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#### Review

# Critical review of the role of PPE in the prevention of risks related to agricultural pesticide use



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# ABSTRACT

Personal protection equipment (PPE) holds a privileged position in safety interventions in many countries, despite the fact that they should only be used as a last resort. This is even more paradoxical because many concerns have arisen as to their actual effectiveness under working conditions and their ability to provide the protection attributed to them by certain occupational safety strategies and marketing authorisation procedures. Are these concerns justified? This article is intended to provide an update on what we know of the issue based on a critical analysis of the literature to date.

Analysis focuses on the assessment of the effectiveness of coveralls used to protect from plant protection products in OECD countries. All forms of assessment were retained: discussion of the observed effectiveness of PPE in relation to the underlying assumptions of marketing authorisation procedures, laboratory tests of equipment, practical field tests in which PPE-wearing practices were controlled and uncontrolled, analyses of the efficiency of preventive instructions based on wearing such coveralls.

Findings show that recommending the use of PPE is key to the granting of marketing authorisation. Some dangerous products only get marketing authorisation because it is assumed that wearing PPE will considerably limit exposure. They would be banned if it were not for this assumption of protection. However the actual effectiveness of PPE in working conditions may be over-estimated. In addition many factors (cost, availability, thermic and mechanical discomfort) may make instructions to wear PPE inapplicable. Advising the use of PPE does not always mean effective protection.

# 1. Introduction

The health consequences of agricultural pesticide exposure have drawn increasing concern and become a sensitive political and media issue. From all quarters – be they political, scientific, or other – come reminders of the severe gaps in updating and disseminating knowledge of the risks associated with pesticides. In France, for example, groups of

experts were charged with extracting and reporting the available evidence on these themes on the demand of the French National Institute of Health and Medical Research (Inserm) (Baldi et al., 2013) and of the French National Agency for Food, Environmental and Occupational Health & Safety (Anses) (Laurent et al., 2016). The epidemiological data summarised in the Inserm report highlighted links between certain chronic illnesses and occupational exposure to agricultural pesticides. It

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notably concluded that there is a high likelihood that these pesticides contribute to the appearance of several neurological illnesses and some cancers (Parkinson's disease, prostate cancer, malignant non-Hodgkin lymphoma including multiple myeloma). The Anses report examined what measures could be taken to protect farm labour from pesticide exposure. The results showed that personal protective equipment (PPE) is central in discussions of chemical risk prevention in agriculture. PPE includes skin and eye protective equipment (gloves, coveralls, safety shoes, helmets, and goggles) and respiratory protective equipment (respirators). Our findings indeed confirm that occupational safety interventions accord PPE the greatest importance in many countries. They are the focus of numerous interventions by safety professionals from industry, state services and agencies, and advisory suppliers.

Even so, as the International Labour Organisation has stressed (Alli, 2008), one of the fundamental principles of occupational health and safety is that PPE should be considered as the last line of defence, after other measures have been taken. Their role is clearly defined in European directive 89/391/EC (EC, 1989) concerning the implementation of measures for the improvement of occupational health and safety. This regulation provides a hierarchy of prevention actions. It specifies that other measures come before PPE: first, the elimination or reduction of the source of danger (e.g., reduction of the use of dangerous products), then reduction of the chances of transmitting danger (e.g., organisation at work sites ), and lastly, if the preceding actions are still insufficient, use of protective equipment. There is a distinction between collective protection (such as a ventilation and filtration system in a building) and personal protection (wearing a mask, coveralls, gloves, etc.). Collective protection systems should be put in place before PPE. In some countries such regulations only explicitly apply to wage-earning employees. However, these principles seem relevant for all persons working on farms, whether they are employees (permanent or casual workers employed by the farm or another organization such as a service provider) or not (self-employed farmers, family labour, self-employed workers [brought in to repair sprayers, for example], or other workers not employed by the farm). The emphasis on PPE in controlling agricultural chemical risks is thus paradoxical because they should only be used as a last resort.

The paradox is even greater as there have been many concerns about the real effectiveness of PPE under working conditions and its ability to completely fulfil the protective role attributed to it by certain chemical risk prevention strategies and regulations setting criteria for marketing authorisation. Are these concerns justified? This article aims to answer this question through a critical analysis of the available literature.

So as to avoid compromising the precision of the analysis with an overly broad field of study, we focused on research addressing one type of PPE (chemical protective coveralls), one category of pesticide (plant protection products: PPPs), and a group of countries with relatively comparable economic and regulatory characteristics (OECD countries). The reasons for these choices are explained in Section 2. Analysis of the literature on the effectiveness of protective coveralls shows that the protective role that may be attributed to them in marketing authorization and in occupational health recommendations is not demonstrated (Section 3). These findings call for a discussion of crucial issues in chemical risk reduction in agriculture that remain unresolved for the time being (Section 4).

#### 2. Methods

# 2.1. The parameters of the study

An inspiring discussion of the PPE literature took place at a joint Anses-European Food Safety Authority (EFSA) conference in October 2014 (Garrigou, 2014; Gerritsen-Ebben et al., 2014). The results highlighted the low number of available publications, but the great variety of situations under which they had studied PPE effectiveness. This is why the analysis presented here focuses more specifically on particular products, aspects of PPE, and geographical areas. This narrowed field reduces the variety of situations, thus making it possible to analyse all dimensions of the debate over assessment of PPE effectiveness (the role of PPE in granting marketing authorisation, observations of their effectiveness, efficiency of interventions recommending their use in order to reduce chemical exposures).

- The term 'pesticide' can be conceived of broadly, including all pesticides used in agriculture that could engender occupational exposure and associated chemical hazards: (i) plant protection products used in plant production (European marketing of which is governed by European Union (EU) regulation 284/2013) (EU, 2013); (ii) biocides used for building and materials disinfection (EU regulation 528/2012 concerning biocidal products) (EU, 2012), and (iii) some veterinary medications (EU directive 2001/82/CE and EU regulation 726/2004) (EC, 2001; EU, 2004), especially external antiparasitics used in livestock rearing. The vast majority of the literature on agriculture addresses plant protection products (PPPs), however, and so they are the focus of this article.
- The term 'PPE' includes a wide array of equipment. For example, EU regulation 2016/425 (EU, 2016) states that, within the EU, 'personal protective equipment' (PPE) means: (a) equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety [such as a coverall or respirator]; (b) interchangeable components for equipment referred to in point (a) which are essential for its protective function [such as a respirator filter]; (c) connexion systems for equipment referred to in point (a) that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use [such as a tube bringing air into a respirator]'. This regulation entered into force on 21 April 2018, repealing the 1989 directive, and applies to all EU member-states. PPE can protect from various forms of exposure.

Many years of field studies of agricultural pesticides have shown that deposits from occupational exposure primarily occur on the skin (Brouwer et al., 1994). This article focuses on a kind of PPE that is particularly important in protecting from such exposure: coveralls. The EU regulation distinguishes three categories of coveralls, according to the level of protection that is provided (Box 1).

All countries use agricultural pesticides, but their technical, social, and economic conditions of farming are quite diverse (for instance, in

**Box 1** Categories of PPE in the EU.

EU regulation 2016/425 (EU, 2016) classifies PPE into three risk categories (found in Appendix 1 of the regulation):

- Category I: work equipment covering minimal risks;
- Category III: safety equipment for risks that may have irreversible or deadly consequences;
- Category II: specific protective equipment for risks other than those provided for in categories I and III.

All apparel for personal protection from chemical hazards (including pesticides) is considered as having to protect from serious risk, and fall under category III.

farmers' economic ability to purchase PPE and follow occupational safety advice). Most of the literature available on international databases concerns OECD countries, and the following analysis concentrates on them.

### 2.2. Selecting articles for analysis

Three major databases were searched for articles using search terms in English and with no date restrictions. Literature reviews were also included. Unpublished research findings were not taken into consideration.

Articles were included if they provided information on the assessment of the effectiveness of coveralls used for PPP protection in OECD countries. All forms of assessment were retained: discussion of the real effectiveness of PPE against the underlying assumptions of marketing authorisation procedures, laboratory tests of equipment, and field tests with controlled and uncontrolled PPE wearing practices. Articles on the efficiency of occupational safety instructions based on using such coveralls were also included.

Initially 86 articles were identified on the Scopus database (43 were selected), 21 on the Pascal database (9 selected), and 81 on the PubMed database (31 selected). After removing duplicates and reading the abstracts, 70 publications meeting our criteria were retained for full analysis. This list was updated through periodic checks and expanded by the authors until September 2018, ultimately adding up to a total of 66 articles that provided data. It is a limited number, but nonetheless consistent with the observation made by several other authors having conducted similar reviews that there was little research on the subject (Keifer, 2000; Lehtola et al., 2008; DeRoo and Rautiainen, 2000; Matthews, 2008; Bourguet and Guillemaud, 2016).

#### 3. Results

### 3.1. The role of PPE in PPP marketing authorisation

A first finding from analysis of the literature concerns the role PPE plays in marketing authorisation procedures. It is crucial in the evaluation of exposure levels. Several authors (e.g. Tiramani et al., 2007; Gerritsen-Ebben et al., 2007a) have questionned the degree of protection attributed to PPE in models for determining exposure levels. In order to fully understand the central importance of PPE in risk assessment, procedures for granting marketing authorisation must be explained. We will focus on the situation in Europe in order to keep the

analysis precise, but the same general principals are also relevant in other countries and to other products (biocides and veterinary medications for external use).

# 3.1.1. Wearing PPE: a central decisional factor in marketing authorisation procedures

In Europe, applying for marketing authorisation for a plant protection product requires a risk assessment including exposure scenarios for people working on farms. It likewise concerns people handling the products, referred to as 'operators' in regulatory texts (application, mixing, loading sprayers), and people who might be subject to secondary exposure, referred to as 'workers'. Exposure scenarios are based on mathematical models for estimating exposure that take account of use and non-use of PPE. The most frequently used were 'UK poem', the 'German model', and the more recent 'Agricultural operator exposure model' (AOEM) (EFSA, 2014a; Tiramani et al., 2007). The experimental data used in these models came from exposure studies that were for the most part conducted by the industry applicants themselves and often unpublished (Großkopf et al., 2013). The data retained for estimating the risks of any and all exposure situations must be considered 'representative' based on the tasks and crop type concerned, and should result from observations conducted according to protocols meeting given conditions (OECD, 1997, 1998). In practice, only the results of a limited number of experimental studies are retained (EFSA, 2014b).

These models then compare these estimated exposure levels to toxicological reference values such as the 'Acceptable Operator Exposure Level' (AOEL) to assess the health risk of the products for users. The AOEL represents the maximum quantity of an active substance to which a person may be exposed daily without dangerous consequences for his or her health. It is calculated by dividing the exposure level having no observable adverse effects on animals by an uncertainty factor, usually 100. This factor is intended to take account of inter- and intra-species variations.

If the exposure level estimated with such models is greater than the reference values, the models predictively consider that the estimated exposure value could be reduced by wearing PPE. The protective factor attributed to wearing PPE varies according to the type of PPE and the part of the body concerned. It may also vary depending on the availability of observational data, especially in national databases (Hinz and Hornicke, 2001). When data on the protection provided by PPE is lacking, EFSA (2014a) recommends using default values, in this case considering that coveralls let through a maximum of 5–10 per cent of the product to which users are exposed (Table 1). This amounts to

**Table 1**Default values proposed by EFSA when data on the protection provided by PPE is lacking.

Technical control/PPE item		Penetration factor	Specific exposure value affected
Protective (chemical-resistant) glov	es	Operators, liquids 10%; operators, solids 5%; workers, solids 10%	Dermal exposure - hands only
Working clothing or uncertified cot	ton coverall	Operators 10%	Dermal exposure - body only
Protective coverall (this is used instead coverall)	ad of working clothing/uncertified cotton	Operators certified protective coverall 5%	Dermal exposure - body only
Hood		Operators 50%	Dermal exposure- head only
RPE mask type; Filter type (a)		-	-
Half and full and similar	FP1, P1 and similar FFP2, P2 and similar	25% 80% 10% 80%	Inhalation exposure Dermal exposure - head only Inhalation exposure Dermal exposure - head only

(a): Hood and visor are considered as an alternative to the RPE.

RPE, respiratory protective equipment.

Source: EFSA, 2014a, Table 7, p. 15 'Default personal protective equipment (PPE) (modified from EFSA PPR Panel, 2010, based on Gerritsen-Ebben et al. (2007b); Van Hemmen, 2008)'.

assume that this equipment can reduce PPP exposure by 90 to 95 per cent. The assumptions are of the same order of magnitude where biocides are concerned (EC, 2000/2009). This means that the exposure prediction models accept the fact that PPE, and notably coveralls, do not completely protect users, and let through some of the product to which they are exposed, as long as the level of exposure does not exceed the AOEL.

# 3.1.2. Challenging the reliability of simulations of exposure levels

The structure and parameters of these prediction models raise many questions, as was the case when the AOEM model was discussed recently during EFSA public consultation proceedings (EFSA, 2014b). These questions particularly concern the relevance of the data used to estimate exposure levels, the availability of PPE that is taken as a reference in the regulation, and the harmonisation of regulatory approaches.

In order for marketing authorisation to be based on a proper assessment of risk, reliable and relevant data must be employed in the models predicting exposure. This is highlighted by Tiramani et al. (2007) in their study of the risk analysis process in the pre-marketing phase of plant protection products for two models (German and UK poem). The authors analysed the elements retained as the basis of PPE wearing recommendations to reduce exposure during application. The study concerns 395 exposure scenarios for 52 active substances. They found that the reduction factors in use had been established in the 1990s, and could be considered obsolete by the time of their analysis (2007). They concluded that exposure levels are sometimes underestimated, which calls into question the degree to which applicators are actually protected under working conditions. Gerritsen-Ebben et al. (2007a) also identified the problem of using obsolete data to define the parameters of exposure models as a problem. Given the time needed to gather and analyse data, such studies are not yet available for the AOEM model. Meanwhile, EFSA (2014b) acknowledges that there is a dearth of data on many situations that is necessary to defining the parameters of exposure scenarios.

There is also much controversy over how exposure data should be generated. Data is collected using protocols respecting guidelines ('good laboratory practice', OECD, 1997, 1998) that may differ from real working conditions (e.g., concerning PPE use and maintenance practices,) and underestimate actual exposure levels (Laurent et al., 2016). Moreover, they do not account for the sampling conditions that would have to be respected in order to document the diversity of existing production systems (OECD, 2006). It thus seems rather unlikely that exposure levels in a grove of hundreds of hectares in Florida would be relevant to setting the parameters of models for small family-run orchards on the Mediterranean rim. This limit is well identified by EFSA, which suggests specifying certain scenarios at the national level. For example, speaking of the hypothetical number of hectares treated per day, EFSA stated: 'It is acknowledged that what is present in the Guidance might not be applicable to all existing scenarios in the EU; however there is always the possibility of further refinement considering the national specific conditions' (EFSA 2014b, p. 33). We did not identify any studies analysing the scale of such adjustments using the AOEM model, however.

A second condition that must be met for marketing authorisation based on a proper risk assessment is the actual availability of the PPE cited in the assessment. In the European Union, regulation<sup>2</sup> states that the exposure of people working in agriculture must be estimated during the assessment procedures for market authorisation and take account of 'effective and readily obtainable protective equipment, which is feasible to be used in practice' when the exposure level surpasses the AOEL (article 7.2.3.1 of the 2013 regulation). It should be pointed out that until 2013, PPP marketing authorisations only recommended wearing

'appropriate protective equipment' without specifying which ones, and did not take account of whether they were available on the market or not. The situation has changed for plant protection products in Europe, but as Shaw (2010) has stressed, there is no international agreement over the characteristics that PPE for PPP users should have, the role it should have in marketing authorisation procedures, or how their performance should be tested. Such variable norms and fragmentary knowledge of the intrinsic properties of PPE reduces the possibility of developing an overarching international approach to the rigorous assessment of PPE performance and the materials from which it is made.

Gerritsen-Ebben et al. (2007b) agree that the harmonisation of international standards must be discussed. Above all, estimates of the limits of the effectiveness of PPE use must be harmonised in the PPP approval process. But after analysing the regulatory situation in North America, Europe, and Australia, they highlighted the diversity of approaches regulatory authorities take to assess this effectiveness. These observations are corroborated by the international comparison conducted by the OECD (2006) to engage a policy dialogue on exposure assessment. Gerritsen-Ebben et al. (2007b) conclude upon the necessity of working toward an international harmonisation of factors to be taken into account in these procedures. In a paper presented at the Anses conference in October 2014, Gerritsen-Ebben et al. (2014) reasserted the need for this discussion to take place in a formal setting in order to arrive at genuine regulatory harmonisation. They demonstrated that changes in PPE performance, expressed by a mitigating factor to protect from PPP exposure, vary according to the methods recommended by each country. They declared that research should be conducted to fuel discussion of the limits of current approaches and to correct them as needed. This context led to an initiative to develop new international norms through the International Standardizing Organization (ISO, 2017). However, as Van Wely (2017) argues, developing ISO norms that overlap with various national laws does not make up for the lack of regulatory harmonisation.

The lack of international agreement over how to measure PPE performance also leads one to wonder how the actual effectiveness of PPE is studied, and what the basis is for the assumption that coveralls reduce exposure by 90-95 per cent (as postulated in European marketing authorisation procedures). Tiramani et al. (2007), Gerritsen-Ebben et al. (2007a, b) and Gerritsen-Ebben et al. (2014) all highlight the likelihood of under-estimating exposure, which necessitates new studies and summaries of existing data, an issue raised by other authors as well (Tsakirakis et al., 2014; Mandic-Rajcevic et al., 2018). They especially stressed the need to use reliable, up-to-date data from real-world settings after products are marketed, and likewise for the exposure levels, to provide empirical content to models guiding the granting of marketing authorisations. These same difficulties appeared when the AOEM model was under debate (including lack of field data and controversies over the hypotheses retained for determining exposure scenarios). These questions also concern the long-term performance of PPE and its constituent materials (Shaw, 2010). Indeed, as we shall see, laboratory data and field observations reveal situations that can sometimes differ significantly from the hypothetical data used in simulations.

# 3.2. Laboratory-based performance evaluation of PPE

The first level for testing PPE performance is in the laboratory, including at the site where the equipment is made. At this level, performance tests of PPE that are intended to protect from chemical products have undergone a normalisation process.

Twenty years ago, Shaw et al. (2000) described the three main methods used to assess PPE performance in accordance with European regulation defining its marketing. They encouraged all concerned parties to work together to define a broader normalisation process adapted to the specificities of agriculture. Shaw, 2012 then discussed the possibility of a new international procedure for standardising PPE performance. Along the same lines, Hinz et al. (2012) proposed definitions and categories of PPE. All these articles raise many questions, since

<sup>&</sup>lt;sup>2</sup> EU regulation 545/2011, repealed by regulation 284/2013 establishing new requirements in terms of data applicable to plant protection products.

# **Box 2**Quality control of PPE in the European Union.

In order for PPE to be put on the market, European regulation demands that it be designed and manufactured so as to protect people against specific hazards when it is used for its intended purposes and maintained properly. EU regulation 2016/425 lists design requirements and anticipates recourse to the development of norms for technical rules for manufacturing. In addition, 'Member States should take all appropriate measures to ensure that PPE covered by this Regulation may be placed on the market only if, when properly stored and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does not endanger the health or safety of persons' (p. 81).

PPE is thus evaluated on the basis of 'norms standardizing testing methods and performance requirements. In certain norms, test results lead to the attribution of a performance level (for protective gloves, respirators, coveralls, and the like). This performance level should be taken into account in the selection of PPE for a given work situation.

The performance levels of coveralls and gloves for protection against chemical products are determined by taking account of 'penetration' and 'permeation'. Penetration designates chemical products passing through the equipment through imperfections in the materials (holes, cracks), seams, and joints. It also designates entry through pores in the material used to manufacture coveralls (woven or non-woven). Permeation designates the intrinsic permeability of the material to a chemical product, its ability to pass the product at an intra-molecular level. A distinction must thus be made between penetration and permeation tests of gloves and coveralls. Technical manuals for this kind of PPE must provide the results of these tests as documentation of the performance of PPE materials.

To guarantee that the PPE conforms to design requirements and norms, a conformity certification procedure has been implemented. It consists either of internal monitoring of manufacturing or, in the EU, a procedure called 'EC type-examination' for PPE against highly dangerous products, accompanied by sampling-based monitoring of manufacturing or verification of the quality assurance system, the choice being up to the manufacturer.

laboratory assessments of performance levels, even when they are conducted with standardised tests (Box 2), cannot take account of all use conditions encountered under real working conditions (Brouwer et al., 2001).

Two major types of study discuss the issue of PPE effectiveness monitoring. The first type addresses the intrinsic quality of the materials composing the equipment and its capacity to effectively protect people (e.g. Moore 2014). The second is intended to explain the limitations of laboratory-simulated tests relative to actual use conditions in the field.

For the first type, many analysed publications agreed that laboratory evaluation of PPE is complex, especially when it is of coveralls for protecting farmers during PPP use (Staiff et al.,1982; Moody and Nadeau, 1994; Goumenou and Machera, 2001; Karolia and Joshi, 2003; Suri et al., 2001; Tsakirakis and Machera, 2007; Shaw and Abbi, 2004; Shaw et al., 2001; Gerritsen-Ebben et al., 2007b, Moore, 2014). They use a wide range of assessment methods that do not necessarily lead to the same results, even under equivalent experimental conditions. As Gerritsen-Ebben et al. (2007a) have stressed, a major percentage of PPE is designed and tested in reference to other professional sectors that also use PPE (the chemical industry for one), under very different working and exposure conditions (particularly with lower risk of heat stress from not working in the sun).

To be as rigorous as possible, these evaluations should consider a variety of physicochemical phenomena that contribute to pesticides passing through the materials of protective apparel: repellence, penetration, absorption, permeation, frictional transfer. All of them should be taken into consideration in overarching evaluations of PPE performance in protecting from pesticides. These phenomena are in no way equivalent, and must be added as assessment criteria and analysed in specific ways that account for their particularities. These tests should furthermore account for many other factors to represent the diversity of exposure scenarios and concrete situations encountered in practice. Practical uses are indeed quite varied.

This is why some studies set out to connect laboratory-simulated tests and field use of PPE (see Table 2). In the 1990s, Branson and Sweene (1991), Easter and Nigg (1992) and Methner and Fenske (1994) discussed the difficulties of predicting the protective effects of PPE in the field based on laboratory tests of their materials. Several specific mechanisms were documented:

- The protective effectiveness of certain garments covered in a repellent varies widely according to the way that it is cleaned (manually or mechanically), the kind of soap used, and its resistance to UV rays (Oliveira and Machado-Neto, 2005; Lebesc et al., 2015).

- Friction may lead to the transfer of solid pesticides from the outside of the coverall to inside. This kind of transfer has been as high as 12 per cent in some studies (Yang and Li, 1993).
- In practice, the tested molecules can indeed be used in a wide variety of situations and formulations that are not all tested in the laboratory: undiluted in powder form, in granule or liquid form while mixing or cleaning equipment, sprayed application, fumigation, and so on.
- Several authors discuss the underestimation of penetration and permeation rates (Methner and Fenske, 1994; Garrigou et al., 2011). For instance, the Pestexpo study (Garrigou et al., 2011) considered several potential determinants for exposure and ultimately demonstrated that PPE effectiveness under uncontrolled working conditions should hardly be taken for granted. As already observed in another situations (Hardt and Angerer, 2003), the study demonstrates that contamination may be higher for workers wearing PPE than for those not wearing it because the PPE absorbed products. The authors showed that the coveralls typically recommended by occupational safety organisations had not been tested for resistance to permeation by the pesticides being used, which explains how some products migrate through the coverall (some within ten minutes). The products used to test coveralls' resistance to permeation were acids and bases commonly used in industry. They matched products that the norms suggest for PPE testing, but do not respond to the characteristics of pesticides on the market.

These observations were corroborated by the laboratory study of Berthet et al. (2014), which demonstrated that the herbicides bentazone (Basagran® and Basamais®) and isoproturon (Arelon® and Matara®) rapidly permeated nearly all the coveralls being tested after 20–30 min of exposure. Among the four coveralls tested (two type-3 coveralls and two type 4), only one of types 3-4-5 was effective for all tested formulations for a minimum of five hours. The tested formulations were in undiluted liquid form, with the exception of Basagran®, a powder that was diluted in the same concentration as Basamais®. These results support those obtained by Garrigou et al. (2011) and explain the high contamination levels that were measured despite protective coverall use. Additionally, a higher temperature inside protective clothing may increase its permeation, and worker contamination along with it (Perkins and You, 1992; Evans et al., 2001; Zimmermann et al., 2011).

Penetration and permeation alone do not explain how active matter passes through PPE materials. Gerritsen-Ebben et al. (2007a) stressed that 'Skin Protective Equipment-design related deposition and transfer processes are assumed to play a role as well. In addition, the human

Table 2
Laboratory-based performance evaluation of PPE.

Author(s) - Year	Type of study - Goal of the study - Type of Product - Type of PPE	Main results and conclusions
Branson and Sweene (1991)	Book chapter – Literature review on PPE Goal: To review the scientific literature on protective clothing and their efficiency to reduce pesticide exposure. The review includes four areas: legislation and standard development, studies on PPE assessment, PPE design, and design and material evaluation through field studies. Pesticides used: Different active ingredients, including chlorpyrifos, diazinon, carbaryl, and atrazine. Type of PPE: Different fabrics.	Clothing evaluation studies have shown that protective clothing and coveralls of various materials and designs were effective in reducing exposure. Some studies suggested that the farmer's typical work clothing was more effective than fabric penetration results suggested. 'This apparent conflict is not surprising, given the methods used in both types of research. The field studies use pads placed in various areas under the clothing. This method assumes that exposure is uniform over entire body regions. But fluorescent tracer research has shown that this is not a valid assumption'. (page 104)
Easter and Nigg (1992)	Book chapter – Literature review on PPE Goal: To review the scientific literature on protective equipment researches. It defines what is PPE (excluding gloves), their properties and how they protect workers. Pesticides used: insecticides, and other chemicals. Type of PPE: Different fabrics.	Protective clothing evaluation showed variations in their results due to various fabric designs, pesticide formulations, and differences between laboratory and field simulations. The market includes so many choices regarding fabric designs and chemical compounds and formulations that it is difficult to make proper decisions to select the best protective clothing for a user. For the authors, manufacturers must recommend the appropriate clothing for pesticide protection.
Yang and Li (1993)	Type of study: Fabric test in laboratory (absorption, desorption, and transition of pesticides between fabrics).  Goal: To study the frictional transition of pesticides and the transfer from contaminated protective clothing to skin due to rubbing.  Pesticides used: Carbaryl, atrazine and metolachlor.  Type of PPE: Three protective clothing fabrics: cotton, polyester, polyester/cotton (65/35) and three crock fabrics: cotton, nylon and silk.	Up to 12% of the pesticide may be transferred from contaminated clothing to skin by rubbing. The frictional transition depends on the water solubility of active ingredient and on the affinity of pesticide to the fabric. Higher solubility in water induced greater wet transition (both water and perspiration) than dry transition. Similarly, underwear materials had an influence on obstructing the pesticide transition. Nylon was more effective than cotton to prevent frictional transition of the studied pesticides. A low fractional transition was observed with textile materials which had a high affinity to the pesticide. A direct transfer to the skin was observed with the absence of an underwear layer.
Fenske et al. (2002)	Type of study: 33 airblast applications involving 6 workers. Measurement of fluorescent tracer deposition on skin surfaces beneath garments with a video imaging analysis instrument (VITAE system), and by alphacellulose patches placed outside and beneath the garments.  Goal: To assess worker protection of chemical protective clothing during pesticide applications in central Florida citrus groves using fluorescent tracer.  Pesticides used: Organophosphorus insecticide ethion.  Type of PPE: PPE not prescribed. Coverall were replaced between applications. Cotton workshirt and pants; Cotton/polyester coveralls; SMS coveralls Kimberly non-woven; Sontara coveralls non-woven Dupont.	dependent both on low fabric penetration properties and proper design.
Oliveira and and Machado- Neto (2005)	Type of study: Fabrics testing in laboratory.  Goals: To determine under laboratory conditions the permeability of two types of cotton fabrics (Jeans and AZR treated with Teflon) to the insecticide methamidophos with and without laundering.  Pesticide used: insecticide methamidophos.  Type of PPE: two types of cotton fabrics (Jeans and AZR treated with Teflon).	New AZR and Jeans fabrics were practically impermeable to methamidophos.  Comparison of the permeability results obtained for the two types of fabric irrespective of the number of washes, washing method and use or not of washing soap showed that the AZR fabric was always more permeable than the Jean fabric.
Gerritsen-Ebben et al. (2007a)	Type of study: Research report.  Goal: To investigate "current views and facts on the use of default values or approaches for the estimation of exposure reduction effectiveness of (PPE) in registration processes of pesticides". To propose harmonized default protection factors international regulatory purposes.	Several tests for material performance were carried out in Europe and North America; however, they were designed for exposure conditions and scenarios in chemical industries not for agricultural practices. Actually, the criteria required to test PPE performance do not consider exposure scenarios simulating agricultural practices. The Skin Protective Equipement-design should consider deposition and transfer processes as well as the human factor, e.g. the way workers put on and take off gloves to determine the overall protection.
Garrigou et al. (2011)	Type of study: 200 observed treatment operations. Exposure was assessed with the application of pads (under and over clothes), collection of the hand washing liquid, air sampling. Comparison between workers wearing coverall and workers not wearing coveralls.  Goal: Contribution to chemical risks prevention: an ergotoxicological investigation off the effectiveness of coverall against plant pet risk in viticulture.  Pesticides used: Formulations used in vineyard, but detailed active ingredients or formulations were not listed.  Type of PPE: PPE not prescribed. Protective equipment usually used by the workers participating to the study (i.e., coveralls to no PPE).	The PPE dedicated to agriculture have been more or less directly transferred from industrial processes. Furthermore, although this is the class of coverall recommended by the prevention management institutions (Ministère de l'agriculture et CCMSA, 2007), there was evidence that the tests on resistance to permeation by liquids for these coveralls were not conducted using active substances present in pesticides but with various sulphuric acid and sodium hydroxide-based solutions.
Berthet et al. (2014)	Type of study: In vitro study using fresh human skin from abdominoplasty surgeries.	The two herbicides bentazon (Basagran® and Basamais®) and isoproturon (Arelon® and Matara®) permeated rapidly through almost every

#### Table 2 (continued)

Author(s) - Year	Type of study - Goal of the study - Type of Product - Type of PPE	Main results and conclusions
	Goal: Human skin in vitro permeation of two herbicides formulations with or without protective clothing suit. Pesticides used: bentazon and isoproturon.  Type of PPE: Coveralls type 3 and 4 protecting against chemical products.	combination tested, or after 20 to 30 min of exposure. Four different combinations were tested (two type 3 and two type 4), but only one type 3-4-5 was effective for all formulations tested for at least 5 h. The formulations tested were in liquid and undiluted form, except for Basagran® whose powdered formula was diluted in the same concentrations as Basamais®.
Moore et al. (2014)	Type of study: Fabric testing in laboratory.  Goal: Use of a human skin in vitro model to investigate the influence of 'every-day' clothing and skin surface decontamination on the percutaneous penetration of organophosphates  Pesticides used: Chlorpyriphos and dichlorvos.  PPE used: No PPE but every day-clothing,	Using human skin in vitro, absorption of chlorpyrifos ( $500 \text{ ng/cm}^2$ ), was shown to be significantly reduced when applied to clothed skin (cotton shirt). The majority of applied dose was retained within the clothing after 4 h exposure. This study has shown that 'every-day' clothing, although not designed for protection, could significantly reduce dermal exposure to chemicals. Rapid removal of the clothing will also reduce the dose in contact with skin and any subsequent dermal absorption.' (p. 264)
Lebesc et al. (2015)	Type of study: Fabric testing in laboratory.  Goal: Comparison of the performance of textile and non-woven materials against penetration and permeation of liquid pesticides.  Pesticides used: 9 plant protection products in liquid preparation.  PPE used: 3 woven coveralls, 3 woven and water repellent treatments coveralls and 6 non-woven coveralls.	Importance of the number of washes. 'The performance of coveralls with water repellent treatment against penetration decreased with the number of launderings, particularly for the diluted products.' (p. 310)  The permeation depends on the on the nature of the pesticides and the level of dilution. 'The highest cumulative permeations through the material and seams (with Tyvek classic plus) were obtained for the undiluted product Noverxone/Anti-liseron Nufarm. For the diluted product Rovral aqua flo, significant cumulative permeations were observed after 240 min.' (p. 310)
Shaw and Schiffelbein (2016a)	Type of study: Fabric testing in laboratory.  Goal: A review of research studies to identify a pesticide formulation which might be used as test chemical in test performance of pesticide penetration through textile materials. Pesticides used: 10 pesticide formulations tested at different concentrations: 3 formulations of glyphosate, 2,4-D and 2,4-DB, Phenmedipham, Ethyl parathion, Pendimethalin, Diazinon, Malathion, Endosulfan. Type of PPE: Six fabrics were tested: Woodpulp/polyester, cotton (plain and twill weave), polyester with and without repellent finish, Polyester/cotton.	Based on the formulations tested at different concentrations, results showed that emulsifiable concentrate diluted to 5% active ingredient (pendimethalin) (Prowl 3.3 EC) should be selected as a reference test liquid. The data analysis showed that this formulation at the selected concentration had a mean percent penetration similar to or higher than most tested chemicals.
Shaw and Schiffelbein (2016b)	Type of study: Fabric testing in laboratory.  Goal: To develop a systematic approach in order to evaluate the performance of fabrics used for garments worn by operators spraying pesticides.  Pesticides used: 0.2 ml of 5% Prowl 3.3 EC [an emulsifiable concentrate (EC) diluted to 5% active ingredient (pendimethalin)]. Choice based on results from the study of Shaw and Schiffelbein (2016a). Type of PPE: 101 woven, nonwoven, and multicomponent fabrics were tested.	Among the variety of fabrics tested, air-impermeable fabrics and fabrics with repellent finish provided a higher level of protection for operators exposed to pesticides. Nonwoven fabrics had high standard deviation for percent penetration, the performance of these materials were thus difficult to predict. To determine if a fabric passes or fails the penetration tests, standard deviation or high individual values should be used in addition to mean values. The coverall that might be a basis for performance comparison due to its acceptable performance in field trials was the Mauser coverall.
Shaw et al. (2018)	Type of study: Fabric testing in laboratory.  Goal: To develop a systematic approach in order to evaluate the performance of fabrics used for garments worn by operators spraying pesticides.  Pesticides used: Prowl with 11 formulations.  Type of PPE: 3 cotton/polyester fabrics that met the ISO 27065 level C1.	Variability of the penetration: 'Mean % penetration of the PPP tested in Brazil was estimated to 31.7% (SD = 2.38) and varies between 25.1% and 34.6%. Mean % penetration of the PPP tested in France, was estimated to 32.8% (SD = 5.99) and varies between 3.5% and 40.7%.' Section 3.1.2.) 'Means % penetration vary from 26.1% (FR-Prowl) to 39.5% (FR-SC5) when the 12 PPP are tested with the fabric B, and from 27.9% (FR-SC7) to 39.0% (FR-EC1) when tested with the fabric C.' (Section 3.2.1.)

factor, e.g. the way workers put on and take off gloves, determines the overall protection' to a considerable extent (p.51). Fenske et al. (2002) also indicated that chemical protective clothing's ability to reduce exposure is dependent on its low fabric-penetration properties and on proper design of garment openings such as neck and sleeves.

Assessment of protective clothing has typically been divided into two phases: laboratory testing and field performance testing. The authors all emphasise that laboratory testing can provide information regarding pesticide penetration and permeation through fabric, but only field-testing under realistic exposure conditions can determine the overall effectiveness of the design and its ability to reduce penetration. Yet, given the number of commercially available formulations, the fact that exposure can combine multiple products, the variety of working conditions, and the low standardisation of agricultural practices, one might wonder about the feasibility of such an undertaking for all PPE use scenarios in all kinds of agriculture. And indeed, as we shall see, there is very little published data on these issues.

# 3.3. Assessment of PPE effectiveness under working conditions

Analysis of the literature led to the identification of two major types of what could be qualified as field studies of PPE use. In the first one PPE wearing practices are controlled, requiring that a particular kind of PPE be worn. The second consists of field studies where PPE wearing practices were uncontrolled, meaning that the choice of PPE or whether to use any at all was not imposed. This second type may thus include observations of individuals who only protect themselves with everyday clothing.

# 3.3.1. Assessment of PPE effectiveness in field studies in which PPE wearing practices are controlled

An extremely small number of peer-reviewed studies in which PPE wearing practices are controlled have been published. The studies aiming at assessing the effectiveness of protective coveralls for PPPs were published between 1986 and 2016 (Table 3). They primarily

Table 3 Assessment of PPE	Table 3           Assessment of PPE effectiveness with controlled PPE-wearing practices.	ng practices.		
Author Year - Area	Goal of the study -Type of product	Type of PPE -Number of people	Method	Main results regarding PPE effectiveness
Nigg et al. (1986) USA Florida	Goal: Exposure monitoring of mixer- loaders and applicators in Florida citrus groves.  Pesticide: dicofol.	Type of PPE: Abanda Tyvek, style 1412 coverall and normal cotton work uniform.  PPE imposed by the study n = 4 operators.  Operators were monitored Exposure monitored during 6 week.	Alpha-cellulose pads were placed inside and outside regular work clothing. When protective suits were in use, pads were also placed outside the suit.	Reduction of 38% by wearing a Tyvek suit, 27% by wearing gloves, 65% by wearing both.  Regular work clothing provides 91% of protection and coverall 97%, both 95%.  Because of discomfort from heat, the workers refused coveralls at a certain moment of the observation.
Nigg et al. (1990) USA Florida	Goal: Protection afforded citrus pesticide applicators. Pesticides: ethion, dicofol.	Type of PPE: SMS (polypropylene, non-woven), reusable treated twill and untreated twill. PPE imposed by the study. $\mathbf{n}=4$ applicators.	Four airblast applicators of the pesticides dicofol and ethion to Florida citrus were monitored for pesticide exposure with pads placed inside and outside two types of protective coveralls.	The penetration of ethion through a reusable treated twill suit was $8\pm2\%$ and through a disposable synthetic suit was $6\pm4\%$ ; corresponding values for dicofol were $4\pm1\%$ and $1-0\%$ , respectively. While these four penetration values could not be separated statistically at $p<0.05$ , it is probable ( $p<0.20$ ) that ethion was the better penetrator, and the disposable synthetic suit the better protector against dicofol.
Nigg et al. (1992) USA Florida	Goal: The effect of wearing coveralls on the heat stress of ten professional airblast applicators to Florida citrus.  Pesticide: ethion.	Type of PPE: Propylene FabricPolyester/wood pulpe fabric. Cotton/polyester fabric- PPE designed and imposed by the study, n = 10 males.	Penetration measurements used $10.2 \times 10.2$ cm alpha-cellulose pads. Heat stress also evaluated by measuring the mean skin temperature, oral temperature, and heart rate of pesticide applicators.	Median penetration of ethion through the various fabrics ranged from 0.8% for the treated Sontara fabric to 3.8% for the untreated SMS 1.8 fabric.  It is unconscionable that a pesticide label would give a blanket recommendation for protective clothing and sometimes a respirator without consideration of the environmental conditions of use and the heat stress effects on the health of the worker.
Nigg et al. (1993) USA Florida	Goal: Protection afforded greenhouse pesticide applicators by coveralls.  Pesticide: chloropyrifos, fluvalinate, ethanol.	Type of PPE: 3 types of coveralls: — 35/65% cotton/polyester twill; untreated twill; polyptylene coverall.  Coveralls were imposed by the study,  n = 3 experienced males, 25–27 years old	Pads placed inside and outside 3 types of protective coverall.	For a same type of coverall, the penetration rate differs with the type of fabric and the type of PPE. Overall penetration of pesticide through was: (1) for a disposable synthetic, $3\pm1\%$ for chlorpyrifos and fluvalinate and $35\pm9\%$ for ethazol. (2) for reusable treated twill coverall, $19\pm6\%$ for chlorpyrifos, $22\pm13\%$ for fluvalinate and $38\pm5\%$ for ethazol. (3) For untreated coverall $17\pm9\%$ for fluvalinate. For a same type of coverall, the penetration rate differs with the PPP that is used.
Methner and Fenske (1994) USA	Goal: Evaluation of protective clothing performance during greenhouse high pressure handspray applications.  Pesticide: fluorescent tracer substitute to pesticide.	Type of PPE: Four garments constructed of nonwoven, chemical-resistant fabric were tested in an initial study (TyvekTM, Saranex 23-P TyvekTM, ComfortgardTM II, KleenguardTM). n = 3	Fluorescent compound was added to the applicator's spray. Video imaging. Patches outside and inside the protective garment	All garments exhibited chemical breakthrough after a 1-hour application period. Garments with special treatments to enhance chemical resistance exhibited relatively low levels of breakthrough, whereas garments without such treatments allowed substantial breakthrough. Breakthroughs for Tyvek and Kleenguard garments occurred between 5 and 15 min following the start of the application.  Contact with treated foliage represents a special hazard during greenhouse applications, and many chemical protective clothing products in current use are inadequate for worker protection. It was concluded that none of the garments could be considered chemical resistant under the use conditions observed.  The authors highlighted that 'these products should be redesigned and field-tested to ensure that greenhouse workers do not contact pesticides by this exposure pathway' (p. 567).
Archibald et al. (1995) Canada	Goal: Estimation of pesticide exposure to greenhouse applicators using video imaging and fluorescent tracer.	Type of PPE: complete PPE: coveralls (Tyvek(R) or rubber), an apron (Tyvek or rubber), safety goggles or visor, gloves (neoprene), rubber	Video imaging and used of patches, air simples, analyse of urine. The fluorescent tracer, 4-methyl-7-	Deposition of pesticides/tracer is non uniform, and that the use of patches to measure pesticide exposure has several limitations. Inner patch deposits were highly variable.

Author Year - Area	Goal of the study -Type of product	Type of PPE -Number of people	Method	Main results regarding PPE effectiveness
	Pesticides: Pirimicarb, N-methyl carbamate, deltamethrin and a synthetic pyrethroid.	boots, and a waterproof hat or helmet. PPE were imposed,  n = 5 males and 6 separate exposure assessment sessions were conducted with each applicator.	diethylaminocoumarin, was predissolved in Assist Oil Concentrate.	When applicators were instructed to follow a protective operating procedures (POP) they had to wear PPE (cf. third column), this did not significantly change the total per-hour tracer deposition during high-volume application. However it resulted in a significant reduction in deposition of tracer when using low-applications techniques. In general, low-volume applications using POP did not result in detectable levels of tracer or pesticides deposition on inner patches.
Krieger et al., 1998	Goal: Protectiveness of coveralls during Mixing. Loading and Airblast Application in Treefruits.  Pesticides: Dormant oil/organophosphate insecticide.	PPE: coveralls Kleengard® LP and Tyvek®-Saranev® 23-P, n = 2 workers.	Monitoring of 14 days. Protective clothing was changed each day.  Daily analyzes of urine specimens for a suite of six dialkyl phosphates in 24-hour collections made in 2 L polypropylene bottles.	"Workers who mixed/loaded and applied organophosphate/dormant oil sprays wearing work attire plus either KGLP or TVS absorbed very small amounts of insecticide during a 14-day trial employing continuous urine biomonitoring' (p. 460).  KGLP coverall provided superior comfort and equivalent protectiveness against pesticide exposure.
Fenske et al. (2002) USA Florida (cirtus groves)	Goal: Fluorescent tracer evaluation of chemical protective clothing during pesticie applications in central Florida citrusgroves.  Pesticides: ethion.	Type of PPE 4 garment types were tested: 2 traditional garments (cotton work shirt/work pants, woven Cotton/polyester coveralls) and 2 made non-woven fabrics (sms Kimberly, Sontara Dupont). n = 6 workers in 2 cooperatives. 33 airblast applications.  8 replicate exposures of each garment.	A commercially available fluorescent whitening agent, 4-methyl-7-diethylaminocoumarin (Calcofluor RWP), was employed as a tracer of pesticide residue deposition. Video imaging. Dermal patches to estimate protective clothing penetration.	Fabric penetration was detected for all test garments; 5% to 7% of the ethion measured outside the gaments was found beneath the garments. The authors observe that "the clothing materials tested were not chemically resistant under these field conditions"; non-woven coveralls resulted in significantly greater exposure than did traditional woven. This can be explained primarily because of the design factors of the coveralls (e.g., large sleeve and neck openings) as documented by video imaging. Traditional laboratory tests do not characterize this. 'Claims regarding the ability of garments to protect workers should be qualified unless performance has been demonstrated under realistic conditions (field tests)'. (p. 329)
Machera et al. (2009) Greece	Goal: Field performance of two coverall designs used by pesticide applicators in greenhouse.  Pesticides: Malathion.	Type of PPE: A cotton /polyester material treated with a water-repellent Resist Spills* finish, A coverall using a woven, un- treated cotton material. Study linked with ECPA.  n = 11 operators during 22 applications.	Dermal exposure of Malathion, was measured during 22 applications conducted with 11 operators using similar hand-held spray guns.  The application conditions selected for the present study can be considered as a high-exposure scenario.	Comparing the total amount of the a.s. recovered from outer and inner dosimeters (potential dermal exposure = $2.38.8$ mg kg <sup>-1</sup> a.s. for the cotton coverall and $160.44$ mg kg <sup>-1</sup> a.for the Resist Spills* coverall). Mean penetration of $0.4\%$ for the water-repellent coverall and $2.3\%$ for the cotton coverall. Protection provided by the coverall types, the Resist Spills finish coverall (penetration $0.42\%$ ) provided approximately $5.5$ times greater protection than the cotton coverall. Under the field trial conditions evaluated, both the coverall designs gave better protection than the default values used in the most relevant predictive exposure model. They could be considered as appropriate tools of personal protection when both comfort and field performance is taken into account under the specific application scenario'. (p. 573)
Tsakirakis et al. (2014) Greece	Goal: Dermal and the inhalation exposure of five operators during fungicide applications in vineyards.  Pesticide: penconazole.	Type of PPE: PPE were imposed. Type A coverall (50/50 cotton/polyester with Resist Spills* finish) and type B coverall (100% cotton).  Practices: All operators were instructed to follow their normal spraying practice. Ten field trials were carried out by n = 5 operators using a tractor assisted hand-held lance with spray gun.	The dermal exposure was measured using the whole body dosimetry method while the inhalation exposure with the use of personal air sampling devices with XAD tubes located on the operator's breathing zone.	The operators of type A coveralls had potential body exposure levels ranging from 43 to 304 (geometric mean 120) mg/kg a.s.  The same operators using type B coverall the respective values ranged from 67 to 296 mg/kg a.s (geometric mean 140 mg/kg a.s.).T he actual body exposure levels for operators using type A coveralls the values ranged from 0.79 to 6.71 mg a.s./kg a.s (geometric mean 2.0 mg a.s./kg a.s) with the respective values for operators using type B coveralls being 0.74–11.1 (geometric mean 2.0 mg a.s./kg a.s.).

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Author Year - Area	Goal of the study -Type of product	Type of PPE -Number of people	Method	Main results regarding PPE effectiveness
				The German model is 'protective' for the operator using PPE considering the 75th percentile but 'non-protective' when the exposure geometric mean values are considered.  The evaluation of two types of protective coveralls used in the trials indicated that both provided satisfactory protection (up to 98.4%) for the operators under the specific application scenario, highlighting once more the use of proper personal protection equipment as a parameter of major importance for the operators' safety.
Thouvenin et al. (2016a) France	Goal: To measure level of operator exposure and check effectiveness of PPE with operators using backpack motorised mist-blower power sprayers.  Pesticide: Fungicide Selva containing a nominal content of 30 g of .cymoxanil per litre.	Type of PPE: Category III Type 4-5-6 coverall.  Tyvek Classic Plus, model CHA5a. Protective nitrile gloves (Ansell Sol-Vex, 37-675 (EN 374-3 standard)).  Practices. One team working for a vine growing farm (n = 4 people) and 2 teams of 3 people working for a contractor company. Motorised mist-blower power sprayers (12–15 L).	To assess actual body exposure, an inner layer of clothing consisting of a full-length cotton undergarment (100% white cotton long-sleeved T-shirt and long johns; Gebr.Oelkuch GBR) was worn below the protective coverall.	The transfer factor (TF) calculated during application considering either the 75th or the 95th percentile was lower for the coverall in the experimental exposure study. For the gloves, the TFs calculated using the 75th and 95th percentiles were respectively 4 and 11 times higher in the experimental operator exposure study than in the EFSA model' (secrion 3.3).  The study shows differences of results between the field experience conducted in vineyards and EFSA model.  The transfer factors that were determined from the experimental study indicated that Caregory III Type 47.56 coveralls (according to Directive 89/686/EEC) offer a protection to operators'. 'When high exposure is likely to occur under field conditions, a high level of performance for protective clothing is required, i.e., level 3 in ISO 27065:2011' (section 4).
Thouvenin et al. (2016b) France	Goal: To measure operator dermal exposure and protection provided by PPE and working coveralls during mixing/loading, application and sprayer cleaning in vineyards.  Pesticide: Insecticide Success 4 or Musdo 4.	Type of PPE: non-certified water-repellent finish polyester/cotton coverall plus a certified gown during the mixing/loading and the cleaning phases. Controlled practices: Insecticide foliar application to a vineyard was selected as the exposure scenario and the workers had to used the imposed coveralls, n = 15 workers.	This study was based on the whole-body dosimetry method documented in the OECD.	The protection afforded by water-repellent finish polyester/cotton coverall was 98.5% (75th percentile) and 94.9% (95th percentile). The protection afforded by a coverall plus a gown worn when necessary was 99.5% (75th percentile) and 98.7% (95th percentile), which proved to be a very effective combination of clothes for body protection? 'Transfer via gloves was calculated only for three operators (0.37%, 0.24% and 0.41% during mixing and loading'. (p. 7)

concern tree-fruit growing (citrus), grape farming, and greenhouses. They observed few people, from three to 15. They were conducted in three European countries (France, the Netherlands, Italy), the United States and Canada.

The quantity of PPP passing through protective clothing was found to vary according to the area of the body and the nature of the material from which clothing is made, and in relation to the kind of pesticide under study (Nigg et al., 1992; Nigg et al., 1993). It may significantly vary when the same protective garment is exposed to multiple pesticides. It can nonetheless be challenging to objectify these variations.

Several studies conclude that protective equipment provides significant protection, often over 90 per cent (Archibald et al., 1995; Nigg et al., 1986; Nigg et al., 1992; Nigg et al., 1993; Tsakirakis et al., 2014; Thouvenin et al., 2016a, 2016b). Clothing treated with a water-repellent product seems more effective than cotton overalls (Machera et al., 2009; Tsakirakis et al., 2014). Some studies also show that work wear described as 'regular clothing' provides significant protection. This protection can range from 84 to 91 per cent however it is less than that of specific protective clothing (Nigg et al., 1986; Tsakirakis et al., 2014).

Two studies found lower levels of protection than expected (Methner and Fenske, 1994; Fenske et al., 2002). In their analysis of use of PPE in greenhouses, Methner and Fenske (1994) conclude that none of the garments can be considered chemical resistant under the observed conditions of use.

Several authors thus emphasise that PPE should be considered as effective only when both comfort and field performance are taken into account (Nigg et al., 1986, 1992; Fenske et al., 2002; Machera et al., 2009). They stress that the pesticide approval process must include consideration of operators' working conditions, particularly thermal conditions that could be a source of heat stress.

# 3.3.2. Assessment of PPE effectiveness in field studies in which PPE wearing practices are uncontrolled or partially controlled

There are also few published peer-reviewed field studies in which PPE wearing practices are uncontrolled. Those that we identified were published between 1989 and 2017 (Table 4). They all relate to users of PPP in tree-fruit growing, grape growing, greenhouses, and field crops (maize and rice). The number of observed persons ranges from four to 204. They were monitored over periods of varying lengths up to twelve months. The studies were conducted in Europe (France, Denmark, Italy) and the United States (Florida).

# Analysis of these studies reveals several points:

- Some studies show a non-linear relationship between the quantities of pesticides measured on workers' clothing, on their skin, and in their urine (Rubino et al., 2012). This non-linear relationship can make it difficult to develop reliable models for simulation or to make reliable estimations of the relation between the level of exposure and the quantity of pesticides that is applied. Mandic-Rajcevic et al. (2015) suggest that the exposure assessment models used in PPP marketing authorisation procedures underestimate the quantity of active substance touching the skin, especially in instances involving small quantities of pesticides. A study by Baldi et al. (2014) shows that the phases of activity that models associate with low exposure, such as re-entry into treated areas and wine grape harvesting, actually lead to high exposure levels.
- Stamper et al. (1989) show some marked differences in coverall protection levels depending on the material from which they are made and the nature of the pesticide used. This means that there is no generic material offering the same level of protection against any and all pesticides. Similarly, coveralls or rubber boots would not provide the same level of protection for any given PPP because they are composed of different materials.
- However several studies conclude that wearing protective

equipment, especially gloves and protective coveralls, limits exposure (Fenske et al., 2002; Lander and Hinke, 1992; Samuel et al., 2002; Stamper et al., 1989; Vitali et al., 2009; Mandic-Rajcevic et al., 2015, 2018; Baldi et al., 2014). Some show that so-called 'work clothing' gives a degree of protection, even if it is less than that of coveralls (Mandic-Rajcevic et al., 2015, 2018; Protano et al., 2009). Non-woven materials are said to provide more protection than woven (Fenske et al., 2002).

- Some studies in which PPE wearing practices were not controlled show that the measured level of protection is nowhere near the anticipated level, and this for protective coveralls (Garrigou et al., 2011), aprons (Lander and Hinke, 1992), boots (Stamper et al., 1989), gloves (Lander and Hinke, 1992), and work clothing (Vitali et al., 2009). Garrigou et al. (2011) have shown that in wine grape growing, people wearing protective coveralls could be more contaminated than those not wearing them during the sprayer-cleaning phase.
- Fenske et al. (2002) emphasise that the cut of coveralls for PPP protection may explain certain instances of contamination (coveralls with wide sleeve openings, for example).
- Ultimately, studies of uncontrolled situations allow the most detailed understanding of exposure under usual working conditions. We note, however, that there are still not enough studies of this kind, and that those that exist generally concern limited numbers of operators or situations. They are thus far from providing us with information on all working configurations that can be found across Europe and OECD countries.

# 3.4. PPE often absent in work situations

Nearly all authors addressing the wearing of PPE, whether in exposure studies or PPE performance studies as such, have observed that a great many PPE field use conditions do not correspond to what is assumed in the regulatory provisions and its marketing authorisation.

Field observations show that actual wearing of PPE is well below stipulated recommendations, although it varies according to type of task. This is a widespread observation in studies where wearing practices are uncontrolled and addressing protective coverall use issues, even in OECD countries where conditions might seem to be the most favourable (Lander and Hinke, 1992; Lander et al., 1992; Avory and Coggon, 1994; Stone et al., 1994; Samuel et al., 2002; Coffman et al., 2009; Perry et al., 2002; Perry and Layde, 2003; Hines et al., 2007; Giannandrea et al., 2008; Macfarlane et al., 2008; Nicol and Kennedy, 2008; Reynolds et al., 2008; Strong et al., 2008; Garrigou et al., 2011; DellaValle et al., 2012; MacFarlane et al., 2008, 2013; Baldi et al., 2012, 2014; Levesque et al., 2012; Remoundou et al., 2015; Kearney et al., 2015; Damalas and Habdollahzaded, 2016; Snipes et al., 2016; Cerruto et al., 2008, 2018; McLaughlin et al., 2014; Mandic-Rajcevic et al., 2018; Rubino et al., 2012) (Table 5). Of the publications from nine countries taken into consideration, we found only one study reporting a high rate of PPE use (Coffman et al., 2009), but the authors themselves highlighted the limitations of their observation protocol.

How to explain the persistent non-use of PPE? Preliminary hypotheses concern the influences of educational level, social status, onfarm working relations, and the availability of such equipment to workers.

# 3.4.1. Non-use of PPE explained by personal characteristics

When PPE is not used, the first idea that comes to mind is to educate the concerned persons by training them to be aware of the risks they are taking, the recommended practices, and how to implement them. Several studies report interventions of this kind (Damalas and Abdollahzadeh, 2016; Beard et al., 2014; Lévesque et al., 2012; Perry and Layde, 2003; Snipes et al., 2016). But when research tries to make a link between this training and wearing PPE, the results are mixed. For example, a study by Perry and Layde (2003) presents the results of a controlled randomised intervention that followed up on a training

 Table 4

 Assessment of PPE effectiveness in field studies in which PPE wearing practices are uncontrolled or partially controlled.

Author(s) Year - Area	Goal of the study -Type of Product - Type of PPE	Number of persons - Level of control of PPE and practices	Main results and conclusions
Stamper et al. (1989) USA Florida (greenhouses)	Goal: Pesticide Exposure in greenhouses. Handgunners. Pesticides: Fluvalinate, Chloripyros, Ethazol, Dicofol. Type of PPE: Usual protective clothing Tyvek coverall, aprons, gloves, googles and respirators.	Number of persons. 4 Workers (2 males, 2 females) Observations during 12 months.  Prescriptions: Workers were asked to wear usual PPE and not change their practices.	Significant differences of protection according to type of PPE and according to type of pesticide.  TheTyvek coverall afforded 99 + 1% protection from fiuvalinate, 89 -+ 5%; from chlorpyrifos, 66 + 1% from ethazol, and 96 + 2% from dicofol.  Rubber boots provide different protection according to products and provides less protection than the other PPE for fluvalinate.  'The unusual ability of ethazol or any other chemical to contaminate the breathing zone of a handgunner and to appear beneath his protective clothing in unexpectedly large amounts warrants further research'. (p. 521)
Lander and Hinke (1992) Denmark (greenhouses, flowers)	Goal: Indoor Application of Anti-Cholinesterase Agents and Influence of PPE on Uptake.  Pesticides: organophosphate and carbamate.  Type of PPE: face mask, wearing of rubber or synthetic gloves, wearing of protective clothes such as a rubber apron or whole-body clothes chemically resistant.	Number of persons: 125 sprayers (117 men and 14 females). 26 sprayers spray without protective clothing.  Prescriptions: PPE and practice not prescribed.	'Especially in the individuals most extensively exposed, wearing of whole- body clothes seemed to be of significant protective value' (p.164). Comparing cholinesterase activities in a group of 44 workers according to the type of protection adopted (nothing [n = 21], rubber apron [n = 6], whole-body cloth [n = 17]), they observe that rubber aprons may have a very limited protective influence. The wearing of whole-body protective clothes seems to be of particular value in preventing percutaneous absorption.
Lander et al. (1992) Denmark (greenhouses, flowers)	Goal. Indoor Application of Anti-Cholinesterase Agents and Influence of PPE on Uptake.  Pesticides: organophosphate and carbamate.Type of PPE. Personal cloths, rubber or synthetic gloves.	Number of persons: 204 greenhouse workers (146 women) and 360 non-exposed control.  Prescriptions: PPE and practice not prescribed.	No significant differences in ChE inhibition according to glove wearing habit. 'Greenhouse workers, exposed to a mixture of anti-ChE agents, chronically absorb amounts that cause a measurable ChE inhibition. The use of protective gloves is apparently not sufficient to prevent percutaneous absorption'. (p. 161)
Keifer (2000) USA	Goal: Review on effectiveness of interventions in reducing pesticide overexposure and poisonings.	Cochrane Collaboration review methodology. Search strategy for articles that tested the effectiveness of interventions in reducing human pesticide exposure or poisonings.	'Application procedures, packaging, mixing, use of personal protective equipment, and biological monitoring reduced pesticide exposure under controlled condition. Most of the studies that addressed the effectiveness of PPE were generally small and were controlled by crossover to conventional practice or non-use of the intervention.' (p.87) 'While it is intuitive that PPE would reduce poisoning by reducing exposure, the use of the PPE by exposed populations is not tested by merely proving the equipment reduces exposure in a controlled setting'. (p. 87–88) 'Similarly, tests of PPE efficacy or even closed-system pesticide transfer tools in controlled field trials do not necessarily trans- late into effective interventions in real world situations'. (p. 88)
Garrigou et al. (2011) and Baldi et al. (2006) France (viticulture)	Goal: Ergonomics contribution to chemical risks prevention in viticulture, ergotoxicological investigation of the effectiveness of coveralls.  Pesticides: dithiocarbamate.  Type of PPE: Comparison between workers wearing coverall (various types) and workers not wearing coveralls.	Number of persons: 38 workers, observations in 48 days, for 3 tasks, preparation/mixing (n = 65), applications (n = 71), cleaning (n = 26). With or without PPE, focus on coveralls.  Prescriptions: PPE and practices not prescribed.	Unexpected results: higher contamination when wearing coveralls.  During the application phase, workers wearing coverall had the double level of contamination (in median) than people not wearing coverall. During the cleaning phases, the workers wearing coverall were 3 times more contaminated (in median) than people who did not.  Proposed interpretation confirmed by Afsset 2010: The permeation (migration at the molecular level) of the pesticides through the coverall could result in high level of product inside the PPE, being source of specific exposure.
Protano et al. (2009) Italy	Goal: to measure performance of different work clothing types for reducing skin exposure.  Pesticide: Azin PB 30 (azinphosmethyl), Lasso Micromix (terbutylazine and alachlor), Rogor (dimetho-ate), and Sivel 21S (dicamba).  Type of PPE: clothing worn by the operators (4 with complete PPE set -Tyvek coverall, helmets, gloves and rubber boots- others with various cloths (shot/long sleeves cotton shirts, etc.).	Number of persons: n = 10 operators.  Prescriptions: Data collected for the complete treatment (mixing, loading, and application).  Dermal exposure by the pads technique.  During the workshift, operators wore rewashed cotton garments or new Tyvek coveralls and gloves in order to avoid skin and garment contamination due to carry-over from previous work days.	Penetration factors values for operators who worked with a complete set of PPE (full mask, Tyvek coverall, rubber boots and gloves) ranged from: penetration factor of 0,0% to 2,1%. Work with a no complete PPE set: penetration factor of 0,9% to 2,1%. Work with usual cotton clothing: penetration factor of 7,5% to 2,4%. Regarding cotton garments, pesticide characteristics seem to be insignificant in determining the penetration factor. Significant variations of the PF values of different cotton garments varies for all the operator. The Upper body (chest, back and arms) had the highest PF values. The autors note that except the German Model, all models indicate penetration factors values 10–30 times higher than in the study for protective coveralls.

#### Table 4 (continued)

Author(s) Year - Area	Goal of the study -Type of Product - Type of PPE	Number of persons - Level of control of PPE and practices	Main results and conclusions
Vitali et al. (2009) Italy (crops)	Goal: Operative modalities and exposure to pesticides during open field treatments among a group of agricultural subcontractors.  Pesticides: azinphos-methyl, dicamba, dimethoate, terbuthylazine, and alachlor.  Type of PPE: helmet with full-mask with A2P3 filter, Tyvek suit and gloves. 6 wear cotton garments.	Number of persons 10 male professional subcontractors. Prescriptions: PPE semi- controlled. 4 operators use complete protection. Practices not prescribed.	'Penetration through specific protective garments was less than 2.4% in all cases, although penetration through general work clothing was as high as 26.8%. (). Comparisons between exposure levels and operative modalities highlighted that complete PPE and properly equipped tractors contributed to a significant reduction in total exposure to pesticides during agricultural activities'. (p. 193) 'Data show that through normal cotton clothing, penetration factor ranged from 11.2 to 26.8%, while through protective Tyvek coveralls, penetration factor was less than 2.4% in all cases'. (p. 200)
Rubino et al. (2012) Italy (rice and maize)	Goal: Exposure to herbicides in North Italy: Assessment under real-life conditions in small-size rice and corn farms.  Pesticide: propanil and terbutilazine.  Type of PPE: 3 workers used standard PPE (masks,coveralls, gloves, boots). 16/28 standard PPE except boots, 7/28 only gloves. 1/28 only coverall, 1/28 all PPE except coverall.	Number of persons. 28 rice and maize herbicide applicators.  Prescriptions: PPE and practice not prescribed.	Strong positive correlation was found between contamination on garment and on skin. 'It was estimated that the penetration factor of garment contamination is 4–20% with a proportionally higher potential exposure of products for workers who spray lower amount of pesticides (those who work in smaller farms) than for those who spray higher amounts (those who work in larger farms)'. (p.193) 'Fairly strong non-linearity of the relationships: (a) of the amount of pesticide measured on applicators' clothes to that applied in the field; (b) of the amount of pesticide measured on applicators' skin to that on applicators' clothes; (c) of the amount of pesticide excreted in the applicators' urine to that on applicators' skin'. (p. 196)
Baldi et al. (2014) France (viticulture)	Goal: Measure of dermal exposure in reentry and harvest.  Pesticide: Dithiocarbamate and Folpet.  Type of PPE: Usual cloths of workers.	Number of persons: 36 workers + 1 farmer for re-entry tasks, 46 workers + 1 farmer for harvest.  Prescriptions: PPE and practice not prescribed.	Evidence of significant level of exposure when completing tasks that were usually considered not to be source of exposure in vineyards (re-entry and harvest).  Evidence of less contamination when wearing gloves, long sleeves and trousers.
Mandic-Rajcevic et al. (2015) Italy (viticulture)	Goal: Dermal exposure and risk assessment of pesticide applicators in vineyards. Measures and comparisons with predictions of the German model. Pesticide: tebuconazole.  Type of PPE: Cotton coveralls and underneath white cotton shirt and boxers supplied by the investigation. Other PPE not supplied by the team.	Number of persons: 7 workers followed-up during 12 working days.  Prescriptions: PPE. Partly supplied by the investigators. Farm practices not prescribed.	The median protection factor provided by cotton coverall was 98% (range: 90–99). Hand exposure was responsible for 61% of total exposure and was reduced more than 50% for workers using gloves (i.e. higher values than that re-ported by other authors for standard cotton garments, 73% – 88%). Results suggest that the pre-authorisation models underestimated the fraction of active substance which reaches the skin when small amounts are used.
Mandic-Rajcevic et al. (2018) Italy (viticulture)	Goal: Environmental and biological monitoring for the identification of main exposure determinants in vineyard pesticide application.  TPesticide: mancozeb.  Type of PPE: Masks, gloves, coverall, feet protection are described (Table 4).	Number of persons: 29 workers and 38 working days follow-up.  Prescriptions: Designed as "real life" conditions but tight follow-up of actual practices (3 followers) and PPE partly made available. 'Most workers were equipped with new mono-use coveralls, and most used normal clothes below the coveralls' (p. 3).	Mono-use coverall provides the highest body protection, followed by the multi-use coverall and regular clothes. Mono-and multi-use coveralls were able to block almost 99% of potential exposure, while normal clothes prevented only around 65% of potential exposure from reaching the skin. For the authors, the use of gloves during application resulted in 10 times lower median hand exposure with open tractors but 3 times higher median hand exposure in cabin filtered tractors.

programme for 400 grain farmers. The assessment was conducted six months after the training, and showed significant effects on glove use and the reduction of the number of pesticides used, but little impact on wearing all of the recommended PPE.

A correlation between educational level and the wearing of recommended PPE is sometimes put forward by the literature, but the nature of the connection between the two is difficult to interpret. It might be because such studies focus on specific training programmes and do not account for other possible training and the potential benefits of repeated messages throughout user education. Indeed, several authors highlight that there is significant observable non-use of PPE even when the great majority of PPP users are proven to be aware of how important such protection is (Matthews, 2008; Remoundou et al., 2015; Damalas et al., 2016). There is not necessarily a difference in behaviour between people who received special training and those who did not (Reynolds et al., 2008).

In line with this observation, systematic reviews show that training-based intervention seems to have a limited effect. DeRoo and

Rautiainen (2000) also systematically reviewed the literature on evidence of the effectiveness of farm injury prevention, and concluded that 'Methodologic problems made it difficult to assess program efficacy of many of the farm safety interventions reviewed'. They went on to add, 'Although many of the papers on educational safety interventions reported some positive results, they are difficult to interpret' (p.60). Lehtola et al. (2008) conducted a systematic review of interventions for the prevention of injuries in agricultural workers that demonstrated that there is 'no evidence in the meta-analyses to suggest that educational interventions had an injury-reducing effect'.

The reasons for not wearing PPE can be multiple and difficult to untangle. Giannandrea et al. (2008) analysed PPE use among pregnant greenhouse workers in Italy and risk factors related to the non-use of appropriate protective measures. They found the use of protective measures was inadequate among less-educated women. Should we deduce that these women are less attentive to protecting themselves and their future children because they have a low level of education? Or is it only an indicator of poverty, which comes with greater subordination at

work and makes it more difficult to demand that their employer provide them with adequate training and PPE?

Indeed, the role of employers and the nature of working relationships seem important. In Quebec, Samuel et al. (1994) observed that workers for private companies wore their PPE less often than those working with the Ministry of Forests, who were better informed about risks. More recently, Cameron et al. (2006) studied PPE-wearing among 425 migrant farm workers in Florida and Illinois. They found that agricultural firms made very little PPE available, even when workers were found to have PPP exposure-related symptoms (skin irritation and respiratory problems) upon re-entering fields after treatment. In another case, 'the non-provision of PPE [was] the rule for applicators and even more so for employees with indirect exposure' according to a multi-site sociological study in France, Spain, and Morocco between 2004 and 2009, based on archives, participant observation, and 160 semi-structured interviews with migrant farm workers, union members, social workers, doctors, labour inspectors, regional occupational health advisors, and national authorities (Decosse, 2013).

From another perspective, McLaughlin et al. (2014) note that 'employers say they will make PPE available, but workers often do not want to use it, and they generally do not require them to do so'. They found that, 'in general, migrant workers are under-trained and underequipped to deal with the multiple hazards that they encounter in their workplaces, these standards varying significantly across agricultural operations. However, training and PPE alone do not ensure safe worksites, and to be truly effective OHS [occupational health and safety] legislation must ensure that workers are empowered to question, learn about, revise or refuse work tasks when their health or safety is in question' (p. 14). The impacts of social or professional status on various PPE-wearing habits are rarely addressed, however (Stone et al., 1994).

Several of these studies examine the conditions of effectiveness for safety training programmes. Non-use of PPE in agriculture may be interpreted as resulting in part from very different risk aversion profiles (DellaValle et al., 2012), as some people regularly adopt the riskiest behaviours. This line of research is still little explored. Other reasons may also be determinant for explaining PPE non-use related to intrinsic properties of PPE.

3.4.2. Non-use of PPE explained by characteristics of the equipment itself
Potential users complain of several characteristics of PPE (Table 6):
thermal and mechanical discomfort; negative image of PPE among
neighbouring non-farming populations; burden and significant expense
of respecting all instructions for use. Researchers discussing the challenges of testing PPE effectiveness with controlled PPE wearing practices also sometimes mention such limitations. For instance, Nigg et al.
(1986) report that they were unable to conduct a PPE effectiveness test
with controlled wearing practices because workers refused to wear the

proposed gloves, coveralls, or masks when it was too hot.

Although they are few, some studies have objectively examined and confirmed problems connected to heat stress hazard. In agriculture, working in hot environments is an issue in many tropical countries (Park et al., 2009; De Almeida et al., 2012; Garrigou et al., 2012), but it is also relevant elsewhere, including parts of Europe and North America (Nigg et al., 1992; Keifer, 2000; Callejón-Ferre et al., 2001; Spector et al., 2014, 2016; Grimbuhler and Viel, 2018). Ergonomics and the physiology of work have long studied the risks associated with activities conducted in hot environments. Parsons (2000) drew attention to the effects of working in high heat, especially the physiological effort needed to ensure thermoregulation that can come at a significant and dangerous additional cardiac cost to the heart. But wearing PPE (especially a coverall) can disrupt or even stop thermoregulation, resulting in faintness (Kuklane and Holmer, 2000).

The restricted movement engendered by certain kinds of PPE is also commonly cited by users (Snipes et al., 2016; Kearney et al., 2015). It has been studied objectively under a variety of conditions, in real work

conditions (Archibald et al., 1994) as well as the laboratory (Kincl et al., 2002). Using a microprocessor-based force platform system in the laboratory, Kincl et al. (2002) demonstrated that 'there is a difference in postural stability in workers wearing different levels of protective equipment while having fatigued postural muscles. In particular, the sway length response was sensitive enough to detect changes in postural stability due to fatigued postural muscles while wearing PPE'. They go on to explain that 'This test requires the subject to rely on higher centers of the brain, which may be the most altered under heat strain' (p. 265).

Under these conditions, PPE-dependent risk prevention faces a dilemma: the more a piece of PPE protects from pesticides, the more likely it is to be uncomfortable or even impossible to wear. Moreover, the higher its effectiveness, the more likely it is to be costly.

We could identify very few studies on PPE cost, and those we did find mainly address a few developing countries (including Sri Lanka, Nepal, and Niger) (Bourguet and Guillemaud, 2016). We found no studies from developed countries providing data on the full cost of PPE use following all safety recommendations for all products and all persons working on farms. This is despite the fact that users frequently cite the cost of PPE as an on-going challenge. Several studies report that farmers mention the high price of PPE to explain why they do not use it, or do not use it according to instructions (see, for example, DellaValle et al., 2012; Kearney et al., 2015; Damalas et al., 2016).

Overall, studies in which PPE wearing practices are uncontrolled arrive at a rather widespread consensus on PPE non-use. The suggested explanations are of several orders. It is notable, however, that of all the arguments put forth by people not wearing PPE, the suspicion that PPE might only be of limited effectiveness is seldom reported.

# 3.5. Converging evidence for examining the extent of protection provided by PPE

Results show that recommendations for wearing PPE are a key element in granting marketing authorisation for plant protection products in the European Union. For a great many products, the implementation of risk reduction measures (wearing effective PPE) to avoid surpassing the acceptable operator exposure level (AOEL) must be postulated in order to obtain marketing authorisation. Several conditions must be met so that PPE can truly provide the protection attributed to them in these procedures and so that the risk will not be underestimated, notably:

- They are effective;
- They are comfortable enough to be used in practice;
- Their cost is accessible and allows them to be replaced according to recommendations on any and all farms.

And yet the empirical evidence from the academic literature available for one specific scenario – PPE coveralls for protection against PPPs – indicates that these conditions are not verified, regardless of the analytical approach of the study (laboratory testing, studies in which practices are controlled or uncontrolled, observation of the wearing of coveralls).

The effectiveness of protection coveralls is challenged by most field studies. Laboratory tests have provided some plausible explanations of their failings. Indeed, some published studies in which PPE wearing practices are controlled show a satisfactory level of protection from using PPE (over 90 per cent) but they are few and based on procedures of reference that may differ from actual on-farm practices. Most available research in which PPE wearing practices are uncontrolled notes that the coveralls were not as effective as expected. The materials used to make the coveralls can prove less protective than anticipated. Moreover, other elements such as design may have consequences on exposure levels that are not testable in the laboratory. These observations highlight the necessity of making sure that the PPE referenced in

 Table 5

 Proportion of persons wearing PPE when field work conditions are not controlled (data from observations carried out with different goals including measures of exposure and assessment of PPE effectiveness).

Authors - Year -Area -Production	Method -Type of PPE under study	Main conclusion regarding wearing of PPE
Lander et al. (1992), Denmark, greenhouse	Method: A cross-sectional study with random measurements of plasma-ChE.  131 sprayers.  Type of PPE: All types.	68% use face mask. $64%$ were wearing gloves. Only $51%$ were wearing whole body clothes.
Lander and Hinke (1992), Denmark, greenhouses	Method: Cross-sectional study with random measurements of the plasma-ChE activities among healthy greenhouse sprayers. 125 sprayers followed-up (117 men and 14 females).  Type of PPE: All types.	89% used mask, 84% used gloves and 62% used whole body clothes when they sprayed insecticides.
Avory and Coggon (1994), UK, various crops	Method: Interviews. 84 workers. Type of PPE: All types.	61% use gloves and 40% use coverall when manipulating pesticides.
Stone et al. (1994), USA, greenhouses	Method: Mail survey. 185 answers.  Type of PPE: All types.	40% of employees wore disposable coveralls and 10% of the self-employed. 20% of employees wore near always chemical resistant apron and 10% of the self-employed. 50% of the employees wore near always chemical cartridge respirator and 40% of the self-employed.
Keifer (2000), USA, various crops	<b>Method:</b> Cochrane Review. Worker and general population. <b>Type of PPE:</b> All types.	'While it is intuitive that PPE would reduce poisoning by reducing exposure, the use of the PPE by exposed populations is not tested by merely proving the equipment reduces exposure in a controlled setting'. (p. 87)
Carpenter et al. (2002) USA, different agricultural activities	Method: mail survey of 2483 farmers in six Midwestern states with telephone follow- up addressed PPE usage related to sun exposure, noise abatement, chain saw usage, welding and metal work, handling of large animals in and out of confinement facilities, feed handling, manure storage facilities, and mixing and applying chemicals.	In the case of mixing or applying agricultural chemicals, 'Use of chemical resistant gloves was fairly regular. The use of other types of PPE was rare (i.e., nuisance dust masks, dust/mist masks, dust/mist/fume masks, face shields, chemical coveralls or aprons, and chemical protective footwear)". (p. 242)
Perry et al. (2002) USA, various crops	Method: Questionnaires. 220 randomly selected Dairy farmers.  Type of PPE: All types.	57% were using none of the required gear. Less than 50% of the farmers fully complied with PPE requirements. The majority of the applicators of nine pesticides used no PPE during application.
Samuel et al. (2002) Canada, greenhouses	Method: Exposure assessment. 6 workers.  Type of PPE: All types.	Less than 28% of the workers wore gloves when water plants.
Perry and Layde (2003) USA, various crops	Method: Randomized controlled study 540 private applicators.  Type of PPE: All types.	62,5% of the applicators without training intervention and 70% of the applicators with a training interventions, wore gloves. 40% of the applicators without training and 64% of the applicators with training intervention use other gear.
Damalas et al. (2006) Greece, tobacco	Method: 310 survey questionnaires mailed out, response rate of 72%.  Type of PPE:All types.	Despite awareness of potential health risks 46% of the farmers reported not using any special PPE when spraying pesticides. 'Those who reported that they use PPE, most stated that they normally use a hat (47%) and boots (63%). Only few farmers reported using a face mask (3%), gloves (8%), and coveralls (7%) on a regular basis' (p.333).
Hines et al. (2007) USA, orchards	Method: Observational study, exposure assessment. 74 private orchard applicators.  Type of PPE: all types	Rubber gloves were the most frequently worn protective equipment (68% mix; 59% apply), followed by respirators (45% mix; 49% apply), protective outerwear (36% mix; 37% apply), and rubber boots (35% mix; 36% apply).
Cerruto et al. (2008) Italy, greenhouses	Method: 187 farms. Interviews of farmers.  Types of PPE: All types during different phases (mixing, application, cleaning).	Wearing of overalls during: (a) mixture preparation (20,5% waterproof, 21,7% disposable, 22,9% textile, 34,9% none). (b) mixture application (29,6% waterproof, 25,7% disposable, 30,7% textile, 14% none), (c) equipment cleaning (18,1% waterproof, 15,7% disposable, 10,8% textile, 55,4% none).
Giannandrea et al. (2008) Italy, greenhouses	Method: Questionnaire administered by trained interviewers. 232 Pregnant female workers.  Type of PPE: All types.	Less than 50% wore gloves during preparation of pesticides and only 62% wore gloves during application. 21% wore protective uniform during preparation and 17% during application.
	Method: Cross-sectional survey by questionnaire. 1102 farmers.	Non-use of PPE was frequently reported. 10–40% never use

# Table 5 (continued)

Authors - Year -Area -Production	Method -Type of PPE under study	Main conclusion regarding wearing of PPE
	Method: Cross sectional telephone survey 119 applicators. Type of PPE: All types.	63% indicated that they usually wore PPE during application. Gloves were worn in $84%$ of the cases, spray suit in $77%$ and breathing suit $75%$ .
Reynolds et al. (2008) USA, various crops and livestock activities	Method: Self-reported questionnaire with 144 pesticides operators.  Type of PPE: All types.	Pesticide applicators in this study reported little use of PPE during both mixing and application. 59% use always gloves during mixing and 25% during applications. Disposable clothing were not used. 95% never used respirator during mixing and 98% during application.
Strong et al. (2008) USA, various crops	Method: data from a community-community-randomized intervention trial. Interviews. 571 farmers.  Type of PPE: All types.	Less than 50% reported wearing protective clothing.
Coffman et al., 2009, USA, various crops	Method: Questionnaire. 702 certified pesticides applicators. Type of PPE: All types.	80% use chemical gloves. 49% use safety glasses. 47,6% use hat. 63% use regular work clothes. Only 22% use Tyvek coverall. 9% use cotton/polyesters coveralls.
Vitali et al. (2009), Italy, various crops	Method: Exposure assessment. 10 male professional subcontractors.  Type of PPE: All types.	Only 40% wore complete PPE (Full-face mask with type A2P3 filter, Tyvek suit with hood, gloves, and rubber boots).
Damalas and Hashemi (2010), Greece, cotton	<b>Method:</b> survey to study the perception risk to pesticide and the use of personal protective equipment in young (below 35 years old) and old (above 50 years old) cotton growers. Interviews with 76 + 72 growers. Direct observations in the field.	'Young growers revealed higher levels of risk perception due to adverse effects of pesticide on users' health than old growers, who felt that pesticides are safe if used according to the manufacturer's instructions and less hazardous compared with other farming activities'. (p. 363) 'Regarding utilization of protective equipment, hat and boots were the most frequently used items, but most of the growers reported low use of gloves, goggles, face mask, coveralls, and respirator. The use of these items was considerably lower for old growers than for young growers, whereas the respirator was not used at all'. (p. 369)
Garrigou et al. (2011), France, vineyards	Method: Field study. 67 treatments applied.  Type of PPE: All types.	50% of the wine-growers did not wear gloves, 40% wore gloves during either the preparation stage or spraying stage (2%), and only 10% wore the gloves for both of these stages; 58% never wore coveralls, 24% wore them for one of the two stages (of which only 4% wore them for treatment spraying) and 18% for both; 61% never wore a mask, 36% wore a mask for one of the two stages (of which only 4% wore one for spraying) and 3% for both stages.
Baldi et al. (2012), France, vineyards	Method: Field study and exposure assessment. 37 treatments observations with dithiocarbamates, 30, treatments observations with folpet. 45 workers.  Type of PPE: All types.	In 54% of observations workers wore coverall, 48% wore gloves and 38% wore mask during mixing. In 35% of the observations workers wore coverall, 15% wore gloves, 11% wore mask during spraying.
Dellavalle et al. (2012), USA, various crops	Method: Questionnaire, Cohortes of 25,166 participants.  Type of PPE: All types.	For Private applicators: 46% use PPE when applying. Between 76 and 82% use PPE when mixing. For applicator type commercial: 54–61% use PPE when applying. 93% use PPE when mixing.
Rubino et al. (2012), Italy, rice and maize	Method: Exposure assessment. 28 rice and maize herbicide applicators. Type of PPE: All types.	Mixing and loading. Only 3 workers used standard PPE during this phase (coverall, mask, gloves and boots). 16/28 did not wear boots, 7/28 wore just gloves, one worker wore just the coverall without any other PPE, and one worker wore everything except the coverall.  Application (from tractor from a tractor equipped with a boom fitted with spraying nozzles) 27/28 of the workers wore gloves during the treatment, 22/28 wore a mask, 18/28 wore a coverall, and only 4/28 wore boots.
Mcfarlane et al. (2013), Australia, various crops	Method: Review.  Type of PPE: All types.	PPE reduces dermal pesticide exposure but compliance among the majority of occupationally exposed pesticide end users is poor. PPE use may be poor among pesticide end users.
Baldi et al. (2014), France, vineyards	Method: Field study and exposure assessment. 36 workers and one farm owner.  Type of PPE: Gloves, cotton sleeves and trousers.	56% wore T-shirts, 43% wore shorts and only 27% wore gloves.
McLaughlin, et al. (2014), Canada,	Method: Interviews survey. 100 migrant workers.	75% wore gloves, less than 5% wore mask or other PPE.

Table 5 (continued)

Authors - Year -Area -Production	Method -Type of PPE under study	Main conclusion regarding wearing of PPE
Remoundou et al. (2015), Greece, Italy, UK, orchards, greenhouse, arable crops	Method: Survey on perceptions of the risks and regression analysis in Greece, Italy and UK 158 residents, 173 bystanders, 144 operators, 141 workers, all pesticides. Type of PPE: All types.	In UK 68–70% of the operators used PPE during mixing, application and cleaning. In Greece 98% used PPE during mixing, application and cleaning. In Italy 95% of the workers used PPE during mixing, application and cleaning.
Damalas and Abdollahzadeh (2016), Greece, cotton	Method: 148 Randomly selected farmers face to face interviews.  Type of PPE: All types.	49,3% of farmers showed potentially unsafe behaviour with respect of PPE. 75,5% did to received training on PPE use. Only 23,6% systematic use of PPE. About 30% never use coverall.
Mandic-Rajcevic et al. (2018), Italy, vineyards	Method: Exposure assessment. 29 workers followed-up during 38 working days Type of PPE: All types.	97% wore gloves during mixing and 34% during application. 84% used respiratory protection during mixing and 38% during application. 74% of the workers wore mono-use coverall, 16% multi-use coverall and 10% none.

marketing authorisation procedures is actually available and that its effectiveness is ensured for each product category and commercial formulation, and this by independent studies under real working conditions in addition to laboratory conditions.

The available literature shows that the very principle of a sustained activity while wearing PPE raises many problems:

- PPE themselves may be a source of constraint. The stipulated wearing of PPE specific to a product may be difficult or impossible to implement under practical conditions: the restriction of movement may be a source of fatigue, can upset thermoregulation while working in hot conditions, or, in conjunction with heavy effort, may engender other problems including exhaustion, heat stroke, and fainting.
- The variety of products handled, different phases of treatment activities (such as application, cleaning, re-entry), conditions of exposure, and the one-time use recommended for certain specific PPE should logically lead to several changes of equipment per day in farms with mixed production. These instructions can prove difficult to follow in practice given their cost (cost of PPE and cost of time needed to manage using it) and impact on how work is organised. These elements are reported as factors behind the failure to make PPE available to employees and even family workers. The reality of these economic and organisational constraints can lead to significantly reduced protection in actual working conditions when, for example, a disposable protection coverall is used the entire season instead of being discarded after one-time use, as its instructions would have it
- Poorly used, PPE can be a source of additional contamination. A certain degree of technical mastery is required to prevent this from happening, along with adequate information, recurring training, and the possibility of being able to implement health and safety rules that can be difficult to respect in practical conditions (concerning, for example, available water sources, suitable storage areas, and specific places set up for washing and changing without contaminating oneself or one's clothing). And yet, it should be stressed that in the marketing authorisation process, user safety is primarily approached through the wearing of personal protective equipment. The safety data sheets provide very general instructions on handling and storing products. Usually PPE are the only prevention means mentioned, without any specific instructions as to how work should be organised or designating appropriate technical means, or collective protection measures.

In sum, it seems that people working in agriculture may be exposed to more danger from chemicals than previously thought. Analysis of the literature shows that these dangers cannot be attributed solely to worker negligence. These hazards may furthermore have consequences of greater or lesser gravity, depending on the toxicity of the active substances and additives in commercially available pesticide formulations and their conditions of use.

Consequently, it seems that exposure scenarios should take full

account of the difficulties that could potentially be encountered in actual use so that the PPE's protective abilities are not overestimated in the marketing authorisation process or during interventions aiming at reducing pesticide occupational exposures.

# 4. Discussion: Some possible paths to improvement?

In this context, other than the need highlighted by many authors for more empirical studies on the actual effectiveness of PPE, three main courses of supplementary research are discussed. They concern risk reduction and developing PPE better adapted to practical working conditions, how to approach the issue and make necessary improvements in connecting knowledge scattered across many disciplines, and the emergence of new concerns arising from advances in knowledge about the effects of low-dose exposure and presence of nano particles in pesticides.

### 4.1. Risk reduction

The literature discusses two main approaches for reducing risk.

- The first is reducing hazards at the source and encouraging the development of farming systems using fewer or even no pesticides.
   It also advises reducing use of the most dangerous products, especially those classified as carcinogenic, mutagenic, or reprotoxic.
   Public health agencies play an essential role in the withdrawal of substances identified as dangerous.
- The second approach advocates for the development of coveralls designed to be more specifically adapted to agriculture than the clothing used today. This is the approach taken by an international consortium of pesticide manufacturers, researchers, and representatives of state services and agencies from a handful of countries (mainly France, the United States, and Brazil) (Shaw, 2016). This consortium developed a new ISO norm (ISO 27065) for manufacturers of protective clothing. This norm details the 'performance requirements for protective clothing worn by operators applying pesticides and for re-entry workers'. It is intended to meet the challenge of designing PPE that specifically protects from agricultural PPPs and is comfortable, reusable, washable, and inexpensive.

As a result, advice regarding PPE might change. For instance, one current trend in France is to recommend protective coveralls made in a polyester/cotton blend and treated with a water-repellent, that resemble ordinary work clothing. These garments are sometimes presented as alternatives to classic PPE because they are more comfortable, an improvement that helps to reduce the number of persons refusing to wear PPE. The effectiveness of this approach remains to be demonstrated, however, and should be examined by independent studies as well.

 Table 6

 Difficulties to use PPE in working condition (discomfort, heat stress, cost, appearance).

Authors - year - area	Goal of the study	Method	Main results
Nigg et al. (1992) USA	Field Evaluation of Coverall Fabrics: Heat Stress and Pesticide Penetration.	Method: Field study.  Type of PPE: 'Polypropylene coverall, polyester/ woodpulp coverall, Cotton/polyester coverall'".  n = 10 males subjects.  Heat stress was evaluated by measuring the mean skin temperature, oral temperature, and heart rate of pesticide applicators. Subjects also provided subjective evaluations.	Heat stress: 'While the air temperature and solar intensity rose, the falling relative humidity could not compensate, so that the physiologically important WBGT and Botsball temperatures also rose, albeit less rapidly". ()  Near or at the end of the sampling period, physiological variables peaked. The overall mean daily maximum skin temperature was 35.64 °C (96.15 F); the thermal comfort consultants had advised us to remove the suit immediately from any worker whose skin temperature rose to 36.00 °C (96.80 F). Mean skin temperature had clearly risen to near critical levels; and, since these are mean values, critical levels were occasionally exceeded and suits were removed. () Differences among fabrics in these mean values of the daily maximum physiological responses were slight'.(p. 284–285)
Damalas et al. (2006) Greece	Exploration of knowledge, attitudes, and practices towards safety issues of pesticide handling among tobacco farmers.	Method: 310 survey questionnaires mailed out, response rate of 72%.  Type of PPE: All types. 96% of the farmers viewed pesticides as a guarantee for high tobacco yields and high product quality. Almost all (99%) thought that pesticides can have serious adverse effects on users' health.	Discomfort, Price Despite awareness of potential health risks 46% of the farmers reported not using any special PPE when spraying pesticides. The authors summarise their observations as follow: 'Those who reported that they use PPE, most stated that they normally use a hat (47%) and boots (63%). Only few farmers reported using a face mask (3%), gloves (8%), and coveralls (7%) on a regular basis. The reasons for not using protective equipment during pesticide handling were that protective equipment is uncomfortable (68%), too expensive to buy (17%), time-consuming to use (8%), not available when needed (6%), and not necessary for each case (2%)'. (p. 339)
Nicourt and Girault (2009) France	Sociological study aiming at understanding why winegrowers and technicians do not seek to resolve the uncertainties on health effects resulting from occupational pesticide exposure.	Method: Semi-structured interviews. Qualitative analysis.  Type of PPE: All type considered. n = 51 wine growers and 19 wine growing extensionists of the Languedoc-Roussillon area in France.  Interviews carried out between 2005 and 2007.	Personal appearance: 2/3 of the respondents avoided questions about the links between health and pesticide exposure. Reasons evoked for not using PPE: cost, discomfort in wearing (including heat stress), poor adaptation to working conditions, doubts about their effectiveness.  The inappropriateness of the protections prescribed for work situations requires winegrowers to suffer them by denying the problems, or to seek to become actors in exposure situations again. Respondents were aware of the risks and the limits of official prevention prescriptions. Winegrowers avoided wearing personal protective equipment during sprayingin order not to disturb neighbours, limit sources of conflict and manage conflicting relationships with neighbours on pesticide spraying.
DellaValle et al. (2012) USA	Study about the use of PPE in various culture.	Method: Questionnaire Cohorts of 25,166 participants. Type of PPE: all types.	Heat stress: 'Decisions to use PPE may be based a variety of factors including; social norms, perceived effectiveness, experiencing of pesticide related health problems, safety training, cost and perception of risk as well as PPE requirements of specific chemicals and comfort (e.g. heat stress)'. (p. 5)
Garrigou et al. (2012) France	Field study in bananas culture during herbicide spraying.	Method: Effort and heat stress was evaluated by measuring heart rate. Type of PPE: Tyvek Coverall. $\mathbf{n}=1$	Heat stress: In a banana plantation, the worker was wearing a type 4 suit with hood and mask with a 35 °C temperature and an 80% relative humidity. The pesticide treatment phase lasted 3h07. The heartbeat corresponded to that of a strenuous effort for 2h20.

# Table 6 (continued)

Authors - year - area	Goal of the study	Method	Main results
Levesque et al. (2012) USA	Association between workplace, housing conditions and use of pesticide safety practices and PPE among North Carolina farmworkers.	Method: Administration of a structured questionnaire to collect self-reported measures on housing and workplace conditions.  Type of PPE: All types.  n = 187, aged 18 to 62.	Housing conditions: Use of pesticide safety practices and PPE was greater when farmers provide decontamination supplies. Improvement of housing and workplace conditions are crucial to increase use of pesticide safety practices and PPE.
Arcury et al. (2015) USA	Heat exposure, heat symptoms and heat illness among farmworkers (tobacco, vegetables, and berries).	Method: Heat exposure and symptoms characterization based on a baseline interview and follow-up contacts in a community-based participatory research project.  Type of PPE: gloves (80,2% participants) and rain suits (65,4%) (rain suits used to to reduce exposure to nicotine). n = 101 farmworkers.	Heat exposure: *Heat symptoms, heat illness and behaviours to reduce the effect of heat are reported for those working outdoor in extremely hot weather conditions (n = 68) and those working indoor in extremely hot weather conditions (n = 18).  Use of personal protective equipment (gloves, rain suits) was not associated with experiencing heat illness while working outdoors.
Kearney et al. (2015) USA	Assessment of PPE use among farmers.	Method: Cross-sectional study, using telephone interviews.  Type of PPE: All types.  n = 129 farmers.  Several questions regarding the factors that influenced farmers' personal decision on whether to use PPE.	Comfort, cost, time involved, personal appearance:  31% wore coverall/apron suit, when applying, mixing or loading PPE.  'The decision to wear PPE was most strongly influenced by the following factors: desire to avoid injury (70%), followed by government warning stickers or labels (54%), family members telling them to wear PPE (38%), ease of using PPE (36%), and cost of equipment (22%). Time involved to put on PPE (20%) and personal appearance (15%) were reported as factors least likely to influence a farmer's decision to wear PPE' . (p. 48)
Snipes et al. (2016) USA	Intervention in order to increase PPE use in Mexican migrant farmworkers through tailored prevention messages.	Method: Ethnographic observations to understand what prevents PPE use .  Type of PPE: All types.	Comfort:  Their evaluation showed that 'the program was viewed by workers as acceptable and appropriate to their cultural attitudes, and demonstrated very strong feasibility as an integrated intervention platform (PPE provision coupled with an individually and dynamically tailored Health motivational app). Satisfaction with the PPE component of the intervention was primarily linked to farmworkers' consideration that the PPE was comfortable and would not (or minimally) negatively impact work productivity'. (p. 8) In this case training programs elaborated with the workers could enhance the use of PPE.
Van Wely (2017)	Regulation analysis of current global standards for chemical protective clothing.	Method: Regulation analysis. Current global standards. PPE: All types.	Discomfort:  'Appropriate protection is critical, and so is comfort as it contributes to protective clothing use compliance by wearers. Reduced comfort will reduce a person's efficiency and with heat stress can induce physiological harm to the wearer. There are many comfort factors, most frequently cited in wearer trials include ease of movement when bending/stretching, weight of the garment, feel on the skin, and breathability of the garment'. (p. 496)
Grimbuhler and Viel (2018) France	Field study in vineyards.	Method: Field observations.  PPE garments were randomly allocated: HF Estufa polyamide (Brisa*),Tyvek* Classic Plus, andTychem* C Standard.  n = 42 workers from seven vineyards consented to field observations.	Heat stress:  'PPE assessment indicated that the properties of the coverall fabric influence the cardiac strain in vineworkers under a specific work scenario (vine-lifting in very humid conditions). These results confirm that the idea of using generic coveralls in any farming activity is unsuitable. Compromises are necessary to balance physiological costs and protection, depending on the agricultural task performed, the crop grown, and the environmental conditions encountered. The public health objective of vineyard worker safety compliance requires additional field investigations and technical innovations among manufacturers, health and safety specialists, and ergonomists'. (p. 7)

#### Table 6 (continued)

Authors - year - area	Goal of the study	Method	Main results
Varghese et al. (2018)	The study concern occupational illness, injury and productivity losses due to hot weather in a changing climate.	Method: Literature review based on systematic search in Embase, PubMed, Scopus, CINAHL, Sciences Direct and Web of science.	Heat exposure: Occupational injury due to hot temperature. Increased risk of occupational injuries was found among the 'electricity', 'manufacturing', 'utilities', 'transport', 'agriculture', 'fishing' and 'construction' industries. The study has pointed out that behavioural factors, clothing and personal protective equipment, levels of physical exertion and personal factors (age, health, medications, etc.) influence how our bodies react to heat.

# Several points should be noted:

- The norm ISO 27065 (ISO, 2017) defines three levels of protection: C1, C2 and C3. Clothing classified in levels C1 and C2 must undergo laboratory penetration tests, but only those of level C3 are subjected to permeation tests. Level C1 protective clothing is considered 'suitable when potential risk is relatively low' (page v), setting the maximal permissible penetration of PPPs at 40 per cent (p. 6), which amounts to an acceptable protective performance of 60 per cent. Level C2 is recommended 'when it has been determined that the protection required is higher than that provided by Level C1 protective clothing.' (page v); it allows for maximum penetration of 5 per cent, and thus has a performance level of 95 per cent (p. 6). But as Van Wely (2017) has remarked, the performance of level C2 is 'between C1 and C3 but not so high as to require the use of liquidtight materials' (p. 487). It is moreover indicated in the norm that levels C1 and C2 are not suited to the use of concentrated PPP formulations. Only level C3 corresponds to a high potential risk level. But instructions for C3 coveralls state that they should only be used for short periods because they can produce excessive heat leading to exhaustion and heat stress. Here we encounter a wellknown difficulty: how to reconcile high protection and comfort.
- The protective equipment associated with these three levels corresponds to category III in EU regulation 2016/425/CEE, providing protection from 'risks that may cause very serious consequences such as death or irreversible damage to health'3. The little available empirical data on the effectiveness of protective coveralls developed to meet the demands of ISO 27065 justifies certain questions: How is the 40 per cent tolerance to penetration of C1 compatible with risk category III PPE in EU regulation 2016/425/CEE, which must protect against dangerous or deadly substances such as PPPs? How is the absence of permeation testing for levels C1 and C2 compatible with the idea that level C2 coveralls may be used for PPP handling, even in dilution? We ask these questions not as a way of suggesting that permeation tests be conducted on woven cotton coveralls, which would make no sense, but to challenge the idea that such coveralls could be considered adequately protective of persons handling liquid PPP in real use conditions.
- One response stipulated by the ISO 27065 norm for level C2 is advising the wearing of additional PPE such as aprons, especially for mixing. This presents two problems. One is that the effectiveness of these aprons has yet to be proven. The other is that the text passes responsibility for risk assessment along to other actors.

Indeed, it is stipulated that '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 (page v).

These recommendations remain vague, but as the text of the ISO 27065 norm makes clear, 'It is the responsibility of the risk assessors to determine the PPE required for risk mitigation.'; 'risk assessment is beyond the scope of this document' (p. 17). And yet, users and their advisors have even fewer options for evaluating the risks since they have only limited information. The recommended PPE that respond to the ISO 27065 norm have only been tested for very few substances. There is no systematic procedure for field studies by independent organisations making it possible to verify effectiveness and confirm that layering multiple types of partial PPE indeed provides protection under practical conditions. The literature available on the subject is also rare.

In the short term, though, the marketing of such PPE seems to be increasingly widespread. It is thus necessary to discuss its establishment in agriculture, especially since it is presented by many actors (from industry, extension services, regulatory agencies, etc.) as a novel solution to combining a high level of protection and of comfort. Several concerns can be formulated even now. This kind of PPE looks like ordinary cotton work clothing. This might facilitate PPE wearing, by reducing neighbours' concerns based on how applicators look, for example (Kearmey et al., 2015). But the risk is that farmers and farm workers confuse the categories, which could be to their detriment. If these garments are used both to handle pesticides and as ordinary clothing, they could be used as such for farm tasks other than pesticide handling, all day long. This could increase the risk of pesticide transfer to users' skin, and also engender new contamination in the work area, vehicles, the domestic sphere, and beyond. In addition, care of such clothing, from washing conditions (technical sheets say they can be washed up to 30 times) to ironing, may also impact their performance. This is precisely the point that led French public authorities to issue a recommendation in 2019 requesting that some of these coveralls (C2) be withdrawn from the market because they lost their protective properties after only five washings (JORF 2019).

# 4.2. Addressing crucial open questions

It is even more important to improve analysis of the protecting role of PPE given growing concerns over certain issues.

 Repeated exposure to one dangerous product over time and combined exposure to multiple dangerous products, give rise to increasing apprehension. The complexity of agricultural work is

 $<sup>^3</sup>$  As such, manufacturers must subjected them to a conformity evaluation procedure requiring testing by a 'notified body', meaning a third party designated for this purpose by one or more states to ensure compliance with the technical documentation provided during certification.

particularly favourable to exposure of this sort. People working in agriculture are not simply exposed to one crop protection product. They are also exposed to a variety of other agrochemical, biocidal, and/or veterinary products used on farms (Canning, 1995, 1997; Watterson, 1999; Reynolds et al., 2008; Laurent et al., 2016). Risk assessments have not anticipated cumulative exposure to a product or exposure to multiple products. This concerns direct as well as indirect exposure. Strong evidence in the literature has shown the extent of indirect exposure during the performance of a variety of tasks, through residues of various products that may accumulate in varying doses on plants, soil, animals, walls, and farm equipment (Ramwell et al., 2007). In addition to accumulation, product persistence must be taken into account when addressing PPE protecting role. Indeed, these characteristics raise two major issues: (i) the conduction of risk assessments on a product-by-product basis, for one day of treatment or one day of re-entry, (ii) the non-inclusion in risk assessments of the workdays not dedicated to pesticide use. This gap between exposure situations as they are envisaged in evaluation and the possibilities of exposure in real working conditions raises new questions about the protective role attributed to PPE as it is considered in risk assessment.

- The appearance on the market of pesticides containing nano particles also raises questions about the relevance of classic tests used to assess PPE effectiveness, tests whose performance can already be problematic with chemical products composed of larger particles. This issue is a complete unknown. Relevant risk assessment methods have yet to be developed. The issue is all the more important because of the widespread use of nanomaterials in PPP as revealed by the French 'R-Nano' inventory (Ministère de la transition écologique et solidaire, 2017).
- Recent advances in knowledge have also shown some active substances may have significant effects on health in low doses. This is potentially the case for endocrine disrupters and neurotoxic agents. This should henceforth call into question the very principle of marketing authorisation procedures and chemical risk prevention initiatives relying on PPE that allow a percentage of the product through.

# 4.3. Connecting scattered knowledge by developing interdisciplinarity

Lastly, several authors have stressed the need to develop multidisciplinary approaches to better connect knowledge related to hazards, techniques, human beings, and human activities (Guldenmund, 2000; Sari-Minodier et al., 2008; Garrigou et al., 2011; Laurent et al., 2016) and overcome the current situation wherein the PPE literature is highly scattered and produced in isolated communities.

This would make it possible to connect a range of approaches that ought to be taken into account to allow full comprehension of the role of PPE in occupational safety procedures:

- Technological approaches seeking to develop materials (particularly coveralls) that protect from pesticides.
- PPE effectiveness evaluations conducted according to different methodological perspectives and consideration of the methodological approaches and protocols to be implemented (especially for sampling procedures) so as to produce reliable data and make the most of existing unpublished data (e.g. Driver et al., 2007).
- Ergonomic and exposure assessment approaches that seek to evaluate physiological constraints, particularly additional strain on the heart from PPE-induced restriction of movement and thermoregulation processes, and identify the situations of greatest exposure and their determinants. These determinants may be technical, organisational, or related to personal characteristics (particularly educational level, perceptions and images of hazards).
- Sociological and anthropological approaches that make it possible to situate PPE use among collective and cultural practices and belief

systems, which determine what uses are considered acceptable or inacceptable (to all people working on, living in and visiting the farm who could be exposed).

- Economic approaches that analyse the benefits of different models of agriculture and different ways of mobilising human labour. These models constrain (sometimes heavily) work and its organisation, and thus possibilities for designing and implementing occupational safety advices.
- Legal and regulatory approaches that study how the legal and regulatory measures in force (marketing authorisation in particular) do or do not contribute to risk prevention, and how they may or may not favour recognition of the existence of damage and harm allowing reparations to be obtained (Jouzel and Prete, 2017; Boudia and Jas, 2014).
- Biotechnical approaches (agronomy, animal science) to practices that could be a bridge between agricultural production and exposure prevention.

The disciplinary fragmentation of analyses obscures whole swathes of this field of knowledge for most parties concerned, including those in academia. It especially reduces the contribution that available knowledge could make to improving understanding of PPE's role in safety procedures.

#### 5. Conclusions

The analysis ultimately leads to five main conclusions:

- The possibility of having PPE that is comfortable, suitable to practical conditions, affordable, and protects from contamination by any and all handled products has yet to be demonstrated. Numerous studies have found significant gaps between this ideal theoretical model and reality.
- There is no mechanism allowing systematic monitoring of the feasibility and actual effectiveness (in post-marketing conditions) of the protection provided by PPE as they are postulated in marketing authorisation procedures. Data is still incomplete, fragmentary, and scattered.
- We were able to identify only a handful of published studies dealing with the effectiveness of PPE, despite the fact that we chose a focus for analysis (coveralls, PPPs, OCDE countries) likely to provide us with the greatest chances of finding publications. For this reason, it is difficult to confirm the relevance of models and hypotheses used to predict exposure levels in marketing authorisation applications.
- 3. There is, however, evidence confirming that in studies in which PPE wearing practices are uncontrolled, PPE does not always fulfil the protective role attributed to it in marketing authorisation procedures. Analysis of the available literature shows that many gaps exist between work safety in theory and the complexities of real practical conditions. These gaps are all sources of risk for people. It is important to take them into account and include them in regulations concerned with preserving the health of people working in agriculture.
- 4. There are many determinants that could influence the efficiency of recommendations based on PPE use. It is thus essential that evaluation of this efficiency include the full range of use situations, people concerned, and actual practices. A realistic approach to PPE's role in occupational safety strategies demands a deep revision of evaluation protocols. In particular, it requires the production of new data on the permeation of materials and implementation of new principles of observation and sampling for gathering field data following the granting of marketing authorisation. Data could also be mobilised for other fields of improvement: methodical treatment and inclusion of new information on PPE under real conditions by organisations responsible for granting marketing authorisations,

integration of contributions from separate disciplines to develop integrated forms of prevention of chemical risk, and the provision of information for potential PPE users and advisors.

5. Advances in toxicology (on the effects of low doses) and developments in chemical technologies (with the emergence of nanomaterials) call for a radical re-examination of the role that PPE can play in preventing chemical risk.

In Europe as elsewhere, the hierarchy of the means of prevention (European Directive 89/391) (EC, 1989) states that PPE should be considered, after others steps have been taken; avoiding risk and combating the risks at source (reduction of pesticide use in this case). replacing the dangerous by the non-dangerous or the less dangerous (substitutes for dangerous pesticides), recourse to collective forms of protection (organising work in a way that respects health and safety rules and regulations), giving collective protective measures priority over individual protective measures (PPE). At the end of this analysis, there is nothing allowing us to say that recent knowledge on PPE calls for a reconsideration of their place in this hierarchy. To the contrary, the review calls attention to the fact that some dangerous products have received marketing authorisation only because it is assumed that wearing PPE considerably limits exposure. Without this assumed protection, they would be banned. Deeper examination of PPE coveralls reveals that PPE has many limitations. Its effectiveness is not always confirmed under working conditions. They may be a source of dangerous discomfort, and are not always available. Recommending the wearing of PPE does not always mean effective protection.

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