PPE for Pesticide Operators

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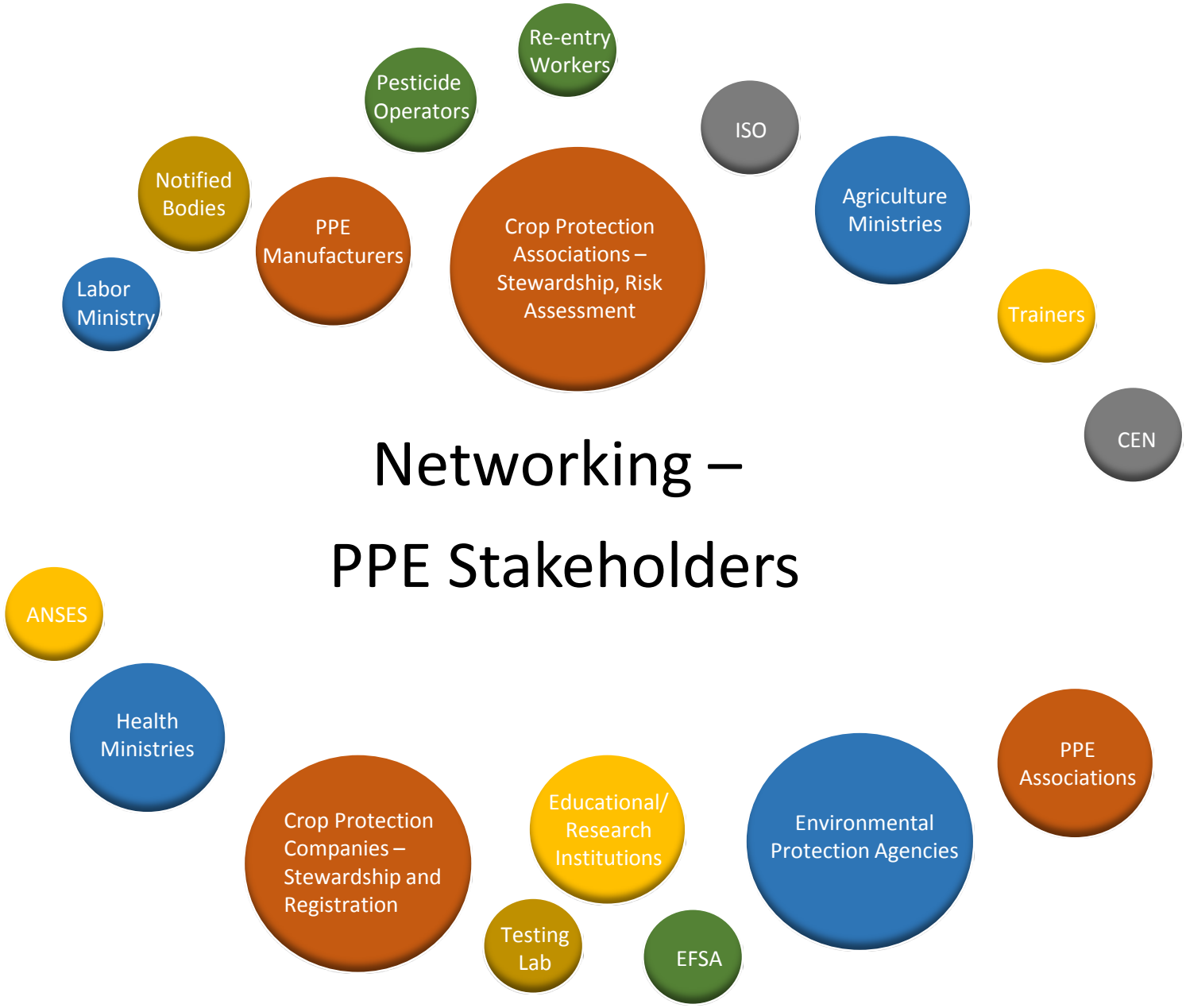
About PPE

- 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
  - PPE issues contain different levels of significance and thus require involvement
- PPE issues typically vary by country/region
  - 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
  - Very few stakeholders have the opportunity to see the “big picture”.



- 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
ISO and ASTM – International Standards Organizations
ANSES – French Agency Responsible for Risk Assessment

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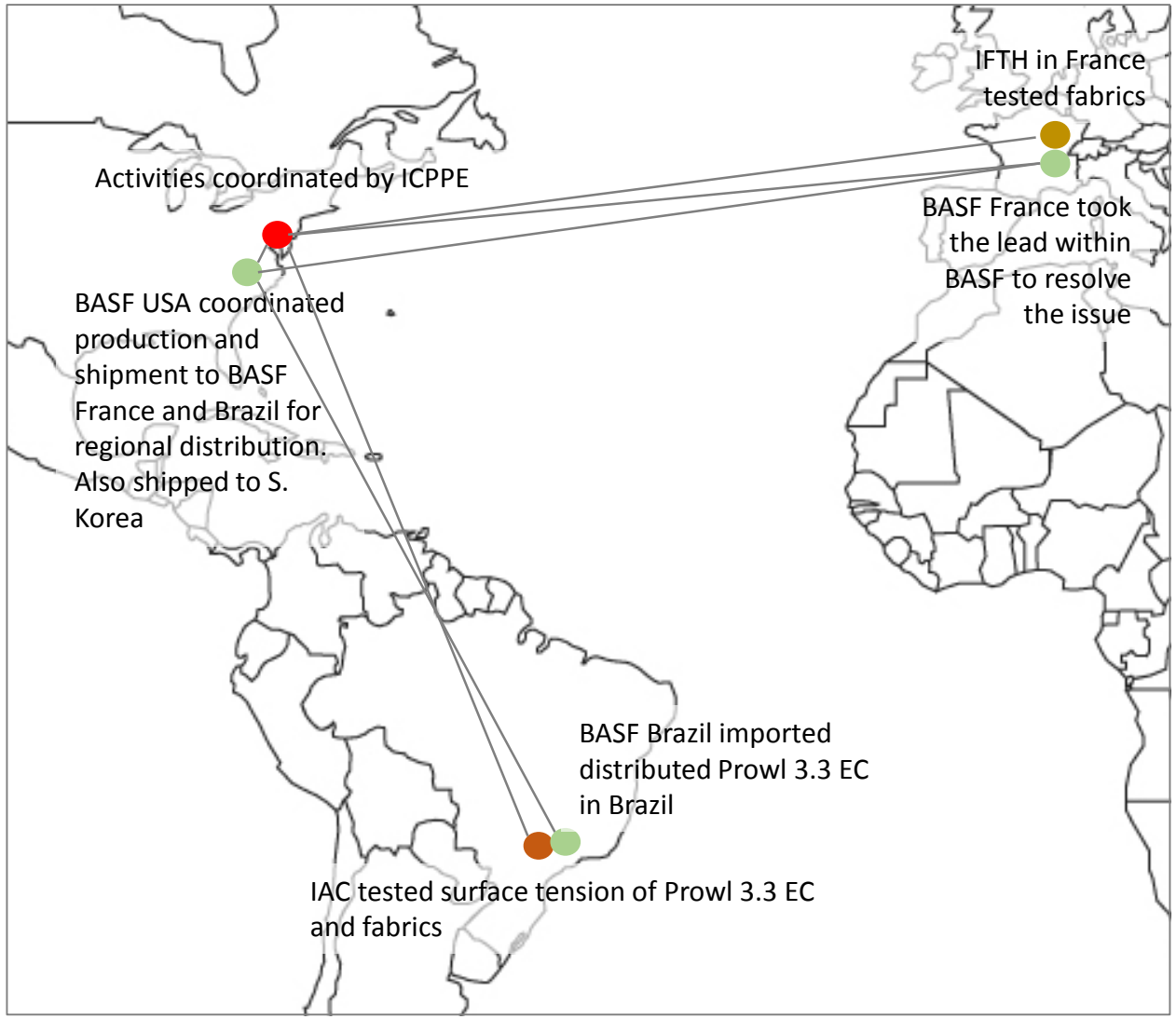
Interconnectedness through Networking



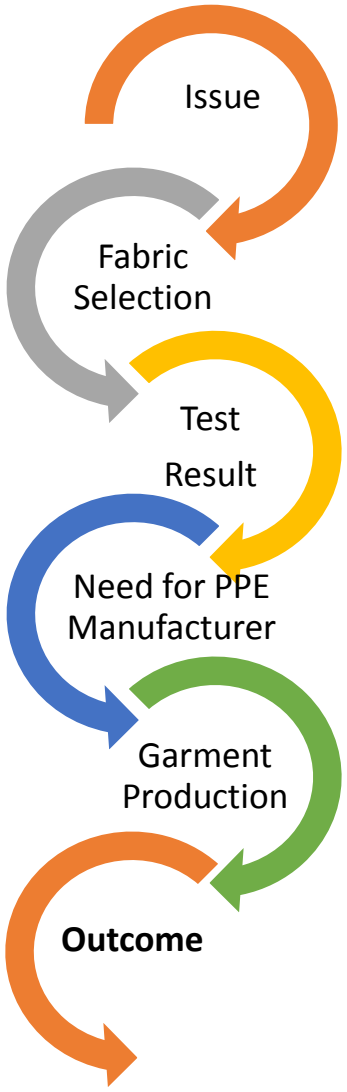
Test Chemical for ISO standards

- 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



- 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.

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

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

- 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.

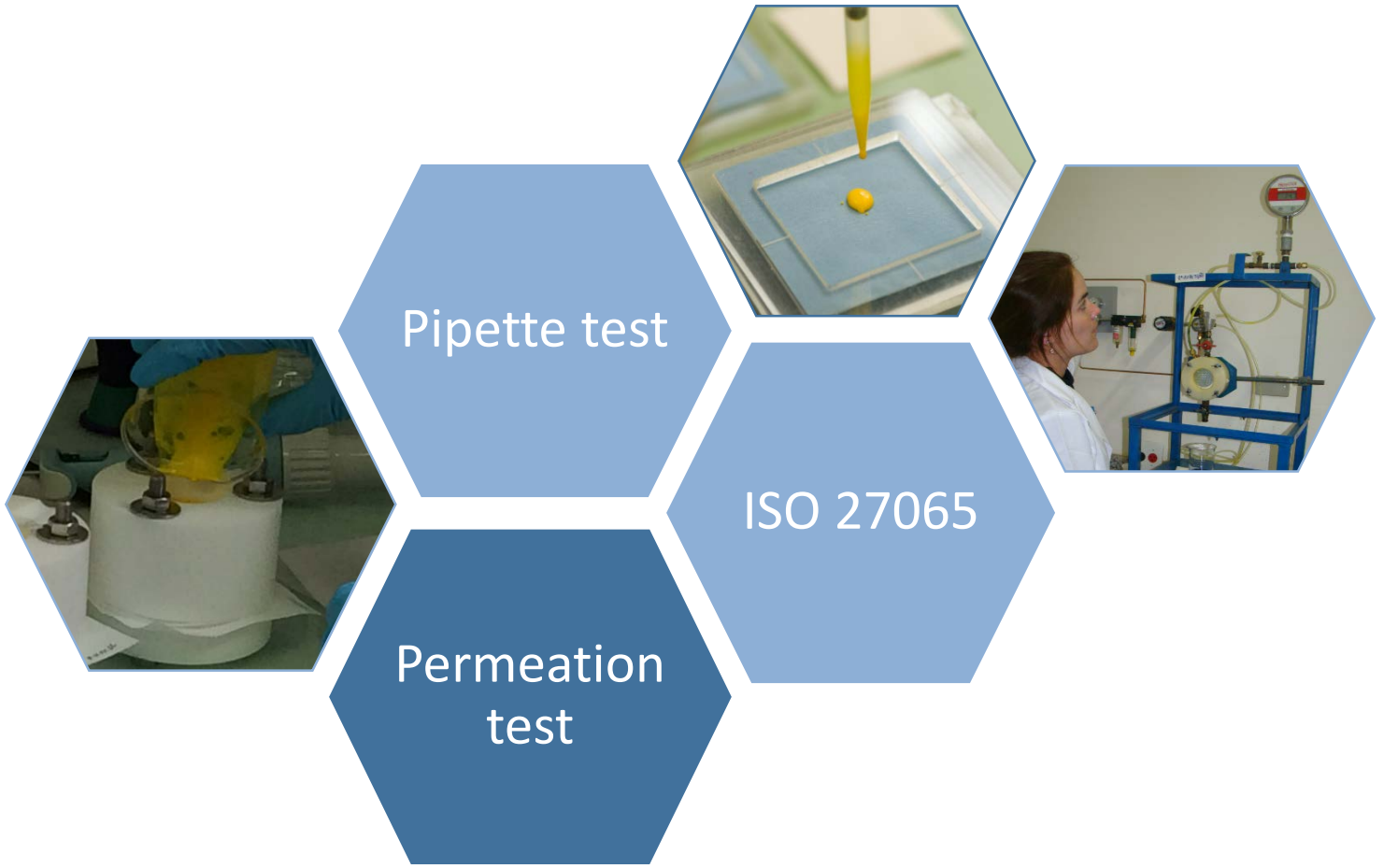
- Manufacturer in Slovenia signed the non-disclosure agreement and UIPP emailed the CAD files.
- The garments were produced within a week and sent to University of Maribor for washing.

- **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

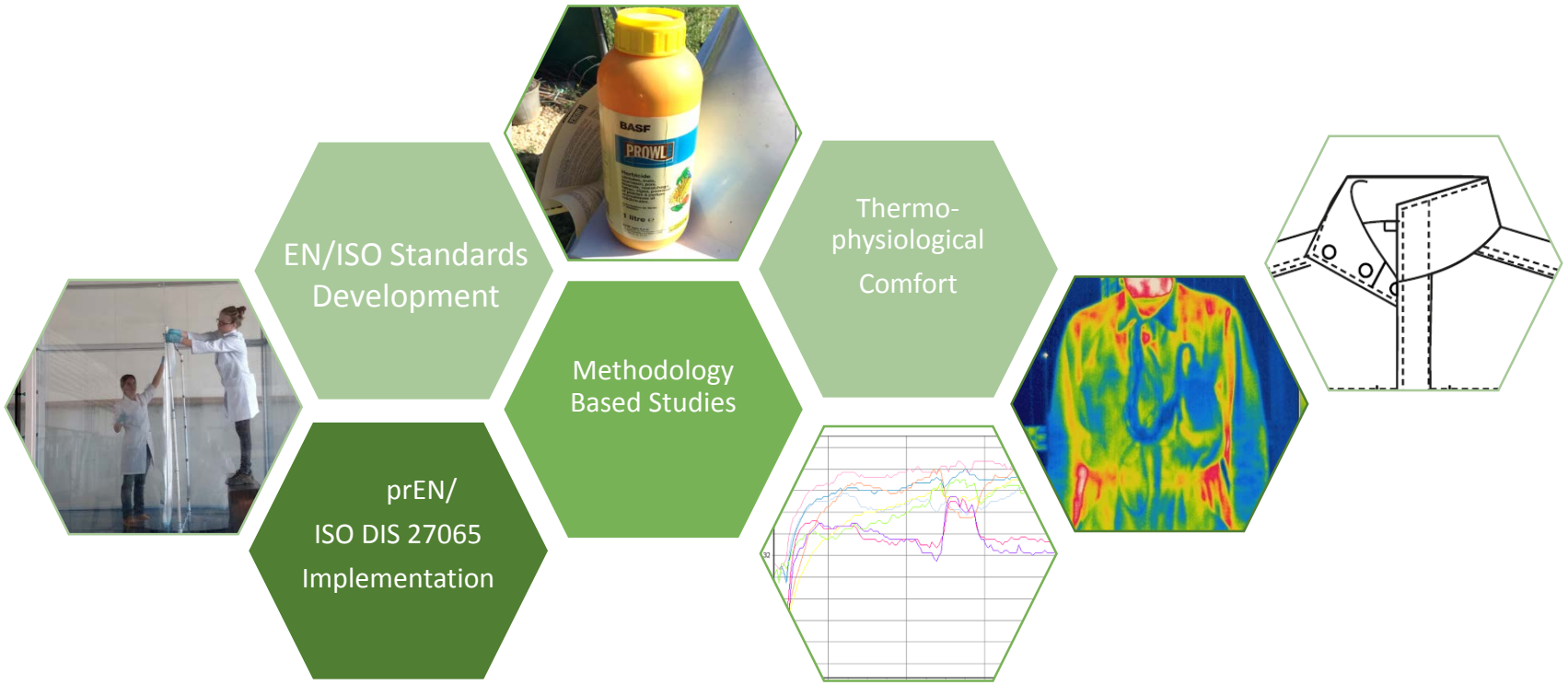
Previous Work: Methodology Research and Standards Development



Previous Work: Methodology Research and Standards Development

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

Ongoing Projects – Activities in 2015



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.
  - In Europe and Brazil, EN 374-1 is used to determine glove requirements. Gloves have a EC mark.
  - In Germany, *Guidelines for Requirements Concerning Personal Protective Equipment* requires testing of gloves in accordance with DIN EN 374-3 with seven chemicals.
  - 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

Solvent Category	Barrier Laminate	Butyl Rubber **≥ 14 mils**	Nitrile Rubber **≥ 14 mils**	Neoprene **≥ 14 mils**	Natural Rubber **≥ 14 mils**[a]	Poly-ethylene	Polyvinyl Chloride (PVC) **≥ 14 mils**	Viton® **≥ 14 mils**
A (dry and water based)	**High**	**High**	**High**	**High**	**High**	**High**	**High**	**High**
B	**High**	**High**	Slight	Slight	None	Slight	Slight	Slight
C	**High**	**High**	**High**	**High**	Moderate	Moderate	**High**	**High**
D	**High**	**High**	Moderate	Moderate	None	None	None	Slight
E	**High**	Slight	**High**	**High**	Slight	None	Moderate	**High**
F	**High**	**High**	**High**	Moderate	Slight	None	Slight	**High**
G	**High**	Slight	Slight	Slight	None	None	None	**High**
H	**High**	Slight	Slight	Slight	None	None	None	**High**

Glove Research Data for Reusable Gloves

	Product	Gesaprim® 500	Prowl® 45.5	Prowl® 3.3 EC	Herbadox®	Sabre®	Lorsban®
Material	Thickness mil	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Cumulative permeation of a.i. (µg/cm^2) in concentrates through reusable gloves in 15 minutes							
PVC	**12**	**1.1 (0.12)**	**0.3 (0.04)**	**51.0 (26.29)**	**55.7 (28.73)**	**56.87 (33.25)**	**366.2 (78.93)**
Natural Rubber	18	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ	<LOQ
Nitrile	15	<LOQ	0.15 (0.06)	0.2 (0.14)	0.4 (0.71)	<LOQ	0.3 (0.56)
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
Cumulative permeation of a.i. (µg/cm^2) in dilute formulations through reusable gloves in one hour							
PVC	**12**	**5.7 (1.11)**	**3.5 (.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/cm^2 against all pesticide formulations.

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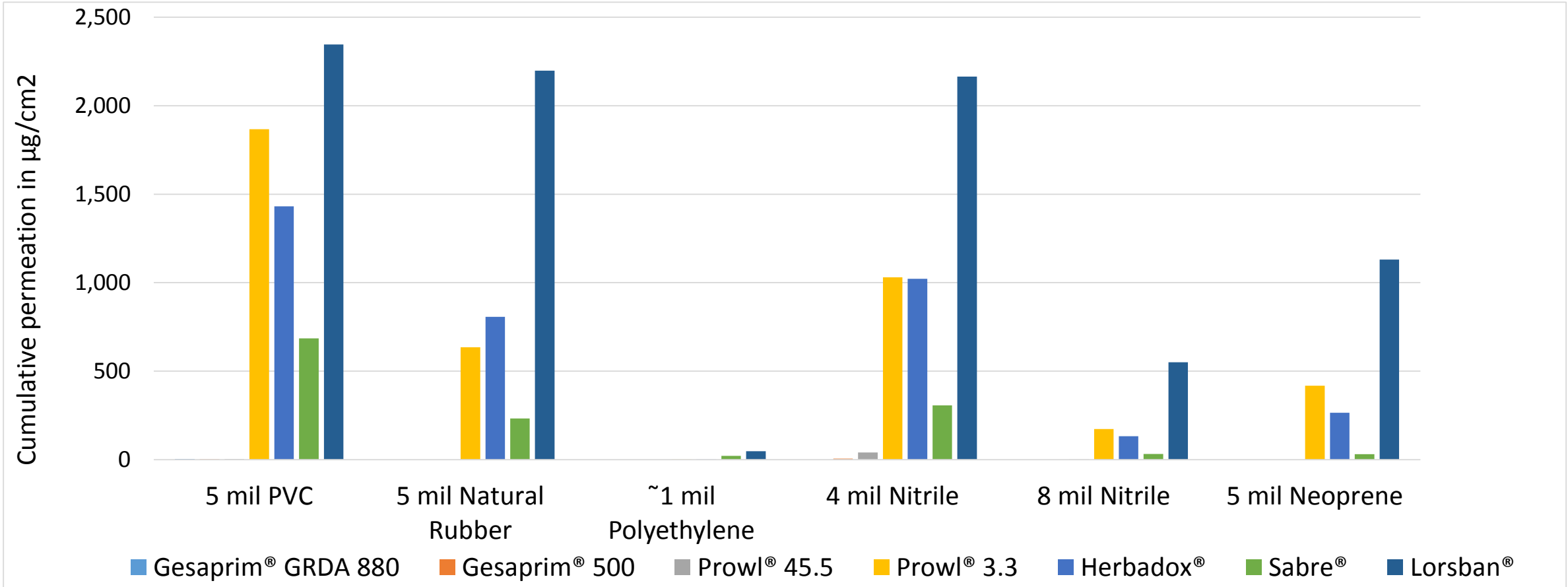
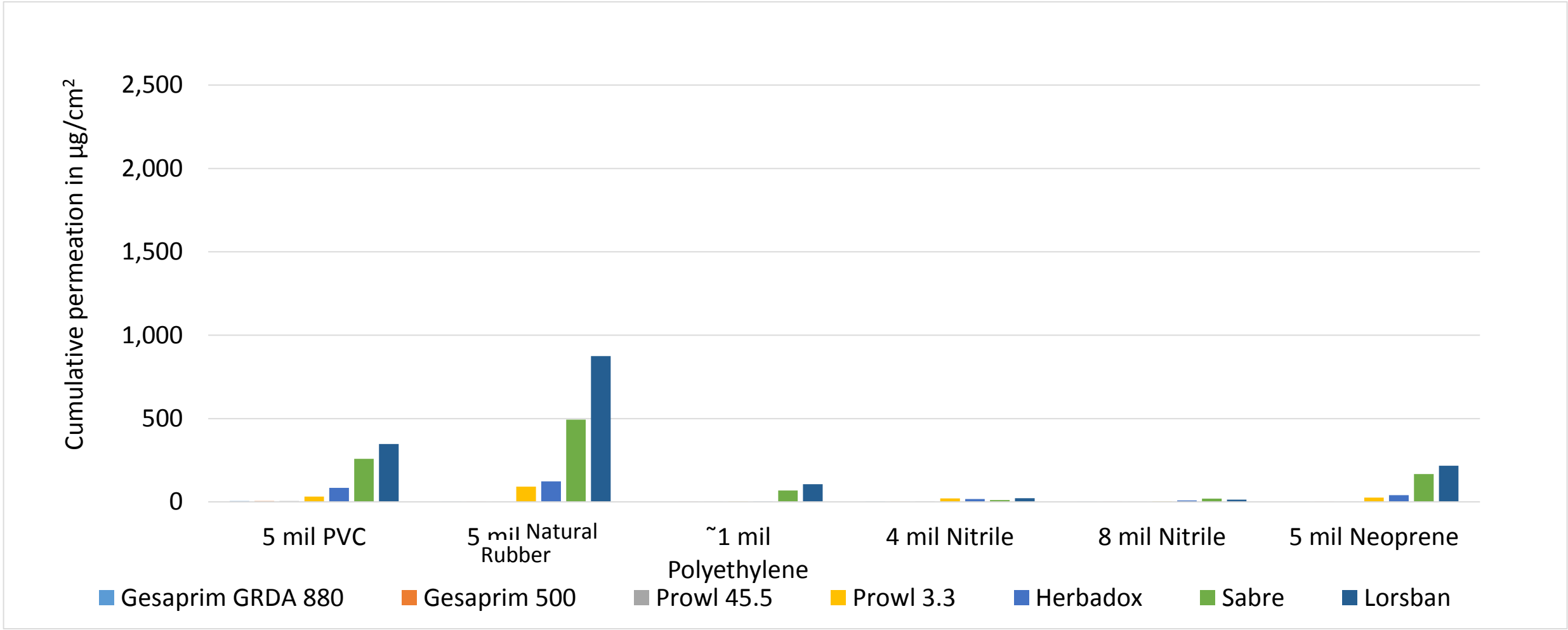
Cumulative Permeation of a.i. (µg/cm^2) in Concentrates through Disposable Gloves in 15 Minutes



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.

Cumulative Permeation of a.i. (µg/cm^2) in Formulations through Disposable Gloves in One Hour



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

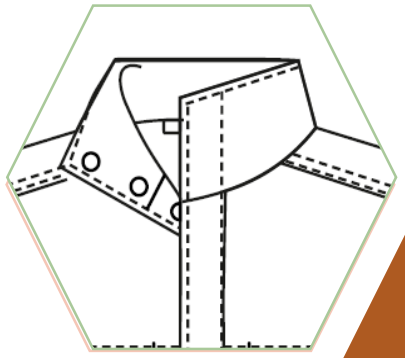
Testing with 50 EU Formulations for Risk Assessment

- 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 Fench 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



Reaserch Activities

Implementation of prEN/ISO DIS 27065

Standards Development

Plans for 2016-17
(Pending Support beyond September 2016)

- Standards Development
  - Inter-laboratory trials for pesticide penetration and permeation tests
  - Work with ISO and CEN member countries on revision and approval of standards
  - Work with crop protection industry to find a long term solution for testing chemicals
- Implementation of prEN/ ISO DIS 27065
  - Continue to work with French stakeholders on implementation
  - Work with notified bodies to ensure consistency in test data for pipettes and permeation
  - Expand generic pesticide penetration database
  - Work with stakeholders to ensure availability of PPE in countries where standard is implemented
- Research Studies
  - Wear study for Level 2 garments scheduled for 2017
  - Thermo-physiological comfort and user acceptance

Possible Research and Outreach Activities (Pending Support Beyond 2016)

- Studies on use and care of garments
  - 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?