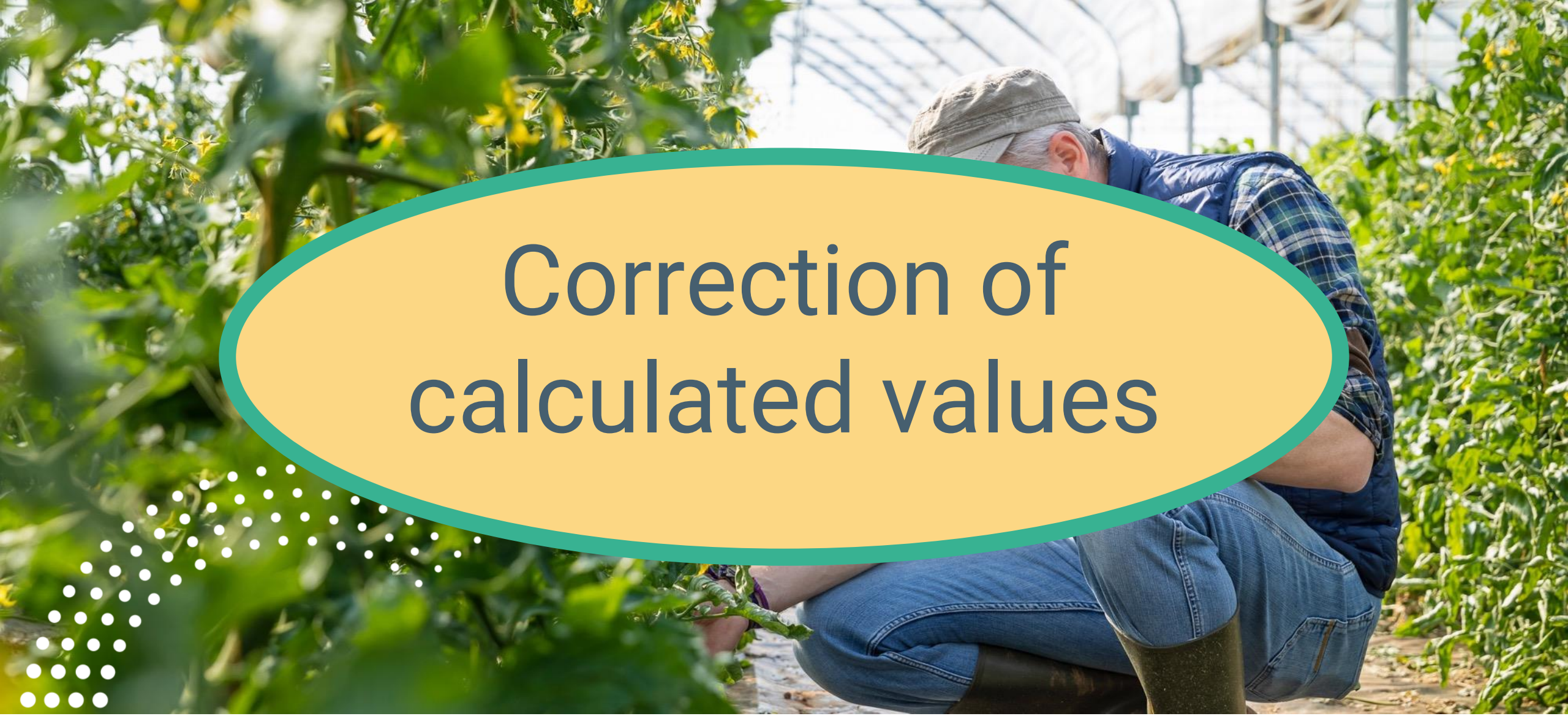
EFSA updated OPEX Calculator
Frederique Istace

EFSA OPEX project
Arianna Chiusolo

Closure of the event
Arianna Chiusolo

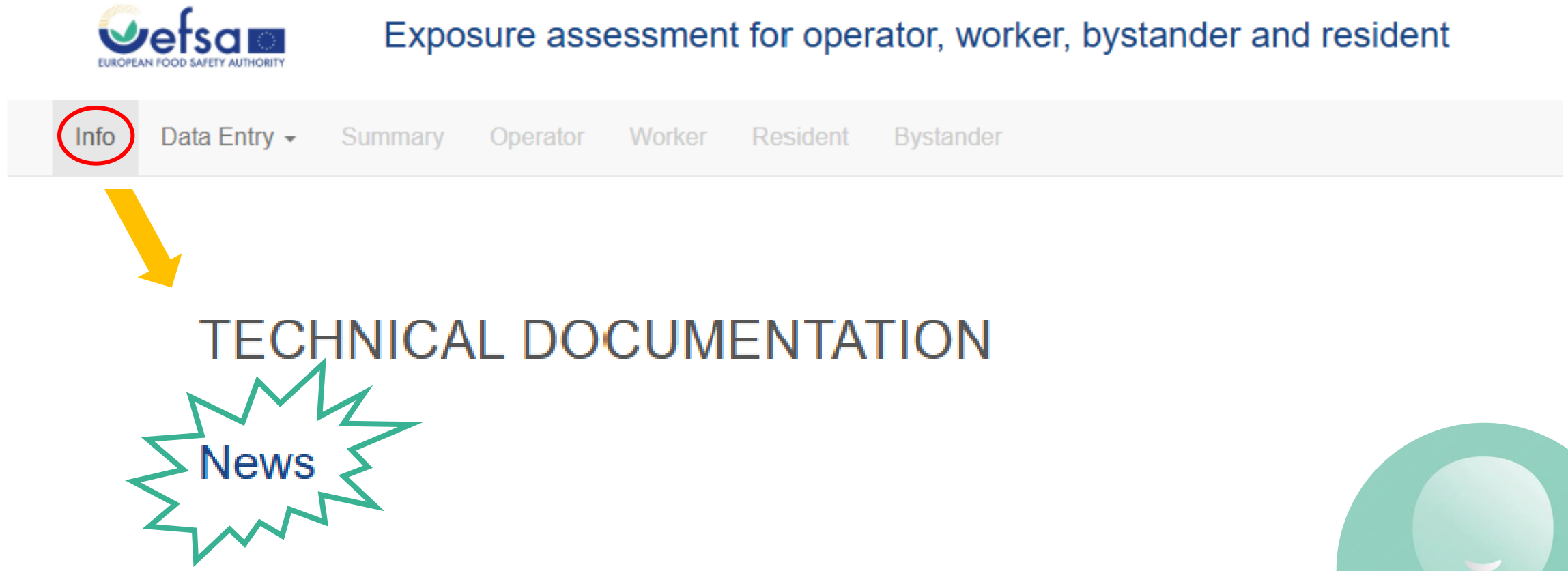
UPDATE OF THE OPEX CALCULATOR

- Operator, worker, resident and bystander exposure assessment
- EFSA guidance(s) and calculator(s)
- Update : Correction of calculated values
- Update: Increased flexibility
- Update: Ad hoc reports



Correction of calculated values

CALCULATOR 2025: CORRECTIONS



CALCULATOR 2025: CORRECTIONS

Examples (V.1.1.0)

- FIX bug: In case of Amenity grassland and the Turf harvesting, cutting and handling activity for worker, the calculation of the safe re-entry interval for combined exposure is now correctly based on the default Turf Transferable Residue (TTR). In previous versions this was wrongly based on default Dislodgeable Foliar Residue (DFR).

- FIX Correction unit TTR in reported tables convert kg/ha into ug/cm2

- Re-entry TC values for strawberries (indoor) and cane fruit for Searching/reaching/picking are corrected.

- Treated area values for vehicle mounted non-arable land are corrected.

- Adjusted calculation of entry into treated crops risk for bystander/resident in bare (non) arable land

CALCULATOR 2025: CORRECTIONS

Examples (V.1.1.1)

- FIX Citrus: add outdoor - dense scenario

- FIX Drift reduction allowed for downward and upward spraying

  - FIX Registration report if no AAOEL specified and single substance
  - FIX Registration report for worker combined results if no results for some PPE

Increased flexibility of the tool

CALCULATOR 2023: INCREASED FLEXIBILITY

- 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

CALCULATOR 2025: INCREASED FLEXIBILITY

Info | Data Entry | Summary | Operator | Worker | Resident | Bystander

Active Substances

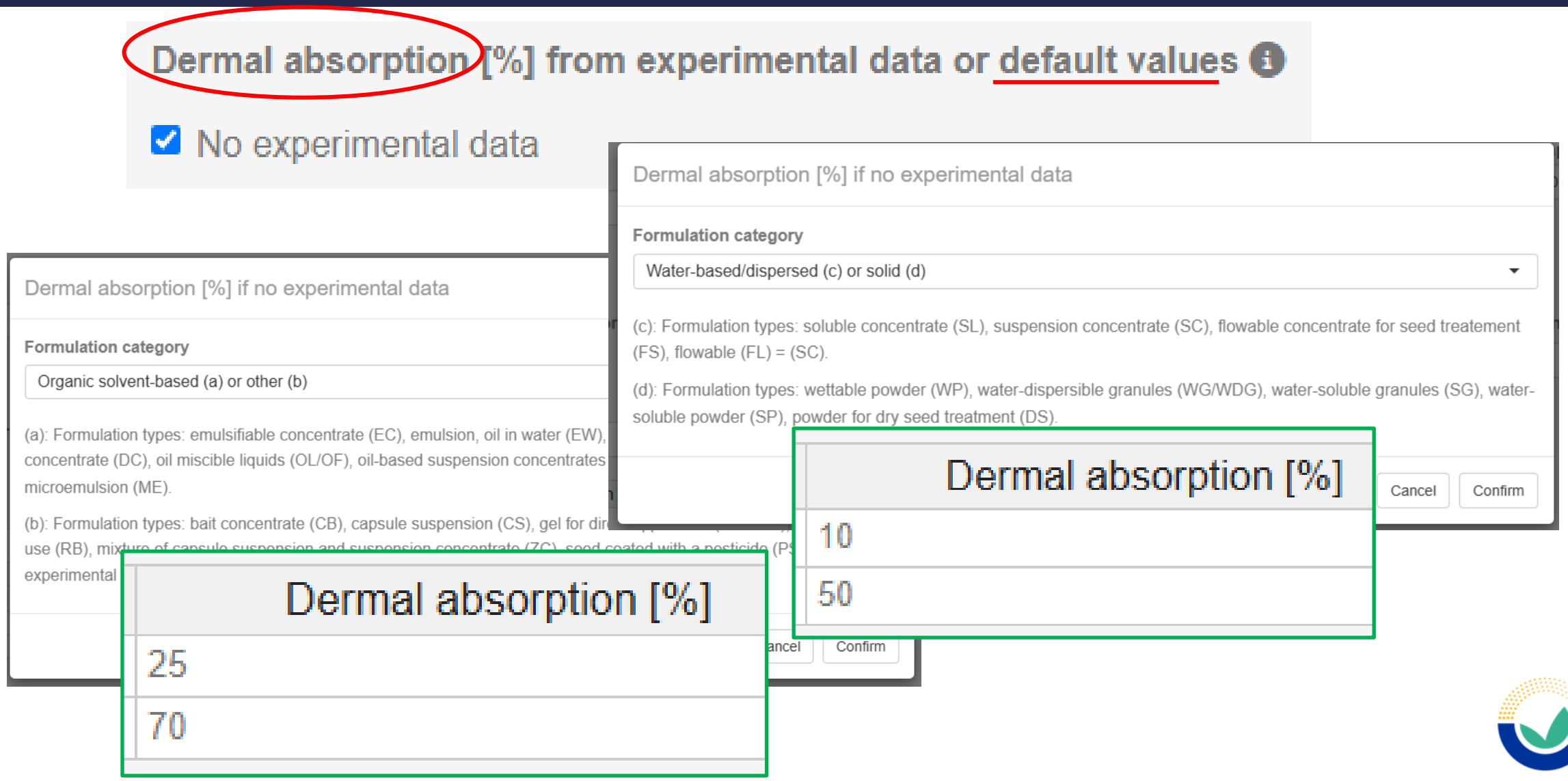
Absorption of the Active Substance

Dermal absorption [%] from experimental data or default values

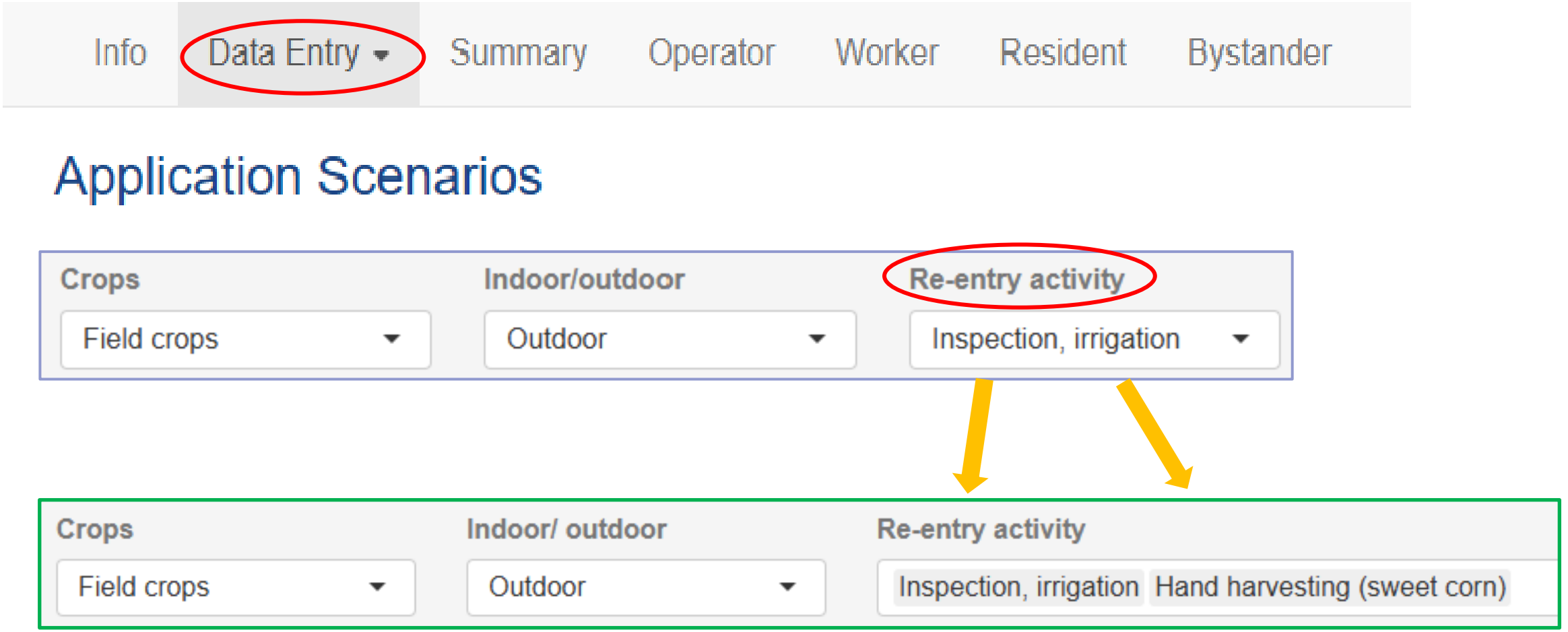
☐ No experimental data

	Concentration [g a.s./l or kg]	Dermal absorption [%]
Concentrate (product)	300	5
Dilution 1 tested	0.3	10
Dilution 2 tested		

CALCULATOR 2025: INCREASED FLEXIBILITY



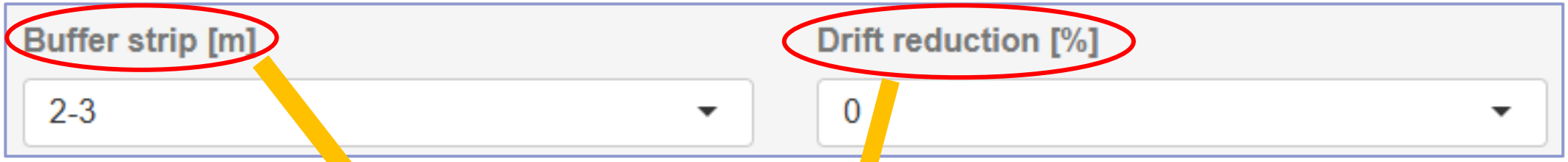
CALCULATOR 2025: INCREASED FLEXIBILITY



CALCULATOR 2025: INCREASED FLEXIBILITY

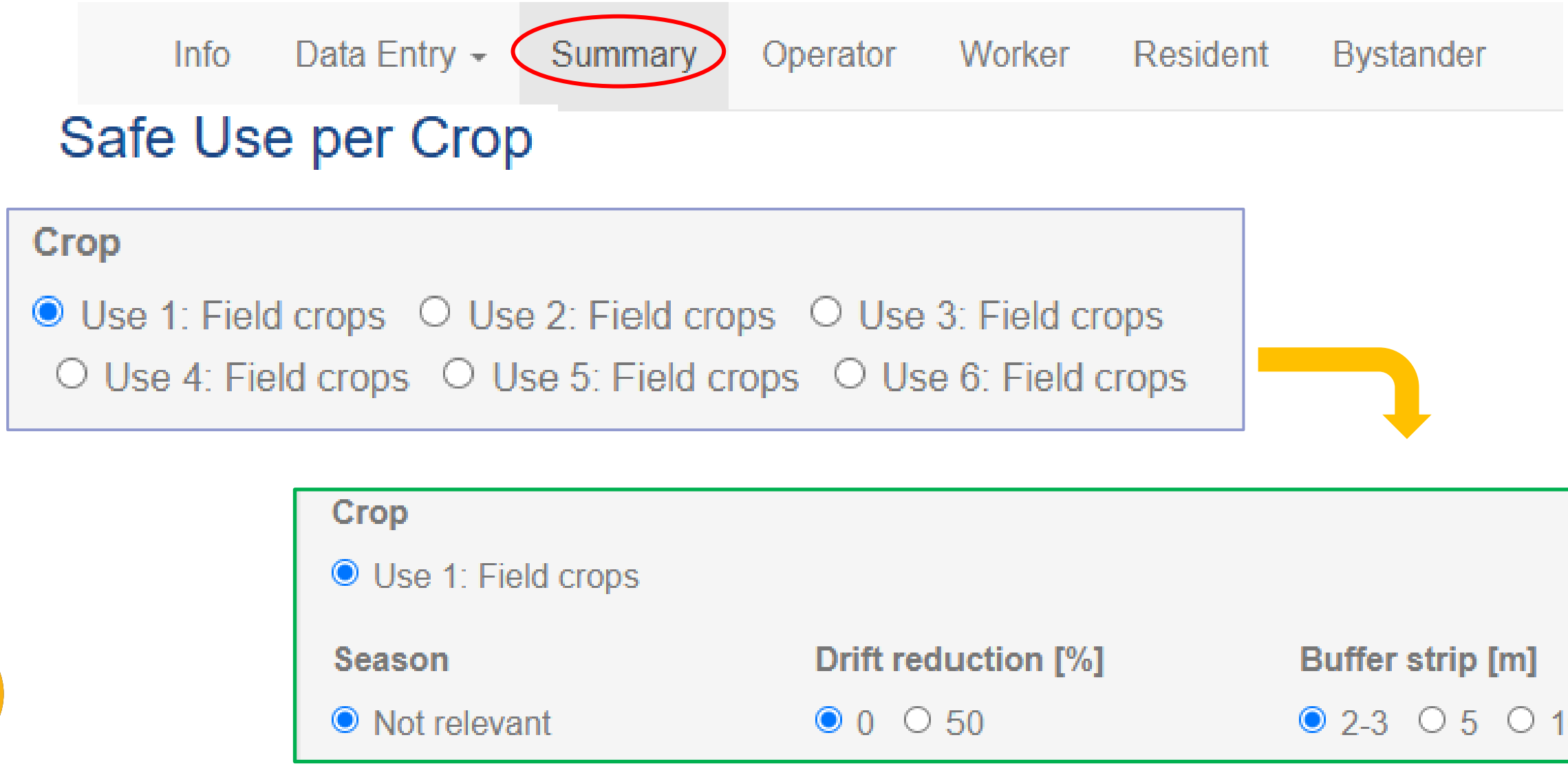
Application Scenarios

Method of Application



Buffer strip [m]	Drift reduction [%]	Include?
2-3	0.00	☑
5	0.00	☐
10	0.00	☐
2-3	50.00	☐
5	50.00	☐
10	50.00	☐

CALCULATOR 2025: INCREASED FLEXIBILITY



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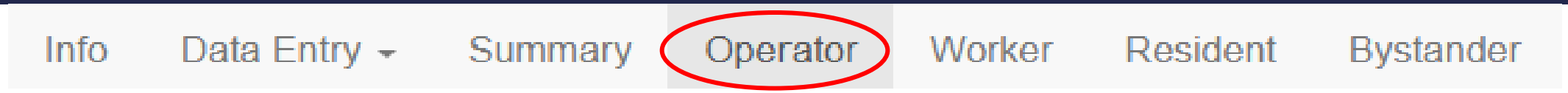


All Combinations of PPE

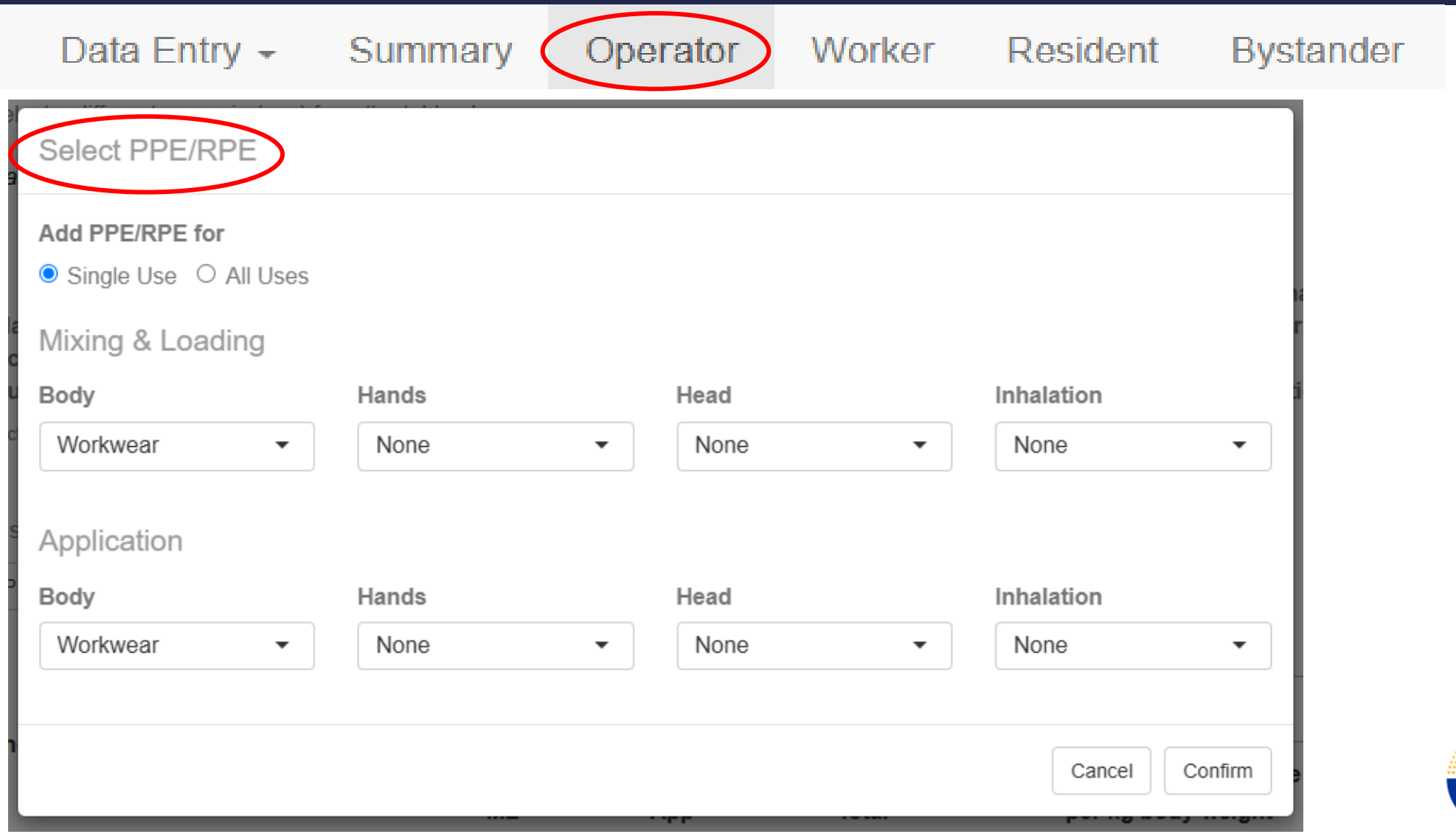
Exposure

◉ Short term (75th percentile) ○ Acute (95th percentile)

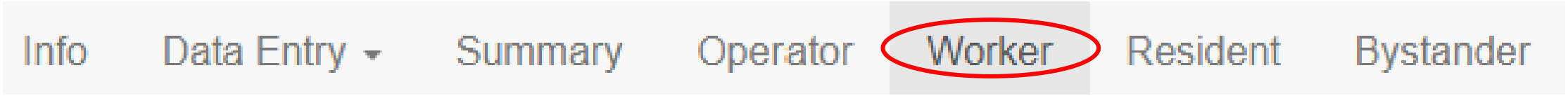
Estimates for using no protection, workwear and least cumbersome safe protection for short term and acute exposure.

+ Add more PPE/RPE × Reset

CALCULATOR 2025: INCREASED FLEXIBILITY



CALCULATOR 2025: INCREASED FLEXIBILITY



Crop

◉ Use 1: Field crops ○ Use 2: Field crops

All Substances

Per Substance | Combined exposure

Active SC1

PPE	Dermal exposure (mg a.s./day)	Inhalation exposure (mg a.s./day)	Total exposure (mg a.s./day)
Total potential exposure	5.8	NA	5.8
Arms, body and legs covered	0.6	NA	0.6
Hands, arms, body and legs covered	0.6	NA	0.6
Hands covered, no workwear	NA	NA	NA

All Scenarios and Combined Exposure (Use 1: Field crops)

Per Substance | Combined exposure

Active SC1

Re-entry activity: Hand harvesting (sweet corn)

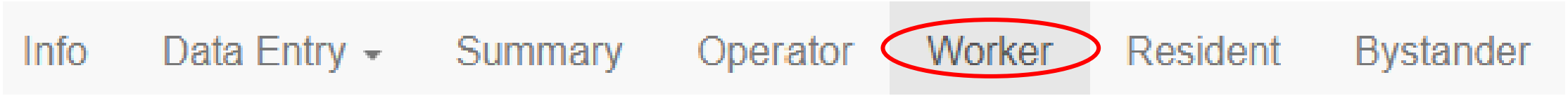
PPE	Dermal exposure (mg a.s./day)	Inhalation exposure (mg a.s./day)	Total exposure (mg a.s./day)
Total potential exposure	NA	NA	NA
Arms, body and legs covered	42.6	NA	42.6
Hands, arms, body and legs covered	NA	NA	NA
Hands covered, no workwear	NA	NA	NA

Active SC1

Re-entry activity: Inspection, irrigation

PPE	Dermal exposure (mg a.s./day)	Inhalation exposure (mg a.s./day)	Total exposure (mg a.s./day)
Total potential exposure	5.8	NA	5.8
Arms, body and legs covered	0.6	NA	0.6
Hands, arms, body and legs covered	0.6	NA	0.6
Hands covered, no workwear	NA	NA	NA

CALCULATOR 2025: INCREASED FLEXIBILITY



Calculation of safe re-entry interval

Output for custom re-entry interval

Re-entry interval [days]

10

PPE	% of AOEL at day 10				Hazard index at day 10	
	Active SC1		Active SC2		Combined exposure	
	Hand harvesting (sweet corn)	Inspection, irrigation	Hand harvesting (sweet corn)	Inspection, irrigation	Hand harvesting (sweet corn)	Inspection, irrigation

CALCULATOR 2025: INCREASED FLEXIBILITY

Info | Data Entry | Summary | Operator | Worker | Resident | Bystander

Crop

◉ Use 1: Field crops ○ Use 2: Field crops ○ Use 3: Field crops
○ Use 4: Field crops ○ Use 5: Field crops ○ Use 6: Field crops

Crop

◉ Use 1: Field crops

Season	Drift reduction [%]	Buffer strip [m]
◉ Not relevant	◉ 0 ○ 50	◉ 2-3 ○ 5 ○ 10

CALCULATOR 2025: INCREASED FLEXIBILITY

Info | Data Entry | Summary | Operator | Worker | Resident | Bystander

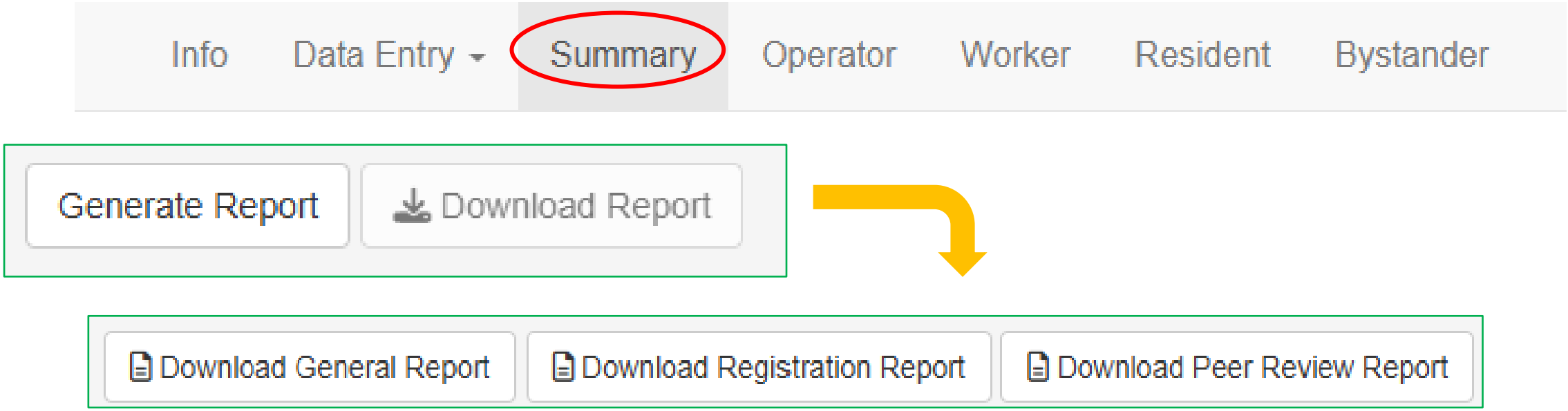
All Scenarios and Combined Exposure (Use 1: Field crops)

Active SC1

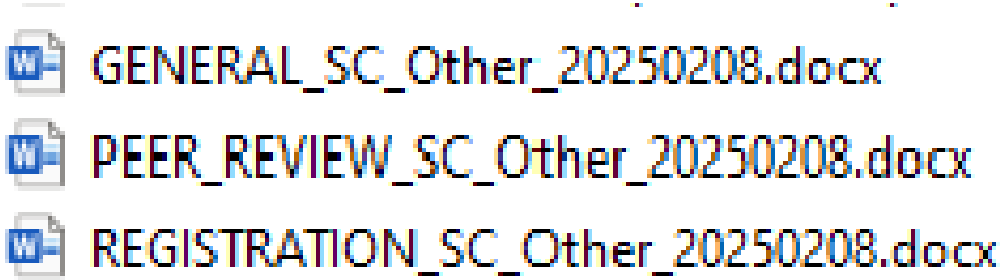
- Season: Not relevant | Buffer strip [m]: 2-3 | Drift reduction [%]: 0
- Season: Not relevant | Buffer strip [m]: 5 | Drift reduction [%]: 0
- Season: Not relevant | Buffer strip [m]: 10 | Drift reduction [%]: 0
- Season: Not relevant | Buffer strip [m]: 2-3 | Drift reduction [%]: 50
- Season: Not relevant | Buffer strip [m]: 5 | Drift reduction [%]: 50
- Season: Not relevant | Buffer strip [m]: 10 | Drift reduction [%]: 50

Generation of ad hoc reports

CALCULATOR 2025: AD HOC REPORTS



3 reports can be generated



CALCULATOR 2025: AD HOC REPORTS

General report

Exposure assessment for operator, worker, resident and bystander

Product: SC Other

OPEX version: 1.1.0

08 February 2025

3. Operator

3.1. Use 1 : Field crops (Outdoor - Drift reduction [%] 0)

Short term exposure

Mixing/loading	Application	Active SC1 (% AOEL) Normal & vehicle-mounted	Active SC2 (% AOEL)	Combined (hazard index)
		**67.7**	677	7.44
		43.4	434	4.78
		5.3	**52.6**	**0.578**

4. Worker

4.1. Use 1 : Field crops (Outdoor)

4.1.1. Scenario 1 : Hand harvesting (sweet corn)

	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
			Hand harvesting (sweet corn); Outdoor Work rate: 8 hours/day ; Interval: 7 days ; Body weight: 60 kg TC (potential): NA cm²/h TC (workwear (arms, body and legs covered)): 23000 cm²/h TC (workwear (arms, body and legs covered) and gloves): NA cm²/h TC (gloves): NA cm²/h	
	Active SC1		Application rate: 3 x 0.3 kg a.s./ha Dermal absorption: 10 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
	Workwear	0.7	709	85

5. Resident

5.1. Use 1 : Field crops (Outdoor)

5.1.1. Scenario 1 : Season not relevant, drift reduction 0 [%] buffer strip 2-3 [m]

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:7 days; Minimum volume of water: 200 l			
Active SC1		Application rate: 3 x 0.3 kg a.s./ha Dermal absorption: 10 % DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.004	4.1
	Vapour (75th perc.)	0.0008	0.8
	Deposits (75th perc.)	0.002	1.7
	Re-entry (75th perc.)	0.01	13
	Sum (mean)	0.01	14.7
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.001	1
	Vapour (75th perc.)	0.0003	0.3
	Deposits (75th perc.)	0.0005	0.5
	Re-entry (75th perc.)	0.007	7.2
	Sum (mean)	0.007	6.9

7. Appendix

CALCULATOR 2025: AD HOC REPORTS

Peer Review report

1. OPERATOR

1.1. Active SC1

Application method	PPE/RPE*	%AOEL	%AAOEL
SC_Other *Use 1: Field crops, Outdoor, 3 x 0.3kg a.s./ha, 200-1000 L water/ha* *Model: EFSA Opex (v1.1.0) results expressed as % of AOEL (short term exposure) or % of AAOEL (acute exposure)*			
Vehicle-mounted, Downward spraying, drift reduction: 0%, crop density: normal	MLA: Workwear	43.4	37.6
Vehicle-mounted, Downward spraying, drift reduction: 50%, crop density: normal	MLA: Workwear	41.2	33.3

*PPE/RPE: personal protective equipment/respiratory protective equipment

2. WORKER

2.1. Active SC1

Re-entry task	PPE	%AOEL
SC_Other *Use 1: Field crops, Outdoor, 3 x 0.3kg a.s./ha, 200-1000 L water/ha* *Model: EFSA Opex (v1.1.0) exposure estimates as % of AOEL (short term exposure)*		
Hand harvesting (sweet corn)	Workwear	709
Inspection, irrigation	Workwear	10.8

3. RESIDENT and BYSTANDER

3.1. Active SC1

Exposure pathway	Spray drift	Vapour	Surf. deposits	Entry	All pathways (mean)
SC_Other *Use 1: Field crops, Outdoor, 3 x 0.3kg a.s./ha, 7-day interval* *Season: Not relevant, Buffer 2-3 m, Drift reduction 0 %* *Model: EFSA Opex (v1.1.0) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)*					
Resident child	4.1	0.8	1.7	13	14.7
Resident adult	1	0.3	0.5	7.2	6.9
Bystander child	1.9	0.2	1	2.6	
Bystander adult	0.5	0.05	0.3	1.4	
Use 1: Field crops, Outdoor, 3 x 0.3kg a.s./ha, 7-day interval *Season: Not relevant, Buffer 5 m, Drift reduction 0 %* *Model: EFSA Opex (v1.1.0) results expressed as % of AOEL (short term exposure for residents) or % of AAOEL (acute exposure for bystanders)*					
Resident child	2.7	0.8	0.7	13	13.2
Resident adult	0.5	0.3	0.2	7.2	6.5
Bystander child	1.2	0.2	0.4	2.6	
Bystander adult	0.2	0.05	0.1	1.4	

CALCULATOR 2025: AD HOC REPORTS

Registration report

3. WORKER

3.1. Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 3 x 0.3kg a.s./ha, 200-1000 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.0

3.2. Estimated worker exposure (acute exposure)

3.2.1. Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Re-entry restriction [days]
Hand harvesting (sweet corn); Outdoor ; Work rate: 8 hours/day ; Interval: 7 days							
		Active SC1			Active SC2		
		Application rate: 3 x 0.3 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days			Application rate: 3 x 0.3 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		
Body weight: 60 kg	Workwear TC: 23000 cm²/h/person	0.7	709	85	0.7	7093	185

2. OPERATOR

2.1. Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 3 x 0.3kg a.s./ha, 200-1000 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.0

2.2. Estimated operator exposure (acute exposure)

2.2.1. Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL
Field crops/Outdoor/Downward spraying/Vehicle-mounted/Drift reduction: 0%/95th percentile Crop density: Normal						
	Active SC1			Active SC2		
Spray application	Application rate: 3 x 0.3 kg a.s./ha			Application rate: 3 x 0.3 kg a.s./ha		
(EFSA; 95th percentile) Body weight: 60 kg	M/L: Potential exposure App: Potential exposure	0.4	81.2	M/L: Workwear App: Workwear	0.2	No safe use (376)

Model data	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL	Level of PPE	Total absorbed dose [mg/kg bw]	% of systemic AAOEL
	M/L: Workwear App: Workwear	0.2	37.6	M/L: Workwear + Protected hands App: Workwear	0.04	80.8

4. RESIDENT and BYSTANDER

4.1. Exposure models for intended uses

Critical use(s)	Use 1: Field crops, 3 x 0.3kg a.s./ha, 200-1000 L water/ha
Model(s)	Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products. EFSA Journal 2022;20(1):7032 calculator version: opex 1.1.0

4.2. Estimated resident exposure (short term exposure)

4.2.1. Use 1: Field crops

Model data	Level of PPE	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL	Total absorbed dose [mg/kg bw per day]	% of systemic AOEL
Outdoor; Season:Not relevant; Buffer zone:2-3m; Drift reduction:0%; Interval between treatments:7 days					
		Active SC1		Active SC2	
		Application rate: 3 x 0.3 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days		Application rate: 3 x 0.3 kg a.s./ha DFR: 3 µg/cm² foliage per kg a.s./ha DT50: 30 days	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.004	4.1	0.004	40.8
	Vapour (75th perc.)	0.0008	0.8	0.0008	8
	Deposits (75th perc.)	0.002	1.7	0.002	17.5
	Re-entry (75th perc.)	0.01	13	0.01	130
	Sum (mean)	**0.01**	**14.7**	**0.01**	**147**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.001	1	0.001	9.7
	Vapour (75th perc.)	0.0003	0.3	0.0003	2.7
	Deposits (75th perc.)	0.0005	0.5	0.0005	5.3
	Re-entry (75th perc.)	0.007	7.2	0.007	72.3
	Sum (mean)	**0.007**	**6.9**	**0.007**	**68.7**

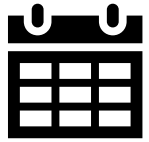
ONGOING UPDATE OF THE OPEX GUIDANCE/CALCULATOR

- Stakeholders' workshop – **March 2022**

Identification of **priorities** (**Seed, R&B, W**)

- **Raw data collection** through dedicated webpage **and FMB** (Pesticides_NDE@efsa.europa.eu)
- **Data analysis** outsourced to ART36 consortium (**GP/EFSA/PREV/2022/02**)-modular approach (3WPs-18 deliverables)

- **Working Group** of experts to implement regulatory changes in the OPEX Guidance/Calculator
- Mandate (M-2023-00066) **timelines**:
  - **Seed**: PC by 4Q2025 & finalisation by 2Q2026 (*current plan*)
  - **R&B, W**: PC by 1Q2027 & finalisation by 4Q2027
  - Stakeholders' event by 1Q2028



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