ICPPE Risk Assessment & Mitigation Tool: Facilitating Pesticide Risk Evaluation for Operators* using hand-held spray equipment

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ICPPE
Risk Mitigation for
Pesticide Operator Safety

*Pesticide applicators

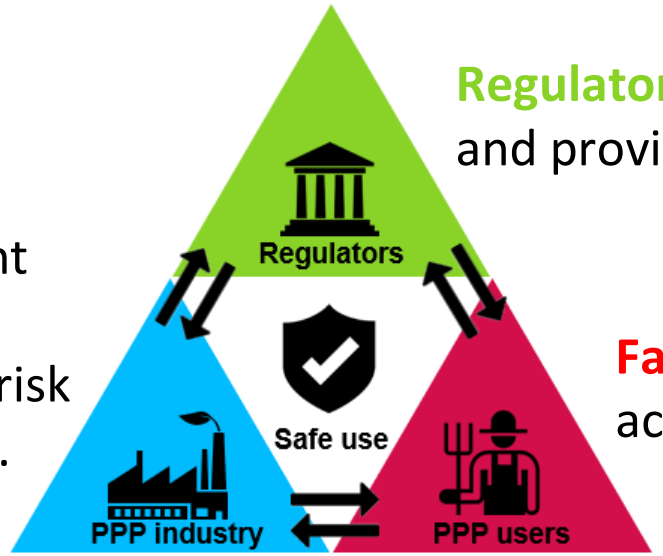
Magic triangle of a safe pesticide use

Pesticides are regulated products, and their authorization for sale and use is granted by respective countries.

To be clear: **Pesticides are chemicals**, with effects and possible side effects**, and should be handled as such!**

An essential part of the registration process is **determining whether the product can be used with acceptable risk for operators** under local agronomic conditions and realistic risk mitigation measures.

Industry needs to ensure that plant protection products are safe for operators by generating data and risk assessment that proves the safety.



Regulators control industry and farmers and provide guidance.

Farmers use the product according to label instructions

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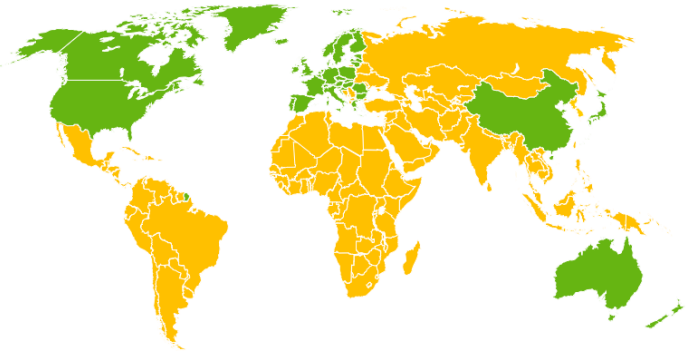
Why do not all countries consider a risk-based approach?

- In many regions and countries around the globe a transparent and consistent **operator risk assessment is part of the local regulation** for pesticide registration.
- However, in many **low and middle-income countries (LMIC)**, operator risk assessments are not considered, or only **following a simplified hazard-based approach**. Why is that? Four possible explanations:



Regulators do not have sufficient **resources** to conduct an OPEX assessment.

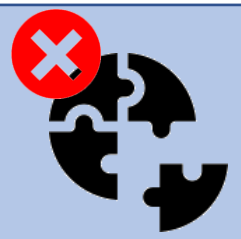
No time!

There is no **binding regulation** that requires OPEX assessments

No mandate!

There is not sufficient **expertise** to run the assessment and/or to interpret the outcome

Too complex!



Existing OPEX models do not consider **local agronomic conditions**

No relevance!

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Meet the reality, meet Akash

Akash is a farmer and lives with his family in an emerging country

This is Akash with his three kids and his pregnant wife

They live all together in a small, 1-room house

Akash rents a piece of land on which he grows spinach

This little bug can destroy the entire spinach field within 2 weeks

Akash uses Roket 44% EC (Cypermethrin + Profenofos) to fight this bug

He mixes the product at the same spot where his wife usually makes dinner

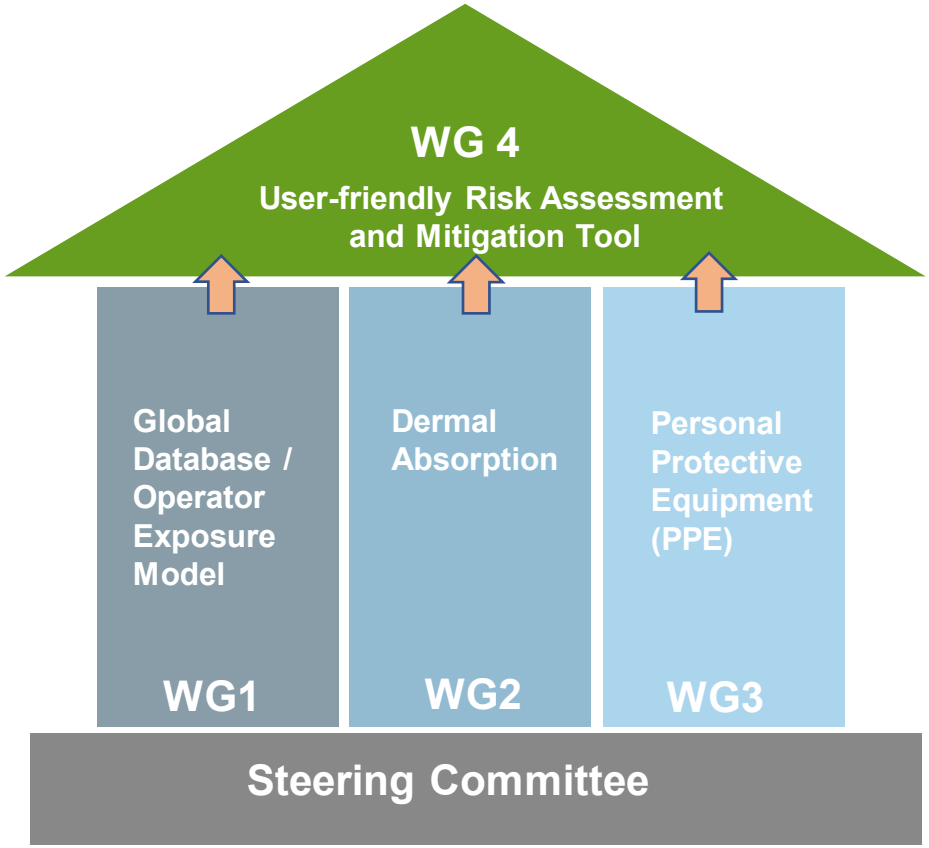
His little son helps him mixing the product

He applies the products w/o sturdy shoes, no certified clothing, gloves or other protection.

He intends to harvest some of his spinach a couple of days later to sell it at the local food market:

The ICPPE initiative aims to reduce complexity of operator risk assessments and to improve relevance

ICPPE strategy house



Goal: Improving Operator Safety in LMIC

A global collaboration between academia, industry, governments and observers from FAO and WHO

13 pesticide regulators from Brazil, Germany, Greece, Kenya, Switzerland, S. Korea, Taiwan, USA

Regulators

16

Industry

industry experts from CropLife International member companies

9

Observers/Others

FAO & WHO observers, FAO trainers, PPE certification, manufacturer, academia

- Alignment on a common goal: Improving operator safety
- Reducing perceived conflict of interests
- Consensus-based decisions
- Full transparency

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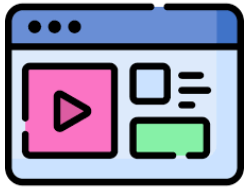
Four sub-groups within **WG4** have been established

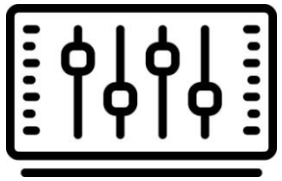
WG4-1:
Feedback and input from countries in Asia, Africa and Latin America

- **Input from local regulators** is crucial to increase acceptance.
- We need to understand **the needs and concerns** to develop a tool that is also considered in risk-based regulations



WG4-2:
Frontend and visualization as well as connection with back-end (discussion with IT experts)

- A complex **back-end needs to be linked to a user-friendly interface**.
- A **visualization** facilitate interpretation by local regulators.
- Tool can also be used as a pure exposure assessment tool to **identify the most appropriate PPE**.



WG4-3:
Input parameters + defaults – (w/ support from WG1, WG2 and WG3)

- Input parameters and **defaults values** should be proposed by the expert functions. **Focus lies here on flexibility!**
- The biggest challenge is to find the **right balance between precautionary principles and realistic assumptions**.

WG4-4:
Communication and training

- Once the **tool** is developed, the tool **must be promoted** and introduced to LMICs
- **Trainings and workshops** are needed to improve the acceptance.
- **Feedback loops** and changes of the tool are important to consider proposals by regulators.

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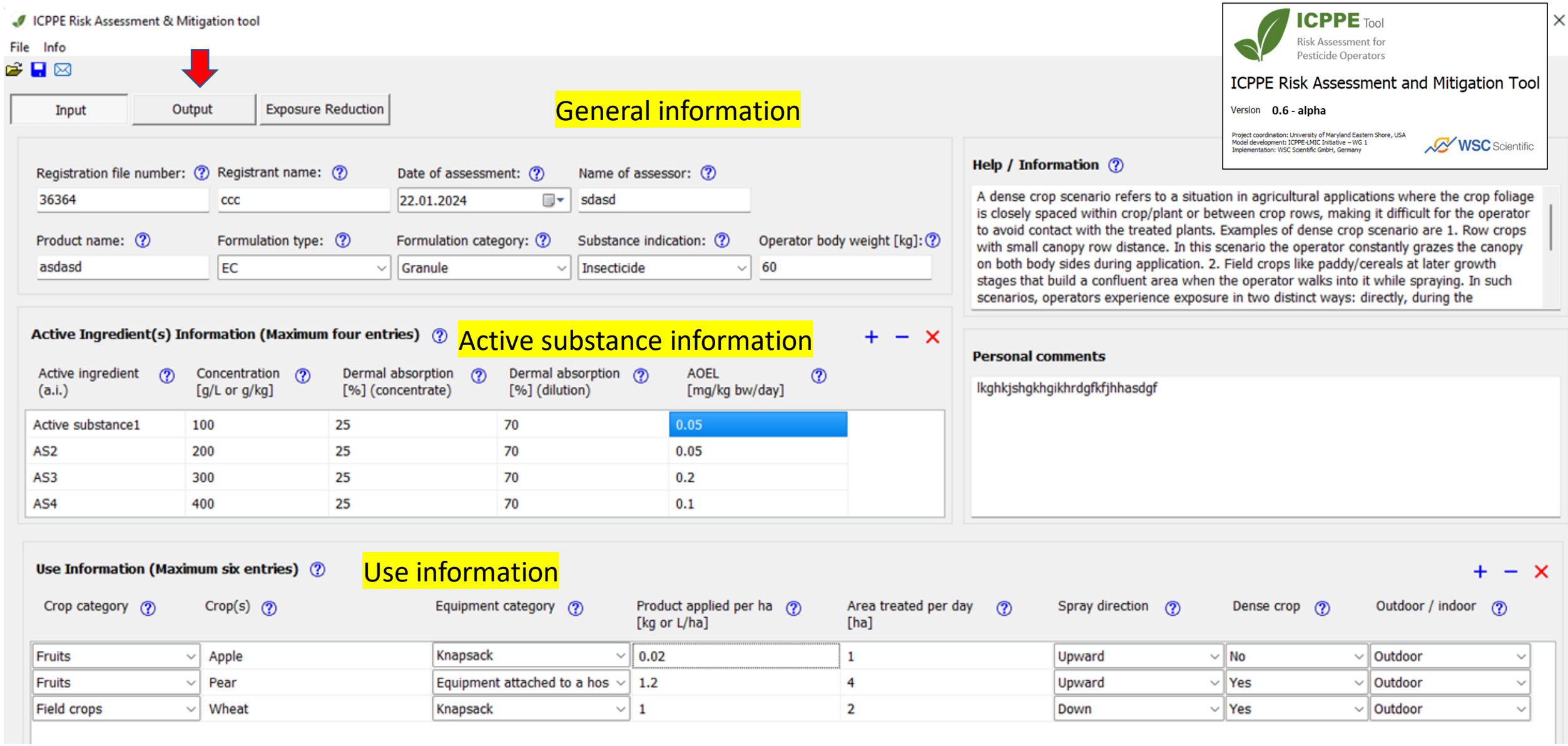

Tool is not yet available – alpha version only

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ICPPE Risk Assessment & Mitigation tool

File Info

Input | Output | Exposure Reduction

ICPPE Tool
Risk Assessment for Pesticide Operators

ICPPE Risk Assessment and Mitigation Tool

Version 0.6 - alpha

Project coordination: University of Maryland Eastern Shore, USA
Model development: ICPPE-LMIC Initiative – WG 1
Implementation: WSC Scientific GmbH, Germany

WSC Scientific

PPE selection

Summary for all uses

Uses	Crop(s)	Equipment	Tier 1 Eval.	PPE list for label
1	Apple	Knapsack	✓	'ML': C1,GL - 'A': C1,GL
2	Pear	Equipment attached	!	'ML': C1,GL - 'A': GL,C3
3	Wheat	Knapsack	!	'ML': C1,GL - 'A': C1

PPE selection

For Mixing and Loading ('ML')	For Application ('A')
Minimum clothing	
☑ C1 PPE/Workwear and sturdy shoes - **Minimum**	☐ C1 PPE/Workwear and sturdy shoes - **Minimum**
Additional PPE for exposure reduction	
☑ Certified chemical resistant gloves (GL) **(always recommended)**	☑ Certified chemical resistant gloves (GL)
☐ Respiratory protection (RP) **(always recommended for powders)**	☐ C3 Pants for low crops & paddy (C3P)
☐ Face shield (FS)	☑ C3 Coverall (C3)
	☐ Respiratory protection (RP)
	☐ Face shield (FS)
Additional PPE recommended for safety reasons (no direct impact on exposure assessment)	
☐ C3 Apron (C3A)	☐ C3 Back protection for knapsack (C3B)
☐ Goggles (GO)	

Risk indicator

Detailed calculation

Exposure algorithms

```
#########################   USE 1   ############################

==================   ACTIVE INGREDIENT 1   ==================
Name: Active substance1

Mixing/loading PPE:
- C1 PPE/Workwear and sturdy shoes (C1)
- Certified chemical resistant gloves (GL)

-----   Inhalation exposure (during mixing/loading)   ------------
General model: Log10(Exposure) = 0.6429 * Intercept + -0.7515 * EquipmentOther + 1.31
Applied model: Log10(Exposure) = 0.6429 * 1 + -0.7515 * 0 + 1.31 * 0 + 0.9839 * -2.69
Inhalation exposure ('ML'): 0.0097 µg
-----   Head exposure (during mixing/loading)   ------------------
General model: Log10(Exposure) = 1.2089 * Intercept + -0.4541 * EquipmentOther + 1.10
Applied model: Log10(Exposure) = 1.2089 * 1 + -0.4541 * 0 + 1.1031 * 0 + 0.659 * -2.6
```

Generate Report

Help / Information

Certified particulate filter masks and respirators are used for respiratory protection. A protection factor of 90% is applied for certified respiratory protection. **Certified particulate filter masks** provide respiratory protection against solids (dust and powders) and liquid aerosols (fine droplets or liquid particles > 0.3 µm). Based on exposure assessment, they are required for M&L powders. For application, it can be used for exposure reduction on scenarios such as indoor application where spray droplets may dissipate more

AOEL Indicator

Exposure as % of AOEL

Active ingredient 1	Active ingredient 2	Active ingredient 3	Active ingredient 4
OK!	OK!	OK!	OK!
AOEL -	AOEL -	AOEL -	AOEL -
17.8 %	25.6 %	8 %	19.1 %

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	☐ Respiratory protection (RP)
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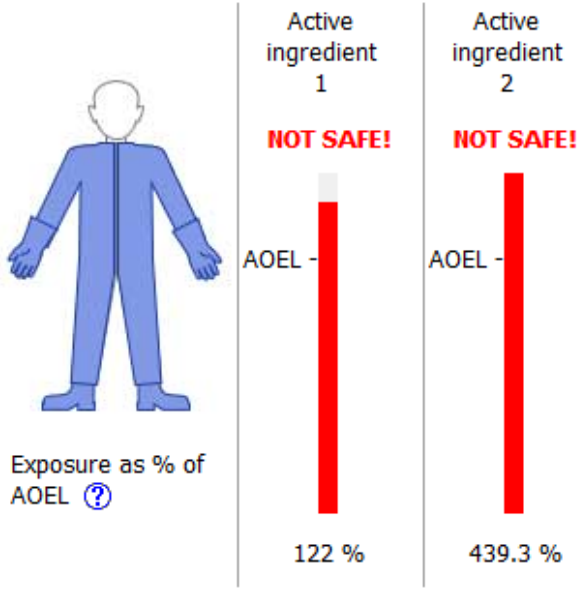
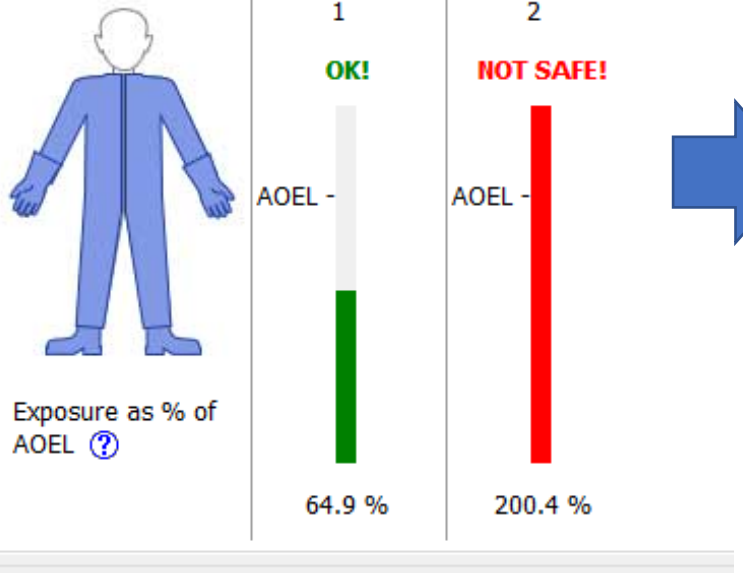
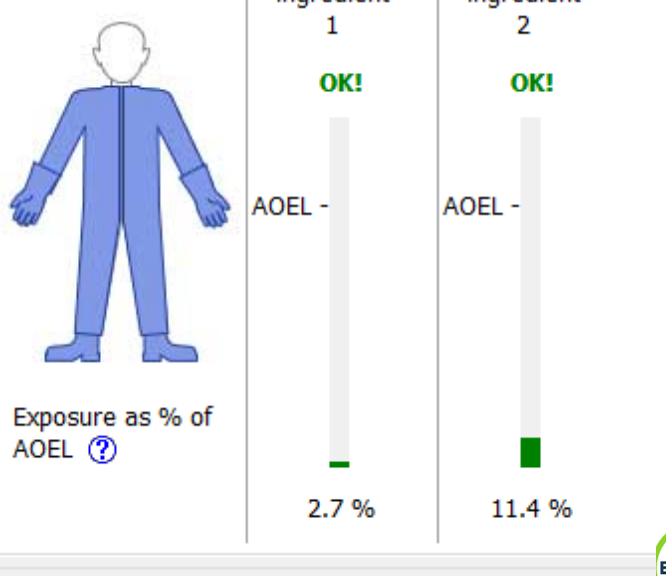
AOEL Indicator



AOEL Indicator 2



AOEL Indicator 3



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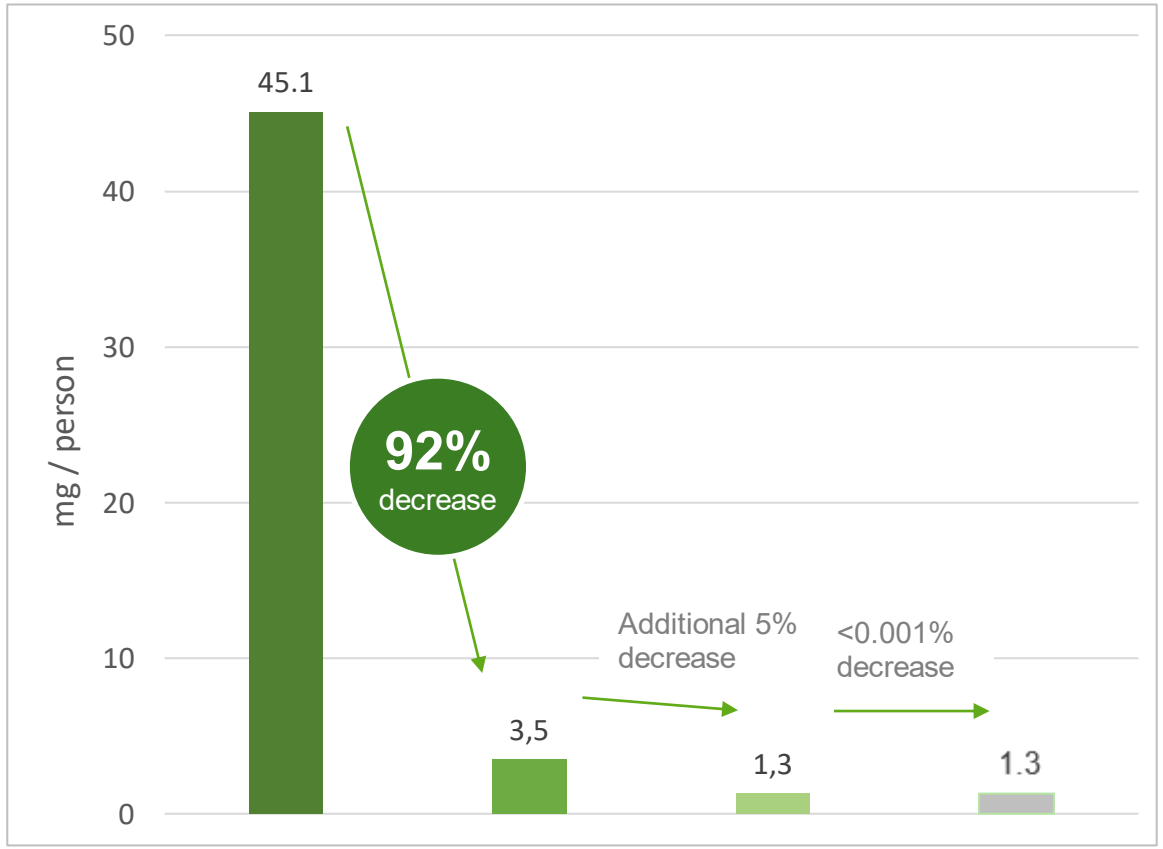
Impact of PPE on exposure



- Potential exposure
- With workwear (coverall, long-sleeve shirt and trouser)
- With workwear + nitrile gloves
- With workwear + nitrile gloves + FFP1 respirator

Workwear such as coverall or long-sleeve shirt and trousers has the **greatest** impact on **exposure reduction**.

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DEVELOPMENT OF THE ICPPE TOOL

2021 Q3 Q4 | 2022 Q1 Q2 Q3 Q4 | 2023 Q1 Q2 Q3 Q4 | 2024 Q1 Q2 Q3 | 2025 Q1

1 ICPPE kickoff workshop
2-day workshop to discuss options to improve operator safety in LMICs

2 Röver et. al (2022)
Outcome of workshop published in peer-reviewed journal:
https://doi.org/10.1007/s00003-021-01359-5

3 Working groups defined
Four working groups have been defined:
- WG1: Global database and exposure model
- WG2: Dermal absorption
- WG3: PPE
- WG4: User-friendly assessment tool

4 Exposure data collection ongoing
Number of studies to be considered in this project grows. Numerous studies were considered for the database.

5 Work in WG2-4 started
Besides WG1, also the other working groups are now active and have regular meetings

6 Finalization of database
Database is now machine readable and ready for analysis

7 Exposure algorithms finalized and alpha version is ready for testing
today
pilot testing,
Impact analysis,
Technical refinements

8 ICPPE Symposium
Workshop in Brazil with all stakeholders
Discussion on future projects

9 Rollout of ICPPE tool
Objective: Consideration of the tool in the FAO pesticide registration toolkit

Thank you for your attention!

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Risk Mitigation for Pesticide Operator Safety

Pilot testing in Kenya and South Africa in March 2024

Name	Affiliation	Country	Ste Co e
Markus Röver	Federal Office of Consumer Protection and Food Safety	Germany	
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Claudia Großkopf	German Federal Institute for Risk Assessment (BfR)	Germany	
Korinna Wend	German Federal Institute for Risk Assessment (BfR)	Germany	
Agathi Charistou	Benaki Phytopathological Institute Institute/EFSA WG	Greece	
Olivier Sanvido	State Secretariat for Economic Affairs	tzerland	
Jeff Evans	Retired EPA, Health Effects Division	A	
Mark Crowley	EPA, Health Effects Division	USA	
Thiago Santana	ANVISA, Brazilian Ministry of Health	Brazil	
Githaiga Wagate	Kenya Pest Control Products Board	Kenya	
Yueh Yi Lee	Taiwan Agricultural Chemicals and Toxic Substances Research Institute	Taiwan	
Si Young Yang	Rural Development Administration	S. Korea	
Debbie Muir	Department of Forestry, Fisheries and the Environment	South Africa	
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Mark Best	Syngenta, CropLife International OPEX team	UK	
Tharacad Ramanarayanan	Syngenta, Chair CropLife International		
Neil Morgan	Syngenta, CropLife Europe DAPT		
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Marcela Giachini	Corteva, CropLife International OPEX team; Brazil dermal absorption	Brazil	
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Richard Brown	WHO liason (Observer)	tzerland	
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Anugrah Shaw	ICPPE/UMES	USA	
Beatrice Grenier	FAO Consultant	France	
Marcelo Macedo	AZR/PPE manufacturer/PPE Initiative	Brazil	
Jurgen Schwarz	UMES/ Ag. Experiment Station	USA	

Regulators

Industry

Academia / Observers