Occupational exposure to pesticides
Challenges for research, evaluation and prevention
Personal protective Equipment – performance and recommendations
Plant Protection products (PPP) – Regulatory Basis

• Plant protection products (PPP):
  -> Regulation (EC) n° 1107/2009

• Data requirements (hazard and risk assessment) for plant protection products:

• Uniform principles for evaluation and authorisation of plant protection products
  -> Regulation (EU) N° 546/2011
B - EVALUATION - Specific principles

2.4.1.3. Member States shall examine the nature and characteristics of the protective clothing and equipment proposed with particular reference to the following aspects:

– obtainability and suitability,

– ease of wearing taking into account physical stress and climatic conditions.

B – DECISION MAKING - Specific principles

2.4.1.2. Where the proposed conditions of use require use of items of protective clothing and equipment, no authorisation shall be granted unless those items are effective and in accordance with the relevant EU provisions and are readily obtainable by the user and ..........

REGULATION (EU) Nº 546/2011
Recommendations – Personal protective Equipment (PPE)

Hazard characterisation
Reg. (EC) N°1272/2008
Reg. (EU) N°545/2011

Risk assessment
Reg. (EU) N°545/2011

PPE recommendations
- Directive 89/686/EEC
- Reg. (EU) N°545/2011
- Reg. (EU) N°546/2011
PPE (according to Directive 89/686/EEC)

PPE category III: to protect against risks which may seriously or irreversibly harm health

- Liquid tight
- Spray tight
- Spray tight (limited)
- Tight Particle

Current testing methods:
not fully applicable to plant protection products
Anses self mandate: to check the recommendations of PPE and work wear for the operators (mixing/loading/application/cleaning):

Different steps

• Survey on PPE (certified) and work wear
  – available in France
  – used by operators

• Performance tests (laboratory: penetration & permeation according to ISO standards)

• Operator field exposure study
Avis de l’Anses
Saisine n° 2011-SA-0216

Maisons-Alfort, le 22 octobre 2014

AVIS
de l’Agence nationale de sécurité sanitaire de l’alimentation,
de l’environnement et du travail

relatif à l’efficacité de vêtements de protection portés par les applicateurs de produits phytopharmaceutiques

L’Anses met en œuvre une expertise scientifique indépendante et pluraliste.
L’Anses contribue principalement à assurer la sécurité sanitaire dans les domaines de l’environnement, du travail et de l’alimentation et à évaluer les risques sanitaires qu’ils peuvent comporter.
Elle contribue également à assurer d’une part la protection de la santé et du bien-être des animaux et de la santé des végétaux et d’autre part l’évaluation des propriétés nutritionnelles des aliments.
Elle fournit aux autorités compétentes toutes les informations sur ces risques ainsi que l’expertise et l’appui scientifique technique nécessaires à l’élaboration des dispositions législatives et réglementaires et à la mise en œuvre des mesures de gestion du risque (article L.1313-1 du code de la santé publique).
Ses avis sont rendus publics.

L’Anses s’est autosaisie le 8 août 2011 sur la question de l’efficacité des vêtements de protection portés par les applicateurs des produits phytopharmaceutiques.
Survey conducted in France on PPE and work wear

- Contractor

- To conduct an inventory of PPE, workwear and protection against chemical risks available on the French market.

- Retailers and users (≈1000 farmers - different crops)

- Specific focus on description of the use of protective equipment by farmers (≈ 100 farmers - different crops)
PPE

Work wear
<table>
<thead>
<tr>
<th>PPE or Work wear</th>
<th>Presence in the farm</th>
<th>Mixing/Loading</th>
<th>Application with cabin</th>
<th>Cleaning</th>
<th>Comfort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Work wear - Coverall</td>
<td>88 %</td>
<td>64 %</td>
<td>76 %</td>
<td>58 %</td>
<td>Good</td>
</tr>
<tr>
<td>Coverall, Cat. III, Type 5/6</td>
<td>56 %</td>
<td>52 %</td>
<td>24 %</td>
<td>28 %</td>
<td>Medium</td>
</tr>
<tr>
<td>Coverall, Cat. III, Type 4/5/6</td>
<td>36 %</td>
<td>26 %</td>
<td>12 %</td>
<td>9 %</td>
<td>Weak</td>
</tr>
<tr>
<td>Coverall, Cat. III, Type 3/4/5/6</td>
<td>25 %</td>
<td>8 %</td>
<td>2 %</td>
<td>6 %</td>
<td>Very weak</td>
</tr>
<tr>
<td>Gown, Cat. III, Type 3/4/5/6</td>
<td>14 %</td>
<td>14 %</td>
<td>-</td>
<td>3 %</td>
<td>Good</td>
</tr>
</tbody>
</table>
Main information from the survey

• Farmers do not always wear PPE or work wear during the different phases, the respect of the recommended conditions of use is decreasing during the working day.

• PPE coverall : comfort level from cat III type 6 to type 3.
• Partial body (gown), comfort ✓.

• Lack of comfort : main reason for using work wear.

• Disposable coveralls : not systematically discarded.
Tests to check the performance of PPE and work wear identified in the survey

• Contractor:

• Tests performed: PPE and work wear identified in the survey

• Additional tests performed on work wear with water repellent finish, available on the market
Performance tests

• Based on **ISO 27065 : 2011** (under discussion at UE level)

  *Protective clothing — Performance requirements for protective clothing worn by operators applying liquid pesticides*

• Permeation test
  – Based on Standard **NF EN ISO 6529:2001**
  – IFTH method developed for assessing cumulative permeation

• Penetration test
  – **Standard : ISO 22608:2004**
Plant protection products tested

- 9 PPP containing different active substances
  - 2,4 D; Isoxaben; Iprodione; Iprovalicarb; Fluazinam; Chlorpyriphos-éthyl; Aminotriazol; Spinosad; Epoxiconazol

- Product type : SC, CS, WG, EC

- Products tested :
  - undiluted and diluted
  - dilutions : mimic the dilutions of application phase and cleaning
Information from permeation tests

• Resistance to permeation
  – Coverall cat.III type 3
  – Gown (PB) cat.III type 3

• No general relationships established:
  – between permeation - type of product - material - level of dilution
Information from penetration tests

• Resistance to penetration

++++ Coverall  cat. III type 3
+++  Coverall  cat. III type 4
++ Working coverall with water repellent (no washing)
+  Coverall cat. III type 5/6
+ Working coverall with water repellent (after washing)
+/- Working coverall

• No general relationships established:
  - between penetration - type of product - material - level of dilution
Performance tests

- ISO standard:
  - ISO 22608:2004 (penetration)
  - ISO 6529:2001 (permeation)
  - ISO 27065 : 2011
  - Can be applied for certification

- ISO 22608:2004 and ISO 6529:2001 are methods to check the performance:
  - ✓ Ranking the performances between materials
  - × Not designed to calculate a penetration factor

- To calculate penetration factors:
  → Field exposure study
Field exposure study

Currently PPE and work wear recommended by notifiers (tractor with cabin & mounted or trailed sprayers):

- Mixing/loading and cleaning: Partial body cat III type 3 + working coverall polyester-cotton with water repellent
- Application: working coverall polyester-cotton with water repellent

- Contractor: [Staphyt GLP Studies]
- In vineyard - South of France in August 2013
- 15 operators – 13 different farms
  - airblast sprayers - insecticide
  - PPE & work wear
  - monitoring: dermal exposure

Gown (PB) cat. III type 3

Working Coverall polyester – cotton
Water repellent
Main Results

- The main parameters (A.M., Min. and Max.) are:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Arith. Mean</th>
<th>Min.</th>
<th>Max.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treated surface area</td>
<td>11 ha</td>
<td>6 ha</td>
<td>24 ha</td>
</tr>
<tr>
<td>Amount a.s. applied</td>
<td>581 g/applicator</td>
<td>288 g/applicator</td>
<td>1200 g/applicator</td>
</tr>
<tr>
<td>Duration M/L</td>
<td>11 min</td>
<td>2 min</td>
<td>21 min</td>
</tr>
<tr>
<td>Duration application (incl cleaning)</td>
<td>294 min</td>
<td>178 min</td>
<td>442 min</td>
</tr>
<tr>
<td>Duration cleaning</td>
<td>20 min</td>
<td>4 min</td>
<td>46 min</td>
</tr>
</tbody>
</table>
Main results

• Penetration factors when considering combined protection
  – coverall and a gown (mixing/loading phase and cleaning phase)
  – coverall (application)
  – < 5%

• Results (PF) are consistent with the proposals of the EFSA guidance document, recently published.

• EFSA. *Table 7: Default personal protective equipment*
  – *Operators certified protective coverall:*
  – *Penetration factor: 5%*
Conclusions and recommendations

For detailed conclusions and recommendations:
Opinion from Anses must be consulted

Key elements from the opinion are the following:

• PPE recommendations: final step after
  • reducing the risk by finding safer alternatives and/or changing work practice
  • applying collective protection(s)

• Anses recommends new initiatives to inform all farmers to health issues and to develop further training.
• Adoption of good practices guide.
Conclusions and recommendations

At European level to continue the work to set up a standard for PPE dedicated to Plant Protection Products
(ongoing work : ISO 27065)

→ Manufacturers of PPE :
  • CE certification for all equipment, based on ISO 27065
  • to provide information for users on the performance and practices concerning the maintenance (washing, etc.).

→ Manufacturers of Plant Protection Products :
  • For each product submitted for an authorisation,
  • To provide test results on the PPE recommended or justify extrapolation of results from existing products with similar characteristics.
THANK YOU FOR YOUR ATTENTION