Steering Committee and Working Group Members

Name	Affiliation	Country	Steering Committee	WG1	WG2	WG3	WG4
Markus Röver	Federal Office of Consumer Protection and Food Safety	Germany	*	*		*	
Sabine Martin	German Federal Institute for Risk Assessment (BfR)/EFSA WG	Germany	*	*	*	*	*
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 SECO / EFSA WG	Switzerland				*	*
Jeff Evans	Retired EPA, Health Effects Division	USA		*			
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 (TACTRI)	Taiwan		*	*	*	*
Si Young Yang	Rural Development Administration	S. Korea		*	*		
Christian Kuester	Bayer, CropLife Europe OBE TSG	Germany	*	*			*
Felix Kluxen	ADAMA, CropLife Europe DAPT	Germany			*		
Christiane Wiemann	BASF, CropLife International OPEX team; CropLife DAPT	Austria		*			*
Carrie Fleming	Corteva, CropLife International OPEX team	USA		*			
Steve McEuen	FMC, CropLife International OPEX team	USA		*	*		
Mark Best	Syngenta, CropLife International OPEX team	UK		*			
Tharacad Ramanarayanan	Syngenta, Chair CropLife International OPEX team	USA	*				*
Neil Morgan	Syngenta, CropLife Europe DAPT	UK			*		
Philip Fisher	Bayer, CropLife International OPEX team; CropLife DAPT	France			*		
Juan Sasturain	BASF, Kenya PPE Initiative	Germany				*	*
Tirso Oteyza	Syngenta, Kenya PPE Initiative	Switzerland				*	
Marc Freyeisen	Syngenta, Application Technology Manager	Switzerland				*	
Kevin Doughty	Bayer, CLI IPM & Responsible Use Project Team	Germany				*	
Jens Peter Lampe Venoe	Bayer, CropLife Asia product safety	Singapore					*
Marcela Giachini	Corteva, CropLife International OPEX team; Brazil dermal absorption	Brazil			*		*
Harold van der Valk	Falconsult	Netherlands		*			*
Friederike Breuer	FAO (Observer)	Italy	*			*	*
Richard Brown	WHO liason (Observer)	Switzerland		*	*		*
Eva Cohen	INSST-CNMP/ Notified Body for testing and PPE Certification	Spain				*	
Jiho Lee	Konkuk University, S. Korean studies	S. Korea		*		*	
Hamilton Ramos	Instituto Agronomico, Sao Paulo State,/ Certified lab for PPE	Brazil				*	
Anugrah Shaw	ICPPE/UMES	USA	*	*	*	*	*
Marcelo Macedo	AZR/PPE manufacturer?PPE Initiative	Brazil				*	
Jurgen Schwarz	UMES/ Ag. Experiment Station	USA	*				

* Coordinator

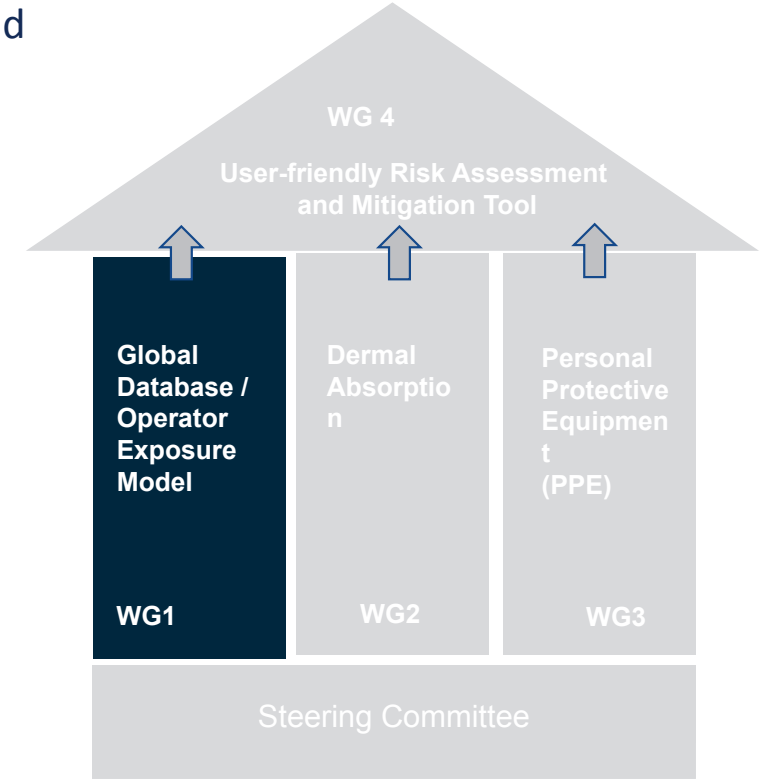
Working Group 1

Coordinator – Sabine Martin

- Global Database Highlights
- Global Database Update

Global Database Highlights

- Diverse Working Group – regulators, industry experts, FAO and WHO Observers
- Global database acceptance criteria for hand-held pesticide applications—based on consensus
- Robust dataset—approx. 50 whole body dosimeter studies
- Exposure data from existing models and “new data”:
  - Existing models - AOEM, AOEM Greenhouse, EPA Reviews
  - Twelve studies from Republic of Korea
  - CropLife International (CLI) member company studies conducted in different regions
  - Additional studies from Greece, India and France



Global Database Structure

- AOEM data template modified for data entry
  - Garment and PPE details added to support risk mitigation
  - Sub-group for hand-held application devices
  - Scenario details – walking into spray; dense crop

- Assignment of studies to application scenarios (images from different regions of the world as well as studies used for assignment)

- Machine readable database prepared for statistical analysis and model development to be done by an independent consultant

	A	B	C	D	E	F	G	H	I	J
1	Study parameters									
2	study code	op no	site	country	OD / GH	spray direction	crop	crop_category	equipment ty	walking into spr
488	CBNU-2	F		S. Korea	OD	upward	paddy	Paddy	2a	yes
489	CBNU-2	G		S. Korea	OD	upward	paddy	Paddy	2a	yes
490	CBNU-2	H		S. Korea	OD	upward	paddy	Paddy	2a	yes
491	CBNU-2	I		S. Korea	OD	upward	paddy	Paddy	2a	yes
492	CBNU-2	J		S. Korea	OD	upward	paddy	Paddy	2a	yes
493	CBNU-2	K		S. Korea	OD	upward	paddy	Paddy	2a	yes
494	KBSI-2	A		S. Korea	OD	upward	paddy	Paddy	2a	yes
495	KBSI-2	B		S. Korea	OD	upward	paddy	Paddy	2a	yes
496	KBSI-2	C		S. Korea	OD	upward	paddy	Paddy	2a	yes
497	KBSI-2	D		S. Korea	OD	upward	paddy	Paddy	2a	yes
498	KBSI-2	E		S. Korea	OD	upward	paddy	Paddy	2a	yes
499	KBSI-2	F		S. Korea	OD	upward	paddy	Paddy	2a	yes
500	KBSI-2	G		S. Korea	OD	upward	paddy	Paddy	2a	yes
501	KBSI-2	H		S. Korea	OD	upward	paddy	Paddy	2a	yes
502	KBSI-2	I		S. Korea	OD	upward	paddy	Paddy	2a	yes
503	KBSI-2	J		S. Korea	OD	upward	paddy	Paddy	2a	yes
504	SNU-3	A		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
505	SNU-3	B		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
506	SNU-3	C		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
507	SNU-3	D		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
508	SNU-3	E		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
509	SNU-3	F		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
510	SNU-3	G		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
511	SNU-3	H		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
512	SNU-3	I		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
513	SNU-3	J		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
514	CBNU-3	A		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
515	CBNU-3	B		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
516	CBNU-3	C		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
517	CBNU-3	D		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
518	CBNU-3	E		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
519	CBNU-3	F		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
520	CBNU-3	G		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes
521	CBNU-3	H		S. Korea	OD	down	cabbage	Fruits_Vegetables	2c	yes

Application Devices and Exposure Scenarios

Application Devices

- Knapsack
  - Manual/hydraulic (≤ 40 psi)
  - Motorized – low pressure (≤ 40 psi)
  - Motorized – high pressure (100-120 psi)
  - Motorized – atomizer (very fine droplets)
- Attached to a hose/semi-stationary
  - Lance
  - Spray gun
  - Spray boom
  - Trolley (pulled)

Application Scenarios

- Outdoor and greenhouse (green house studies only from The US and Europe)
- Spray direction – down and upward
- Walking into spray drift

ICPPE

Global Database Evaluation

- Separate evaluation of Mixing/Loading (ML) and Application (A) (MLA data are included in database but focus for statistical analysis will be on separate datasets for ML and A).
- Consideration of application direction (down, upwards) discussed and agreed based on consensus
- Consideration of different exposure scenarios discussed and agreed based on consensus:
  - Normal crop
  - Dense crop
  - Walking into spray drift
- Factors considered important for model development were highlighted in yellow based on consensus.
- Consideration of particular exposure conditions:
  - Paddy rice

Working Group 1 Update

- Criteria for acceptance of studies discussed, agreed on list of criteria based on consensus.
- AOEM database was modified based on WG1 discussion. Additional columns were completed AOEM and AOEM GH studies. Template prepared for data entry of other studies.
  - Data entered from Excel file provided by EPA were spot checked as these studies had undergone regulatory review.
  - A two-step process was used for data entry and data check for studies that had not been reviewed for regulatory purposes.
- Recovery data check (values below 95% were corrected; values below LOQ not corrected)
- WG1 sub-group meeting held in Berlin in Dec. 2022 and Jun. 2023 to address data issues and develop machine readable file. Statisticians attended the meetings.
- Machine readable database was submitted for independent analysis in July 2023.
- Preliminary analysis was presented by WSC to WG1 sub-group in September 2023. WG1 members were invited to join the sub-group to review the information and prepare documents for the next WG1 meeting.

Working Group 2

Coordinator – Neil Morgan

- Smaller working group with expertise in dermal absorption
- Review default values for regulatory purpose
- Use available vitro studies submitted to EU regulatory agencies for independent analysis

Dermal Absorption – Default Factor

- Dermal absorption calculations are complex. Studies and methods used vary considerably.
- Simplified default absorption values could play an important role in development of robust but user-friendly model for countries with limited resources.
- The goal is to propose scientifically justified default values for the global database/model.
  - Focus on transparency and limiting decision making by end user.
- Engaging in scientific discussions does not imply endorsement of the information by the expert's organization.

Working Group 2 Update

- Decision made to use in vitro studies accepted by regulators in Europe for regulatory purposes.
- A 2-step process will be used for analysis:
  - Step 1: Analysis of data provided by CropLife Europe. This dataset was used for industry proposed default values. It is also part of the dataset used for EFSA defaults, and those by ProHuma in Brazil. Approval to use data given by CLE member companies.
  - Step 2: Follow up analysis on additional newer data provided by CLE member companies.
- The criteria for inclusion of studies has been discussed and consensus achieved
- Important factors discussed and agreement reached on
  - Acceptable number of replicates
  - Recoveries/mass balance
  - Definition of absorbed dose
- The factors to be used for statistical analysis have been identified.
- Statistical analysis to be conducted by an independent company.
  - Pre-meeting with statisticians to reach agreement on approaches scheduled for 4 October 2023.
  - Will help determine best way to stratify defaults (formulation type, concentration, dose?)

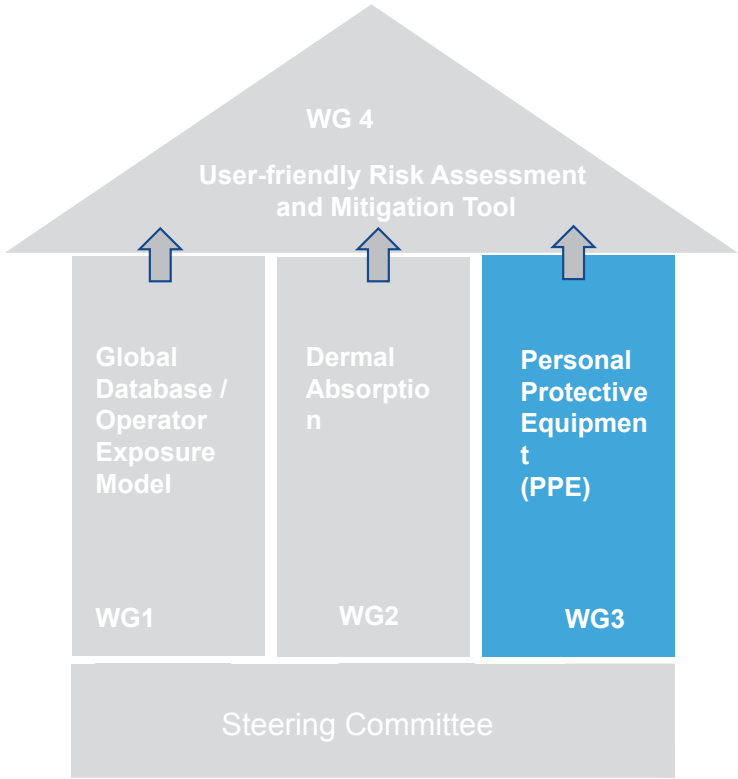
Working Group 3

Coordinator – Anugrah Shaw

- Operator exposure studies as basis for risk mitigation
- Partial-body garments for additional protection
- “Locally” manufactured garments to address availability

Key Points

- Dermal protection is important for risk mitigation, especially for high exposure scenarios.
- Operator exposure studies used to determine equivalencies.
- Descriptive terms lack specificity. Standards effectively communicate the requirements/equivalencies.
  - C1 for basic requirement and C3 for additional protection.
- Balance between protection and comfort is needed for protection in high exposure scenarios. Heat stress and non-compliance are concerns that require consideration.
  - partial-body protection could provide solutions for high exposure scenario.
- Address constraints such as cost, and availability are important.



Equivalencies based on OPEX studies

Constraints: Comfort, Availability, Cost, User Acceptance

- Partial-body garments for additional protection - a balance between protection and comfort.
- Cost and availability addressed at the country/region level:
  - "Locally" manufactured garments could address availability and possibly cost.
  - Brazil an example of easily available, locally made and certified ISO 27065 C2 garments.
- User preferences (style, colors) addressed at the "local" level:
  - Coverall design preferred in Kenya C1 garment.
  - Pant and shirt with front placket the norm in Brazil.
  - Global database being developed for user preference.

Four sub-groups within WG3

WG3-1: PPE Equivalencies based on OPEX Study garments and lab testing	▪ Workwear - Equivalency confirmed with C1 ▪ Impermeable Garments – Equivalency to be confirmed in consultation with WG1.
WG3-2: Partial and whole body C3 garments: Balance between protection and comfort	▪ Analyze OPEX data for partial-body garments ▪ Pilot test methodology for evaluation of C3 garments ▪ Evaluate available partial-body garments and new prototype designs ▪ Conduct risk mitigation studies in different countries
WG3-3: Availability of certified PPE – "Global" framework to support "local" implementation	▪ Develop certified ISO 27065 C1 coveralls in Kenya ▪ Establish framework to address availability and cost constraints ▪ Expand partnerships facilitate availability of PPE
WG3-4: Communication and training	▪ Coordinate communication and training with WG4-4 ▪ Use Kenya as a case study to train-the-trainers ▪ Expand the communication and training in other countries

Working Group 3 Update

- WG3-1: Data for studies with impermeable garments analyzed. Materials being collected for permeation tests in the lab.
- WG3-2: Data for Paddy studies analyzed. Protocol for qualitative assessment of partial-body garments is being pilot tested in S. Korea in paddy fields.
- WG3-3: PPE Partnership Project with BASF, Syngenta and Pest Control Products Board:
  - User input obtained from approximately 100 farmers in Kenya.
  - C1 coveralls based on user survey and discussion are being produced for distribution in Kenya.
  - Final version for certification by Kenya Bureau of Standards will be produced based on feedback from the users of the garment.
- WG3-4: Training to be planned in coordination with WG4-4.

Working Group 4

Coordinator – Christian Kuester

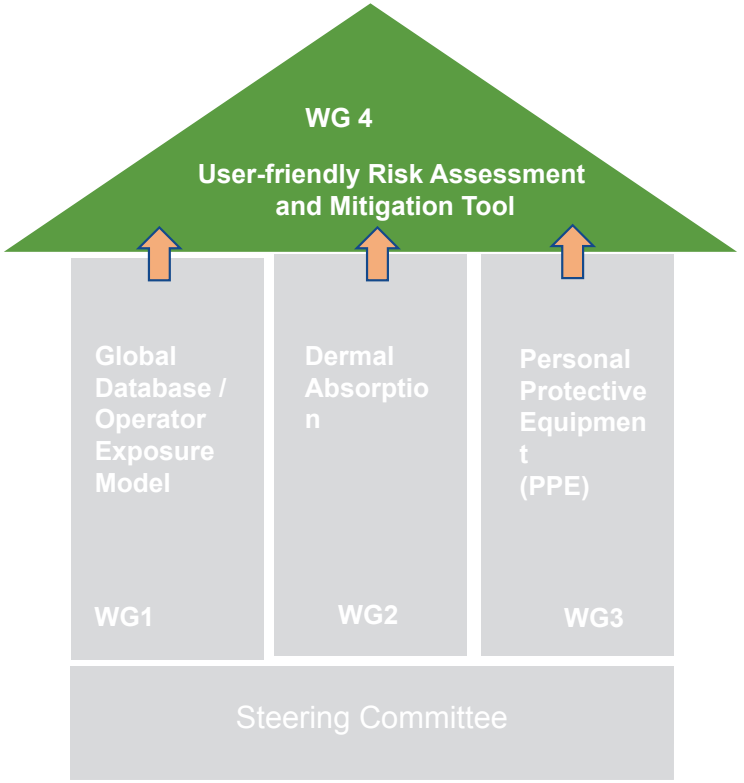
- International expertise in risk assessment
- Input from countries in Africa, Asia, and Latin America to develop a tool that meets their needs
- Comments/input from FAO trainers
- Flexibility, consistency and accuracy

User-friendly Risk Assessment and Mitigation Tool

- A web-based tool developed with “global” data and expertise to address “local” needs.

- Builds on outcomes of Working Groups 1, 2, and 3:
  - Global database/model for hand-held applications developed by WG1.
  - Principles for default values for dermal protection proposed by WG2.
  - PPE for risk mitigation proposed by WG3, in consultation with WG1.

- Input from the users is critical – FAO Toolkit trainers and regulators who attended the training to provide user input.



Builds on WG1, 2, and 3 outcomes

Flexibility, Consistency, Accuracy

A user-friendly tool that balances flexibility with consistency and accuracy.

- Flexibility
  - Default values for factors such as area treated or crop structure with flexibility to enter country specific values
  - Flexibility also in terms of available technology
  - Find the right balance between precautionary principles and realistic assumptions

- Consistency
  - Access to toxicological data of active substance to derive consistent endpoints (AOELs).
  - Principles for default values/ guidelines for dermal absorption

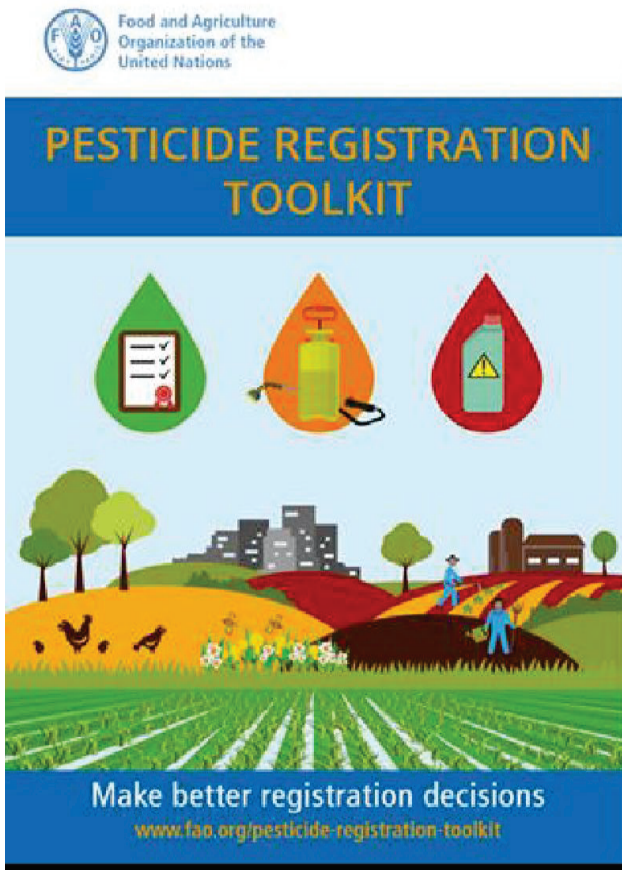
- Accuracy
  - Based on robust global database for hand-held applications
  - Model based on factors agreed by international experts, many engaged in the development of models currently in use.

ICPPE Risk Assessment and Mitigation Tool

Follow factors required by FAO for likely inclusion of the ICPPE assessment tool in FAO toolkit are being addressed:

- Relevant for pesticide application conditions in Africa, Asia and Latin America.
- Both the underlying data and the model are considered scientifically sound after having gone through an independent review
- Hosted by an independent and reputable institution / authority
- Can be freely accessed by pesticide registration staff
- Transparency in all steps

Four sub-groups with coordinator for each sub-group established.



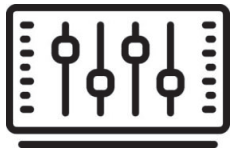
Four sub-groups within WG4

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:
Front-end 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 potential users.
- **Trainings and workshops** are needed to improve the acceptance.
- **Feedback loops** and changes of the tool are important to consider proposals by regulators.

ICPPE

Working Group 4 Update

- WG4-1: We've sent out an initial survey to FAO trainers and regulators who have taken part in the FAO toolkit training. The goal is to gather preliminary feedback and to pique interest. We've received responses from 19 countries, with an equal representation from Asia, Africa, and Latin America. Our next step is to create a sounding board to better understand the needs of the regulators.
- WG4-2: Brainstorming sessions were held to focus of the front-end functionality. Sub-group members have provided ideas for the following:
  - Functionality - tasks performed effectively and accurately with reliable, precise, and timely results.
  - User Experience - clean design, instructions, and easy navigation; minimize the learning curve.
  - Data Visualization – Focus on display of results to make complex data more meaningful.
  - Flexibility - adaptable to a wide range of agronomic conditions and regulatory environments.

  Next step: Scoring table to identify high priority tasks
- WG4-3: No activity as information required will be available after the model is developed and analysis completed for default values.
- WG4-4: The following topics were discussed at the kick-off meeting:
  - Overview to introduce the tool to regulators; advanced training for countries interested in transitioning to risk assessment with training also for other stakeholders in that country.
  - Training format for face-to-face meeting and virtual sessions.
  - Feedback loop.