Dermal Protection for Risk Mitigation: Operator exposure studies as the basis for partial- and whole-body garments for high exposure scenarios

<u>Anugrah Shaw</u><sup>1</sup>, Sabine Martin<sup>2</sup>, Claudia Grosskopf<sup>2</sup>, Githaiga Wagate <sup>3</sup>

 <sup>1</sup> International Center for PPE for Pesticide Operators and Re-entry Workers, University of Maryland Eastern Shore, Princess Anne, MD 21853, USA ashaw@umes.edu
 <sup>2</sup> Federal Institute for Risk Assessment, Department Safety of Pesticides, Berlin, Germany, <sup>3</sup> Pest Control Products Board, Nairobi, Kenya

## Introduction

- Personal protective equipment (PPE) plays a central role in reducing operator exposure.
- Requires consideration in the authorization of pesticide products.
- Understanding potential risk is an important first step to determine the type of PPE required for risk mitigation.
- Agricultural exposure models, based on exposure field studies, are essential in estimating the risks of pesticides and in assigning the necessary PPE.



## The ICPPE-LMIC Initiative: Strategy



#### Steering Committee Strategy and scoping



Development of global database and operator exposure model for handheld applications relevant for LMIC.



Comparison of dermal absorption approaches with focus on default values.



PPE for risk mitigation based on exposure studies; partial body garments to balance protection and comfort



Based on outcome of WG1-3, development of a userfriendly risk assessment tool.

## PPE for Risk Mitigation

- Bridge between risk assessment and risk management
- Requires understanding PPE and PPE constraints
- WG 3 includes experts in risk assessment, risk management, and PPE/PPE Certification.
  - Risk assessors data analysis of global database
  - PPE experts PPE and PPE certification
  - Risk managers constraints and user acceptance.



# PPE for Risk Mitigation

- PPE Equivalencies OPEX Studies
- Constraints
  - Comfort
  - Availability of PPE
  - User Acceptance
- Proposed tables for PPE mitigation

## PPE for Risk Mitigation

Outer and Inner Dosimeter data provides information on dermal protection provided by garments and gloves.

- Gloves for mixing and loading (M/L) and application
  - Certified nitrile gloves used for OPEX studies
  - Hand protection important for M/L
- Garments for dermal protection
  - Studies often conducted with workwear study garments.
  - For two high exposure studies additional data was collected for other study garments.
    - Certified Type 6 garments with repellent finish
    - "Impermeable" rainsuits/rain trousers



Study garment meets C1 requirements

## Normal Spray Application Scenarios: Workwear, gloves, masks

- **Garments** typically provide the highest protection during application.
- Operator exposure is often higher for hand-held applications.
- Hand-held application still primary means of application in many LMICs.
- Focus on garments to reduce exposure during spraying for handheld applications.
  - Operator exposure data to determine if additional protection is required.

#### Airblast application, no cabin 3.5 Assumptions: 3 Application rate: 0.82 kg a.s./ha Exposure (mg/kg bw/day) Treated area: 10 ha 2.5 2 1.5 0.5 0 Potential Work wear/C1 Work wear/C1 Work wear Work wear/ C1 exposure + FFP1 mask (M&L) + FFP1 mask (M&L) + FFP1 mask (M&L) + gloves (M&L) + gloves during M&L and application + impervious/C3 High Crop, Handheld Spraying with spray gun/lance 3.5 Assumptions: 3 Application rate: 1.55 kg a.s./ha Exposure (mg/kg bw/day) Treated area: 4 ha 2.5 2 1.5

Data Source: AOEM Studies

0.5

0

Potential

exposure

Work wear/ C1

Work wear/C1

Work wear/C1

+ gloves (M&L)

+ FFP1 mask (M&L) + FFP1 mask (M&L)

Work wear

+ FFP1 mask (M&L)

+ impervious/C3

+ gloves during M&L and application

## High crop high exposure: Three study garments

- Greenhouse study in pepper in Almeria region in Southern Spain.
  - Rows distance 0.8 to 2.0 m; crop height ranged 1.1 to 2.1 m.
  - Operators frequently brushed against the treated crop.
- Phase 1 Operators 1-10 wore polyester/cotton workwear (Mauser coverall).
- Phase 2 Operators 11-17 wore certified Type 6 coveralls and Operators 18-33 wore rainsuits.
  - Certified Type 6 coveralls polyester/cotton with repellent finish.
     Repellent finish is also used for ISO 27065 C2 garments.
  - Rainsuits were made of fabric with polyurethane coating.

Note: The studies pre-dated development of ISO 27065.



Study garment - rain suit

## Comparison of study garments: High crop high exposure



Outer Dosimeter (µg)

Inner Dosimeter (µg)

## Comparison of study garments: Low crop/high exposure

- Workwear worn by 20 applicators in the greenhouse study in Italy
  - Crop- melon; height of 10 to 50 cm
  - The study garment polyester/cotton Mauser coverall
- Rain trousers worn by 10 applicators for the follow up study
  - Crop melons; height of 20 to 60 cm
  - Cotton workwear shirt/jacket and PVC-coated rain trousers. The PVC-coated rain trousers were not sampled; potential exposure was not calculated for legs.



#### Comparison of study garments: Low crop/high exposure

**Outer Dosimeter -**



OD - Torso OD - Arms OD - Legs



# **PPE Equivalencies**

Terminology based on international performance-based standards provide a framework for consistent communication/requirements.

- ISO 27065 Level C1 garments minimum requirement equivalent to workwear study garments
- ISO 27065 Level C3 garments partial and whole-body garments for additional protection.
  - Study on "impermeable" materials (including rain suits) is ongoing.

**ISO 27065:2017(en)** Protective clothing — Performance

requirements for protective clothing worn



by operators applying pesticides and for reentry workers https://www.iso.org/obp/ui/#iso:std:65660:en

| Table of contents                                    | Available in: EN F → Redlines ▼ Q   |  |
|--|---|--|
| Foreword   | Level C1 protective clothing, including partial-body, is suitable when the potential risk is  |  |
| Introduction   | relatively low. Level C1 protective clothing provides the least protection and is not suitable for use with concentrated pesticide formulations. It can be used as the base protective clothing with additional items worn when the potential risk is relatively higher. See Annex F for additional information on risk assessment and use of PPE for risk mitigation.  |  |
| 1 Scope  |   |  |
| 2 Normative references                               |   |  |
| 3 Terms and definitions                              |   |  |
| 4 Classification and testing requirements            |   |  |
| <ul> <li>5 Pre-treatment and conditioning</li> </ul> | Level C2 protective clothing, including partial-body, is suitable when it has been determined that the protection required is higher than that provided by Level C1 protective clothing. Level C2 protective clothing typically provides a balance between comfort and protection. This protective clothing is not suitable for use with concentrated pesticide formulations. It can be used as the base protective clothing with additional items worn when the potential risk is relatively higher. |  |
| 5.1 Pre-treatment by cleaning                        |   |  |
| 5.2 Conditioning                                     |   |  |
| ▼ 6 Performance requirements of protective           |   |  |
| 6.1 General  |   |  |
| 6.2 Material resistance to penetration               |   |  |
| 6.3 Material Repellency (pipette test)               | Level C3 protective clothing, including partial-body, is suitable for use when it has been determined that the potential risk is high. Precautionary measures such as short duration for use are necessary for Level C3 suits/coveralls that may cause heat build-up resulting in heat exhaustion/stress. Level C3 protective clothing, including partial-body is suitable for use with diluted as well as concentrated pesticides  |  |
| 6.4 Material resistance to permeation                |   |  |
| 6.5 Material tensile strength                        |   |  |
| 6.6 Material tear resistance                         |   |  |
| 6.7 Material puncture resistance                     |   |  |
| ▼ 7 Performance requirements of seams                | Personal Protective Equipment (PPE) is often used for risk mitigation. See Annex F for information on risk assessment and use of PPE for risk mitigation. Since protective clothing can be contaminated in various ways (e.g. fine spray, contact with wet surface,   |  |
| 7.1 General  |   |  |
| 7.2 Seam resistance to penetration                   |   |  |
| 7.3 Seam resistance to permeation                    |   |  |
| 7.4 Seam tensile strength                            | contact with pesticide product sprayed under pressure, contact between the protective   |  |
| ▼ 8 Performance requirements of protective           | rate materials and clothing rather than simulate the various field conditions.  |  |
| Figures  | ISO 16602 focuses on industrial chemicals, whereas this document focuses on protection against pesticides that are frequently applied in aqueous solutions. Penetration, permeation, and repellency tests in ISO 16602 are typically done with  |  |
| Tables   |   |  |
|  |   |  |

# PPE for Risk Mitigation

- PPE Equivalencies OPEX Studies
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  - Comfort
  - Availability of PPE
  - User Acceptance
- Proposed tables for PPE mitigation

## 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.
- User preferences (style, colors) addressed at the "local" level.
  - Brazil an example of easily available, locally made and certified ISO 27065 garments.
  - Level C2 garments preferred in some countries in Europe.



# Partial-body garments to balance protection and comfort

Hand-held application often have higher exposure.

- Partial body garments may provide options to balance protection and comfort. Focus on:
  - Back protection for knapsack spray application
  - Leg protection for:
    - Low crop high exposure scenario
    - Paddy spray application
  - Head and torso protection for overhead spraying



# Cost and Availability : International/National Collaboration

Ongoing collaboration in Kenya: Locally manufactured and certified Level C1 PPE for risk mitigation

- Stakeholder collaboration
  - Kenya fabric and PPE manufacturer
  - Kenya Bureau of Standards
  - Kenya Pest Control Products Board
  - BASF, Global PPE Initiative
  - Syngenta, Sustainable and Responsible Use/ Africa
  - ICPPE
  - Instituto Agronomico (Brazil)

## Framework for User Acceptance

User acceptance is crucial for adoption of PPE. A grassroots approach to engage potential users PPE development.

Step 1: Information on cultural norms from persons working closely with farmers/operators

Step 2: Input from farmers/operators in small group settings

- Questionnaire will be completed by the participants prior to group discussion.
- Group discussion on garment features that impact cost, comfort, and protection
- PPE "designed" collectively to be proposed for consideration.

Step 3: Wear study (only for C3 garments)

## Framework for User Acceptance

User acceptance is crucial for adoption of PPE - engage potential users PPE development.

- Pilot testing in Kenya by BASF and Syngenta.
- Kenya PPE Collaboration:
  - IAC, Brazil (fabric testing)
  - AZR, Brazil (protype manufacturing)
  - University of Maribor, Slovenia (functional design)
  - BASF team (Kenya logistical support and data collection; headquarters planning)
  - Syngenta team (Kenya data collection)
  - ICPPE/UMES, database development, planning/coordination.

## Future Plans

- Data analysis of high exposure scenarios
  - Lower leg protection for paddy field
  - Overhead application scenarios
- C3 fabric testing and equivalency
- Evaluation of partial-body garments
- Expand user acceptance framework

# Special Thanks

- ICPPE-LIMIC Working Group 3
- Kenya PPE collaboration team

| ICPPE LMIC Initiative – Working Group 3 |   |  |
|---|---|--|
| Name                                    | Affiliation   |  |
| Agathi Charistou                        | Benaki Phytopathological Institute Institute/EFSA WG                  |  |
| Anugrah Shaw+                           | ICPPE/UMES  |  |
| Claudia Großkopf                        | German Federal Institute for Risk Assessment (BfR)                    |  |
| Eva Cohen                               | INSST-CNMP/ Notified Body for testing and PPE Certification           |  |
| Githaiga Wagate                         | Kenya Pest Control Products Board                                     |  |
| Hamilton Ramos                          | Instituto Agronomico, Brazil/ Certified lab for PPE                   |  |
| Juan Sasturain                          | BASF, Kenya PPE Initiative  |  |
| Kevin Doughty                           | Bayer AG, CLI IPM & Responsible Use Project Team                      |  |
| Marc Freyeisen                          | Syngenta, Application Technology Manager                              |  |
| Marcelo Macedo                          | AZR/PPE manufacturer  |  |
| Markus Röver                            | Federal Office of Consumer Protection and Food Safety                 |  |
| Olivier Sanvido                         | Swiss State Secretariat for Economic Affairs/ EFSA WG                 |  |
| Sabine Martin                           | German Federal Institute for Risk Assessment (BfR)/EFSA WG            |  |
| Thiago Santana                          | ANVISA, Brazilian Ministry of Health                                  |  |
| Tirso Oteyza                            | Syngenta, Kenya PPE Initiative  |  |
| Yueh Yi Lee                             | Taiwan Agricultural Chemicals and Toxic Substances Research Institute |  |
| * WG Coordinator                        |   |  |