PPE for Pesticide Operators: Risk Assessment, PPE Requirements and Labeling

Overview

The registration of pesticides for sale and use is required by most countries. Regulations mandate the requirements for safe use of pesticides, including operator/applicator safety. To ensure operator safety, use of Personal Protective Equipment (PPE) may be required while handling (e.g., mixing/loading and applying) pesticides. PPE for dermal protection includes protective clothing, aprons, gloves, and headgear. When PPE is required for risk mitigation, the requirements should be clearly stated on the pesticide/plant protection product label.

PPE is a term used quite often in risk assessment and labeling without a clear understanding of how the seemingly random processes related to PPE are interconnected. This paper provides information on various aspects of risk assessment, mitigation and product labeling related to PPE. It helps to show how a global approach that utilizes international performance standards for protective clothing and gloves can lead to a harmonized, streamlined approach for defining terms that are used consistently for risk assessment, risk mitigation, and pesticide product labeling.

January 29, 2013

Risk Assessment

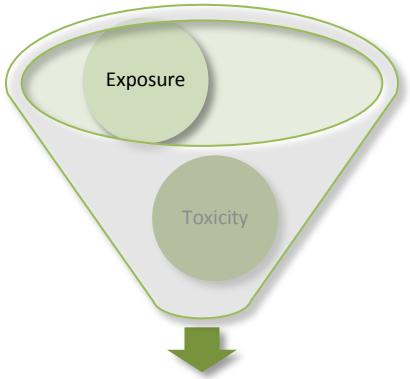
Pesticide regulations were established once the use of pesticides became more prevalent. Countries developed their processes for evaluating and registering pesticide products. An important part of the registration process is determining whether the product can be used safely. Operator safety while handling and applying pesticides is one of the factors typically determined as part of the risk assessment process.

This section on risk assessment includes:

- An overview of the risk assessment process with three examples that show the similarities and differences in the risk assessment process as it relates to operator safety
- PPE aspects of existing exposure studies
- Comparison of assigned protection factors used for risk mitigation

Note: Regional differences are seen in terminology. For example, the U.S. uses the term pesticide, while the European Union (EU) uses the term plant protection product. To the extent possible, terms in this document have been standardized. In some instances the term or spelling appropriate to the country or region has been used.

In general, the initial task in the risk assessment process is to calculate the hazard based on toxicity. Once that is calculated, further calculations are made to determine the extent to which a person can be exposed without the exposure impacting the health and safety of the operator. The United States uses the term Margin of Exposure (MOE) to describe the acceptable limit. In Europe, the term used is Acceptable Operator Exposure Level (AOEL).



Margin of Exposure (MOE)
Acceptable Operator Exposure Level (AOEL)

MOE and AOEL are used to determine whether risk mitigation is required to protect the operator. Since toxicity of the chemical cannot be changed as it is intrinsic to the substance, factors that can reduce exposure to the product, such as PPE and engineering controls, are used for risk mitigation. Protection factors assigned to PPE enable the regulators to determine the level of protection that is provided by the PPE. The exposure depends on the exposure scenario; thus, the calculation is required for each scenario for which the product is being recommended. Currently, only limited data are available for exposure scenarios such as knapsack sprayers.

Bottom Line: Risk mitigation is required if it is determined that the health and safety of the operator could be affected if the operator is not protected. As PPE is used for risk mitigation, an understanding of the level of protection provided by different types of PPE is important. Also, since exposure study data are the foundation of determining exposure, a robust data set is necessary for determining potential exposure.

RISK ASSESSMENT – Exposure Models

Initially, companies were required to provide exposure data for the product that was being registered. Over time the regulatory authorities and the chemical industry in the United States, Canada, as well as some countries in Europe agreed that exposure is not chemical specific, and therefore allowed the use of generic exposure study databases for exposure assessment. Parallel operator exposure databases were developed in these countries in the late 1980's and early 1990's since there was no collaboration among the countries. Collaboration among countries within a region was seen for databases developed after the early 1990's.

Databases developed in the late 1980's and early 1990's

- In the United States (US) and Canada, the idea of a generic database was proposed in 1984. The Pesticide Handler Exposure Database (PHED) was first released in 1992. The database was developed jointly by the industry, US EPA and Health Canada. Companies that had conducted exposure studies prior to establishment of the database contributed their data. The companies waived their rights to data compensation, and therefore the database was available to all registrants, regardless of whether they contributed.
- The United Kingdom (UK) POEM was developed in the United Kingdom in 1986. The model was developed jointly by the UK regulatory authorities and the industry; data were provided by UK regulatory authorities. The database was available to all registrants.
- The German Model was jointly developed by crop protection industry and German authority with release of the model in 1992. Companies that had conducted exposure studies prior to establishment of the database contributed their data for the model. The database was available to all registrants.
- The Dutch Model and the Dutch Greenhouse Model were developed in the Netherlands in 1992. The Dutch authorities used data from open literature to develop the two databases.

Newer studies have been conducted to address changes in formulations and handling systems as well as exposure study protocol. Whole body dosimeters were used for the majority of the studies conducted after the late 1990's. Studies were conducted either to replace older models or to fill gaps.

Newer studies developed since the 90's

- In the United States and Canada, the Ag Handler Exposure Database® (AHED) is being developed by Agricultural Handler Exposure Task Force, L.L.C. (AHETF). This proprietary database includes existing as well as new operator exposure studies. For new studies, a whole body, inner dosimeter worn under regular work clothing is used to quantify the dermal exposure under typical work conditions. The handler exposure data is of the amount of pesticide measured under the personal clothing worn by the handler; PPE such as gloves, headgear, and aprons are provided as needed to comply with the label. The ATHEF data have been approved to replace several but not all scenarios; the EPA Health Effects Division's policy is to use the best available data for risk assessment.
- In Europe an attempt was made to replace the German and the UK POEM models with a harmonized model (EUROPOEM) that included all studies available to the regulatory authorities at that time. Due to the variability in data, the EUROPOEM model funded by the European Commission is of limited use for regulatory purposes.
- The European Crop Protection Association (ECPA) developed the greenhouse model to fill in gaps in data regarding exposure in greenhouses in Southern Europe. All studies have been conducted with cotton/polyester garments, but in dense crops (contact with sprayed leaves), impermeable garments have been used as outer dosimeters. In addition, ECPA introduced the Safe Use Initiative in which different types of fabric and clothing were tested under laboratory and field conditions. Garment information is well-documented.
- The European Food and Safety Authority (EFSA) is currently developing a guidance document that is intended to provide a tool for a harmonized approach for estimation of operator exposure to replace existing models being used in Europe.
- Information from existing studies is being used to develop a database as part of the BROWSE project in the EU.
- A new exposure model was developed and will be published in 2013 as a result of a BfR (Germany), CRD (UK), ANSES (France), EFSA, TNO (Netherlands) and ECPA (crop protection industry) initiative using new operator exposure studies.
- ANDEF (Brazil Crop Protection Association) is working with AHETF (USA) to conduct exposure studies in Brazil. These studies will fill gaps for scenarios in Brazilian agriculture practices for which data are currently not available.
- US EPA is working with Chinese regulators on exposure studies being conducted in China.

Bottom Line: There is considerable variability in the methodology to measure pesticide penetration. New studies are being conducted to replace older studies and to fill in gaps. In newer studies there is collaboration within and between regions. The clothing worn affects the pesticide penetration values. Therefore, it is important to categorize the clothing . An international, protective clothing performance standard could be used to categorize protective clothing information in existing models. For new studies it is proposed that a standardized format be included to document PPE information.

RISK ASSESSMENT PROCESS: United States, European Union, Brazil

United States

Risk Based Process for Assigning PPE

1. Assign interim PPE based on acute toxicity of the product.
2. Estimate occupational risk based on MOE and uncertainty and safety factors.
3. Conduct handler assessment.
   a. Calculate MOE.
   b. Estimate the occupational exposure levels using the PHED & AHED exposure models with no PPE. Other proprietary data may also be used. Potential exposure is calculated for all scenarios based on product label.
   c. Use PPE protection factors to achieve MOE.
4. Develop PPE requirements that meet Worker Protection Standard (WPS) requirements.

- Product dossier is submitted by the manufacturer to the Office of Pesticide Programs (OPP), Environmental Protection Agency (EPA).
- The Health Effects Division conducts the risk assessment of the active ingredient and assigns the PPE based on risk assessment. Additional PPE may be added based on the acute toxicity of the product to meet the WPS and other rules.

European Union

Risk Based Process for Assigning PPE

1. Assign PPE based on Hazard Identification of the product (considering the toxicological properties of all ingredients).
2. Assign PPE on the basis of risk assessment.
   a. Estimate the occupational exposure levels using calculations models and/or exposure studies with no PPE. The term 'no PPE' varies by model. It is defined as short-sleeved shirt and shorts in the German model and working coverall in UK- POEM.
   b. Assess the occupational risk by comparing the estimated exposure levels to AOEL when no PPE is considered.
   c. Re-estimate occupational exposure levels using protection factors assigned to PPE. (Protection factors are not consistent in different operator exposure models).
   d. Assess the occupational risk comparing the estimated exposure levels to the AOEL when PPE is considered.
3. Develop PPE requirements based on outcomes of 1 and 2.

- Product dossier is submitted by the manufacturer/ applicant to EU Member State (MS) Competent Authority (CA). Each MS identifies its CA .
- The CA determines the possible effects of the pesticide (incl. occupational and residential risks).
- The CA concludes whether the product can be authorized at the national level and under which conditions its use is safe (including PPE recommendations).

Brazil

Assigning PPE (Risk-based process under review)

1. A risk-based approach is currently not being used for assigning PPE. The same PPE is required for all products.
2. In 2011 the Brazilian Ministry of Health (ANVISA) published a public consultation proposal to establish new legislation. This document clearly states the intention to change the decision-making process from a hazard - based to a risk assessment-based process.
3. The new legislation is still under revision. Once the legislation is implemented, the PPE requirements will be based on risk assessment.

- Product dossier is submitted by the manufacturer to the Ministry of Agriculture (MAPA), Ministry of Health (ANVISA), and Ministry for the Environment (IBAMA).
- MAPA checks whether the substance works as it should - efficacy.
- Toxicology and risk is assessed by ANVISA.
- Environmental evaluation is conducted by IBAMA.
- National registration permit is issued by MAPA .

Bottom Line: Common threads are seen in the risk assessment processes used in the United States and Europe. Exposure models are used in both regions to estimate exposure. Margin of Exposure, used in the United States, and Acceptable Operator Exposure Level, used in the European Union, determine whether risk mitigation is required. Although the process is similar, the tools used for calculation are different, resulting in different PPE requirements for similar pesticide products. In Brazil the risk assessment process is currently under revision. It is not being used to determine PPE requirements yet.

RISK ASSESSMENT - Variability in Estimated Exposure Levels

Measured Field Data Compared with Model Estimations

Application Scenario:

Greenhouse application: Fully grown pepper, 1.6 m high

Type of formulation: EC, insecticide

Application technique: Spray gun

Application rate: 1.5 kg a.i./ha

Applied volume: 1500 L/ha

Treated area: 0.16 ha; *Task duration*: 1 hr

Number of operators: 20

Garment: Polyester/cotton **with repellent finish**

Monitoring Method: Whole body dosimeter

Measured Dermal Operator Exposure

Trial Results: 0.4% transmission to skin

Estimated Operator Exposure

EUROPOEM Model: 20% transmission to skin

German Model: 5% transmission to skin

Dutch Greenhouse Model: 10% transmission to skin

ECPA Safe Use Initiative, high crop in Greece: 2.3% transmission to skin, standard work clothing (cotton coverall)

Bottom Line: This example illustrates a need for better estimations when clothing with repellent finish is used. In addition, there is a need for harmonization to reduce the variability that currently exists when different models are used for estimating operator exposure.

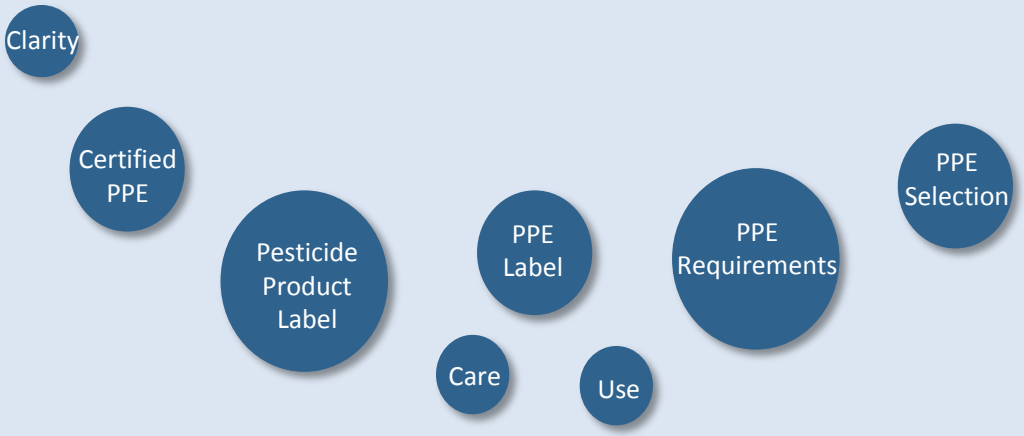
RISK ASSESSMENT – Assigned Protection Factors

Assigned protection factors are used to allow the risk assessors to calculate the risk reduction provided by the use of the PPE. The value assigned is dependent on the level of protection provided by the PPE. Although the risk assessors agree that the protection provided by different PPE varies, there is no consensus on the level of protection provided by each type of garment. As a result, for an exposure scenario the PPE requirements may be different based on the assigned protection factors used for the model. Given below are examples that illustrate the differences between assigned protection factors.

	United States	EU - German Model	EU - UK POEM
Single Layer Clothing	Protection factors are typically not used. Exposure estimates are based on inner dosimeter measurements beneath a single layer worn by exposure study participants. 50% reduction of exposure* 0.5 Protection Factor is used if measurements beneath the single layer are not available for the exposure scenario. * 50% reduction of exposure is based on inner and outer dosimeter values from PHED data analysis.	95% reduction of exposure 0.05 Protection Factor	98% - 80% reduction of exposure .02 – 0.2 Protection Factor
Double Layer of Clothing	75% reduction of exposure 0.25 Protection Factor Note: 75% reduction of exposure is extrapolated from single layer garment data. An additional layer provides an additional 25% reduction.		
Chemical Resistant Gloves	90% reduction in exposure 0.1 Protection Factor	99% reduction of exposure 0.01 Protection Factor	99-90% reduction of exposure 0.01 – 0.10 Protection Factor

Bottom Line: Assigned protection factor is important as it links the risk assessment process with PPE requirements on pesticide products. The existing discrepancies are a result of variations in exposure studies as well as the current requirements. A harmonized, tiered protection factor system could serve as the underpinning for the development of consistent PPE requirements.

PPE Requirements and Labeling



Protection factors that were used for risk mitigation need to be communicated to users so that they are aware of safety measures required when handling pesticides. The product label is the legal and most important means for communicating the risk mitigation requirements to users. A robust risk assessment process with inadequate, inaccurate, or general PPE statements on the label negates the time, effort and resources expended in conducting the risk assessment and establishing protections for applicator/operator safety. More important, an individual should be able to select the appropriate PPE based on PPE information provided on a pesticide product.

This section on PPE and labeling includes:

- PPE requirements - clothing, gloves, headgear and aprons
- Labeling requirements on pesticide products
- Labeling requirements for PPE

PPE Requirements

The requirements for PPE vary considerably. Most countries start with a minimum requirement and then add to the requirement if extra protection is needed based on the outcome of the risk assessment. Examples that highlight the differences in clothing requirements include:

- In Brazil the operators are required to wear certified protective clothing. These garments have to meet at least Level 2 requirements specified in the ISO 27065:2011 performance specification standard for protective clothing for pesticide operators.
- The minimum requirement for clothing in the United States is long-sleeved shirt and long pants (single layer of clothing). For additional protection, two layers of clothing are required. Currently, there is no requirement to comply with performance standards. Discussions are underway to move to a performance-based system using international standards.
- In Europe the requirements are based on different directives/ regulations. The plant protection product (PPP) regulation 1107/2009 states that labels should be in accordance with regulation 1272/2008, a classification, labeling and packaging (CLP) regulation. The CLP requires use of very general label statements such as “Wear protective clothing.” The PPE directive requires that all PPE (including protective clothing) sold in Europe be certified. There is currently no EN standard to certify protective clothing for pesticide operators. There is ongoing discussion on the development of an ISO/EN or EN standard for protective clothing.

Garment fabric performance varies considerably and the protection, to a great extent, depends on the material and the finish applied to the fabric. For example, garments that look and feel the same may have very different performance due to the addition of a repellent finish in one set. Data show that a pant/shirt can have much better protection than some coveralls. Use of standards with harmonized performance requirements would assist in the standardization of protective clothing terminology.

Bottom Line: Use of PPE that meets performance specification or certification requirements has the ability to communicate the minimum requirements effectively. Language on pesticide product labels and PPE must be consistent.

PPE REQUIREMENTS AND LABELING – PPE Requirements

United States

Protective Clothing

- Levels of protection are based primarily on garment type and layers.
- Requirements from lowest to highest protection are: long-sleeved shirt and long pants; coveralls over short-sleeved shirt and short pants; coveralls over long-sleeved shirt and long pants; and chemical resistant suit.
- No certification is required for garments.
- Adoption of ASTM/ISO standards with three levels of performance is being discussed.

Chemical Resistant Gloves

- No gloves is the lowest level of hand protection.
- The EPA Chemical Resistance Category Selection Chart, which consists of eight categories, eight types of materials , and four levels of protection – none, slight, moderate and high – is used for glove selection.
- The chart is based on material and breakthrough time of the solvent against which the material was tested. No certification required.

European Union

Protective Clothing

- The PPP directive requires that product labeling include protective clothing requirements, if it is determined that PPE is required. Statements included in the Annex are very general.
- Protective clothing sold in EU must comply with European Directive 89/686/EEC and must be certified.
  - Certified Type 6 and Type 4 chemical protective clothing are typically used to increase protection factor.
  - DIN 32781 is used in Germany to assess only one level for protective clothing in agriculture.
  - Currently, an EN or ISO/EN standard for PPE for pesticide operators is being discussed in CEN.
- Non-certified work clothing is not considered PPE.

Chemical Resistant Gloves

- The type of gloves to be worn, including the type of material and the breakthrough time of the glove material, must be specified.
- Information is specified in accordance with EN 374: 2003. Breakthrough time is typically reported for solvents.

Brazil

Protective Clothing

- Certified protective clothing is required in Brazil.
- The garments must meet ISO 27065 Level 2 or Level 3 requirements.
- The law allows the use of garments that have been certified in accordance with Level 2 or Level 3. There is no differentiation in the requirements based on level of protection.
- Regular work clothing cannot be worn while applying pesticide in Brazil.

Chemical Resistant Gloves

- Chemical resistant gloves are required for all products.
- No certification is required.

Bottom Line: Language on labels and in labeling guideline documents needs to be specific and clear. A performance-based process that provides levels of protection would clarify the labeling process and improve communication to users.

PPE REQUIREMENTS AND LABELING – Pesticide Product Label

United States

Label Information

The Worker Protection Standard states that PPE requirements must be included on all pesticide products used for agriculture.

- Clothing – Description for protective clothing is used consistently. One of the following terms is seen on labels: long-sleeved shirt and long pants; coveralls over short-sleeved shirt and short pants; coveralls over long-sleeved shirt and long pants; chemical resistant suit. If needed, more than one requirement is included on the label based on exposure scenario or type of activity.
- Gloves – Descriptions used for gloves vary considerably.
- Additional dermal toxicity and/or skin irritation PPE for toxicity category I or II
  - Chemical resistant headgear for overhead exposure. Headgear may also be assigned based on risk assessment.
  - Chemical resistant apron for mixing and loading.

European Union

Label Information

Very general precautionary statements that are part of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) are used. Given below are the phrases for PPE:

- P280 - Wear protective gloves/protective clothing/eye protection/face protection (manufacturer/supplier of PPP to specify type of equipment).
- P281 - Use personal protective equipment as required (no details are provided).
- P284 - Wear respiratory protection (manufacturer/supplier of PPP is to specify type of equipment).

Given below are examples of specifications provided by manufacturer of PPP:

- Use suitable, appropriate or adequate protective clothing.
- Use air impermeable clothing.

Brazil

Label Information

- Pictograms are used for mixing and loading and application.
- According to the pictograms on pesticide product labels, all products require the use of protective clothing, gloves, etc.

Bottom Line: Language on labels and in labeling guideline documents needs to be specific and clear. A performance-based process that provides levels of protection would clarify the labeling process and improve communication to users.

PPE REQUIREMENTS AND LABELING – Performance Standards

Performance specification standards based on laboratory and field data are now available to enable development of performance-based requirements for protective clothing for pesticide operators. The following standards have similar requirements:

- ISO 27065:2011, Protective clothing – Performance requirements for protective clothing worn by operators applying liquid pesticides.
  - In Brazil protective clothing is certified in accordance with ISO 27065, Level 2 and 3 requirements.
- ASTM F2669-12 – Standard Performance Specification for Protective Clothing Worn by Operators Applying Pesticides.
- A Japanese Industrial Standard (JIS), based on ISO 27065:2011, is currently under consideration.

The above performance specification standards include minimum requirements for three levels of protection. The level of testing increases for protective clothing that provide higher protection.

- Level 1 – Protective clothing in this category is suitable when the potential risk is relatively low. The performance requirement for Level 1 is based on cotton and cotton/polyester garments typically worn for exposure studies.
- Level 2 – Protective clothing in this category is suitable when the potential risk is higher, but not so high as to require the use of chemical resistant materials.
- Level 3 – Protective clothing in this category is suitable when the potential risk of contamination requires use of garments made with impermeable chemical resistant materials.

Labeling Requirements for Protective Clothing

Performance standards specify the labeling requirements for the garments. As the care requirements for garments vary considerably, the standards require reusable garments to be cleaned 30 times in accordance with the manufacturer's care instructions prior to testing. Information on the level of protection as well as instructions on care, use and maintenance is required on the garment label. Clear and concise requirements on certified garments provide a means for communicating information required by the user.

Importance of Consistent Information

Bottom Line: National/regional/international standards with similar requirements make it easier to develop consistent requirements in different regions of the world. Minimum requirements for different levels of protection provide a mechanism to balance protection and comfort. Certified garments can be referenced in pesticide product labels.

Risk Assessment + PPE and Labeling

RECOMMENDATIONS

Use International Performance Standards for Standardizing Risk Assessment, Requirements, and Labeling

International Performance-Based Standards

- Use ISO 27065 and equivalent standards as the basis to define protective clothing. All clothing would be referred to as Level 1, 2, or 3.
- Develop performance requirements for gloves.

Risk Assessment

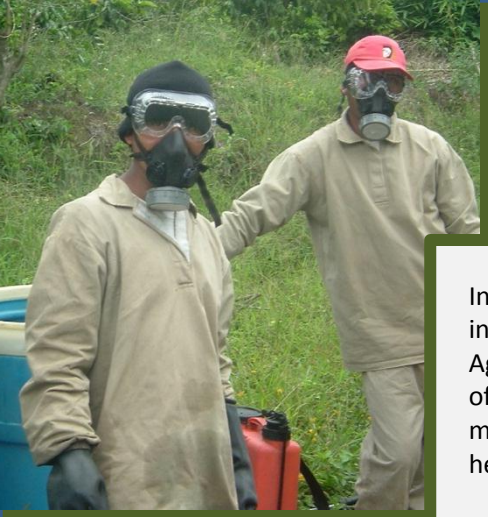
- Assign level to clothing worn in existing exposure studies.
- Collaborate to conduct future exposure studies to fill gaps.
- Assign protection factors for each level of clothing and gloves.

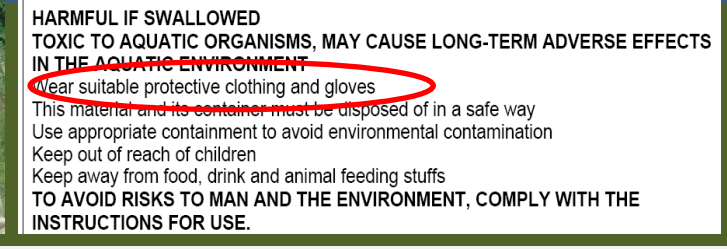
PPE Requirements and Labeling

- Use levels based on performance of PPE to define requirements.
- State level of clothing and gloves required on pesticide label.
- Ensure availability of protective clothing and gloves for the levels required.

Operator Health and Safety

- Use a simplified, more efficient system of garment labeling using Levels 1, 2, and 3, which can be clearly understood by the industry, regulatory groups, trainers, and users.
- Use standardized terminology based on international performance-based standards to provide a framework for global communication; individuals from different countries can speak and understand the same PPE language.
- Standard terminology helps connect the dots to make the process more systematic.
- Use a scenario-based (rather than country/region-based) approach for exposure studies to allow a mechanism for the global community to work together to ensure that the data are robust enough for all scenarios, mechanized as well as handheld. This approach allows countries to work with others to fill in the gaps.
- Apply consistent terminology based on performance standards to define the clothing that were worn in existing exposure studies to help in harmonizing existing models.
- Use pictograms or text to convey clear and concise information that is easy to understand to assist in effectively communicating the requirements.
- Information for care, use, and maintenance must be stated on the PPE as part of the international PPE performance specification standard. Therefore, issues of care will be addressed by standards, and they would not have to be included on the pesticide product label.





Information about pesticide registration, exposure studies and PPE requirements was presented by invited speakers about their respective countries/regions at the International Symposium on PPE for Agricultural Pesticide Operators held in 2012 in Brazil. Equally important was the initiation of a coalition of international stakeholders and interested organizations who are eager to continue the PPE-risk mitigation dialogue and enrich the science behind risk assessment for the use of PPE that affects the health and safety of pesticide operators.

This paper was written by Dr. Anugrah Shaw as part of National Association of State Departments of Agriculture Research Foundation's project to enhance pesticide safety programs nationally and internationally. One of the activities supported by NASDARF's Cooperative Agreement (X8-83456201) with the United States Environmental Protection Agency is to build new national and international coalitions to develop improved pesticide safety programs for protecting agricultural workers, pesticide handlers and applicators, growers, as well as members of the agricultural community.

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Ms. Ana Carolina de Aguirre - Coordinator, ANDEF Risk Assessment Technical Committee (Brazil)
Ms. Eva Cohen - Head of the Technical Unit of Protective Clothing, CNMP-INSHT (Spain)
Dr. Hans Felber - Project Manager, ECPA Safe Use Initiative (Switzerland)
Mr. Jeff Evans – Environmental Scientist, Health Effects Division, Office of Pesticide Programs, EPA (USA)
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This paper builds upon the information presented by the invited speakers at the international symposium held in Brazil last year. Information from the presentations was used to highlight the similarities and differences in registration, PPE requirements, and labeling. Future plans include expanding the base to form a broad coalition that could work together in addressing issues at a global level. For comments and additional information, email Dr. Anugrah Shaw at anugrahshaw@hotmail.com.

Personal Protective Equipment (PPE)

Applicators and other handlers (other than Mixers and Loaders) must wear:

- Long-sleeve shirt and long pants
- Shoes plus socks
- Protective eyewear
- Chemical Resistant Gloves - Category A (e.g. barrier laminate, butyl rubber, nitrile rubber, neoprene rubber, natural rubber, polyethylene, polyvinyl chloride (PVC) or Viton®)