

WEBINAR:

OPEX calculator for nondietary exposure to plant protection products





Agenda and contributors



TIME	ITEM
11:00 - 11:05	Introduction and webinar outline
11:05 - 12:05	Overview of the OPEX Calculator
	functionalities
12:05 - 12:15	Q&A session and conclusion

Speaker: Arianna Chiusolo (EFSA)

Speaker: Frederique Istace (EFSA)

Speaker: Mathilde Colas (EFSA)

Contributors: José Cortinas Abrahantes (EFSA), Dagmar Bemelmans (ext), Denise Bloch (ext), Sabine Martin (ext), Paul Hamey (ext), Peter Craig (ext)

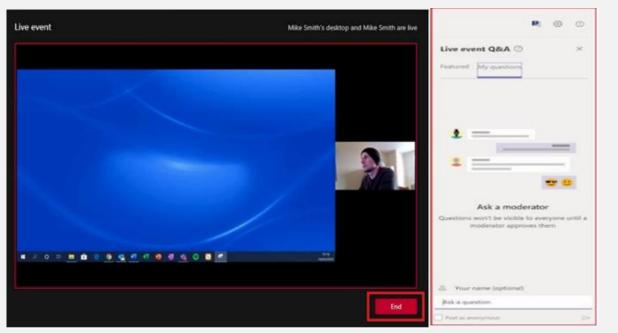
Webinar guide for attendees



- This webinar is being recorded
- The webinar **is in English** and questions should be submitted in English through the platform.
- You are automatically connected to the audio broadcast. One-way audio (listen only mode).

Presentation window



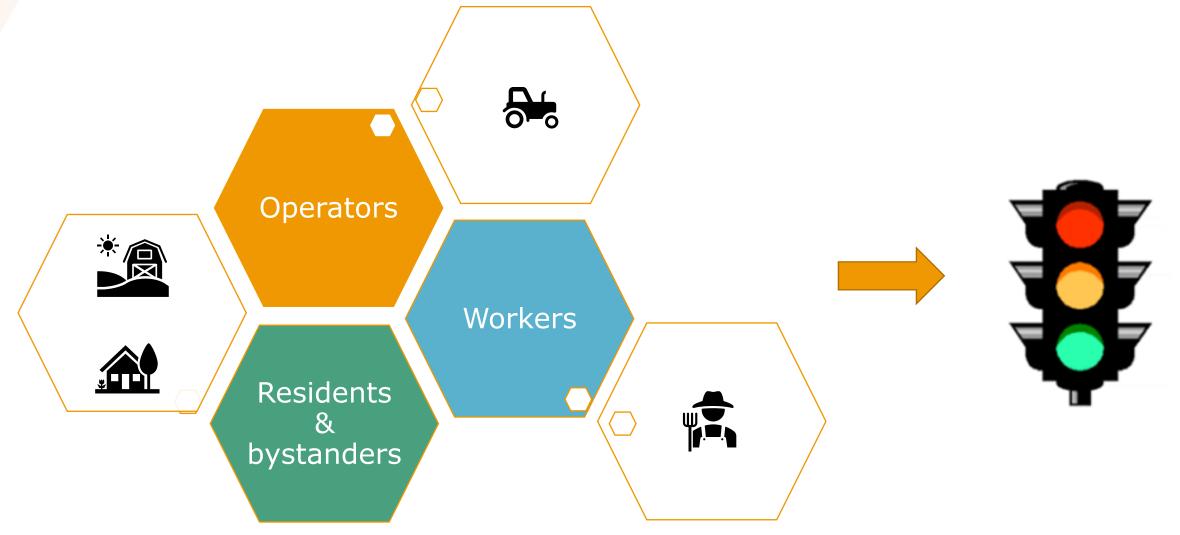




Q&A box: For any questions related to the topic or unexpected IT issues

OPEX online calculator





Background (1)



- First <u>EFSA Guidance</u> 'on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products' 2014
 - Excel calculator: scenarios for outdoor uses, and for worker re-entry in greenhouses, including different risk mitigation measures (e.g. protective equipment, technical equipment, buffer zones)
 - First EU validated approaches for non-dietary exposure assessment

Background (2)



- Update of EFSA Guidance (...) 2022
 - Including greenhouse scenarios
 - Including a revision of crop and human parameters
 - Offering a new online calculator
 - With improved functionalities
 - With a manual of formulas used in the calculations
 - With an impact assessment in Annex E of the Guidance

New calculator: how to access (1)



Link on EFSA website:

https://www.efsa.europa.eu/en/efsajournal/pub/7032



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



New calculator: how to access (2)





Guidance Document | ₫ Open Access | ⓒ • 😑

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

European Food Safety Authority (EFSA) . Agathi Charistou, Tamara Coja, Peter Craig, Paul Hamey, Sabine Martin, Olivier Sanvido, Arianna Chiusolo, Mathilde Colas, Frédérique Istace

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Requestor: European Commission **Question number:** EFSA-Q-2018-00274

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Update: This scientific output, approved on 30 November 2021, supersedes the previous output published on 24 April 2015 (EFSA Guidance, 2014). The European Commission will decide the implementation time for the mandatory use of this guidance in the regulatory context.

Declarations of interest: The declarations of interest of all scientific experts active in EFSA's work are available at https://ess.efsa.europa.eu/doi/doiweb/doisearch.

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Adopted: 30 November 2021





Abstract

Summary

1 Introduction

2 Assessment

3 Conclusions and recommendations

Supporting information

References

Abbreviations

Glossary

Appendices A to J

Annexes A to G

New calculator: how to access (3)



Supporting Information Filename Description efs27032-sup-0001-Annex_A.docx Word 2007 CIPAC formulation codes document, 95.2 KB Public literature on dislodgeable foliar residue efs27032-sup-0002-Annex_B.docx Word 2007 document . 125.5 KB efs27032-sup-0003-Annex C.docx Word 2007 Protocol for the review of relevant DT studies document, 109.6 KB efs27032-sup-0004-Annex_D.xlsx E DT Data collection spreadsheet, 132 KB efs27032-sup-0001-Annex_E.docx Word 2007 New calculator document, 597.8 KB efs27032-sup-0006-Annex F.docx Word 2007 Table overview open call document, 138.5 KB efs27032-sup-0007-Annex_G.docx Word 2007 Outcome of Public Consultation on the draft EFSA document, 358.5 KB Guidance

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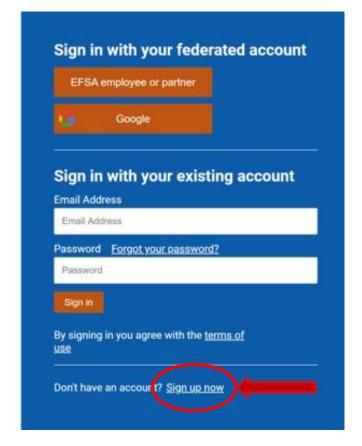
ANNEX E:

First access to the calculator: https://r4eu.efsa.europa.eu/



Welcome to R4EU

By signing in you will access the EFSA R4EU platform, hosting a suite of different models commonly used in assessments by EFSA.



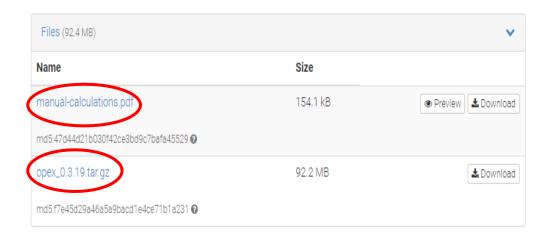
New calculator: how to access (4)

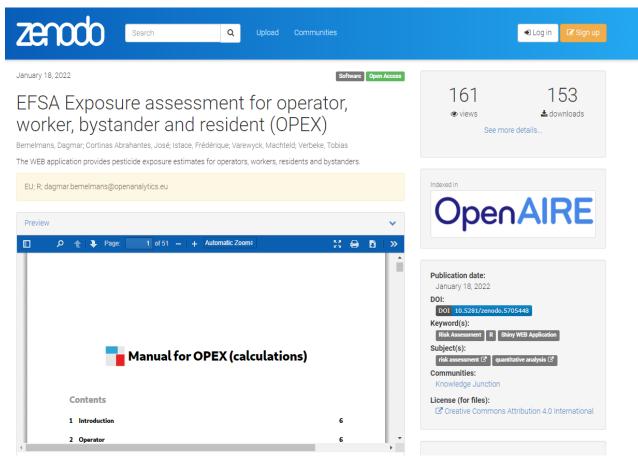


ANNEX E:

• Access to the manual with the formulations (and R-package):

www.doi.org/10.5281/zenodo.5705448







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2.1.1.1.2 95th percentile

Mixing & loading

```
\begin{split} \log(\mathsf{Hands}) &= 3.74 + 0.69 \log(\mathsf{TA}) + 0.71 [\mathsf{SC}] + 1.21 [\mathsf{WP}] \\ \log(\mathsf{Protected hands}) &= 3.29 + 0.53 \log(\mathsf{TA}) + 0.83 [\mathsf{SC}] + 1.39 [\mathsf{WP}] \\ \log(\mathsf{Body}) &= 3.87 + 0.69 \log(\mathsf{TA}) + 0.72 [\mathsf{SC}] + 1.29 [\mathsf{WP}] \\ \log(\mathsf{Protected body}) &= 2.09 + 0.78 \log(\mathsf{TA}) + 0.44 [\mathsf{SC}] + 1.58 [\mathsf{WP}] \\ \log(\mathsf{Head}) &= 2.19 + 1.00 \log(\mathsf{TA}) + 0.39 [\mathsf{SC}] + 0.11 [\mathsf{WP}] - 1.16 [\mathsf{Faceshield}] \\ \log(\mathsf{Inhalation}) &= 1.81 + 0.49 \log(\mathsf{TA}) - 0.92 [\mathsf{SC}] + 1.54 [\mathsf{WP}] \end{split}
```

If water soluble bags are used, take 10% of the result for all body parts.

Application

$$\begin{split} \log(\mathsf{Hands}) &= 2.96 + 0.73 \log(\mathsf{TA}) + 0.61 [\mathsf{Droplets = Normal}] - 0.21 [\mathsf{Equipment = Normal}] \\ \log(\mathsf{Protected hands}) &= -0.46 + 0.12 \log(\mathsf{TA}) + 1.79 [\mathsf{Droplets = Normal}] + 2.19 [\mathsf{Equipment = Normal}] \\ \log(\mathsf{Body}) &= 1.94 + 1.00 \log(\mathsf{TA}) + 1.51 [\mathsf{Droplets = Normal}] - 0.82 [\mathsf{Equipment = Normal}] \\ \log(\mathsf{Protected body}) &= 0.47 + 1.00 \log(\mathsf{TA}) + 1.05 [\mathsf{Droplets = Normal}] - 0.77 [\mathsf{Equipment = Normal}] \\ \log(\mathsf{Head}) &= 1.16 + 1.00 \log(\mathsf{TA}) + 1.03 [\mathsf{Droplets = Normal}] - 1.12 [\mathsf{Equipment = Normal}] \\ \log(\mathsf{Inhalation}) &= 1.27 + 0.58 \log(\mathsf{TA}) + 0.33 [\mathsf{Droplets = Normal}] - 1.14 [\mathsf{Equipment = Normal}] \\ \end{split}$$

If area treated [ha/day] is smaller than or equals to 10, use small area equipment. Otherwise use normal equipment.

If there is any drift reduction, the droplets are coarse. Otherwise the dorplets are considered normal.

2.4 Final step

At this point, the user should have results for six different body parts for both mixing & loading and application (hand, protected hands, body, protected body, head and inhalation). To make the distinction clear, the results from mixing & loading are indicated by "(M/L)" and the results from application are indicated by "(App)". This section applies to both solubles and granules.



- Correction for absorption (dermal and inhalation)
- Correction for additional protection (PPE/RPE)
- Sum up for M/L and App and comparison to (A)AOEL



. 31 31 31 31 31 31 31 32 32 32 33 33 33 33 33 33 34 34 34 34 34

30

3	Woi	rker		25	4 Resident
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	٠.٠	Jaie	e-endy intervace.	23	5 Bystander

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6 Appendix

		Crop type	activity	activityTSF	hours bodyPrts	TCUCV	TcCV1	TcCV2	TcCV3	indoor category	TSF
.1 Glossa .2 Worke	er table	Cane fruit/High berries	Inspection, irrigation	Inspection, watering	2 Hand; body	12,500	1,400	1,250		1 both	0.01
	ent & bystander tables	Field crops	Inspection, irrigation		2 Hand; body	12,500	1,400	1,250		1	
6.3.1	Spray drift: Dermal spray drift exposure	Field crops	Hand harvesting (Only sweet	1	8 Hand; body		23,000			1	
	6.3.1.1 50th percentile		corn)								
	6.3.1.2 Sth percentile	High	Cutting, sorting, bundling, carrying	including cutting and	8 Hand; body	14,000	5,000	1,400		1 other	0.10
	6.3.1.3 95 percentile			bundling							
6.3.2	Surface deposit Drift percentage	High ornamentals	Cutting, sorting, bundling, carrying	Harvesting, including cutting and bundling	8 Hand; body	14,000	5,000	1,400		1 herbicide	0.01

6.3.1 Spray drift: Dermal spray drift exposure

6.3.1.1 50th percentile

Application Method	Buffer Strip (m)	Adults Dermal Spray Drift Exposure	Children Dermal Spray Drift Exposure	Adults Inhalation Spray Drift Exposure	Children Inhalation Spray Drift Exposure		
Downward Spraying	2-3	0.22	0.18	0.00011	0.00012		
Downward Spraying	5	0.12	0.12	9e-05	1e-04		
Downward Spraying	10	0.11	0.1	8e-05	8e-05		
Upward Spraying	2-3	NA	NA	NA	NA		
Upward Spraying	5	3.68	1.11	0.0017	0.00083		
Upward Spraying	10	3.68	1.11	0.0017	0.00083		

NEW CALCULATOR







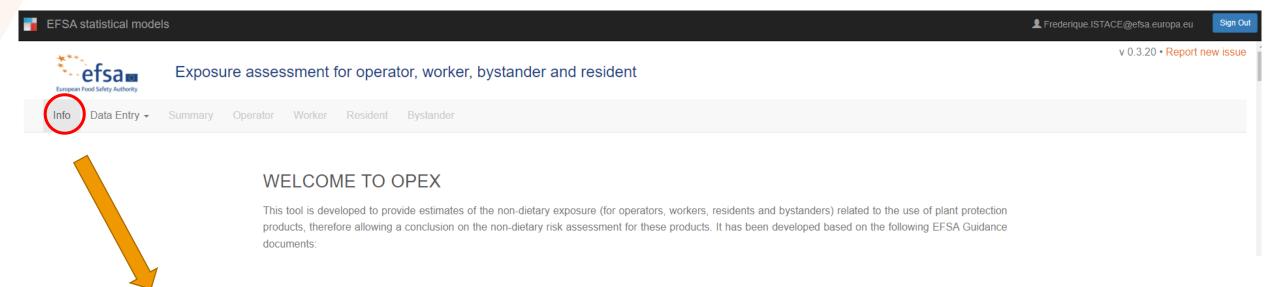
European Food Safety Authority

OPEX

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

1. Info tab





- Description of all registers
- Technical documentation
 - R package
 - Icons legend
 - Abbreviations
 - Background data

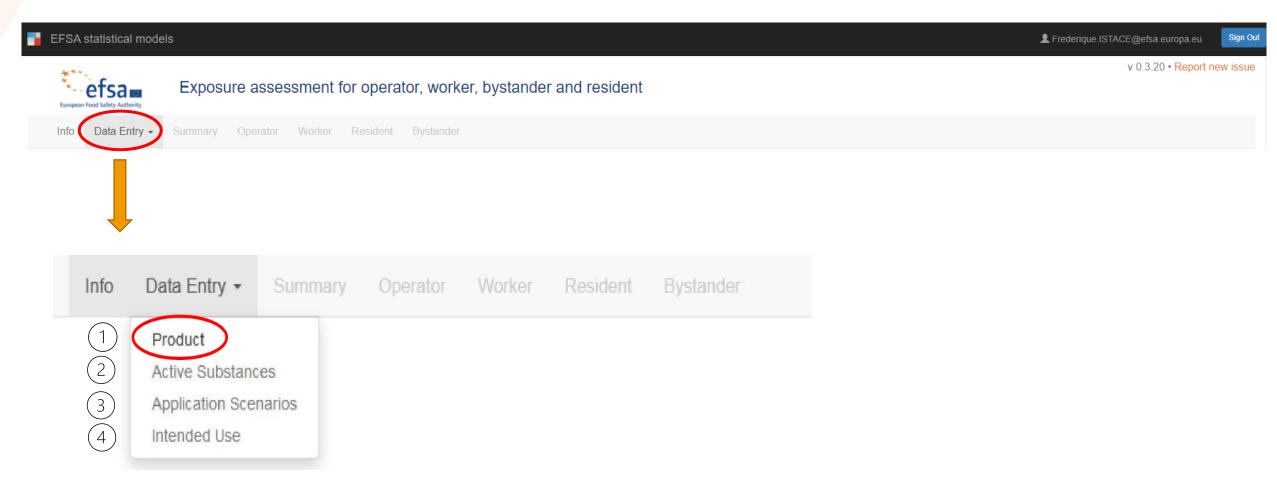
1. Info tab



	Icon	♦ PPE ♦
\bigcirc	No	No safe use
0	None	No Workwear
	Protected Body	Workwear
	Rain Suit Body	Rain suit & trousers
	Coverall Body	Certified protective coverall
	Protected Hands	Gloves
	Visor	Visor

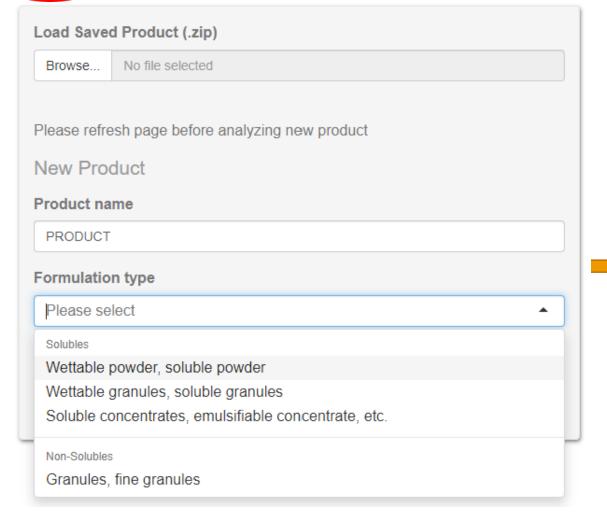
0	Hood	Hood
	Hood and faceshield	Hood & faceshield
	Faceshield	Faceshield
	FP1, P1 and similar	FP1, P1 and similar
	FP2, P2 and similar	FP2, P2 and similar
	Hood and FP1, P1 and similar	Hood and FP1, P1 and similar
HOS	Hood and FP2, P2 and similar	Hood and FP2, P2 and similar
₽₽	Closed cabin	Closed cabin



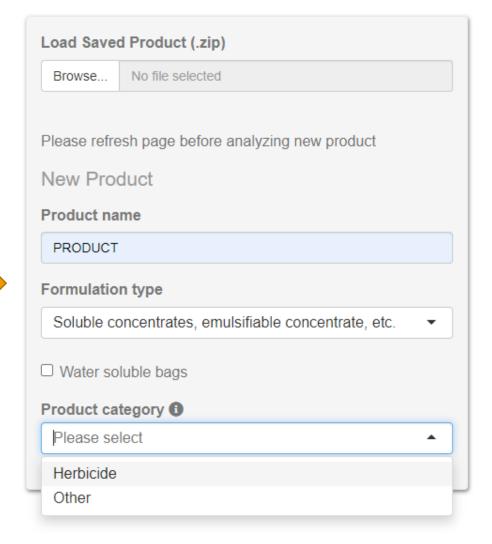








Product





Info

Data Entry ▼

Summary

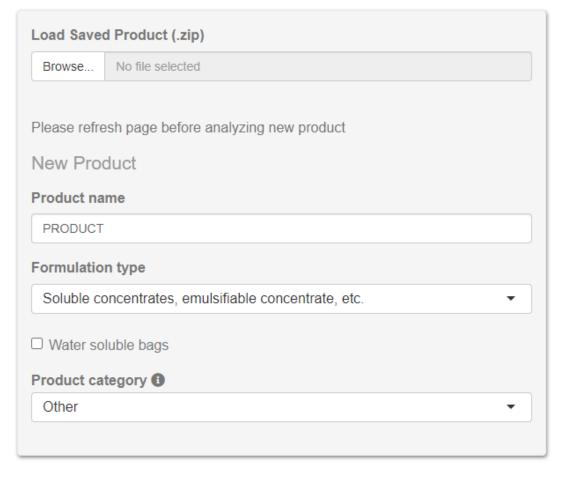
Operato

Worke

Resident

Bystander

Product





Please complete data to download product data.



Product name: PRODUCT

Formulation type: Soluble concentrates, emulsifiable concentrate, etc.

Water soluble bags: No

Product category: other

Active Substances

No data added

Application Scenarios

No data added

Intended Use

No data added









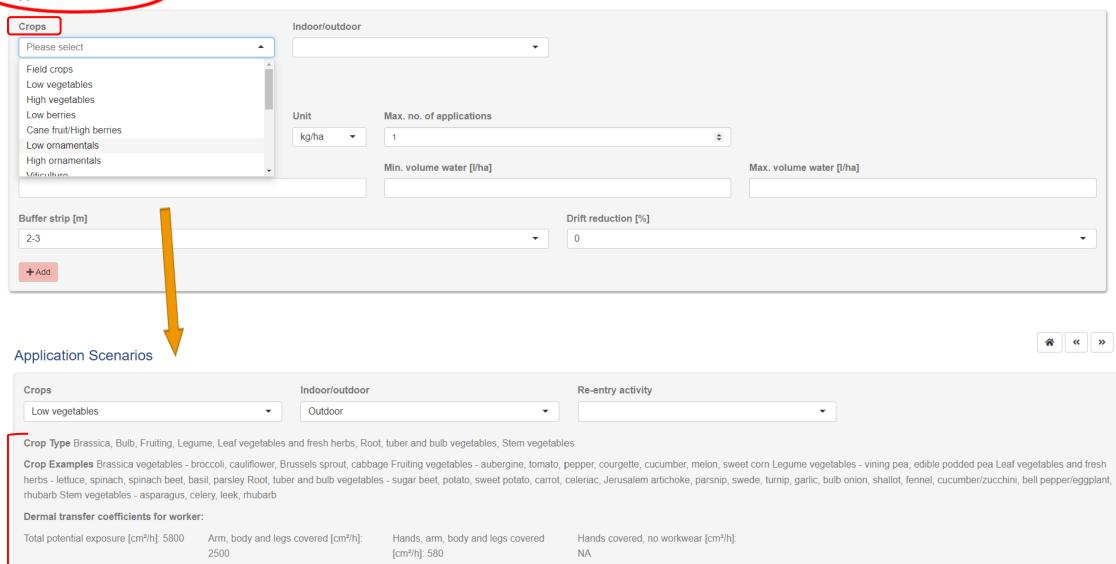
Active Substances Name of active substance Active SC1 Concentration of active substance g a.s./I or AOEL [mg/kg bw/day] Vapour pressure [Pa] 1 AAOEL [mg/kg bw] kg] 🕣 0.001 0.05 0.1 300 Absorption of the Active Substance Dermal absorption [%] from experimental data or default value for concentrate 1 Oral absorption [%] Inhalation absorption [%] Concentration [g a.s./l or kg] Dermal absorption [%] 100 100 300 Concentrate (product) 10 Dilution 1 tested 20 Dilution 2 tested 30 Dilution 3 tested Dilution 4 tested Dilution 5 tested You can add rows by right-clicking in the table. Air concentration calculation 🕕 Molecular weight of the active substance [g/mol] Experimental vapour concentration [mg/m³]



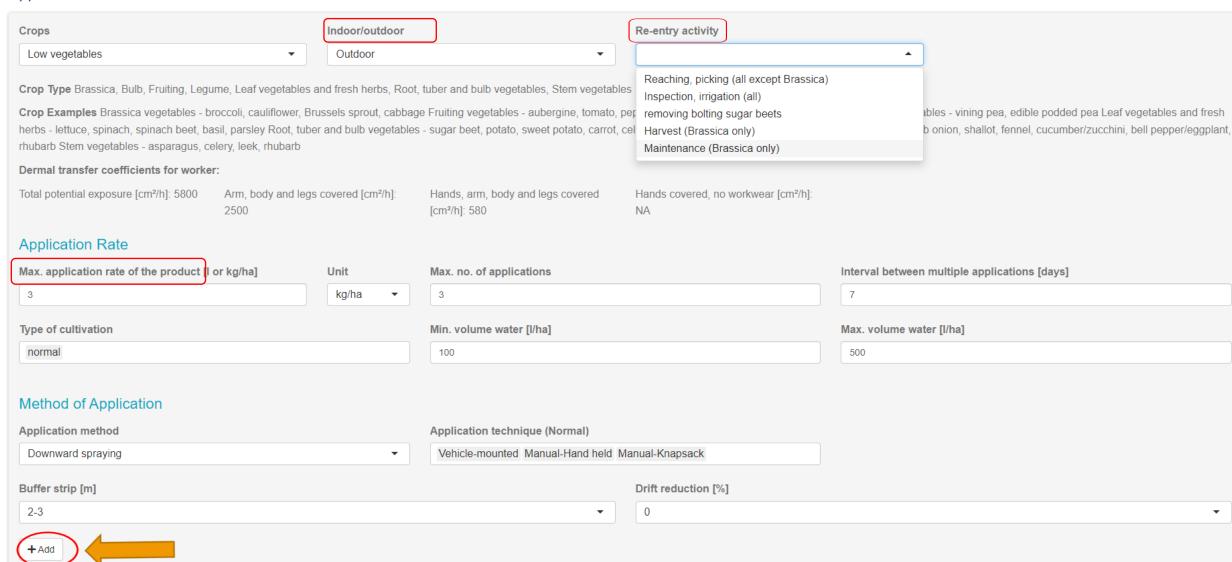
Active substance(s)

+Add									
Name of active substance	AOEL [mg/kg bw/day]	AAOEL [mg/kg bw]	Vapour pressure [Pa]	Oral absorption [%]	Inhalation absorption [%]	Molecular weight of the active substance [g/mol]	Experimental vapour concentration [mg/m³]	Concentration of active substance [g a.s./l or kg]	Dermal absorption [%]
Active SC1	0.05	0.1	0.001	100	100			300	10 💼 🕝
								3	20
								1	30
Active SC2	0.03	0.06	0.001	100	100			200	5 🗑 🗹
								2	10
								0.5	15
	·								





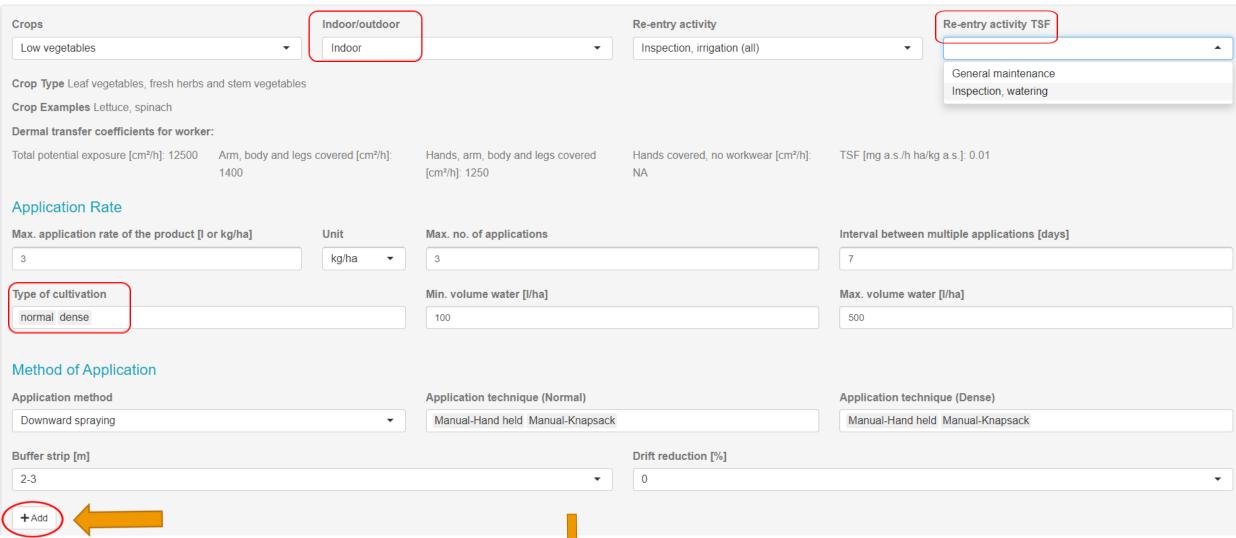






11										
Crops		Indoor/outdoor		Re-entry activity						
Low vegetables	Low vegetables ▼ Outdoor			Inspection, irrigation (all)	▼					
Crop Type Brassica, Bulb, Fruiting, Legu	Crop Type Brassica, Bulb, Fruiting, Legume, Leaf vegetables and fresh herbs, Root, tuber and bulb vegetables, Stem vegetables									
Crop Examples Brassica vegetables - broccoli, cauliflower, Brussels sprout, cabbage Fruiting vegetables - aubergine, tomato, pepper, courgette, cucumber, melon, sweet corn Legume vegetables - vining pea, edible podded pea Leaf vegetables and fresh herbs - lettuce, spinach, spinach beet, basil, parsley Root, tuber and bulb vegetables - sugar beet, potato, sweet potato, carrot, celeriac, Jerusalem artichoke, parsnip, swede, turnip, garlic, bulb onion, shallot, fennel, cucumber/zucchini, bell pepper/eggplant rhubarb Stem vegetables - asparagus, celery, leek, rhubarb										
Dermal transfer coefficients for worker	r:									
Total potential exposure [cm²/h]: 12500 Arm, body and legs covered [cm²/h]: 1400			Hands, arm, body and legs covered [cm²/h]: 1250	Hands covered, no workwear [cm²/h]: NA						
Application Rate										
Max. application rate of the product [I	or kg/ha]	Unit	Max. no. of applications		Interval between multiple applications [days]					
3		I/ha ▼	3	7						
Type of cultivation			Min. volume water [l/ha]		Max. volume water [l/ha]					
normal			100		500					
Method of Application Application method Downward spraying		*	Application technique (Normal) Vehicle-mounted Manual-Hand held	Manual-Knapsack						
Buffer strip [m]				Drift reduction [%]						
2-3			•	0						
+Add				0 50						







v 0.3.20 • Report new issue



Exposure assessment for operator, worker, bystander and resident

Data Entry -

Summary Operator Worker Resident Bystander

Application Scenarios

+ Add





Uses	Crops	Max. application rate of the product [I or kg/ha]	Unit	Max. no. of applications	Interval between multiple applications [days]	Min. volume water [l/ha]	Max. volume water [l/ha]	Indoor/outdoor	Re-entry activity	Re-entry activity TSF	Buffer strip [m]	Drift reduction [%]	Application method	Type of cultivation	Application technique
Use 1	Low vegetables	3	l/ha	3	10	100	300	Outdoor	Reaching, picking (all except Brassica)		2-3	0	Downward spraying	normal	Vehicle-mounted Manual-Hand hel Manual-Knapsac
Use 2	Low vegetables	2	l/ha	3	10	100	300	Indoor	Inspection, irrigation (all)	Inspection, watering	2-3	0	Downward spraying	normal	Manual-Hand hel
														dense	Manual-Hand hel



(4)

Intended Use



To enter manually dermal absorption value(s) you can deselect 'Experimental Data?' (see Info page)

	Name of active substance	Crops	Total amount applied of a.s. [g a.s./ha]	Concentration in the dilution [g a.s./l]	Experimental data?	Dermal absorption [%] (dilution)	Default DFR [µg/cm² foliage per kg a.s./ha]	Default DT50 [days]			
1	Active SC1	Low vegetables	900.00	3.00	✓	20.00	3.00	30.00			
2	Active SC2	Low vegetables	600.00	2.00	☑	10.00	3.00	30.00			
3	Active SC1	Low vegetables	600.00	2.00	2	30.00	3.00	30.00			
4	Active SC2	Low vegetables	400.00	1.33	~	15.00	3.00	30.00			





Intended Use

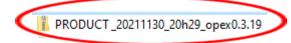


	*	*	*	*	*	*			
Worker	DFR refined worker [µg/cm² foliage per kg a.s./ha]	DT50 foliar worker [days]	DT50 air worker [days]	DT50 soil worker [days]	DFR refined resident [µg/cm² foliage per kg a.s./ha]	DT50 refined resident [days]	Bystander	DFR refined bystander [µg/cm² foliage per kg a.s./ha]	DT50 refined bystander [days]
	3.00	30.00	30.00	30.00	3.00	30.00		3.00	30.00
	3.00	30.00	30.00	30.00	3.00	30.00		3.00	30.00
	3.00	30.00	30.00	30.00	3.00	30.00		3.00	30.00
	3.00	30.00	30.00	30.00	3.00	30.00		3.00	30.00



Summary





Product

Product name: PRODUCT

Formulation type: Soluble concentrates, emulsifiable concentrate, etc.

Water soluble bags : No

Product category: other

Active Substances

Name of active substance	AOEL [mg/kg bw/day]	AAOEL [mg/kg bw]	Vapour pressure [Pa]	Oral absorption [%]	Inhalation absorption [%]	Molecular weight of the active substance [g/mol]	Experimental vapour concentration [mg/m³]	Concentration of active substance [g a.s./l or kg]	Dermal absorption [%]
Active SC1	0.05	0.1	0.001	100	100			300	10
								3	20
								1	30
Active SC2	0.03	0.06	0.001	100	100			200	5
								2	10
								0.5	15

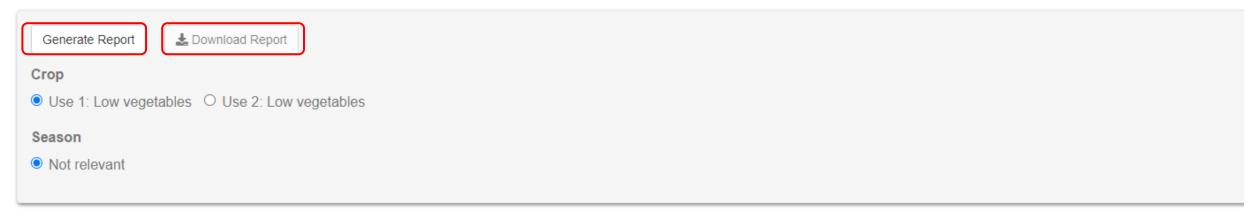
3. Summary





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



Navigate to:



3. Summary: operator



Operator

Low vegetables - Short term exposure (% AOEL)





Mixing/Loading	Application	normal & Vehicle- mounted	normal & Manual-Hand held	normal & Manual- Knapsack	normal & Vehicle- mounted	normal & Manual-Hand held	normal & Manual- Knapsack	
0	0	593	1543	639	369	866	534	
1	1	368	232	104	232	136	88	
		59.3	171	71.9	33.9	96.4	61.6	
		14.4	144	59.8	8.6	80.4	50	

Low vegetables Acute exposure (% AAOEL)

Active SC1 Active SC2

Mixing/Loading	Application	normal & Vehicle- mounted	normal & Manual-Hand held	normal & Manual- Knapsack	normal & Vehicle- mounted	normal & Manual-Hand held	normal & Manual- Knapsack
•	0	1764	1405	519	1104	801	434
M	1	816	654	267	511	373	223
		156	543	225	98.3	303	188
		77.3	511	211	50.6	285	176
		70.1	510	210	45.7	284	175

3. Summary: operator





Low vegetables Short term combined exposure (hazard index)

Mixing/Loading	Application	normal & Vehicle-mounted	normal & Manual-Hand held	normal & Manual-Knapsack
1	0	9.6	24.1	11.7
		6	3.7	1.9

Low vegetables - Acute combined exposure (hazard index)

Mixing/Loading	Application	normal & Vehicle-mounted	normal & Manual-Hand held	normal & Manual-Knapsack
•	0	28.7	22.1	9.5
	1	13.3	10.3	4.9

3. Summary: worker



Active SC1

PPE	% of AOEL at day 0	Safe re-entry interval (days)
Total potential exposure	2024	131
Arms, body and legs covered	873	94
Hands, arms, body and legs covered	202	31
Hands covered, no workwear		

Active SC2

PPE	% of AOEL at day 0	Safe re-entry interval (days)
Total potential exposure	1125	105
Arms, body and legs covered	485	69
Hands, arms, body and legs covered	112	6
Hands covered, no workwear		

Combined Exposure

PPE	Hazard index at day 0	Safe re-entry interval (days)
Total potential exposure	31.5	236
Arms, body and legs covered	13.6	163
Hands, arms, body and legs covered	3.1	37
Hands covered, no workwear		

3. Summary: resident





Active SC1 (% AOEL)

Adults

Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
23.2	0.5	5.9	81.8	81

Active SC2 (% AOEL)

Adults

Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
12.9	0.9	3.3	45.4	45.6

Combined exposure (hazard index)

Adults

Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
0.4	0.01	0.09	1.3	1.3

Children

Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
97.7	1.6	16.2	147	184

Children

Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
54.4	2.7	11	81.8	106

Children

Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
1.5	0.04	0.3	2.3	2.9

3. Summary: bystander





(Active SC1)(% AAOEL)

Adults

Spray drift	Vapour	Surface deposits	Entry into treated crops
29.9	0.3	9	40.9

Active SC2 (% AAOEL)

Adults

Spray drift	Vapour	Surface deposits	Entry into treated crops
16.6	0.5	5	22.7

Combined exposure (hazard index)

Adults

Spray dri	ft Vapour	Surface deposits	Entry into treated crops
0.5	0.007	0.1	0.6

Children

Spray drift	Vapour	Surface deposits	Entry into treated crops
110	0.8	23.9	73.6

Children

Spray drift	Vapour	Surface deposits	Entry into treated crops
62	1.3	15.9	40.9

Children

Spray drift	Vapour	Surface deposits	Entry into treated crops
1.7	0.02	0.4	1.1





Description

Operators are persons who are involved in activities relating to the application of a plant protection product (PPP); such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the PPP and emptying/cleaning the machinery/containers after use. Operators may be either professionals (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users; it is noted that this tool does not include an assessment of this scenario).

Product name	Name of active substance	Total amount applied of a.s. [g ∳ a.s./ha]	Indoor/outdoor \$	Application technique	Type of cultivation	Application method	AOEL [mg/kg ‡ bw/day]	AAOEL [mg/kg bw]	Dermal absorption [%] (concentrate)	Dermal absorption [%] (dilution)	Inhalation absorption [%]
RODUCT	Active SC1	900	Outdoor	Vehicle-mounted	normal	Downward spraying	0.05	0.1	10	20	10
PRODUCT	Active SC1	900	Outdoor	Manual-Hand held	normal	Downward spraying	0.05	0.1	10	20	10
PRODUCT	Active SC1	900	Outdoor	Manual-Knapsack	normal	Downward spraying	0.05	0.1	10	20	10
PRODUCT	Active SC2	600	Outdoor	Vehicle-mounted	normal	Downward spraying	0.03	0.06	5	10	10
PRODUCT	Active SC2	600	Outdoor	Manual-Hand held	normal	Downward spraying	0.03	0.06	5	10	10
PRODUCT	Active SC2	600	Outdoor	Manual-Knapsack	normal	Downward spraying	0.03	0.06	5	10	10



Info Data Entry → Summary Operator Worker Resident Bystander

Description

Operators are persons who are involved in activities relating to the application of a plant protection product (PPP); such activities include mixing/loading the product into the application machinery, operation of the application machinery, repair of the application machinery whilst it contains the PPP and emptying/cleaning the machinery/containers after use. Operators may be either professionals (e.g. farmers or contract applicators engaged in commercial crop production) or amateur users (e.g. home garden users; it is noted that this tool does not include an assessment of this scenario).

Crop O Use 1: Low v	vegetables Use 2:).	_ow vegetables									
Product name	Name of active substance	Total amount applied of a.s. [g \(\phi \) a.s./ha]	Indoor/outdoor	Application technique	Type of cultivation	Application method	AOEL [mg/kg † bw/day]	AAOEL [mg/kg \$ bw]	Dermal absorption [%] (concentrate)	Dermal absorption [%] † (dilution)	Inhalation absorption [%]
PRODUCT	Active SC1	600	Indoor	Manual-Hand held	normal	Downward spraying	0.05	0.1	10	30	100
PRODUCT	Active SC1	600	Indoor	Manual-Knapsack	normal	Downward spraying	0.05	0.1	10	30	100
PRODUCT	Active SC1	600	Indoor	Manual-Hand held	dense	Downward spraying	0.05	0.1	10	30	100
PRODUCT	Active SC1	600	Indoor	Manual-Knapsack	dense	Downward spraying	0.05	0.1	10	30	100
PRODUCT	Active SC2	400	Indoor	Manual-Hand held	normal	Downward spraying	0.03	0.06	5	15	100
PRODUCT	Active SC2	400	Indoor	Manual-Knapsack	normal	Downward spraying	0.03	0.06	5	15	100
PRODUCT	Active SC2	400	Indoor	Manual-Hand held	dense	Downward spraying	0.03	0.06	5	15	100
PRODUCT	Active SC2	400	Indoor	Manual-Knapsack	dense	Downward spraying	0.03	0.06	5	15	100





PRODUCT Active SC2 400 Indoor Manual-Knapsack dense Downward spraying 0.03 0.06 5 15 100

Output





Estimated short term and acute exposure when using no protection and least cumbersome safe protection.

Systemic exposure (mg a.s./day)

Percentile	Mixing & Loading	Application	♦ ML	♦ App	♦ Total	Total systemic exposure per kg body weight (mg/kg bw/day)	
Short term	0	1	0.6	45.7	46.3	0.8	2572
Short term			0.04	0.3	0.3	0.005	18.2
Acute	0	1	1.5	72.1	73.5	1.2	2043
Acute			0.05	0.5	0.6	0.009	15.7





All Combinations of PPE

Exposure

O Short term (75th percentile) • Acute (95th percentile)

The estimated short term and acute exposure when wearing increasing level of protection is displayed as percentage of the (A)AOEL. Results are given for all active substances and all application scenarios.

Legend

- Safe use with workwear
- Safe use with PPE
- No safe use
- No data to calculate the exposure for this scenario

Per Substance

Combined exposure

	Application		Activ	e SC1		Active SC2			
Mixing/Loading		normal & Manual- Hand held	normal & Manual- Knapsack	dense & Manual- Hand held	dense & Manual- Knapsack	normal & Manual- Hand held	normal & Manual- Knapsack	dense & Manual- Hand held	dense & Manual- Knapsack
0	1	242	210	3673	3642	187	177	2052	2043
1	1	59.4	68.8	1331	1340	43.8	58.9	748	763
		28.1	26.6	1299	1298	24.1	23.8	728	728

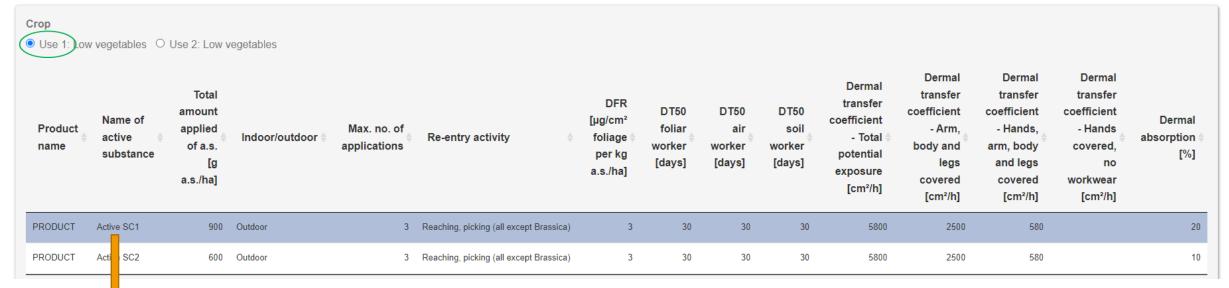
5. Worker



Info Data Entry → Summary Operator Worker Resident Bystander

Description

Workers are persons who, as part of their employment, enter an area that has been treated previously with a PPP or who handle a crop that has been treated with a PPP.



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	60.7	NA	60.7	1	2024	131
Arms, body and legs covered	26.2	NA	26.2	0.4	873	94
Hands, arms, body and legs covered	6.1	NA	6.1	0.1	202	31
Hands covered, no workwear	NA	NA	NA	NA	NA	NA

5. Worker



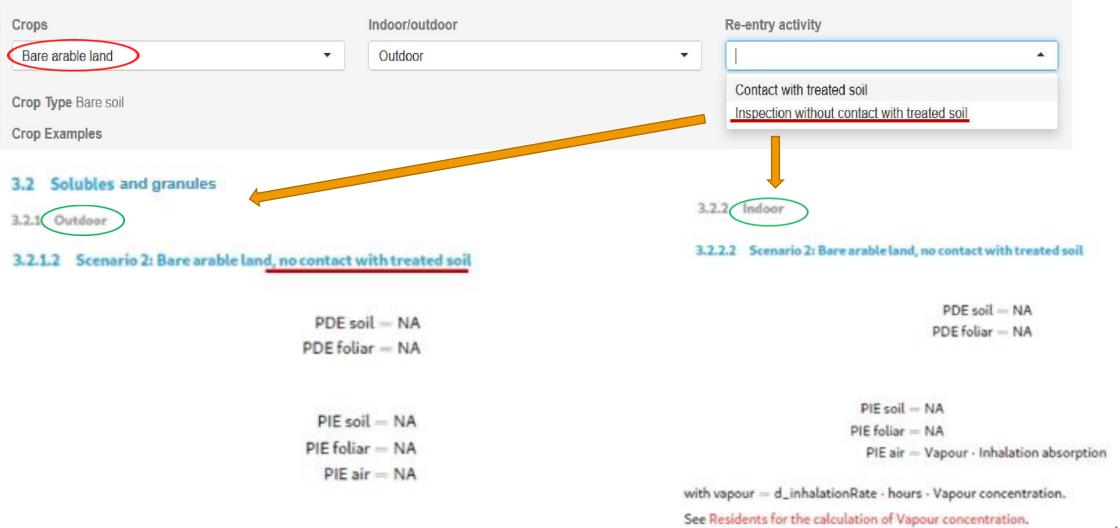
Combined exposure to more than one a.s. in the product

All Substances Combined exposure 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) (Hazard index at day 0) Safe re-entry interval (days) Total potential exposure 43.6 0.03 43.7 0.7 17 123 Arms, body and legs covered 4.9 0.03 4.9 0.08 1.9 29 Hands, arms, body and legs covered 0.03 4.4 0.07 1.7 24 Hands covered, no workwear NA NA NA NA NA NA

5. Worker



Application Scenarios



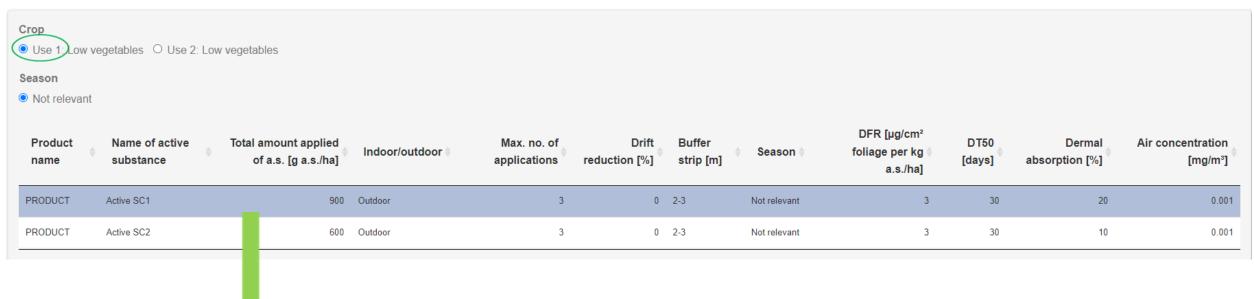
6. Resident





Description

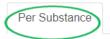
Residents are persons who live, work or attend school or any other institution adjacent to an area that is or has been treated with a PPP; whose presence is quite incidental and unrelated to work involving PPPs but whose position might lead them to be exposed; who take no action to avoid or control exposure; and who might be in the location for up to 24 hours per day (short term exposure).



6. Resident



Use 1: low vegetables - outdoor



Combined exposure

Active SC1

Adults

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Systemic exposure [mg a.s./day]	0.7	0.02	0.2	2.5	2.4
Systemic exposure [mg a.s./kg bw/day]	0.01	0.0003	0.003	0.04	0.04
% of AOEL	23.2	0.5	5.9	81.8	81

Children

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Systemic exposure [mg a.s./day]	0.5	0.008	0.08	0.7	0.9
Systemic exposure [mg a.s./kg bw/day]	0.05	0.0008	0.008	0.07	0.09
% of AOEL	97.7	1.6	16.2	147	184

Active SC2

Adults

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Systemic exposure [mg a.s./day]	0.2	0.02	0.06	0.8	0.8
Systemic exposure [mg a.s./kg bw/day]	0.004	0.0003	0.001	0.01	0.01
% of AOEL	12.9	0.9	3.3	45.4	45.6

Children

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Systemic exposure [mg a.s./day]	0.2	0.008	0.03	0.2	0.3
Systemic exposure [mg a.s./kg bw/day]	0.02	0.0008	0.003	0.02	0.03
% of AOEL	54.4	2.7	11	81.8	106

6. Resident



Use on amenity grasslands: recreational exposure

Adults

	Spray drift	Vapour	Surface deposits	Entry into	All pathways (mean)	Entry into treated
				treated crops		(recreational)
Systemic exposure [mg a.s./day/]	0.04	0.02	0.01	0.03	0.07	0.2
Systemic exposure [mg a.s./kg bw/day]	0.0005	0.0003	0.0002	0.0005	0.001	0.004
% of AOEL	5.4	2.7	2	4.6	11.8	36.5

Children

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)	Entry into treated
						(recreational)
Systemic exposure [mg a.s./day]	0.03	0.000	0.007	0.03	0.04	0.7
Systemic exposure [mg a.s./kg bw/day]	0.003	0.0008	0.0007	0.003	0.004	0.01
% of ACEL	27.2	8	6.8	28.3	37.6	122

7. Bystander



Info D

Data Entry -

Summary

Operator

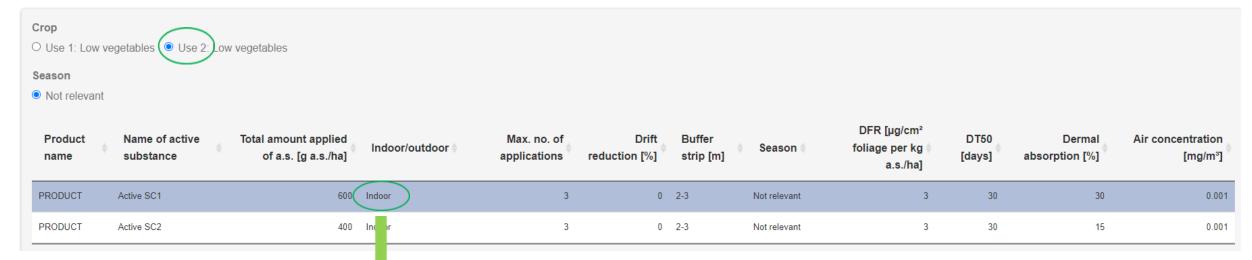
Worker

Resident

Bystander

Description

Bystanders are persons who could be located within or directly adjacent to the area where PPP application or treatment is in process or has recently been completed; whose presence is quite incidental and unrelated to work involving PPPs, but whose position might lead them to be exposed during a short period of time (acute exposure); and who take no action to avoid or control exposure.



Single Scenario

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

Adults

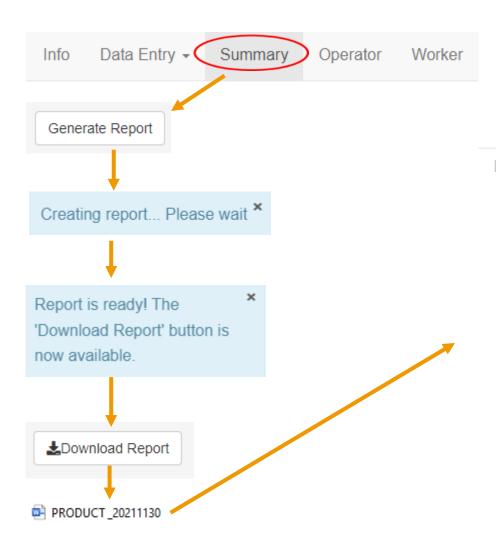
	Spray drift	Vapour	Surface deposits	Entry into treated crops
Systemic exposure [mg a.s./day]	1.8	0.02	0.5	NA
Systemic exposure [mg a.s./kg bw/day]	0.03	0.0003	0.009	NA
% of AAOEL	29.8	0.3	9	NA

Children

	Spray drift	Vapour	Surface deposits	Entry into treated crops
Systemic exposure [mg a.s./day]	1.1	800.0	0.2	NA
Systemic exposure [mg a.s./kg bw/day]	0.1	8000.0	0.02	NA
% of AAOEL	110	8.0	22.4	NA

8. Report generation





Exposure assessment for operator, worker, resident and bystander

Product: PRODUCT

OPEX version: 0.3.19

30 November 2021

ce(s)	 Information on product and active substant
PRODUC	Product name
Spluble concentrates, emulsifiable concentrate, etc.	Formulation type
Othe	Product category
Active so	Name of active substance
30	Concentration of active substance [g a.s./l or kg]
0.0	AOEL [mg/kg bw/day]
0.	AAOEL [mg/kg bw]
10	Inhalation absorption [%]
10	Oral absorption [%]
1	Dermal absorption [%] (concentrate)
2	Dermal absorption [%] (dilution) 3 [g a.s./l or kg]
3	Dermal absorption [%] (dilution) 1 [g a.s./l or kg]
Active so	Name of active substance
20	Concentration of active substance [g a.s./l or kg]
0.0	AOEL [mg/kg bw/day]
0.0	AAOEL [mg/kg bw]
10	Inhalation absorption [%]
10	Oral absorption [%]
	Dermal absorption [%] (concentrate)
1	Dermal absorption [%] (dilution) 2 [g a.s./l or kg]
1	Dermal absorption [%] (dilution) 0.5 [g a.s./l or kg]



Trusted science for safe food

OPEX tool webinar

26 January 2022



Questions and Answers session



	Comment	Answer
1	Differences between exposure values : scenario summaries (report) <i>versus</i> appendix	Generated report: all PPE/RPE up to safe use Appendix: the PPE/RPE leading to safe use
2	Rounding in Report: More significant figures?	Limitation of the number of significant digits: data variability, extra-accuracy
3	Risk assessment for workers – grapes: No TC values leading to conservative exposure estimation Possible refinements?	<u>Workers</u> : TC values and duration of the specific re-entry activities cannot be modified in the OPEX calculator <u>Residents/Bystanders</u> : reduction of the exposure by applying refined DFR/DT50 values, drift reduction, buffer zones
4	Cumulative risk assessment calculation : Sum of hazard quotients index?	CRA = HQs calculated for all a.s. in the product by dividing the individual exposure levels by the respective systemic AOEL
5	Availability of an offline tool	Instructions to be included in the Manual on Zenodo

Questions and Answers session



	Comment	Answer
6	Generated report: error message "Report could not be generated: undefined columns selected"	Recommended approach: 1. All entries complete? 2. Save the product 3. Click on 'report new issue' → Email: zip file + description of the problem
7	Workers entering the field before harvesting: No Pre Harvesting Interval (PHI) needed to calculate the adjusted DFR value?	The model automatically calculates the PHI taking into account the DT50 value
8	Discontinuous work : how to avoid losing the data entries?	Recommendation to save the product in a zip file – timeout extended by circa 20-30 minutes
9	Personal data protection and user tracking	'By signing in you agree with the Terms of Use. You can click on the Terms of Use to see what you are agreeing with, they are in compliance with personal data protection'



Thank you for attending our webinar

In case we did not manage to answer all your questions, please feel free to resubmit them via EFSA Ask a question webform (EFSA.Connect at: https://connect.efsa.europa.eu/RM/s/askefsa)

The **recording** of today's webinar and **ppt** will be available on the EFSA website in few days

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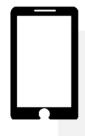
OPEX NEXT: stakeholders event



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	ABOUT V NEWSROOM V TOPICS V RESOURCES V PUBLICATIONS APPLICATIONS V ENGAGE V CALENDAR			
	Home / Calendar / Stakeholder workshop on the next update of the EFSA Guidance on Non-Dietary Exposure to Pesticides			
	Stakeholder workshop on the next update of the EFSA Exposure to Pesticides	A Guidanc	e on Non-Dietary	
	Location: Online Date: 28 March 2022		000	
	Register here Deadline: 14 March 2022 - 12:00 (CET)		Contents	
	28 March 2022, 13:30 – 17:00 (CET)		Documents Related topic(s)	
	Background			
	EFSA recently published the <u>Guidance on the assessment of exposure of operators, workers, residents and bystanders in assessment for plant protection products</u> (OPEX Guidance), as requested by the <u>European Commission</u> . Notwithstar <u>call for data</u> , information/data on a limited number of the open issues have been obtained and considered for the update annexed calculator.	nding an <u>open</u>		
	For the remaining issues listed in the original mandate, insufficient new information was available, and it was agreed with Commission to address them in a subsequent revision, once related data has been made available to EFSA. In addition, it highlighted the need to reconsider the methodology for data collection, with the direct involvement of relevant stakehold stage of the preparatory work.	EFSA		
	EFSA carried out an analysis of the future of non-dietary exposure (NDE) to plant protection products (PPPs). In particular methodology for the collection and assessment of evidence for the update of current approaches used to estimate NDE been proposed in a 'state of the art and perspectives' document. This recommends, as a starting point, engaging with de model developers to identify evidence that could be relevant to the update. Some information/evidence has already beer available, mainly from industry and public organisations. Also, EFSA has been informed about ongoing activities for which and raw data could be submitted in the near future.	to PPPs has ata owners and n made been		
	EFSA's PREV Unit is holding a workshop with relevant stakeholders on the next update of the OPEX Guidance and annext 28 March 2022. The meeting provides an opportunity to gather relevant data/information and discuss what needs to be the update.			
	Objectives of the meeting			
	The overall aim of the meeting is to discuss the approach to be implemented for the next update based on new evidence	e.		
	Specific objectives are to:			
	have a clear understanding of finalised as well as ongoing activities related to the subject matter			
	receive an overview of available data/models			
	 identify possible cooperation among relevant stakeholders (e.g., competent authorities of Member States, public on academia, non-governmental organisations) for the assessment of submitted data/models as well as for the develor models 			
	finalise the 'State of the art and perspectives' document based on stakeholders' feedback (published with this annotation).			
	A survey, published with this announcement (see below), will enable the collection of preliminary information on the aboroints and facilitate the discussion during the event. Registrants are therefore recommended to fill in the questionnaire tregistration deadline (14 March 2022, 12:00 CET).			
	Structure of the meeting			

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