About PPE

• PPE is a term often used during risk assessment, labeling, and training. However, PPE can be applied in a variety of contexts, depending on the lens we look through.

• Stakeholder groups view PPE issues through their own lens
  o PPE issues contain different levels of significance and thus require involvement

• PPE issues typically vary by country/region
  o The level of stakeholder engagement stems primarily from relevant national/regional regulations

• Most of the group/individual engage in activities related to specific aspects of PPE that closely relate to their responsibilities
  o Very few stakeholders have the opportunity to see the “big picture”.

Networking – PPE Stakeholders

Federal agencies responsible for PPE and/or PPP (pesticide) requirements

Entities impacted by PPE and/or PPP (pesticide) regulations

Standards Development Organizations

Third party testing and/or certification laboratories

Users or organizations representing user interest

Neutral Entities – often dependent on support from public or private organizations

Note: Circle size is based on text and not the level of involvement

CEN – EU Standards Organization
EFSA – European Food Safety Authority
ANSES – French Agency Responsible for Risk Assessment
ISO and ASTM – International Standards Organizations
ANSES – French Agency Responsible for Risk Assessment
Interconnectedness through Networking

Test Chemical for ISO standards
- Prowl® 3.3 EC selected based on studies in 2000s
- Prowl® 3.3 EC availability and consistency issues raised by ISO and CEN members
- BASF France worked with BASF USA to secure sufficient products to support testing for 2 years
- BASF France distributed in EU; BASF Brazil in Brazil; BASF USA in other countries
- The surface tension measured in Brazil and data compared with 2003 US data
- Fabric from studies in 2000s were sent to Brazil and France for validation of ISO 27065 requirement
- UMES worked with BASF and the labs in Brazil and France to resolve the issue

Outcome: Integrity of the standard maintained through validation and the availability concerns expressed by notified bodies were addressed
Leveraging Expertise and Connections to Find Solutions
Cooperation and thinking outside the box resulted in use of Level 1 garments for re-entry study

**Issue**
- Company responsible for garment prototypes was unable to find fabrics that met Level 1 requirements.
- UIPP agreed to use Level 1 garments if consortium could get the fabric by mid-July.

**Fabric Selection**
- Potential fabrics selected based on information from previous studies.
- BASF handled coordination with fabric manufacturers.

**Test Result**
- IAC (Brazil) tested the fabrics and emailed the data within a week.
- I worked with BASF and UIPP on fabric selection in early July.

**Need for PPE Manufacturer**
- In mid-July, UIPP was informed that the garments could not be manufactured by the end of August.
- University of Maribor was contacted to identify a PPE manufacturer in Slovenia.

**Garment Production**
- Manufacturer in Slovenia signed the non-disclosure agreement and UIPP emailed the CAD files.
- The garments were produced within a week and sent to University of Maribor for washing.

**Outcome**
- UIPP received the garments that were washed according to the ISO specifications by the end of August 2016.
Build on the Past, Plan for the Future

- Previous work – Methodology research and standards development
  - Selected accomplishments, stakeholders involved, my role, funding source
- Ongoing projects – Activities in 2015
  - Standards Development
  - Implementation of prEN ISO DIS 27065 in France
  - Research Activities
- Future Plans
  - Plans for 2016 -17
  - Possible Research and Outreach Activities
Previous Work: Methodology Research and Standards Development

- Pipette test
- Permeation test
- ISO 27065
<table>
<thead>
<tr>
<th>Selected Accomplishments</th>
<th>Stakeholders Involved</th>
<th>My Role</th>
<th>Funding Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Studies to refine methodology in 1990s</td>
<td>Three universities in the US. International labs participated in inter-laboratory studies</td>
<td>Served as lead Institution</td>
<td>USDA funded multi-state project (US universities)</td>
</tr>
<tr>
<td>Comparison of pipette, gutter, and atomizer method</td>
<td>Three laboratories from Spain, Germany, and US</td>
<td>Coordinated the research and conducted pipette test</td>
<td>Each institution covered its own expenses</td>
</tr>
<tr>
<td>Approval of ISO 22608 (test method to measure pesticide permeation)</td>
<td>Members of ISO WG3 committee on chemical protection</td>
<td>Project Leader – developed draft and worked with member countries</td>
<td>My time and travel covered by the multi-state project</td>
</tr>
<tr>
<td>Research to support protective clothing performance standard</td>
<td>Research conducted at UMES. Pesticides provided by manufacturers in US and Europe</td>
<td>Project Leader</td>
<td>USDA funded multi-state project</td>
</tr>
<tr>
<td>Approval of ISO 27065 (performance requirement for protective clothing)</td>
<td>ECPA - exposure studies data ASTM and ISO committees</td>
<td>Project Leader – developed the draft and worked with member countries</td>
<td>My time and travel covered by the multi-state project</td>
</tr>
<tr>
<td>Development of a method to measure pesticide permeation. Draft to be balloted as an EN/ ISO standard.</td>
<td>Members of CEN WG3, Sao Paulo State University, UMES</td>
<td>Responsible for the development and validation of the cell</td>
<td>UMES - USDA funded multi-state project Sao Paulo State University</td>
</tr>
</tbody>
</table>
Ongoing Projects – Activities in 2015

- **EN/ISO Standards Development**
- **prEN/ISO DIS 27065 Implementation**
- **Methodology Based Studies**
- **Thermo-physiological Comfort**
Update on EN/ISO Standards Development

**Performance Requirement for protective clothing**

- EN ISO/DIS 27065.2 Protective clothing — Performance requirements for protective clothing worn by operators applying liquid pesticides and for re-entry workers.
- To be balloted concurrently as an ISO and EN draft standard. Ballot closes on Feb 17th.
- Results of the ballot to be discussed at the ISO and CEN meetings.
- Proceeds as an EN/ISO standard, if approved by ISO and CEN.

**Test Method for Permeation of Active Ingredients**

- EN ISO 19918 Protective clothing — Protection against liquid chemicals — Measurement of cumulative permeation of chemicals with low vapour pressure through protective clothing, footwear, and glove materials.
- Draft Discussed at the CEN Working Group 8 meeting.
- Draft revisions are being circulated to ISO and CEN members.
- Draft to be discussed at the ISO meeting in March and then balloted.

**Performance Requirement for protective clothing**

- EN ISO/DIS 18889 Protective gloves for pesticide operators — Performance requirements.
- Draft Discussed at the CEN Working Group 13 meeting.
- Draft revisions are being circulated to ISO and CEN members.
- Draft to be discussed at the ISO meeting in March and then balloted.
Glove Requirements

• The glove requirements vary considerably around the world.
• With no test standard to measure permeation of active ingredient with low vapor pressure and/or low solubility in collection media, glove requirements are often based on permeation of solvents or other chemicals.
  o In Europe and Brazil, EN 374-1 is used to determine glove requirements. Gloves have a EC mark.
  o In Germany, Guidelines for Requirements Concerning Personal Protective Equipment requires testing of gloves in accordance with DIN EN 374-3 with seven chemicals.
  o In the United States, the EPA Chemical Resistance Category Selection Chart for Gloves is used to determine glove requirements. This chart is based on glove studies conducted in the 1980s.
## EPA Chemical Resistance Category Selection Chart for Gloves

<table>
<thead>
<tr>
<th>Solvent Category</th>
<th>Barrier Laminate</th>
<th>Butyl Rubber ≥ 14 mils</th>
<th>Nitrile Rubber ≥ 14 mils</th>
<th>Neoprene ≥ 14 mils</th>
<th>Natural Rubber ≥ 14 mils</th>
<th>Polyethylene ≥ 14 mils</th>
<th>Polyvinyl Chloride (PVC) ≥ 14 mils</th>
<th>Viton® ≥ 14 mils</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (dry and water based)</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>B</td>
<td>High</td>
<td>High</td>
<td>Slight</td>
<td>Slight</td>
<td>None</td>
<td>Slight</td>
<td>Slight</td>
<td>Slight</td>
</tr>
<tr>
<td>C</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Moderate</td>
<td>Moderate</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>D</td>
<td>High</td>
<td>High</td>
<td>Moderate</td>
<td>Moderate</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>Slight</td>
</tr>
<tr>
<td>E</td>
<td>High</td>
<td>Slight</td>
<td>High</td>
<td>High</td>
<td>Slight</td>
<td>None</td>
<td>Moderate</td>
<td>High</td>
</tr>
<tr>
<td>F</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Moderate</td>
<td>Slight</td>
<td>None</td>
<td>Slight</td>
<td>High</td>
</tr>
<tr>
<td>G</td>
<td>High</td>
<td>Slight</td>
<td>Slight</td>
<td>Slight</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>High</td>
</tr>
<tr>
<td>H</td>
<td>High</td>
<td>Slight</td>
<td>Slight</td>
<td>Slight</td>
<td>None</td>
<td>None</td>
<td>None</td>
<td>High</td>
</tr>
</tbody>
</table>
## Glove Research Data for Reusable Gloves

<table>
<thead>
<tr>
<th>Material</th>
<th>Thickness mil</th>
<th>Gesaprim® 500 Mean (SD)</th>
<th>Prowl® 45.5 Mean (SD)</th>
<th>Prowl® 3.3 EC Mean (SD)</th>
<th>Herbadox® Mean (SD)</th>
<th>Sabre® Mean (SD)</th>
<th>Lorsban® Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PVC</td>
<td>12</td>
<td>1.1 (0.12)</td>
<td>0.3 (0.04)</td>
<td>51.0 (26.29)</td>
<td>55.7 (28.73)</td>
<td>56.87 (33.25)</td>
<td>366.2 (78.93)</td>
</tr>
<tr>
<td>Natural Rubber</td>
<td>18</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
</tr>
<tr>
<td>Nitrile</td>
<td>15</td>
<td>&lt;LOQ</td>
<td>0.15 (0.06)</td>
<td>0.2 (0.14)</td>
<td>0.4 (0.71)</td>
<td>&lt;LOQ</td>
<td>0.3 (0.56)</td>
</tr>
<tr>
<td>Neoprene</td>
<td>24</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
</tr>
<tr>
<td>Butyl</td>
<td>7</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
</tr>
<tr>
<td>Butyl</td>
<td>13</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
</tr>
<tr>
<td>Barrier Laminate</td>
<td>3</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
<td>&lt;LOQ</td>
</tr>
</tbody>
</table>

**Cumulative permeation of a.i. (µg/cm²) in concentrate formulations through reusable gloves in one hour**

| PVC             | 12            | 5.7 (1.11)              | 3.5 (0.28)            | 14.6 (0.44)            | 20 (1.64)           | 134.1 (14.70)   | 266.1 (12.84)     |
| Natural Rubber  | 18            | <LOQ                    | <LOQ                  | <LOQ                    | <LOQ                | <LOQ             | <LOQ              |
| Nitrile         | 15            | <LOQ                    | 0.2 (0.04)            | 0.2 (0.05)             | <LOQ                | <LOQ             | <LOQ              |
| Neoprene        | 24            | <LOQ                    | <LOQ                  | <LOQ                    | <LOQ                | <LOQ             | <LOQ              |
| Butyl           | 7             | <LOQ                    | <LOQ                  | <LOQ                    | <LOQ                | <LOQ             | <LOQ              |
| Butyl           | 13            | <LOQ                    | <LOQ                  | <LOQ                    | <LOQ                | <LOQ             | <LOQ              |
| Barrier Laminate| 3             | <LOQ                    | <LOQ                  | <LOQ                    | <LOQ                | <LOQ             | <LOQ              |

With the exception of PVC, permeation of active ingredient was below 1 µg/cm² against all pesticide formulations.
Permeation through nitrile gloves was relatively low. Permeation of a.i. in dry and water-based formulations was, but not negligible. Additional studies are recommended to determine if any waterproof glove can be used for dry or water-based pesticide products.
Permeation through nitrile gloves was relatively low. Permeation of a.i. in dry and water-based formulations was, but not negligible. Additional studies are recommended to determine if any waterproof glove can be used for dry or water-based pesticide products.
Implementation of prEN/ISO DIN 27065 in France

- Key stakeholders involved in planning and implementation
  - ANSES - Risk assessment
  - Ministry of Agriculture - PPP registration and labeling, and Occupational Health and Safety policies
  - Ministry of Labor - PPE Directive compliance
  - UIPP- French Plant Protection Association
  - IFTH and CTC - Notified Bodies
  - Garment Manufacturers – Availability of certified garments

- Coordination by O. Briand (French Ministry of Agriculture) and A. Shaw (ICPPE)

**Validation of Laboratory Testing**
- Fabrics used for UMES studies and new EU fabrics tested at IFTH (France) & IAC (Brazil)
- Data used for lab, fabric and test chemical validation
- Process for validation developed by ICPPE
- Reference fabrics selected

**Testing with 50 EU Formulations for Risk Assessment**
- List of PPP products provided by UIPP
- Forty products available in Europe selected for testing reference fabric approved by ANSES
- Ten addition products to be selected for additional tests
- Testing funded by French Ministry of Agriculture
- Database to be developed by ICPPE

**Availability of Certified Level 1 Garments**
- Meetings held by French Ministry of Labor with PPE manufacturers and notified bodies
- Manufacturers assisted in identifying fabrics that meet Level 1 requirements
- Stakeholders working together to ensure availability
Planned Activities for 2016-17

- Implementation of prEN/ISO DIS 27065
- Research Activities
- Standards Development
Plans for 2016-17
(Pending Support beyond September 2016)

• Standards Development
  o Inter-laboratory trials for pesticide penetration and permeation tests
  o Work with ISO and CEN member countries on revision and approval of standards
  o Work with crop protection industry to find a long term solution for testing chemicals

• Implementation of prEN/ ISO DIS 27065
  o Continue to work with French stakeholders on implementation
  o Work with notified bodies to ensure consistency in test data for pipettes and permeation
  o Expand generic pesticide penetration database
  o Work with stakeholders to ensure availability of PPE in countries where standard is implemented

• Research Studies
  o Wear study for Level 2 garments scheduled for 2017
  o Thermo-physiological comfort and user acceptance
Possible Research and Outreach Activities (Pending Support Beyond 2016)

• Studies on use and care of garments
  o Majority of the data is based on studies conducted in the US during the 1980s and 90s. New studies are needed to support use and care recommendations.

• Selection, use, and care guidelines for countries where performance requirements are not used

• Password-protected website to allow members to obtain information and templates to develop training materials
US Involvement

• Research on PPE for pesticide operators was initiated by researchers in the US in 1980s.
• Standards development undertaken as part of multi-state project as it was identified as a deficiency in the EPA Guidance Manual published in 1993.
• Test chemical was provided by BASF (USA).

Questions for US Stakeholders are:

1. Is there any interest in the ongoing PPE activities?
2. If yes, which ones?
3. Would any of the US stakeholder groups be willing to work with ICPPE to plan and support activities to address US PPE issues?