TNO Quality of Life

Utrechtseweg 48
P.O. Box 360
3700 AJ Zeist
The Netherlands

www.tno.nl

T +31 30 694 41 44
F +31 30 695 72 24
info-voeding@tno.nl

TNO report

V7333

Effective Personal Protective Equipment (PPE)

Default setting of PPE for registration purposes of agrochemical and biocidal pesticides

Date	January 8, 2007
Author(s)	Rianda (M.G.) Gerritsen-Ebben Derk H. Brouwer Joop J. van Hemmen
Copy no.	-
No. of copies	100
Number of pages	33 + 62
Number of appendices	1
Customer	Ministerie van SZW
Projectname	-
Projectnumber	010.31954/01.10

Executive summary

On request of the Dutch Ministry of Social Affairs and Employment, TNO has investigated current views and facts on the use of default values or approaches for the estimation of exposure reduction effectiveness of personal protective equipment (PPE) in registration processes of pesticides[1].
On the basis of this it is hoped that an internationally harmonized set of PPE protection factors for regulatory use, can be devised.

In order to reach this goal, it was concluded that recent literature on the issues involved should be evaluated, and that regulatory authorities in North America, Europe and Australia should be asked to indicate their regulatory approaches with respect to PPE effectiveness and the basis of these approaches. In addition to this, several industry organizations and academic groups working in the area were asked to provide their views and underlying evidence.

This approach has led to the development of a *consultation document* as a first step in the process of preparing guidance on the development of an appropriate regulatory approach, which of course has a very high policy-determined aspect. In the consultation document the available evidence and approaches were presented and no choices for approaches were made.

The consultation document was sent to all organizations and persons that had been so kind to provide the requested information for checking the accuracy of the data/information included and provide comments on the text. On the basis of the results of that exercise, the document was improved. Of course not all comments were in line with each other and some even conflicting. Nevertheless the authors have adapted the document with care and the final result is presented as ANNEX A to the present report.

On the basis of the available evidence and current status of the regulatory approaches a set of default protection factors for human exposure was proposed, which takes account of differences between agricultural pesticides and biocides (antimicrobials), operators (mixer/loaders and applicators) and workers (re-entering treated crops and enclosed spaces). For dermal exposure loading, clothing and gloves are considered separately.

Harmonized default protection factors were proposed for regulatory purposes. This so-called *vision document* was sent again to various parties as mentioned above and detailed in the present document. The comments showed some variance in approaches for North-American authorities and European authorities. This has to do with differences in legislation and experiences. On the basis of the comments, the authors have adapted the text again leading to the present report.

It is stressed, however, that the values presented in the present report should only be used after careful consideration of the exposure scenario and pesticide formulation

---

[1] Pesticides are meant to include agrochemicals(, microbiological agents) and biocidal products (antimicrobials), for the present purpose.

involved. These values are listed below, but they are only fit for the purpose after consideration of several boundary conditions which are given in the text and are difficult to summarize.
The present report needs to be discussed amongst experts of regulatory authorities and industry before it may lead to consensus in view of the current state-of-the-art, both in Europe and North-America.

Starting points for the setting of protection factors
In view of all these elements as described above, it is essential to choose the starting points for the present document aiming at harmonization.

The authors suggest taking the following starting points.
The predictive exposure assessment relates to potential exposure loading (combined outer and inner dosimeters). It is hoped that the authorities throughout the world will accept the approach that will be provided by the Agricultural Handlers Exposure Database (AHED) database after a solid evaluation of the exposure algorithm based on statistical evaluation of all underlying data. This may also be essential for using probabilistic assessments accounting for variability and uncertainty in the exposure (and risk) assessment. For the time being this is still something to happen, since the evaluation has not yet been made and is therefore not considered by regulatory authorities on both sides of the Atlantic or even wider.

For the present purpose (the above point not yet effected), the potential exposure loading prediction (outer plus inner dosimeter) will be considered as being a true and valid value, despite the variation in prediction by various models.

The general approach for re-entry exposure modeling (Van Hemmen *et al*., 1995; Whitmyre *et al*., 2005; Hoernicke *et al*., 1998) is similar in Europe and North America, although the transfer coefficient (TC) values and dislodgeable foliar residue levels used for regulatory settings may vary. It is hoped that the current work of the Agricultural Reentry Task Force (ARTF) (although leading to proprietary data) will help in harmonizing approaches on both sides of the Atlantic with respect to the relation between scenario and transfer coefficient choice.

For the use of single measurement series in the exposure assessment, a general approach needs to be developed that takes account of inner dosimeter use, biological monitoring data, and prescribed PPE. It is outside the scope of the present document to develop this further. In the case of measurements for which adequately (representative and robust) show inner dosimeter loading data are available, these data are to be preferred above the use of protection factors with outer dosimeter loading data.

Protection by multiple layers of (protective) clothing is executed by multiplication of the protection (e.g., two layers of 50% reduction each, will lead to 75% reduction.

Skin penetration will not be considered for the present purpose of PPE protection factors.
Agricultural pesticides and biocides must be treated separately. The same holds for operators and workers.

Since the label prescription is developed by industry for its active substance and formulation properties, the assessment of risk in regulatory practice should strictly follow that description. It is up to stewardship of industry and formal inspections by the authorities to make sure that compliance with the label is the rule to which there are hardly any exceptions[2]. This does mean that the prescribed PPE should fit the purpose. This also means that for assessing PPE, only the protection afforded in the field is of relevance. Ergonomics and thermo physiological issues should haven been dealt with before the label is developed.

The safety performance of certified PPE in actual/normal conditions of use, including rapid aging and user-device interactions will in general differ from performance criteria adopted in standards and tests.

One would like to use a tiered approach, which covers all these issues, where the most conservative approach is taken when no data are available on label compliance. The degree of conservatism may be lessened when it becomes clear that the workforce is fully acting according to labels and has got an effective training programme. For the time being it is considered that this is not practical for many European agricultural settings (see Safe Use Initiative in the Annex), possibly also not for some biocidal uses, whereas in industrial settings safety issues are usually covered by educated employees. The tiered approach is thought to be of less importance when the above starting points are kept.

Some essential remarks have to be made before the proposed (default) data can be listed:

- **Engineering controls have a higher (legal) priority than personal protective equipment (PPE).**
- **Any protective equipment must be properly designed, fitted, worn and maintained to be effective.**
- **Gloves must provide protection against hands and lower forearms.**
- **It should be stressed that default protection values should only be used after careful consideration of the exposure scenario and pesticide formulation involved.**

Inhalation exposure loading

It is proposed to use the ‘assigned protection factors’ (APF) as deduced by BSI (British Standards Institution) and ANSI (American National Standards Institute). Since these values are somewhat at variance and since in agricultural settings efficient control and proper training and education with respect to inhalation protection devices, is generally absent, it is good to err on the safe side and to use the lowest of both values, if available. The proposed data are given in Table A on page 20. It is further proposed to use these data for agricultural pesticides and biocides similarly when appropriate. Unfortunately, not all categories correspond between North-America and Europe.

---

[2] The North-American approach is to incorporate PPE requirements **only** in situations where it is known that compliance is feasible and then defer to compliance programs for enforcement of label-specified PPE.

Dermal exposure loading

Differentiations are made for agricultural pesticides and biocides, as well as operators (mixer/loaders and applicators) and (re-entry) workers. A major differentiation in the approach is further for hand and body protection.

Oral exposure loading

Oral exposure loading is only considered in special cases where dermal exposure may be relatively high and the hand-mouth shunt may lead to appreciable oral exposure loading.

PPE for dermal exposure reduction may also lead to a decrease of oral loading, since the hand-mouth shunt is less likely for gloved hands, although it cannot fully be excluded.

The following default values are proposed.

Clothing

Body protection may include shirts, pants, (c)overalls, aprons, hats/caps and the like. These may be fabricated from different materials. The most frequently used are:

- woven cotton and cotton-polyester fabrics
- non-woven fabrics
- woven or non-woven fabrics to which a film of plastic or rubber has been laminated or coated.

It is concluded on the basis of current information and data analysis that it is yet premature to adopt loading-dependent protection factors for clothing of operators, despite the fact that indeed the degree of protection provided does depend on the loading.

Operators

Overall the default protection proposal for single layers of uncoated clothing or coveralls is 90%. For coated coveralls (CEN Type 3 or 4) this is for the time being also 90%. This refers to the whole body (hand, head and neck excluded).

When for exposure to biocides engineering control mechanisms are either fully used or not possible, one might use the same default values as for agricultural pesticides.

Workers

Overall the proposal for single layers of uncoated clothing or coveralls is 80%. This refers to the whole body (hand, head and neck excluded).

Gloves

- Gloves are to be considered as barriers of hands and wrists against liquids (and solids).
- Gloves may behave very differently towards chemicals. No one glove material is a barrier to all chemicals.
- Solvents in pesticide formulations present the greatest challenges to barrier effectiveness of gloves.
- Gloves should be checked for holes/cracks before putting on.
- Gloves should be washed before taking off.

- Taking on and off should be done as little as possible. Gloves should, however, always be removed when entering tractor cabins.

Operators
Overall the default protection proposal for gloves is 90% when liquids are handled and 95% when solids are handled.

When for exposure to biocides engineering control mechanisms are either fully used or not possible, one might use the same default values as for agricultural pesticides.

Workers
Crop workers cannot and should not use protective chemically-resistant gloves for periods longer than hours. The best they might do is wear gloves that protect them against scratches by thorns, irritating/sensitizing plant saps, and the like, or at the most cotton gloves against exposure to pesticides. However, even these gloves should not be used, since they wear out rather quickly and hardly protect since they get wet quickly by contact with several types of foliage.
This indicates that glove protection should only be considered in very specific circumstances and on a case-by-case analysis. This corresponds with the view of the North-American authorities.

Engineering controls
This section is not within the scope of the current project on PPE, but it is added for completeness and covers only the mixing/loading of agricultural pesticides, and the use of enclosed cabs.

Mixing/loading of agricultural pesticides
The proposal is to fit with the Cal-DPR definition of closed systems: closed systems are systems designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled. Such systems must function properly and be used and maintained in accordance with the manufacturer's written operating instructions. For mixing/loading this means “a procedure for removing a pesticide from its original container, rinsing the emptied container, and transferring the pesticide and rinse solution through connecting hoses, pipes and couplings that are sufficiently tight to prevent exposure of any person to the pesticide or rinse solution. No rinsing is required when the pesticide is used without dilution or the container is a returnable or reusable container that will be sent back to the registrant.”

Overall the default protection proposal is to use 90% for closed systems when liquids are handled and to use 95% when solids are handled. This reflects dermal exposure loadings. A problem here is confirmation of adequate functioning of the closed transfer systems.

Closed cabs
The definition of a closed cab is difficult to describe. It should include at least positive air pressure inside the cab and a system of filtration units that functions. These are very difficult to meet in the field.

Overall the default protection proposal is to use 90% for closed cabs. This reflects dermal and inhalation exposure loadings. It is emphasized that the conditions for proper functioning are not easily met.

It is to be noted that special protection factors are used in several parts of the world for good reasons. This again underlines that the above-mentioned proposed default values should be treated with great care and only after careful considerations, several of which are mentioned in the present document.

Research recommendations

In the document based on the many considerations some specific recommendations for research are made, which are listed below.

- It is clear that further work is needed on the development of harmonized predictive exposure models. Work is in progress with AHED and a statistical evaluation of the exposure data to design possibly a better algorithm for the potential exposure assessment.
- Work is in progress on further evaluation of data on comparison of outer and inner dosimeters, as well as with whole body garments. The results may affect the quality of the arguments that underline choices for default penetration values.
- Further integration studies are needed on the work on material/fabric penetration and/or permeation and field studies with garment attires of chosen fabrics.
- There is a need for an agricultural standard for testing of protective clothing in Europe. The preferred standard seems to be the German standard DIN 32781. This requires actions at standardization level in Europe (CEN and ISO).
- The effective efficacy of PPE against chemical in real conditions of use (and not in standardized simulated work activities) is in particular depending on many factors which are not often correctly or sufficiently considered when drafting standards often based on empirical/conventional test methods and specifications. All these issues need to be more deeply checked trough inter-laboratory studies.
- There is hardly sufficient information on the relation between exposure scenarios, dermal loading and protection by clothing attires. The work in the Safe Use Initiative by ECPA seems an appropriate approach for studying these aspects, as well as the effect of training the operators (and workers) to prevent exposure and to improve the protecting effect of clothing and gloves.
- In particular, biological monitoring or whole-body dosimeter studies should focus on woven (launderable) and nonwoven (disposable) materials conducted over realistic time periods (e.g., a week with coveralls worn over long-sleeve shirt and long pants and a week with long-sleeve shirt and long pants without a coverall worn over them). This is important to factor in individual operator's habits as well as PPE maintenance, decontamination, and durability.[3]
- The present proposals for default values can be better underpinned when more solid data become available.

---

[3] Generally studies of this type will show significantly decreased protection factors versus studies using only new PPE for short periods of time.

Contents

ANNEX

1 Introduction

On request of the Dutch Ministry of Social Affairs and Employment, TNO has investigated current views and facts on the use of default values or approaches for the estimation of exposure reduction effectiveness of personal protective equipment (PPE) in registration processes of pesticides[4]. On the basis of this it is hoped that an internationally harmonized set of PPE protection factors for regulatory use, can be devised. This does require that regulatory authorities are prepared to adapt their current approach.

In order to reach this goal, it was concluded that recent literature on the issues involved should be evaluated, and that regulatory authorities in North America, Europe and Australia should be asked to indicate their regulatory approaches with respect to PPE effectiveness and the basis of these approaches. In addition to this, several industry organizations and academic groups working in the area were asked to provide their views and underlying evidence.

This approach has led to the development of a consultation document as a first step in the process of preparing guidance on the development of an appropriate regulatory approach, which of course has a very high policy-determined aspect. In the consultation document the available evidence and approaches were presented and no choices for approaches were made.

The consultation document was sent to all organizations and persons that had been so kind to provide the requested information for checking the accuracy of the data/information included and provide comments on the text. On the basis of the results of that exercise, the document was improved. Of course not all comments were in line with each other and some even conflicting. Nevertheless the authors have adapted the document with care and the final result is presented as Annex I to the present document.

On the basis of the available evidence and current status of the regulatory approaches a set of default protection factors for human exposure was proposed, which takes account of differences between agricultural pesticides and biocides (antimicrobials), operators (mixer/loaders and applicators) and workers (re-entering treated crops and enclosed spaces). For dermal exposure loading, clothing and gloves are considered separately.

Harmonized default protection factors were proposed for regulatory purposes. This so-called *vision document* was sent again to various parties as mentioned above and detailed in the present document. The comments showed some variance in approaches for North-American authorities and European authorities. This has to do with differences in legislation and experiences. On the basis of the comments, the authors have adapted the text again leading to the present *discussion document*.

---

[4] Pesticides are meant to include agrochemicals(, microbiological agents) and biocidal products (antimicrobials), for the present purpose.

The purpose of the present document is to give an overview of preferred approaches with respect to the use of default protection factors for regulatory purposes of agricultural pesticides and biocides (antimicrobials), and to indicate what these default values could be, using the most adequate information at hand.

In doing so, it is essential to consider the current approaches for exposure assessment and their starting points in legislative procedures, as well as the possible ways that protection factors can be estimated and implemented, as covered in the Annex.

2 General approach

Agricultural pesticides and biocides
In considering the use of pesticides, the differentiation between agricultural pesticides and biocides (antimicrobials) is very important. The main reason is that biocides are often used in industrial processes where normal control mechanisms -as for general chemicals- can be used. This does not hold for all biocidal applications and certainly not for many agricultural applications, where for instance local exhaust ventilation is generally not possible or irrelevant. Furthermore, in agriculture the number of possible exposure scenarios is relatively small, though increasing with new application techniques, and the toxicity of pesticides is generally high compared to that of general chemicals. Effective controls in agriculture lie therefore more in the nature of the formulation, the packaging, the quality of the application equipment and its correct use and certainly in applied personal protective measures, and thus the human factor.

Operators and (re-entry) workers
Operators are the people who handle concentrates, dusts or diluted sprays in settings where they work close to mists/clouds of pesticides. Re-entry workers handle either crops or fruits of crops in a surrounding where there is no spray mist, but they may be exposed to residues on the crop foliage (and to some extent on the fruits for that matter). In other situations, workers may have to enter enclosed spaces treated with pesticides. The same may hold for biocides.
It is evident that the use of PPE or other protective actions may differ largely between operators and workers.

Protection, ergonomics and thermo physiology
Another issue of major importance is whether for PPE the ergonomics and thermo physiological issues are taken into account next to the protective quality of the garment ensemble in the regulatory process. This appears to be different for different regulatory authorities. Some indicate that they will only prescribe PPE when compliance is possible and others state that industry is to sort out whatever type of PPE is required (fit for the purpose) and put that on the label.

Label compliance[5]
A further issue that requires attention is the fact that some authorities presume that whatever is on the label prescribed is/should and can be followed in practice (it is feasible/practical and reasonable!). This may be verified by formal inspections. Other authorities take the label prescription as the starting point for the assessment of health risks, but take a more conservative approach since it is 'known' or assumed that labels are generally not read, but certainly not always followed in practice. It should further be noticed that label definitions are not always very prescriptive.

---

[5] The present document covers only workers. In general, residential uses of a pesticide product assume no additional protection afforded by PPE with few exceptions. Recently, AD has considered the use of PPE such as gloves for do-it-yourself (DIY) antifouling painting for recreational boats and for backyard swimming pool applications.

Trained workers

The applications that are done with pesticides (and for that matter: biocides) may be carried out in different ways. It may be that operators are affected by the presence or not of a skull on the label. They may or may not know exactly why PPE is required and how to handle that in a proper fashion. In other words the level of exposure may be to a large extent determined by the level of competence of the operator, which may in itself be determined by training or licensing.

This also holds for re-entry workers who *e.g.* harvest a crop that still has residues on the foliage. They should *e.g.* be aware of the fact that damp materials (either foliage or clothing and skin) may lead to increased transfer of contaminant from the foliage to the worker and possibly increased dermal absorption.

Anyhow, protective measures are more effective when used properly, which may require quite a bit of training. Fit-testing for respirators is one of the important issues.

Predictive exposure modeling and measurements

The use of predictive exposure modeling is done differently in Europe and North America. In part this is due to differences in agricultural practices, which may lead to different exposure loadings. On the other hand within Europe the use of different models (UK POEM, German model, Dutch model, EUROPOEM) by different countries may also lead to differences in risk assessments for very similar agricultural practices.

All these models are somehow based on exposure loading data, but they use different sets and may even use different statistical approaches for determining the surrogate exposure value. Recent developments are very promising in the sense that industry in Europe and North America are developing a database with data from recent field exposure studies. This may very well lead to a much better harmonization of the assessment methodology where the difference are determined by differences in agricultural applications and not by local differences in the models used (Van Hemmen *et al.*, 2005).

The use of actual measurement series for the compound under consideration or another active substance in a very similar exposure scenario may also differ between authorities. Some require data on potential exposure loadings (outer dosimeters), others on actual exposure loading (inner dosimeters), and some on both. Some authorities favor the use of biomonitoring data when pharmacokinetic data support the interpretation. Other authorities presume that industry may not provide the right data for the purpose using these approaches with only few replicates and human pharmacokinetics based on few human volunteers. On the other hand it should be accepted that human biomonitoring data provide the only source of information where the effects of all relevant measures (application techniques, practical conditions, used PPE, the human factor itself) can be considered together, when pharmacokinetic details allow full interpretation.

Skin penetration

For most cases, the risk assessment is based on whatever enters the body for systemic uptake, and separately for local effects on the skin. In principle one would therefore like to know the protection afforded for systemic uptake, which would include possible effects of lower exposure skin loading on skin penetration. Several

comments on the consultation document have challenged this, mainly for reasons of clarity.
Several authorities mitigate local effects on the skin such as dermal irritation or the elicitation of dermal sensitization to occupational workers qualitatively by requiring PPE (e.g., long pants, long sleeved shirts, gloves).

Starting points for the setting of protection factors
In view of all these elements as described above, it is essential to choose the starting points for the present document aiming at harmonization.
The authors suggest taking the following starting points.
1) The predictive exposure assessment relates to potential exposure loading (combined outer and inner dosimeters). It is hoped that the authorities throughout the world will accept the approach that will be provided by the Agricultural Handlers Exposure Database (AHED) database after a solid evaluation of the exposure algorithm based on statistical evaluation of all underlying data. This may also be essential for using probabilistic assessments accounting for variability and uncertainty in the exposure (and risk) assessment. For the time being this is still something to happen, since the evaluation has not yet been made and is therefore not considered by regulatory authorities on both sides of the Atlantic or even wider.
2) For the present purpose (point 1 not yet effected), the potential exposure loading prediction (outer plus inner dosimeter) will be considered as being a true and valid value, despite the variation in prediction by various models.
3) The general approach for re-entry exposure modeling (Van Hemmen *et al*., 1995; Whitmyre *et al*., 2005; Hoernicke *et al*., 1998) is similar in Europe and North America, although the transfer coefficient (TC) values and dislodgeable foliar residue levels used for regulatory settings may vary. It is hoped that the current work of the Agricultural Reentry Task Force (ARTF) (although leading to proprietary data) will help in harmonizing approaches on both sides of the Atlantic with respect to the relation between scenario and transfer coefficient choice.
4) For the use of single measurement series in the exposure assessment, a general approach needs to be developed that takes account of inner dosimeter use, biological monitoring data, and prescribed PPE. It is outside the scope of the present document to develop this further. In the case of measurements which adequately (representative and robust) show inner dosimeter loading data are available, these data are to be preferred above the use of protection factors with outer dosimeter loading data.
5) Protection by multiple layers of (protective) clothing is executed by multiplication of the protection (e.g., two layers of 50% reduction each will lead to 75% reduction.
6) Skin penetration will not be considered for the present purpose of PPE protection factors.
7) Agricultural pesticides and biocides must be treated separately.
8) The same holds for operators and workers.
9) Since the label prescription is developed by industry for its active substance and formulation properties, the assessment of risk in regulatory practice should strictly follow that description. It is up to stewardship of industry and formal inspections by the authorities to make sure that compliance with the label is the rule to which there are hardly any exceptions. This does mean that the prescribed PPE should fit the purpose. This also means that for assessing PPE, only the protection

afforded in the field is of relevance. Ergonomics and thermo physiological issues should haven been dealt with before the label is developed.

10) The safety performance of certified PPE in actual/normal conditions of use, including rapid aging and user-device interactions will in general differ from performance criteria adopted in standards and tests.

11) One would like to use a tiered approach[6], which covers all these issues, where the most conservative approach is taken when no data are available on label compliance. The degree of conservatism may be lessened when it becomes clear that the workforce is fully acting according to labels and has got an effective training programme. For the time being it is considered that this is not practical for many European agricultural settings (see Safe Use Initiative in the Annex), possibly also not for some biocidal uses, whereas in industrial settings safety issues are usually covered by educated employees. The tiered approach is thought to be of less importance when the above starting points are kept.

In the following paragraphs, the determination of default protection factors is considered and its current status with respect to our knowledge, and indicating where relevant the lack of knowledge is used for the proposal of several default values.

Since the main issues of concern lie with dermal exposure loadings, it seems essential to consider the methodology for assessing dermal exposure loading in some detail.

From the work of Schneider *et al.* (1999) on what is called the conceptual model for dermal exposure, and the recent results of a CEFIC LRI project (Brouwer *et al.*, 2005; see paragraph on scoping in ANNEX I) it is evident that our current methodology for estimating dermal exposure loading is not adequate enough. For the time being there is, however, no better approach available. One should consider that the current methodology as used in agricultural practice for estimating pesticide exposure is probably overestimating the relevant amount in several cases. This holds at least for the majority of data points that are currently available in the databases underlying the predictive potential exposure models. This is an even more important point when inner and outer dosimeters are compared for assessing the degree of transfer from outer clothing to inner clothing (or even more difficult) to the skin. For estimating external dermal exposure (frequently called potential exposure), usually a monitoring material is used that absorbs or rather retains the liquid or solid that is to be captured. [The use of monitoring materials that leads to run off of the spray may not give the right level of contamination when it is to predict the exposure to a worker without that clothing material.] The same holds for the inner dosimeter, meaning that the degree of transfer observed in this way is dependent on the two monitoring materials used and of course the conditions under which the experiment is carried out, such as humidity and degree of pressure at the two layers. This may of course affect the degree of transfer in both ways when deriving default values that need to describe the efficacy of protection in practice, either under protecting or over protecting, depending on the actual field conditions for which the default value is meant. This no doubt leads to the conclusion that for relevant comparisons of inner

---

[6] The North-American approach is to incorporate PPE requirements **only** in situations where it is known that compliance is feasible and then defer to compliance programs for enforcement of label-specified PPE.

and outer dosimeters, one needs to consider materials that mimick the actual clothing in the fields as much as possible.
It is hoped that in the current approaches by industry (both in North America and in Europe) to derive an approach for setting default values for different clothing attires and use scenarios on the basis of available databases (see next chapter), somehow these issues will be taken into account.

A major point that needs attention before discussing the possible approaches on determining the effectiveness of PPE is to see whether it has a similar (or the same) meaning in Europe and North-America. The relevant North-American definitions[7] are given in the footnote.
Both North-American definitions identify coveralls as PPE. For example, the US Worker Protection Standard (WPS) distinguishes between a coverall and a chemical-resistant suit. A coverall is defined as a loose-fitting one- or two-piece garment that covers, at a minimum, the entire body, except head, hands, and feet. The WPS states that coveralls are made of fabric such as cotton or a cotton-polyester blend and are not chemical-resistant. The EU legislation does not consider an overall as PPE, unless specifically designed for that purpose.
Relevant EU legislation on the design and use of PPE[8] has been provided by Directives 89/686/EEC and 89/686/EEC, whereas guidance for the selection, use, care and maintenance of PPE is given by CEN standards, e.g. EN 529 and EN/TR 15419 (PPE: see references).

---

[7] In North America, the following definitions are widely used:
"Personal protective equipment means apparel and devices worn to minimize human body contact with pesticides or pesticide residues that must be provided by an employer and are separate from, or in addition to , work clothing, PPE may include chemical resistant suits, chemical resistant gloves, chemical resistant footwear, respiratory protection devices, chemical resistant aprons, chemical resistant headgear, protective eyewear, or a coverall (one- or two-piece garment) (California Code of Regulations, Title 3. Food and Agriculture Division 6. Pesticides and Pest Control Operations Chapter 1. Pesticide Regulatory Program Subchapter 1. Definition of Terms Article 1. Definitions for Division 6). Contn'd on page 12.
"Personal protective equipment means devices and apparel that are worn to protect the body from contact with pesticides or pesticide residues including, but not limited to coveralls, chemical-resistant suits, chemical-resistant gloves, chemical-resistant footwear, respiratory protection devices, chemical-resistant aprons, chemical-resistant headgear and protective eyewear." (40 CFR, Part 170, Subpart B, US EPA Worker Protection Standard for Agricultural Chemicals).

[8] "Personal Protective Equipment" is defined as "any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards". European Union Council (EU): Personal Protective Equipment (EU Directive 89/686/EEC), Brussels, Belgium, EU, December, 1989.

3 Default protection factors

3.1 Introduction

The first question to tackle is, how the efficacy of clothing to protect against penetration can be determined. The main approach for this is by material testing. Lots of papers have been published on these issues. The most recent collection of these data can be searched for on www.umes.edu/ppe at the University of Maryland Eastern Shore (Prof. Anugrah Shaw). The database (password protected) currently houses information of approximately 130 materials. Garment source and availability information is also available through the system.

Since it is well-known that effectiveness of protection is not only determined by the nature of the fabric (woven, non-woven, weight, twill, knit, etc.) but also by the garment ensemble with seams, openings and buttons or zippers, it is essential to study such garments also in field studies where the material is used as is, either when worn new or after several days in use, or even after frequent washings.

The PHED database has been searched for sets of inner and outer dosimeter data on clothing that may give proper indications of the protective nature of the material (There were not sufficient data for whole body garments). Powell of California Department of Pesticide Regulation has started such work for the NAFTA Technical working Group on Pesticides[9]. The results were -to our knowledge- never finished, but some results were published (Ross *et al.*, 1997). The main observation was that there were differences between the types of clothing and that the degree of penetration through the clothing was dependent on the loading i.e. penetration being higher with lower loading. A wide variety of pesticides were used for obtaining the data. With linear regression analysis (Ross *et al.*, 1997) it appeared on the basis of the data used that

$$\text{percent penetration} = 3.3\ (\text{outer loading in } \mu\text{g/cm}^2)^{-0.3}$$

This leads to on average 11% penetration at levels of 0.007-0.047 ug/cm^2, according to a table representing the data. This means about 140-940 µg on the body (20,000 cm^2)[10], assuming homogeneous loading. The range of 0.047 to 0.511 µg/cm^2 (940-10,200 µg on the body) amounts to an average 6 % penetration. These data are very similar to the data of Powell.[9] In a table in that report 90% upper prediction limits are also given. For penetrations below 10%, the dermal loading must be higher than about 2 µg/cm^2. This amounts to about 40 mg on the whole body (assuming homogeneous distribution).

There is no explicit quantitative information on the effect of the garment material on the degree of penetration. The above data describe an overall picture using all relevant available data from the PHED database.

---

[9] International Harmonisation Position Paper. Protection factors. Part I. Analysis of PHED Data (draft), October 1997.

[10] The use of surface areas of 20,000 cm^2 is according to other authorities very high. California DPR uses 1.9 m^2 for the entire body; the portion covered by single-layer work clothes has an area of about 1.6 m^2.

This work is currently being extended/revisited by Infoscientific.com on behalf of the American Chemistry Council.
On the other hand, the work of Powell has been re-emphasized in a comment of the North-American regulatory authorities on the present document. **It is concluded[11] that it is yet premature to adopt loading-dependent protection factors for operators.**

The authors have further been informed that a similar approach will be undertaken using the data in AHED (Agricultural Handler's Exposure Database) which contains much more information on involved materials and is based on recent exposure loading data for operators from Europe and North America.

A similar approach as the one of Powell[9] and Ross et al. (1997) has been taken by the Agricultural Reentry Task Force (ARTF) for their data on penetration of clothing (cotton coveralls) by dislodgeable foliar residues of pesticides (Baugher, 2005).
It appeared that there was no reason to assume, for the data involved (taken from a series of 26 re-entry studies with a large variety of exposure scenarios), an inverse relationship between degree of penetration and outer dosimeter loading, as was observed for operators (see above). The degree of penetration observed depended on

---

[11] We propose that it is premature to adopt loading-dependent PFs for handlers. Further data collection and analysis is required before we can move in this direction. Both the data and the analyses done so far demonstrating the relationship of penetration to outer deposition are weak. Hopefully, ongoing and future work will illuminate the issue. Upper-bound estimates of penetration may be warranted due to factors that are not integrated into most study designs, such as inadequate decontamination of woven materials, frequent lack of daily laundering, the variety in design of clothing, the type of weaves, thickness of fabric, and the types of openings and seams. In addition, most pesticide labels contain a range of application rates and application equipment for a variety of use-sites and the complexity that potentially would result from using a tiered approach is not justified based on our current knowledge. The North American regulatory agencies use the following protection factors (US EPA: 50%; Cal DPR 90% and PMRA 75%). If resources permit, we would like to undertake a project to investigate the most appropriate protection factors for this and other skin protection methods. California DPR has revisited the work done in 1997 under the umbrella of the NAFTA Technical Working Group on Pesticides on clothing penetration using PHED, to which the TNO document refers. The data set was revised following suggestions by reviewers. One suggestion was to look at the effect of sampling duration on penetration; it was thought that very short durations might not allow penetration to occur fully. Another comment was that the selection criteria might have biased the results, as patch pairs had been excluded if the outer patch was ND or if the inner residue was higher than the outer. Those pairs were put back into the data file. This time the only exclusion criterion was that a replicate was dropped if all inside *and* all outside patches were ND. The greatest weakness of the PHED data may be the short sampling durations. Of the 317 usable replicates, 45% were monitored for less than 45 minutes, 25% for less than 23 minutes. Predictably, outer deposition was lower for these short samples; unexpectedly, penetration was high. Even though this suggests that the relationship of penetration to outer deposition was the same for short-duration replicates as for the other replicates, those monitored for less than 45 minutes were excluded from further analysis. This seemed like a minimum monitoring time needed for the results to be meaningful. Regression analyses were carried out using the 175 replicates that were monitored for at least 45 minutes. Various subsets of the data (e.g., separating applicators from mixer/loaders; including the short-duration replicates) were tried and various potential covariates (sampling time, amount handled, log and square transformations of those variables, dosimeter type). The best model found was not terribly good. It has log outside deposition, sampling time and sampling time-squared as predictors (even with the exclusion of the very short samples). R^2 is only 0.50, but of more concern is that the model systematically over predicts penetration at the low end and under predicts at the high end. (Every model considered did this.) This generally means that some influential variable(s) have been omitted from the model, or the model has otherwise been misspecified. Another troubling fact is that several almost equally well-fitting models give rather different predictions of penetration. These results should be considered only as illustrative. The data also seem to predict different percent penetration by outside deposition for 1, 4 and 8 hour durations. The inconvenient thing about this model is that penetration depends not only on outside deposition, but also on duration. It can be seen that there is a curvilinear effect of time, with penetration being highest at the middle duration. Further investigation of the effect of sampling time is needed, as there is some possibility it is an artifact of combining disparate studies. If regression of penetration on outer loading were to be used to establish PF for single-layer clothing, the large variability in penetration suggests that PF should be based on upper-bound estimates of penetration.

the location on the body and on the exposure scenario, and was thus highly variable. The arithmetic mean percent penetration varied between 20%, 13% and 8% for respectively lower arm, upper arm/torso and lower body dosimeters.

Specific issues
Generally, exposure loading issues cover inhalation and dermal loading, next to oral exposure loading.

Essential remarks:

- **Engineering controls have a higher (legal) priority than personal protective equipment (PPE).**
- **Any protective equipment must be properly designed, fitted, worn and maintained to be effective.**
- **Gloves must provide protection against hands and lower forearms.**
- **It should be stressed that default protection values should only be used after careful consideration of the exposure scenario and pesticide formulation involved.**

3.2 Inhalation exposure loading

It is proposed to use the ‘assigned protection factors’ (APF) as deduced by BSI (British Standards Institution) and ANSI (American National Standards Institute). Since these values are somewhat at variance and since in agricultural settings efficient control and proper training and education with respect to inhalation protection devices, is generally absent, it is good to err on the safe side and to use the lowest of both values, if available. The proposed data are given in Table A below. These values are presented in bold.

It is further proposed to use these data for agricultural pesticides and biocides similarly when appropriate. Unfortunately, not all categories correspond between North-America and Europe as can for instance be seen in Table IX in the Annex and some respirators are called differently[12] and may even have different efficacies. Both the US federal Occupational Safety and Health Agency (OSHA) and California OSHA accept NIOSH APF (and will enshrine them into regulation in the near future). Standard practice in the US and Canada is to use the NIOSH or ANSI values (which differ mostly with full-face tight fitting APF values). California DPR follows the ANSI values (see Title 3 CCR Section 6738 (h)(2)). Given use of NIOSH APF in North America the NIOSH Respirator Selection Logic (2004) (NIOSH Publication # 2005-100) is an important source.

The big influence of the wearing/fitting of PPE in particular for respiratory protection by the end-users on the real efficacy of the PPE is to be noted. The EU directive on the use of PPE requests a proper information and training of workers on the donning, care, and maintenance of PPE. In practice it is very difficult to apply this provision in particular in very small enterprises and for self-employed people.

---

[12] The general respirator types in the US and Canada are:
TC-84A Particulate Filter (Half Face/Full Face/Filtering Face piece Configurations)
TC-23C Chemical Cartridge (Half Face/Full Face)
TC-21C DFM (PAPR) (Powered Air Purifying Respirator)
TC-14G Gas Masks
TC-19C Supplied Airline
TC-13F SCBA

We should consider a PPE as acceptable only if it can be properly used without specific training only on the basis of the reading of the instructions for use supplied by manufacturers.

It is assumed that for most re-entry activities in crops no inhalation protection is needed, since these activities (*e.g.* harvesting) would then be too cumbersome to carry and should therefore be considered inappropriate and not acceptable in registrations. An exception may be formed for re-entering closed treated environments with either agricultural pesticides or biocides, where the use of inhalation protection may be required for relatively short time periods.[13]

---

[13] In fact, the US Federal Worker Protection Standard prohibits requiring PPE for reentry workers. The definition of re-entry becomes important as the US Federal Worker Protection Standard prohibits the use of respirators for routine early entry activities, such as hand labor tasks or limited-contact tasks, but requires persons reentering treated areas to wear appropriate respiratory protection in specific situations, such as re-entry following fumigation application to monitor air concentrations, to operate ventilation equipment, to remove tarps or other entities designed to confine a fumigant, or to perform a rescue.

Table A. Overview of ‘Assigned Protection Factors’ for filtering devices

Mask type	Filter type	BS 4275	ANSI Z88.2	
Filtering half masks	FFP1	4		
	FFP2	10		
	FFP3	20	**10**	
Half or quarter mask and filter	P1	4		
	P2	10		
	Gas	10	10	
	GasXP3	10	0	
	P3	20	**10**	
Filtering half masks without inhalation valves	FMP1	4		
	FMP2	10		
	FMGasX	10	10	
	FMGasXP3	10		
	FMP3	20	**10**	
Valved filtering half masks	FFGasXP1	4		
	FFGasX	10	10	
	FFGasXP2	10		
	FFGasXP3	10	10	
Full face masks and filter	P1	4		
	P2	10		
	Gas	**20**	100	
	GasXP3	20		
	P3	**40**	100	
Powered filtering devices incorpoating helmets or hoods	TH1 all types	**10**	100	
	TH2 all types	**20**	100	
	TH3 (semi)hood/ blouse	**40**	1000	
Power assisted filtering devices incorporating full, half or quarter masks	TM1 (all types)	**10**	50 (Half face)	100 (full face)
	TM2 (all types)	**20**	50 (Half face)	100 (full face)
	TM3 (half face) particle, gas or combined filters	**20**	50	
	TM 3 (full face) gas or combined filters	**40**	1000	

3.2.1 *Dermal exposure loading*[14]

Differentiations are made for agricultural pesticides and biocides, as well as operators (mixer/loaders and applicators) and (re-entry) workers. A major differentiation in the approach is further for hand and body protection.

3.2.2 *Oral exposure loading*

Oral exposure loading is only considered in special cases where dermal exposure may be relatively high and the hand-mouth shunt may lead to appreciable oral exposure loading.

PPE for dermal exposure reduction may also lead to a decrease of oral loading, since the hand-mouth shunt is less likely for gloved hands, although it cannot fully be excluded.

There is at the moment no way to reduce oral exposure in a direct way with PPE, apart from face masks. Therefore the approach presented will only cover inhalation and dermal exposure loading. In a recent paper, Cherrie *et al.* (2006) have described a conceptual model for oral exposure assessment.

I. Clothing

Body protection may include shirts, pants, (c)overalls, aprons, hats/caps and the like. These may be fabricated from different materials. The most frequently used are:

- woven cotton and cotton-polyester fabrics
- non-woven fabrics
- woven or non-woven fabrics to which a film of plastic or rubber has been laminated or coated.

Operators

Several studies are currently underway in order to assess the protection provided by a single clothing layer. The currently available data show on one hand that the penetration increases with lower loadings (operator studies with PHED data; Ross *et al.*, 1997). For re-entry workers, such an effect was not observed (Baugher, 2005). If such an effect is accepted as being a true phenomenon (as observed for skin penetration as well), then in a conservative assessment, one might differentiate between the levels of loading. However, as is indicated in footnote 10 this is to be considered premature.

The North American regulatory agencies use the following protection factors (US EPA: 50%; Cal DPR 90% and PMRA 75%). A 90% protection default is recommended by Thongsinthusak *et al.* (1990) for various clothing regimes (long-sleeved shirt and pants (cotton and cotton-polyester) and various uncoated coveralls).

Coated coveralls

Thongsinthusak proposes 95% protection when using coated coveralls.

As noted above, the North American agencies would like to put some resources towards identifying the most appropriate default for skin protection, since the data are not yet conclusive. PMRA currently uses the 90% protection factor (Canada requires a laminated or treated Tyvek for liquid formulations whereas for dry

---

[14] The discussion as presented here was thankfully supported by an internal document of PMRA at Health Canada, where several of these data were pulled together.

formulations regular Tyvek is acceptable.) At this time, California DPR will continue to use 95% protection, because, although there were a limited number of studies, these studies demonstrated a range of PF greater than 95%. In general, the US EPA does not require pesticide operators to wear chemical-resistant suits due to concerns about heat-related illness. Instead, if coveralls worn over a long-sleeve shirt and long pants do not adequately mitigate dermal exposures and risks, then engineering controls are required. During the implementation of the US Federal Worker Protection Standard, for routine pesticide handling activities any existing label requirements for a chemical-resistant suit were removed from labels with directions for use on agricultural crops.
It is to be noted that HS-1612 (Thongsinthusak *et al.*, 1993) indicates "Actual protective values will be used when available especially for pesticides with high vapor pressure". But, the high vapor pressure is not yet defined. In Europe this is usually taken to be above 10-100 mPa.
It is further important to note that there are limitations on the use of chemical-resistant suits in CA (CCR, Title 3).[15]

The various authorities use different values, considering their own available data and focused studies. The above-mentioned value of 90% protection is close to what is generally used, but there is some variation, going downwards in Canada and upwards in Germany. The problem is they all use different garment ensembles in their descriptions.

Overall the proposal[16] for single layers of uncoated clothing or coveralls is 90%. For coated coveralls (CEN Type 3 or 4) this is for the time being also 90%. This refers to the whole body (hand, head and neck excluded).

When for exposure to biocides[17] engineering control mechanisms are either fully used or not possible, one might use the same default values as for agricultural pesticides.

---

[15] CCR (g) The employer shall assure that (1) When pesticide product labeling or regulations specify a chemical resistant suit, waterproof or impervious pants and coat or a rain suit, a chemical resistant suit that covers the torso, head, arms, and legs is worn. (2) If the ambient temperature exceeds 80°F during daylight hours or 85°F during nighttime hours (sunset to sunrise) pesticides requiring a chemical resistant suit are not handled by employees unless they are handled pursuant to exceptions and substitutions permitted in (i) or employees use cooled chemical resistant suits or other control methods to maintain an effective working environment at or below 80°F during daylight hours or 85°F during nighttime hours (sunset to sunrise). In warm regions, workers may open part of the suit, which will reduce the PF. If not, workers may get heat stress.

[16] The proposed default values do not take into consideration any quality of the garment, i.e. garment can be impervious or a useless “sieve” type. It is propose to link the default values with a minimum required quality of the garment, e.g. with a European agricultural standard to be elaborated and set. Agricultural garment standards have been set for example by the German guideline DIN 32781 or are proposed in the draft ISO 27065. Alternatively, as proposed for Europe, the atomizer test DIN EN 14786 can be used. A certain minimum standard of garment for agricultural use would allow setting more accurate and garment related default values. The default value of 95% in the German model is linked for example with a minimum requirement of 5% garment penetration in the atomizer test DIN EN 14786 carried out with selected pesticide spray mixtures. The pipette test standard in the draft ISO is for example linked to garment penetration data measured in the field in the course of ECPA’s EOEM project where operators had worn polyester/cotton Mauser coverall (German “Standardschutzanzug (Pflanzenschutz)” for agricultural use). In high exposure scenarios where water impermeable (rain suit type) clothing is necessary and used there is virtually no penetration, i.e. the protection factor could be set high, e.g. 99%.

[17] The following protection factors are used by the USEPA Antimicrobial Division (AD): (1) Single layer of clothing (type of fabric unspecified, e.g., long pants, long sleeved shirt statement on a pesticide label) is

Workers

Data for re-entry workers are hardly available. The only strong database is provided with the results of the ARTF (Baugher, 2005). Their results can be described as (quote)

"The arithmetic mean percent penetration of lower arm, upper arm/torso, and lower body dosimeters was 20%, 13%, and 8%, respectively, but was highly variable and cluster-specific". With clusters is meant various groups crop/activity scenarios.

It is proposed, in view of the quoted statement, to use the 80% protection[18] value for the whole garment. The garments consist of cotton long-sleeved shirts and pants. It is to be noted, however, that the shirts were made of a lighter weight cotton than the pants in the study.

Overall the proposal for single layers of uncoated clothing or coveralls is 80%. This refers to the whole body (hand, head and neck excluded).

II. Gloves

- Gloves are to be considered as barriers of hands and wrists against liquids (and solids).
- Gloves may behave very differently towards chemicals. No one glove material is a barrier to all chemicals.
- Solvents in pesticide formulations present the greatest challenges to barrier effectiveness of gloves.
- Gloves should be checked for holes/cracks before putting on.
- Gloves should be washed before taking off.
- Taking on and off should be done as little as possible. Gloves should, however, always be removed when entering tractor cabins.

Operators

Since it is known for various solvents what are glove materials that may be used and also which ones may not be used, it is essential that the material choice is adequate before any relevant protection can be indicated.

Assuming that the glove material is fit for the purpose (in relation to the pesticide formulation and spray dilution at hand), the protection efficacy depends on the actual use of the gloves in practice (human factor).

The various regulatory authorities use very similar protection values for chemically resistant gloves. The underlying database is, however, relatively small.

---

assigned a 50% PF (second layer/coveralls assigned another 50% PF); (2) Chemical resistant gloves is assigned a 90% PF (glove material type unspecified but indicates chemical resistant, not leather and/or cotton; the selection of glove material for inclusion on a product label is based on characteristics of the pesticide); (3) Respirators – In general, AD uses the PFs assigned by NIOSH. In practice, to mitigate risks in our assessments we often use a 5-fold PF for dust/mist and a 10-fold PF for ½ face masks (type of respirator cartridge selected based on characteristics of the pesticide); (4) Other (e.g., face shield, goggles, aprons) – currently AD has not assigned quantitative PFs for these other types of PPE.

[18] A protection factor of 80% corresponds to about the 85th percentile of clothing penetration. 90 % Protection is about the median. It seems appropriate to use a default value more conservative than the average for two reasons: 1) the ARTF studies are very tightly controlled and may not represent the full range of variability that might be seen in actual field conditions; 2) workers in ARTF studies wear brand new work clothes, which may be more resistant to penetration that the clothing worn in actual field conditions.

Cal-DPR uses 90%. The UK[19] uses between 90 and 99% depending on formulation type. PMRA provides study data between 89 and 99% for various formulations. The highest value is used by Germany (99%). In this case it is used for specifically designed so-called “Universal Schutzhandschuhe (Pflanzenschutz)”, specifically certified for use with plant protection products. The North-American regulatory authorities do not support a 95% protection for solids[20]. They propose to set it at 90%.

Overall the proposal for gloves is 90% when liquids are handled and 95% when solids are handled.

When for exposure to biocides engineering control mechanisms are either fully used or not possible, one might use the same default values as for agricultural pesticides.

Workers

Crop workers cannot and should not use protective chemically-resistant gloves for periods longer than hours. The best they might do is wear gloves that protect them against scratches by thorns, irritating/sensitizing plant saps, and the like, or at the most cotton gloves against exposure to pesticides. However, even these gloves should not be used, since they wear out rather quickly and hardly protect since they get wet quickly by contact with several types of foliage.

This indicates that glove protection should only be considered in very specific circumstances and on a case-by-case analysis. This corresponds with the view of the North-American authorities.[21]

---

[19] When mixing/loading: 90% for solvent based formulations, 95% for water based formulations, and 99% for solids. When spraying: 90% for all liquids.

[20] We support a 90% protection factor for chemical-resistant gloves. However, the same PF should be used for dry (solid) pesticides, rather than 95%. Dry pesticides could generate fines that could get into the space between gloves and the skin more easily than the liquid pesticides. When using PHED data to conduct occupational exposure assessments, North American regulatory agencies use hand unit exposure values in PHED to determine exposure mitigation provided by chemical-resistant gloves. PHED subsets for which there are sufficient replicates with gloves include ML/Open System/WP; ML/Open System/DF; ML/WSP containing WP; ML/Open System/Liquids; Airblast Applicator/Open Cab; Aerosol Can Applicator; Broadcast Spreader Applicator/Closed Cab/Granular. It is noteworthy that most studies do not account for concerns about adequate decontamination and maintenance of chemical-resistant gloves and the likely reduction in protection as the gloves deteriorate and are not routinely replaced.

[21] Our understanding for this section is that “work gloves” refers to non-chemical-resistant gloves worn for certain tasks (whether handler or reentry). North American regulatory agencies do not assign a protection factor to work gloves. For certain re-entry activities work gloves are required for practical reasons (e.g., workers cutting rose stems for propagation need to wear special gloves and a thick polyethylene chap to protect themselves against scratches by thorns; workers have to wear chemical-resistant gloves if sap from plants can cause skin irritation). A protection factor is not normally applied in these instances. In unusual situations chemical-resistant gloves are required for re-entry workers and the protection value assigned to this scenario would be as for operators. The US Federal Worker Protection Standard does not permit routine early entry to perform hand labor activities. However, the WPS does permit, under certain conditions, early entry to perform certain short-term, emergency, or limited-contact tasks. When such entry occurs, workers must be provided coveralls (that must be maintained by the employer) and chemical-resistant gloves made of any waterproof material. In Canada, greenhouse associations have been telling us that, more and more, under the guise of food safety programs, chemical-resistant gloves are being required for workers involved in greenhouse vegetable production (for all activities involving foliar contact, not just during harvesting of vegetables). So in the future, it is conceivable that Canada would incorporate this into its assessments and use a glove protection factor for some categories of re-entry workers.

III. Engineering controls

This section is not within the scope of the current project on PPE, but it is added for completeness and covers only the mixing/loading of agricultural pesticides, and the use of enclosed cabs.

For biocides, the US-EPA Antimicrobial Division (AD) uses the following approach: AD mitigates industrial antimicrobial exposures/risks by requiring engineering controls were feasible instead of relying on PPE. Engineering controls such as closed loading systems and/or ventilation criteria (e.g., air exchange rates and reentry intervals) are used where feasible instead of aprons, double layers of clothing, and/or respirators. The industrial settings for antimicrobial products lend themselves more readily to engineering controls then in agricultural settings. However, in cases where engineering controls are not feasible, PF are still often not used by AD at this time because of the limitations in the existing antimicrobial exposure data base. For example, in cases where only minimal exposure replicates are available, additional uncertainties in the form of PFs are not applied during the risk assessment process. In the near future, the exposure data base available to assess antimicrobial products is expected to increase based on the efforts of the Antimicrobials Exposure Assessment Task Force (AEATF). At that time, AD will be more accommodating to using default PFs when engineering controls are not practical.

Mixing/loading of agricultural pesticides

The proposal is to fit with the Cal-DPR definition of closed systems: closed systems are systems designed by the manufacturer to enclose the pesticide to prevent it from contacting handlers or other people while it is being handled. Such systems must function properly and be used and maintained in accordance with the manufacturer's written operating instructions. For mixing/loading this means "a procedure for removing a pesticide from its original container, rinsing the emptied container, and transferring the pesticide and rinse solution through connecting hoses, pipes and couplings that are sufficiently tight to prevent exposure of any person to the pesticide or rinse solution. No rinsing is required when the pesticide is used without dilution or the container is a returnable or reusable container that will be sent back to the registrant."

To meet this, a closed system must meet defined criteria.[22] It is clear that such criteria are not easily met in full.

---

[22] 1. The liquid pesticide must be removed from its original shipping container and transferred through connecting hoses pipes, and/or couplings that are sufficiently tight to prevent exposure of any person to the concentrate, use dilution, or rinse solution. 2. All hoses, piping, tanks, and connections used in conjunction with a closed system must be of a type appropriate for the pesticide being used and, the pressure and vacuum of the system. 3. All sight gauges must be protected against breakage. Sight gauges must be equipped with valves so the pipes to the sight gauge can be shut off in case of breakage or leakage. 4. The closed system must adequately measure the pesticide being used. Measuring devices must be accurately calibrated to the smallest unit in which the material is being weighed or measured. Pesticide remaining in the transfer lines may affect the accuracy of measurement and must be considered. 5. The movement of a pesticide concentrate beyond a pump by positive pressure must not exceed 25 pounds per square inch (psi) of pressure.

6. A probe must not be removed from a container except when: a. The container is emptied and the inside, as well as the probe, have been rinsed in accordance with item 8. b. DPR has evaluated the probe and determined that, by the nature of its construction or design, it eliminates significant risk of worker exposure to the pesticide when it is withdrawn from a partial container. c. The pesticide is used without dilution and the container has been emptied. 7. Shut-off devices must be installed on the exit end of all hoses and at all disconnect points to prevent the pesticide from leaking when the transfer is stopped and the hose is removed or disconnected. a. If the hose carried pesticide concentrate and has not been rinsed in accordance with item 8, a dry break coupler that will minimize pesticide loss to not more than two milliliters per disconnect must be installed at the disconnect point. b. If the hose carried a pesticide use dilution or rinse solution, a reversing action pump or a

The available Californian data (Thongsinthusak *et al*., 1990, 1993; Thongsinthusak and Ross, 1994) show protection values between 95 and 98%. US-EPA[23] uses values between 90 and 98%. The highest value is for granulates.

In the UK, a study was performed into a comparison of concentrate handling using mechanical devices and the open mixing and loading of the UK POEM model (ACP, 2004). In terms of exposure assessment for operators during mixing and loading, the limited data have not demonstrated unequivocally that closed transfer systems result in lower levels of exposure (hand contamination) compared with induction bowl or tank top filling devices. This was caused mainly because there was a large variation in level of exposure due to malfunctioning of the equipment. This indicates that much more work needs to be done and it again underlines that the description/criteria for the closed transfer systems need large detail.

Overall the proposal is to use 90% for closed systems when liquids are handled and to use 95% when solids are handled. This reflects dermal exposure loadings. A problem here is confirmation of adequate functioning of the closed transfer systems.

Closed cabs

The definition of a closed cab is difficult to describe[24]. It should include at least positive air pressure inside the cab and a system of filtration units that functions.

---

similar system that will empty the hose may be used as an alternative to a shutoff device. 8. When the pesticide is to be diluted for use, the closed system must provide for adequate rinsing of containers that have held less than 60 gallons of a liquid pesticide. Rinsing must be done with a medium, such as water, that contains no pesticide. a. The system must be capable of spray-rinsing the inner surfaces of the container and the rinse solution must go into the pesticide mix tank or applicator vehicle via the closed system. The system must be capable of rinsing the probe, if used, and all hoses, measuring devices, etc. b. A minimum of 15 psi of pressure must be used for rinsing. c. The rinsing must be continued until minimum of 10 gallons or one-half of the container volume, whichever is less, has been used. d. The rinse solution must be removed from the pesticide container concurrently with introduction of the rinse medium. e. Pesticide containers must be protected against excessive pressure during the container rinse operation. The maximum container pressure must not exceed five psi. 9. Each commercially produced closed system or component to be used with a closed system must be sold with: a. Complete instructions consisting of a functional operating manual and a decal(s) covering the basic operation. The decal(s) must be placed in a prominent location on the system. b. Specific directions for cleaning and maintenance of the system on a scheduled basis. c. Information on any restrictions or limitations relating to the system, such as pesticides that are incompatible with materials used in the construction of the system, types (or sizes) of containers or closures that cannot be handled by the system, any limits on ability to correct or over measurement of a pesticide, or special procedures or limitations on the ability of the system to deal with partial containers. Operating Requirements:
10. The system must be cleaned and maintained according to the manufacturer's instructions. If the system is not a commercially produced system it must be maintained on a regular basis. A record of cleaning and maintenance must be maintained. 11. All labeling required personal protective equipment (PPE) must be present at the work site. Protective eyewear must be worn while using a closed system that operates under pressure.

[23] When using PHED data to conduct occupational exposure assessments, North American regulatory agencies ~~uses~~ dermal and inhalation unit exposure values in PHED to determine exposure mitigation provided by a variety of closed systems. PHED subsets for which there are sufficient replicates for closed system (i.e., closed, mechanical pump or gravity feed) include ML/WSP containing WP; ML/Liquids, and Applicator/Broadcast Spreader/Granular. California DPR and PMRA can support a protection factor of 95% for liquid pesticides. This PF was obtained from five studies with an average PF of 96.8 +/- 1.4%. A new protection factor may be used if it is from studies using an acceptable closed system. The 95% PF is intended for liquid pesticides. The same PF should also be applicable for dry pesticides. Maintenance of the system and operating requirements are as important as the criteria in achieving the designated PF. Criteria and information on evaluation of a closed system can be found at: http://www.cdpr.ca.gov/docs/whs/ind_hygiene.htm). We agree that more studies are needed on PF for closed systems.

These are very difficult to meet in the field. If so, the data provided by Thongsinthusak *et al*. (1990, 1993) indicate protection values from 90% upwards for both dermal and inhalation exposure loading. [25]
Overall the proposal is to use 90% for closed cabs. This reflects dermal and inhalation exposure loadings. It is emphasized that the conditions for proper functioning are not easily met.

IV. Other protection factors

California DPR assigns PF to the following items that are not mentioned above.

Item	**DPR PF (%)**
Chemical-resistant apron (chest/stomach, front half of thighs)	95
Goggles, nonvented (½ of face, or ¼ of head)	95
Goggles, vented (½ of face, or ¼ of head)	75
Face shield (face)	75
Chemical-resistant boots (feet)	90

---

[24] Cal-DPR uses the standards of the American Society of Agricultural and Biological Engineers: Agricultural Cabs - Engineering Control of Environmental Air Quality. Part 1: Definitions, Test Methods, and Safety Practices, and Part 2: Pesticide Vapor Filters--Test Procedure and Performance Criteria.

[25] When using PHED data to conduct occupational exposure assessments, North American regulatory agencies uses dermal and inhalation unit exposure values in PHED to determine exposure mitigation provided by closed cabs. PHED subsets for which there are sufficient replicates for closed cabs (i.e., closed cab/closed windows and/or closed cab with filtered air) include airblast applicator, groundboom applicator and aerial applicator/liquids. In terms of protection factors, California DPR and PMRA support the 90% PF for "enclosed cab". In addition, California DPR has adopted a 98% protection factor for "enclosed cab" with positive pressure and a charcoal air filtration unit". DPR's special PF for cabs meeting ASAE S525 is necessary, because it is in the CCR (see definition below). A list of cabs that are certified to meet the ASAE standards S-525 can be found at http://www.cdpr.ca.gov/docs/whs/cac/cacenf99-007.pdf. The following are definitions from CCR, Title 3, Division 6, Section 6000: "Enclosed cab" means a chemical resistant barrier that completely surrounds the occupant(s) of the cab and meets those portions of the requirements in American Society of Agricultural Engineers Standard S-525 (Rev. 5/98) that pertain to dermal protection. "Enclosed cab acceptable for respiratory protection" means an enclosed cab that incorporates a dust/mist filtering and /or a vapor or gas removing air purification system, as appropriate for the exposure situation. Enclosed cabs certified by the manufacturer as meeting American Society of Agricultural Engineers Standard S-525 (Rev. 5/98) are acceptable under this definition. The Director may, upon request, approve other enclosed cabs as acceptable under this definition. "Enclosed" is recommended over "closed" per the California regulations. High protection factor is dependent on upkeep of the cab, procedure to exit and reenter the cab, etc. Information on "maintenance" and "suppliers" of enclosed cabs can be found at: http://www.cdpr.ca.gov/docs/whs/ind_hygiene.htm. The US Federal Worker Protection Standard establishes requirements for enclosed cabs. When an enclosed cab provides only dermal protection, occupants must wear any respirator specified on the pesticide label for that use-pattern. This type of cab corresponds to the ASAE S-525 "ECPAD" – meaning "enclosed cab, pesticide application, dermal protection." The occupants of an enclosed cab are not required to wear the label-specified respirator if the enclosed cab (1) has a properly functioning ventilation system that is used and maintained according to the manufacturer's written operating instructions and (2) is declared in writing by the manufacturer or by a governmental agency to provide at least as much respiratory protection as the type of respirator listed on the pesticide labeling. This second type of cab is termed in the ASAE S-525 an "ECPAR" - meaning "enclosed cab, pesticide application, respiratory protection." However, under the ASAE S-525 every ECPAR cab must provide respiratory protection equivalent to an organic vapor-removing cartridge respirator. Most US pesticide labels that require respiratory protection specify the use of a dust/mist filtering respirator only, not an organic-vapor filtering respirator (since the vapor pressure of many pesticides is low). It is the US EPA's understanding that most enclosed cabs equipped with air conditioners would provide respiratory protection equal to or greater than that provided by a quarter-face dust/mist filtering respirator (with NIOSH PF of 5). However, to their knowledge, currently no enclosed cabs that provide respiratory protection equivalent to a dust/mist filtering respirator (but not equivalent to an organic-vapor filtering respirator) are currently certified by the manufacturer or by a governmental agency. Such cabs would be expected to be less expensive to purchase and maintain.

Shoes plus socks (feet)	90

German BfR/BVL assigns PF to the following items that are not mentioned above.

Item	**BfR/BVL PF (%)**
Protective clothing against chemicals: Type 3	100
Broad-brimmed head gear of sturdy fabric (head)	50
Hood and visor (head)	95

4 Recommendations for research

- It is clear from the above considerations that further work is needed on the development of harmonized predictive exposure models. Work is in progress with AHED and a statistical evaluation of the exposure data to design possibly a better algorithm for the potential exposure assessment.
- Work is in progress on further evaluation of data on comparison of outer and inner dosimeters, as well as with whole body garments. The results may affect the quality of the arguments that underline choices for default penetration values.
- Further integration studies are needed on the work on material/fabric penetration and/or permeation and field studies with garment attires of chosen fabrics.
- There is a need for an agricultural standard for testing of protective clothing in Europe. The preferred standard seems to be the German standard DIN 32781. This requires actions at standardization level in Europe (CEN and ISO).
- The effective efficacy of PPE against chemical in real conditions of use (and not in standardized simulated work activities) is in particular depending on many factors which are not often correctly or sufficiently considered when drafting standards often based on empirical/conventional test methods and specifications. All these issues need to be more deeply checked trough inter-laboratory studies.
- There is hardly sufficient information on the relation between exposure scenarios, dermal loading and protection by clothing attires. The work in the Safe Use Initiative by ECPA seems an appropriate approach for studying these aspects, as well as the effect of training the operators (and workers) to prevent exposure and to improve the protecting effect of clothing and gloves.
- In particular, biological monitoring or whole-body dosimeter studies should focus on woven (launderable) and nonwoven (disposable) materials conducted over realistic time periods (e.g., a week with coveralls worn over long-sleeve shirt and long pants and a week with long-sleeve shirt and long pants without a coverall worn over them). This is important to factor in individual operator's habits as well as PPE maintenance, decontamination, and durability.[26]
- The present proposals for default values can be better underpinned when more solid data become available.

---

[26] Generally studies of this type will show significantly decreased protection factors versus studies using only new PPE for short periods of time.

5 Acknowledgments

The Dutch Ministry of Social Affairs and Employment is thanked for their financial support and great interest in the subject. Specific mention is made of Ad Vijlbrief, MSc and Esther Putman, PhD.
The authors want to thank all persons and institutions (see Table I in ANNEX A) that have contributed to this project by providing information and comments. In particular, the authors want to thank Christine Norman of PMRA who has been instrumental in getting collated comments from the North-American regulatory authorities. Alain Mayer is gratefully thanked for his contributions in the area of PPE testing and maintenance regulations in Europe.
Reading the document in its original and revised forms will indicate that indeed many contributions were very helpful and in several cases essential.

6 References

See Reference list in ANNEX A (page 55).

7 Signature

DEPARTMENT OF FOOD & CHEMICAL RISK ANALYSES

J.C.M. Mossink, M.Sc. Department Manager	J.J. van Hemmen, PhD Project Leader

A Consultation document

Summary

On request of the Dutch Ministry of Social Affairs and Employment, TNO has investigated current views and facts on the use of default values or approaches for the estimation of exposure mitigation efficiency (reduction effectiveness) of personal protective equipment (PPE) in registration processes of pesticides[27].
On the basis of this it is hoped that an internationally harmonized set of PPE protection factors for regulatory use, can be devised.

In order to reach this goal, it was concluded that recent literature on the issues involved should be evaluated, and that regulatory authorities in North America, Europe and Australia should be asked to indicate their regulatory approaches with respect to PPE effectiveness and the basis of these approaches. In addition to this, several industry organizations and academic groups working in the area were asked to provide their views and underlying evidence.

The results obtained are described in the present report. In view of a consultation round, still to be carried out, no choices for reduction factors in relation to type of PPE and use scenario are presented. An approach for this, based on the results of the consultation, will be presented at a later stage.

In the present document basic elements are considered, which can be summarized as follows. Some recommendations are also presented.

* Personal Protective Equipment can be defined as “any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards” (EU, 1989). For pesticides including biocides, both respiratory protective equipment (RPE)[28] and skin protective equipment (SPE) are relevant subgroups.
- Respiratory protective equipment (RPE) can be divided into filtering devices and air supplied devices. Both types of equipment consist of a face piece or mask and a filtering device (filter or filter cartridge) or air supply unit, respectively.
- Skin protective equipment[29] (SPE) can be defined as a combined assembly of garments worn to provide protection to the skin against exposure to or contact with chemicals. It includes all barrier systems intimate to individual persons, protective gloves and chemically impervious protective clothing. In Europe, work wear such as permeable coveralls, caps, etc. are only PPE if the European regulations for chemical protective clothing are fulfilled (*e.g.* performance testing in pre-market introduction tests, such as CE type examination).

---

[27] Pesticides are meant to include agrochemicals, microbiological agents and biocidal products (antimicrobials), for the present purpose.

[28] At EU level the term RPD (Respiratory Protective Devices) is used.

[29] SPE is defined for this paper only to cover chemical protective clothing and gloves, as well as work wear.

- The definition for PPE excludes permeable coveralls. The US Worker Protection Standards do define coveralls as PPE (not mentioning permeability). DPR considers coveralls as PPE.

* The overall performance of RPE to reduce inhalation exposure during actual use has been tested in specially designed workplace protection studies. Overall statistical evaluation of results of workplace protection factor (WPF) studies for types of RPE has resulted in assigned protection factors (APF), *e.g.* ANSI (1992) and BSI (1997). The APF are considered to be valid for 95% of adequately trained and instructed wearers. Since it is unknown if such WPF studies have been conducted in agricultural settings and since it is unlikely that all agricultural pesticides workers are adequately trained and instructed, APF values should be used with some caution.

* Very few data on overall field performance of skin protective clothing (CPC types 1-6) could be found. Most of the data that has been used to derive default exposure reduction vales are related to results (quantitative or pass/fail) of performance standard tests in the laboratory for repellence, retention, and penetration, permeation, or pressure/jet. Only a few intervention types of field studies, using biomonitoring, have been found, indicating lower reduction of exposure or uptake than the defaults used.

* Most of the default reduction factors are for layers of fabric that are worn in addition to normal clothing *e.g.* work clothing, permeable coverall. Retention of the layer or transfer through the layer has been studied by outer/inner dosimeter comparisons, mainly reflecting processes like penetration, permeation and deposition. Meta analysis of large data sets revealed an outer-loading dependency of the penetration (penetration decreases with loading). These studies are currently carried out by industry using new data and/or improved statistical methodology.

* Defaults for performance of protective gloves are generally derived from laboratory (material) integrity test data *e.g.* breakthrough times (BTT). As a basic condition for appropriate protection in practice BTT should exceed duration of actual use when the neat compound is used and the exposure is continuous. These conditions, however, do not happen frequently in practice. Furthermore, it has been demonstrated that the effectiveness of gloves is also, probably even much more importantly, determined by proper design and proper use *i.e.* the human factor. Similar to RPE adequate training and instruction is a basic condition to rely entirely on results of material integrity test results.

* A tiered approach for use of defaults of exposure reduction afforded by PPE might be appropriate. In such an approach the use of the ‘high end of the range’ reduction factors will be limited to those scenarios where adequate training and instruction of users of PPE can be demonstrated/documented.

* Since the use of pesticides in agriculture is very different in many cases to the use of chemicals in general (including many biocides) and in the chemical industry, it seems appropriate to consider the development of specific tests on the effectiveness of protective clothing and PPE that reflect agricultural use better than what is currently considered appropriate (Shaw *et al.*, 2001; 2004). Considerable work is in

progress (draft ISO TC94/SC 13 N: Protective clothing – Performance requirements for work and protective clothing for horticultural and agricultural pesticide workers). Germany is at the moment the only European country having defined a protective clothing standard (DIN 32781) specifically for agricultural workers handling pesticides.

* The default exposure reduction values currently used by different regulatory authorities vary widely and in many cases it is not clear what scientific or other basis they have. In many cases the default values are linked to generic descriptions of clothing or PPE which do not take into account variations which are practically important, such as use scenario and field performance.

CONTENTS (ANNEX A: Consultation document)

Page

LIST OF TABLES

INTRODUCTION

On request of the Dutch Ministry of Social Affairs and Employment, TNO has investigated current views and facts on the use of default values or approaches for the estimation of reduction effectiveness of personal protective equipment (PPE) in registration processes of pesticides[30].
On the basis of this it is hoped that an internationally harmonized set of PPE protection factors for regulatory use, can be devised.

In order to reach this goal, it was concluded that recent literature on the issues involved should be evaluated, and that regulatory authorities in North America, Europe and Australia should be asked to indicate their regulatory approaches with respect to PPE effectiveness and the basis of these approaches. In addition to this, several industry organizations and academic groups working in the area were asked to provide their views and underlying evidence.

The present document is a first step in the process of preparing guidance on the development of an appropriate regulatory approach, which of course has a very high policy-determined aspect. In the present document the available evidence and approaches will be presented and no choices for approaches will be made.

The present document was sent to all organizations and persons that have been so kind to provide the requested information for checking the accuracy of the data/information included and provide comments on the text. On the basis of the results of that exercise, the document was improved, and will be made available to a wider audience for use in regulatory discussions on the issues involved in Europe and possibly elsewhere.

The more detailed approach in the present project was to take the recent report prepared in the context of a CEFIC Long Range Initiative project as a starting point. This report "Skin Protection Strategies: Evaluation of Real and Theoretical Effectiveness of Skin Protective Equipment in Industrial Exposure Scenarios. Summary of Project Results" (Brouwer *et al.*, 2005) gives a good introduction of all relevant aspects when effectiveness of PPE is to be considered.[31]

First of all, the methods used will be described in some detail, followed by the scope of the current approach for the determination of effectiveness of PPE (dermal and inhalation), which focuses on pesticide use scenarios. The results of the literature and overviews of the responses by experts from regulatory authorities, industry and academia are presented in tables. A chapter on current developments as indicated by the respondents is included. The results obtained will be discussed and some preliminary conclusions will be drawn.

---

[30] Pesticides are meant to include agrochemicals, microbiological agents and biocidal products (antimicrobials), for the present purpose.

[31] Exposure terminology used in the present document complies with the glossary adopted by ISEA (Zarterian et al., 2005) and the terminology as proposed by CEN (2006).

METHOD

Literature search

In order to find relevant articles on PPE performance and use, the following databases have been searched and articles from the time period 2000-2005 have been selected:

- OSH ROM: HSELINE
- OSH ROM: CISDOC
- OSH ROM: MHIDAS
- OSH ROM: NIOSHTIC2
- OSH ROM OSHLINE
- OSH ROM MEDLINE OEM
- Current Contents
- PubMed

The search items pestic*, bioci*, and microb* have been used in combination with the following (combinations of) search terms for the literature search: person*, protect*, equip*, efficie*, comfort*, PPE*, default*, effect*, occup*, expo*, glove*, clothi*, respi*, RPE*. Articles have been selected based on their abstracts. Abstracts regarding qualitative and/or quantitative information on PPE performance and use were selected. This means that PPE had to be a relevant subject in the described studies. The articles were read with care and (if the article indeed contained relevant information regarding PPE) were used to prepare the overview.

The choice for the most recent period for the literature search was indicated for two reasons which were not at all based on sound scientific approaches. We were aware of the most relevant literature from the past, which to a very large extent is available in the very important series: Performance of Protective Clothing[32] proceedings of symposia organized for ASTM (American Society for Testing and Materials), where pesticide studies form an important part of. The second reason was that a detailed literature survey was considered to be outside scope and budget of the present project.

Available models/approaches with default factors

An overview is made of models/approaches which are used in the exposure estimates with their default factors for PPE.

Contacts with institutes, authorities and industry

A letter or email with attached letter was sent to several contact persons of authorities, industry and Universities requesting information on PPE. The letter is presented in Appendix 1. Persons who contributed relevant information regarding PPE are presented in Table I.

---

[32] This refers to STP 900 (1986); 989 (1989); 1037 (1989); 1133 (1992); 1237 (1996); 1273 (1997); 1386 (2000); 1462 (2005), ASTM, Philadelphia, PA, USA.

Table I Overview of contact persons contributing relevant information

Authorities	**Country/Region**	**Contact person**
APVMA	Australia	Dave Loschke
BAuA	Germany	Urs Schlueter, Dagmar Holthenrich
BfR	Germany	Dieter Westphal
Cal DPR	California	Joseph Frank, Sally Powell, Thomas Thongsinthusak, Harvard Fong
EPA	USA	Jeff Evans, Timothy Leighton, Alan Nielsen, Timothy Dole
HSE	United Kingdom	Stephen Kinghorn-Perry
ICPS	Italy	Marco Maroni
INRA	France	Thierry Mercier
INSHT	Spain	Pedro Delgado, Eva Cohen
PMRA	Canada	Christine Norman, Cathy Campbell, Mary Mitchell
PSD	United Kingdom	Paul Hamey
INRS	France	Alain Mayer
National Product Control Agency for Welfare and Health	Finland	Jouni Raisanen
Industry	**Country/Region**	**Contact person**
ACC Biocides	North America	Has Shah, John Ross
AHETF	North America	Curt Lunchick
ARTF	North America	Dave Johnson, Eric Bruce, Victor Cañez, Stephan Korpalski
CEFIC Biocides	Europe	Michel Michaux
ECPA	Europe	Wolfgang Maasfeld, Graham Chester; Heinrich Wicke
Academia	**Country**	**Contact person**
University of California at Riverside	USA	Bob Krieger
University of Maryland Eastern Shore	USA	Anugrah Shaw
University of Washington	USA	Richard Fenske
University of Milan	Italy	Manuela Tiramani
Other	**Country**	**Contact person**
SUI-project (ECPA)	Europe	Hans Felber

SCOPE

Following the legally required hierarchy of the risk reduction options with occupational risk management approaches, preference should be given to interventions on the level of source or substance, *e.g.* engineering controls, whereas interventions or controls at the level of persons involved, *e.g.* personal protection, are the least preferable. However, in practice many control measures at higher level may not be appropriate or may not in themselves be sufficient. This specifically holds for application of pesticides.

The use of personal protective equipment often is acceptable, particularly for non-routine operations.

Personal Protective Equipment can be defined as “any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards”. For pesticides both skin protective equipment (SPE) and respiratory protective equipment (RPE) are relevant subgroups. PPE is legally defined in most countries and should fulfill defined test criteria.

SPE can be defined as a combined assembly of garments worn to provide protection to the skin against exposure to or contact with chemicals. It includes all barrier systems intimate to individual persons, such as work wear, protective gloves, and chemical protective clothing.

Respiratory protective equipment (RPE) can be divided into filtering devices and air supplied devices. Both types of equipment consist of a face piece and a filtering device (filter or filter cartridge) or air supply unit, respectively.

PPE is designed to operate by reducing the mass transport of a contaminant towards the respiratory system or the skin contaminant layer (layer on the outside of the skin that may become contaminated). A portion of the mass transported will be retained by the PPE, whereas another part will reach the skin contaminant layer directly. The main processes involved are:

- Permeation, *i.e.* the (diffusion driven) transport at molecular level through a liquid-tight membrane.
- Penetration, *i.e.* the macroscopic transport of a contaminant through small holes in a fabric or material, small imperfections, seams and closures or leakages.

Degradation of the material, *i.e.* change of the physical properties of the material due to chemical reactions, may modify permeation and penetration.

In addition, two other processes are relevant for skin contamination:

- Deposition/transfer, *i.e.* the transport of a contaminant onto the skin not covered by SPE or through openings in garments. It includes also deposition of aerosols underneath SPE resulting from the so called ‘bellows effect’ by movements of the user.
- Transfer, *i.e.* mass transport by contact of the inside of the PPE or the skin underneath with contaminated surfaces, including the outer surface of skin protective equipment. This will often take place during removal of the PPE by the user.

PPE performance evaluation

Clear laboratory test criteria have been developed for filters, cartridges and masks. While this type of testing is still considered appropriate for certification (*e.g.* CE marking in Europe), characterization of the actual level of protection offered to a wearer in an exposure scenario using a particular type of device has been shifted from the use of test criteria to evaluate protection performance (nominal protection factor) in a laboratory to a statistically driven approach of field performance data for RPE. Such studies are known as Workplace Protection Factor studies. In such a study, measurements of the contamination (concentration) inside the respirator face piece and the concentration outside the mask during field studies are collected according to a defined protocol. Protection factors (PF) are expressed as ratios between outside and inside mask concentrations. PF data are evaluated to determine the 95th percentile (lower bound) which is defined as the assigned protection factor (APF). The APF represents a level of protection that is expected to be achieved by 95% of the wearers after an appropriate level of training and supervision. PFs are relative units that indicate the efficiency of mass transport by penetration and (mask) leakage processes. In field studies PFs reflect the interaction between wearer and device. The contribution of penetration and permeation through filtering parts of RPE is considered to be of minor importance to the 'inside mask' concentration, because particle filters and cartridges are subject to standard laboratory tests for certification and their retention efficiency is well-documented.

Similar to pre-market tests required by the European Union (CE marking tests) for filtering device material for respiratory protection, laboratory SPE material integrity tests exist. Analogous to respiratory protection, these include non-substance specific penetration tests where a physical parameter (*e.g.* aerodynamic diameter) is the key factor, and tests that rely on substance-material interactions, *i.e.* substance-specific permeation (and degradation) tests.

Complementary to material tests there are whole garment tests for liquid or gas leakage/ tightness, where results are determined by design and mechanical stability of the SPE. These tests are analogous to laboratory tests for performance of respiratory protection equipment including mask and filtering devices.

Contrary to respiratory protection, no CE marking workplace (simulation) tests exist where SPE-human factor interaction and its effect on overall SPE performance are tested. This hampers the extrapolation from test results to protection in workplace practice and also emphasizes the need to consider how SPE performance should be expressed. It is particularly relevant to investigate the effect of processes where substance specificity is less relevant, *e.g.* deposition, direct contact, and transfer by contamination through use. However, positive developments are currently made ((draft ISO TC94/SC 13 N: Protective clothing – Performance requirements for work and protective clothing for horticultural and agricultural pesticide workers).

Table II summarizes similarities and differences of respiratory and skin protection performance testing.

The performance of PPE has been reported in literature in various metrics. In the present document all quantitative performance data have been recalculated and are expressed as percentage reduction, *i.e.*

$$\frac{[\text{Exposure without PPE} - \text{Exposure with PPE}]}{\text{Exposure without PPE}} * 100\%$$

The performance of RPE is thus expressed as a protection factor which reflects a reduction of the exposure concentration, *i.e.* the ratio of outer/inner RPE exposure concentration. If the conceptual surface over the nose and open mouth is considered to be the exposure surface, it is obvious that reduced exposure concentration will reduce intake, *i.e.* the mass of agent crossing this surface to the respiratory tract.

Table II Similarities and differences for respiratory and skin protection performance testing

	Respiratory protective equipment (RPE)		**Skin protective equipment (SPE)**	
Ultimate goal	Reduction of intake		Reduction of uptake/ contact	
Lab testing: materials/devices	Filtering devices	Penetration (non substance specific)	SPE material	
				Penetration (non substance specific)
		Gas capacity (partly substance specific)		Permeation (substance specific)
				Degradation (substance specific)
	Masks	Penetration (non substance specific)	SPE ensemble (suits)	Penetration (gas/aerosol/liquid-tight suit tests)
			Gloves	Leak tests
User-interaction	Mask + filtering device	Lab simulated work activities	SPE ensemble (suits)	Lab simulated work activities (*e.g.* inward leakage tests)
		Simulated workplace protection studies	SPE (gloves + suits)	Simulated workplace protection studies
Workplace performance	Mask + filtering device	Workplace protection studies		Workplace protection studies

In analogy to these concepts, Brouwer *et al.* (2005) discussed terminology related to the evaluation of in-use performance of SPE. The term ‘protection’ should be assigned to the results of the evaluation of the SPE to reduce uptake (or skin effects) under workplace conditions.

Workplace protection studies are conducted to generate data on PPE performance under conditions of actual use in the workplace. In case actual workforce is used, but workplace conditions, *e.g.* performance of tasks, environmental conditions, are simulated such studies are referred to as simulated workplace protection studies.

Since both uptake and skin effects are substance-specific, it follows that strictly speaking, no SPE generic protection performance can be derived for certain barrier materials.

Quantification of reduction of exposure concentration by SPE would be the second best option. As with uptake, however, there are currently no standardised methods to measure exposure concentration as it has been defined above for RPE. Alternatively, the measurement of either 'exposed skin surface area', 'exposure loading' or 'exposure mass' can be used.

Since different sampling techniques reflect different exposure parameters, measurement results will indicate different parameters of reduction or 'protection'. It is therefore appropriate to indicate the parameter of 'protection' by a generic notation $\mathbf{PF_{XXXX}}$, where $_{XXXX}$ indicates the protection parameter involved. This will prevent confusion and avoid non-comparable results within and between studies on Protection Factors.

It should be noted that reduction of exposure (loading/mass) can only be determined by comparison of scenarios with and without SPE by intervention type of studies. Table III summarizes the different types of protection factors that can be distinguished and indicates in each case the type of measurement that is needed for quantification.

For reason of completeness, the result of an evaluation of the performance of SPE to exclude or retain contaminants is also included in Table III. The evaluation is based on within-experiment comparison of dosimeter results placed outside and inside SPE and reflects reduction of transport of contaminant through SPE (by permeation and penetration) during use. Strictly speaking in this case, the term 'protection' is incorrect; however, to avoid confusion the performance will be expressed as PF_{CNTM}.

Table III Indicators for the evaluation of the in-use performance of SPE

Type	**Metric**	**Remarks**
Evaluation of the performance of SPE to reduce exposure concentration under workplace conditions	(Substance specific) protection factor PF_{CONC} (ratio of exposure concentration without/ with SPE)	Intervention type of studies in combination with reliable methods to assess or estimate exposure concentration, *e.g.* tape stripping
Evaluation of the performance of SPE to reduce exposure loading or exposed surface area under workplace conditions	Protection factor PF_{LOAD} (ratio of reduction of skin loading (without/ with SPE) *i.e.* mass per surface area exposed (mg/cm^2 or mass/ body part over duration of exposure)	Intervention type of studies in combination with reliable methods to assess exposure loading or surface area exposed, *e.g.* direct methods and removal methods
Evaluation of the performance of SPE to reduce exposure mass under workplace conditions	Reduction factor PF_{MASS} (ratio of reduction of exposure mass (without/ with SPE))	Intervention type of studies in combination with reliable methods to assess exposure mass, *e.g.* removal methods (interception techniques)
Evaluation of the performance of SPE to exclude or retain contaminants under workplace conditions	Reduction factor PF_{CNTM} Ratio of reduction of collected mass outer/ inner SPE	Comparison of integrated mass outside SPE versus integrated mass inside SPE, *e.g.* by interception techniques such as (inner/outer) dosimeters

PPE ergo-comfort

The actual use of PPE will be heavily determined by the acceptance of PPE by the end-user. In general, the suitability to perform the task while using PPE will depend on the design and material of the PPE in combination with the ergonomic demands of the task. The (dis)comfort of wearing PPE will depend on comfort and thermo-physiological aspects of the PPE design and the environmental conditions. Items such as anthropometry, biomechanics, biological and sensory aspects, thermal characteristics, communication, psychological aspects, and practicability play a role in the area of ergo-comfort of PPE.

To include ergo-comfort in the selection of PPE factors reported in literature were categorized and clustered in main categories (Goede *et al.*, 2001, Brouwer *et al.*, 2003). For the RPE selection system seven major categories could be distinguished, whereas for the SPE system three categories were identified (Tables IVA and IVB, respectively).

Table IVA Principal categories of ergo-comfort factors for respirators

Main category	**Example of factors**
Vision	Visual field Visual acuity
Communication	Audibility of users' speech Users' hearing
Respiration	In/ exhalation (breathing resistance) CO_2-retention
Physical task performance	Mobility Body posture Dexterity/ stability/ precision
Environment	Heat stress/ Cold Other hazards
Comfort	Overall-fit (skin, eyes, head) Put-on, removal Combination with other PPE
Mental	Responsibility, stress

Table IVB Principal categories of ergo-comfort factors for protective gloves

Main category	**Example of factors**
Biomechanical	Grip Force
Task performance	Precision/ dexterity Mobility Fit
Comfort	Thermo-physiological Put-on removal (Fit)

For respirators many factors have been identified that are considered relevant to evaluate the degree of hindrance and the ability to perform the task. Factors associated with physical parameters (*e.g.* heat stress, breathing resistance, moisture, noise) have been quantified for several types of respirators. Most research emphasizes the importance of (thermo) physiological effects.

Biomechanical parameters such as angle of affection, grip patterns, etc., have been identified as relevant to characterize hand and finger movements. No readily available field methods are known to evaluate related factors such as precision and dexterity, force, grip and mobility for a specific task either quantitatively or qualitatively. For experimental evaluations of grip and force, however, quantitative methods are used. Research in this field mainly focuses on the hindrance caused by the use of protective gloves or clothing.

The level of relevance of the factor for the work task was divided into three categories of 'work task relevance scores' ranging from low priority to high priority. Similarly, PPE device or equipment was categorized into three categories of 'performance scores' ranging from slight hindrance to severe hindrance (Table V).

The concept to integrate ergonomic and comfort aspects into a PPE selection system has not been worked out in more detail. No scientifically-sound work task analysis is available to evaluate the 'relevance' of ergo-comfort factors for the work situation. Hence, major parts of the assessment will be based on subjective estimates. In addition the availability of data on PPE (type) 'performance' (*i.e.* the level of hindrance) is very limited and might be a key factor for further development. Another major challenge is the development of justifiable classification bands for each ergo-comfort factor.

Table V Overview of scoring and weighing method (gloves)

Factor (i-j)	**Work task relevance**	**W-score**	**PPE performance**	**P-score**	**End score**
I	Very relevant	10	Slight/ no hindrance	10	PS_i-WS_i
	Relevant	3	Moderate hindrance	3	
	Not relevant	1	Severe hindrance	1	
J	Very relevant	10	Slight/ no hindrance	10	PS_j-WS_j
	Relevant	3	Moderate hindrance	3	
	Not relevant	1	Severe hindrance	1	
Total					$\Sigma_{I,j}$(/n)

RESULTS OF LITERATURE SEARCH AND SURVEY (INQUIRY)

PPE performance and use in recent literature (2000-2005)
Published studies over the period 2000-2005 were reviewed with respect to data on PPE performance or use. Overall 37 publications were found and categorized (where possible) according to the type of study, *e.g.* field study, survey, review, experimental study, intervention study and the type of PPE performance described in the paper, *i.e.* reduction of uptake, reduction of exposure loading, reduction of contamination or material performance. The results are summarized in Table VI.
Most papers (n=12) address material performance issues, whereas only 6 papers report studies on reduction of uptake by the use of PPE. Two of these six studies were designed as an intervention type. Six papers report studies on reduction of contamination.
Seven studies report surveys on the (determinants) of use of PPE, or address factors related to 'wear ability' otherwise. Three papers report studies on comfort from which two papers report on thermo physiological aspects.

Quantitative data on the effectiveness of PPE, either SPE, RPE or combinations were reported by Acqavella *et al*. (2004) on SPE; Berger-Preiβ *et al.* (2005) on SPE ; Brouwer *et al*.(2002) on SPE; Creely *et al.* (2001) on SPE; Fenske *et al.* (2002) on SPE; Krieger *et al.* (2000) on SPE; Marin *et al*. (2004) on SPE; van der Jagt *et al.* (2004) on SPE/RPE combination, and Lee *et al*. (2005) on RPE.

The studies on reduction of uptake by SPE differ substantially in design, and number of data points, as well as results on reduction of uptake. Brouwer *et al.* (2000) reported median reduction of uptake by about 40% for applicators and re-entry workers and Fenske *et al.* (2002) reported a 38% reduction of uptake, whereas Acqavella *et al.*(2004) and Marin *et al.* (2004) reported 80% reduction. Different pesticides were studied. Van der Jagt *et al.* (2004) also reported reduction of uptake by SPE/RPE combination of about 75%, however, pre- and post intervention scenario were not completely similar in view of potential exposure and pre-exposure metabolite levels. In addition, Brouwer *et al.* (2000) reported reduction of exposure loading of the hands by the use of gloves by 95% (median) for applicators using nitril gloves, and 87% (median) for harvesters using cotton gloves. Berger-Preiβ *et al.* (2005) reported 95%-99% reduction of contamination due to gloves for biocidal antifouling applications in a very limited dataset (3 applicators). Creely *et al.* (2001) also reported a (geometric mean) reduction of contamination due to gloves of more than 99%. Fenske *et al.* (2002) reported 93% to 95% reduction of contamination due to protective clothing.
Lee *et al.* (2005) reported that in more than 50% of replicates monitored no agreement was observed with the assigned protection factor of a type of respirator in an airborne dust and micro organism exposure scenario.

Surveys on the actual use of PPE showed that less than 50% of the users were in compliance with label requirements (Perry *et al*., 2002). Training and educational intervention resulted in more frequent use of PPE (Hwang *et al*., 2000; Mandel *et al*., (2000); Perry *et al.,*2003), as well as in increased effectiveness (van der Jagt *et al*., 2004).

Hayashi *et al.*, (2000 and 2004) reported in two papers the effect of two different SPE (protective clothing) and RPE (mask with and without exhaust valve) respectively, on thermo-physiological aspects. A paper of Stone *et al.* (2005) reported that applicators feel more comfortable wearing cotton liners underneath their chemical resistant gloves.

In summary it can be stated that only a limited number of studies on the effectiveness of PPE (in agro exposure settings) have been reported since 2000. In most cases data on reduction of exposure loading of the hands by gloves are reported. Levels of reduction from 85% up to 99% were reported. Biomonitoring data on reduction of uptake are, as discussed in the previous section, both PPE-type and pesticide specific, and therefore the data are of limited value in view of generic protective performance of PPE. In general, however, the data indicate that reduction of uptake is well below 80%.

Data on the use of PPE are hardly available (Garthwaite, 2002) but they generally show that frequency of use in actual field practice is relatively low, probably due to factors of unawareness and factors related to the ability to wear PPE. Information, education and training will improve the frequency and effectiveness of use, however improvement of design factors related to comfort and ergonomics are expected to be also very beneficial for frequency of use. There may be, however, wide variation in actual uses over countries or even within countries, depending on (quality of) training and regulations, as well as formal inspections.

Specific papers on (ergo)comfort issues of PPE are scarce (Chester *et al.*, 1990) and mainly cover thermo physiological aspects with regard to SPE and RPE.

The PHED database has been searched for sets of inner and outer dosimeter data on clothing that may give proper indications of the protective nature of the material (There were not sufficient data for whole body garments). Powell of California Department of Pesticide Regulation has started such work for the NAFTA Technical working Group on Pesticides[33]. The results were -to our knowledge- never finished, but some results were published (Ross *et al.*, 1997). The main observation was that there were differences between the types of clothing and that the degree of penetration through the clothing was dependent on the loading i.e. penetration being higher with lower loading. A wide variety of pesticides were used for obtaining the data. With linear regression analysis (Ross *et al.*, 1997) it appeared on the basis of the data used that

$$\text{percent penetration} = 3.3\ (\text{outer loading in ug/cm}^2)^{-0.3}$$

This leads to on average 11% penetration at levels of 0.007-0.047 ug/cm^2, according to a table representing the data. This means about 140-940 µg on the body (20,000 cm^2), assuming homogeneous loading. Between 0.047 and 0.511 µg/cm^2 (940-10,200 µg on the body) this amounts to on average 6 % penetration. These data are very similar to the data of Powell.[4] In the table in that report 90% upper prediction limits are also given. For penetrations below 10%, the dermal loading must be higher than about 2 ug/cm^2. This amounts to about 40 mg on the whole body (assuming homogeneous distribution).

---

[33] International Harmonization Position Paper. Protection factors. Part I. Analysis of PHED Data (draft), October 1997.

There is no explicit quantitative information on the effect of the garment material on the degree of penetration. The above data describe an overall picture using all relevant available data from the PHED database.
This work is currently being extended/finished by Infoscientific.com on behalf of the American Chemistry Council.

Table VI Overview of literature (2000-2005)

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
1	Zeigler, J.P., 2000. Protective clothing: exploring the wearability issue, Occupational Hazards, 62 (9): 81-83.	Descriptive	SPE	n.a.	n.a.	Nine elements of wearability are: 1. reliable barrier protection and durability 2. proper fit 3. ease of care, maintenance and repair 4. flexibility and lightweight 5. comfort and heat stress 6. ruggedness of construction 7. donning and doffing characteristics 8. Ease of cleaning, disposal, recycling 9. proper garment design
2	Gao, P., Tomasovic, B., 2005. Change in tensile properties of neoprene and nitril gloves after repeated exposures to acetone and thermal decontamination, Journal of Occupational and Environmental Hygiene, 2: 543-552.	Experimental (laboratory)	SPE	Material performance	n.a.	Investigated the change in tensile properties of neoprene and nitril gloves resulting from thermal decontamination for re-use of the gloves.
3	Guo, C., Stone, J., Stahr, H.M., Shelly, M., 2001. Effects of exposure time, material type, and granular pesticide on glove contamination, Arch. Environ. Contam. Toxicol., 41: 529-536.	Experimental (laboratory)	SPE (gloves)	Material performance	n.a.	Contamination levels for the chemical-resistant glove materials nitril, neoprene, and barrier laminate varied between the time of exposure, material type, and pesticide used. Contamination of nitril was significantly less than neoprene or barrier laminate
4	Hayashi, C., Tokura, H., 2000. Improvement of thermo physiological stress in participants wearing protective clothing for spraying pesticide, and its application in the field, Int. Arch. Occup. Environ.	Experimental (laboratory and field)	SPE (protective clothing)	n.a.	n.a.	Study compared two kinds of protective clothing: Gore-Tex clothing, mask, polyurethane gloves, and rubber boots (A) and pesticide proof clothing, mask, Gore-Tex gloves, and special boots consisting of rubber for the feet and ankle ad Gore-Tex

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
	Health, 73: 187-194.					around the legs (B). In addition, the head and chest were cooled by frozen gel strips fixed in the cap and undershirt. Results show that protective clothing B could reduce thermal stress during spraying of pesticides in an apple orchard in summer.
5	Hayashi, C., Tokura, H., 2004. The effects of two kinds of mask (with or without exhaust valve) on clothing microclimates inside the mask in participants wearing protective clothing for spraying pesticides, Int. Arch. Occup. Environ. Health, 77: 73-78.	Experimental (climate chamber)	RPE	n.a.	n.a.	Study compared two kinds of mask on thermo physiological stress. Clothing microclimate temperature and humidity were significantly lower in the mask with exhaust valve than in the mask without exhaust valve. Cheek chin temperature inside the mask was kept significantly lower in the mask with exhaust valve. Clothing microclimate humidity at trunk level increased more slowly with the mask with exhaust valve for 4 out of 5 participants. Rectal temperature increased more slowly with the mask with exhaust valve for 3 out of 5 participants. Tympanic temperature increased more slowly with the mask with exhaust valve than the mask without exhaust valve for 2 out of 4 participants.
6	Jain, R., Raheel, M., 2003. Barrier efficacy of woven and non woven fabrics used for protective clothing: predictive models, Bull. Environ. Contam. Toxicol., 71: 437-446.	Experimental (laboratory)	SPE (protective clothing)	Material performance	n.a.	Penetration study (% penetration) on 16 woven and non-woven fabrics to develop statistical predictive models
7	Krzemińska, S., Szczecińska, K., 2001. Proposal for a method for testing	Experimental (laboratory)	SPE (gloves and	Material performance	n.a.	Proposal for test method for resistance to penetration of pesticides for clothing and

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
	resistance of clothing and gloves to penetration by pesticides, Ann. Agric. Environ. Med, 8: 145-150.		protective clothing)			gloves
8	Lee, S., Obendorf, S.K., 2005. Statistical model of pesticide penetration through woven work clothing fabrics, Arch. Environ. Contam. Toxicol., 49: 266-273.	Experimental (laboratory)	SPE (woven work clothing)	Material performance	n.a.	Fabric cover factor, yarn twist factor, viscosity of pesticide mixture, critical surface tension of solid, and wicking height are significant parameters affecting pesticide penetration
9	Nielsen, J.B., Andersen H.R., 2001. Dermal in vitro penetration of methiocarb, paclobutrazol, and pirimicarb: effect of nonylphenolethoxylate and protective gloves, Environmental Health Perspectives, 109, nr 2, February 2001, 129-132.	Experimental (laboratory)	SPE (gloves)	Material performance	n.a.	Latex and nitril materials both significantly reduced the percutaneous penetration of three pesticides. Nitril generally offered better protection than did latex, but the degree of protection decreased over time and depended on the pesticides used.
10	Phalen, R.N., Que Hee, S.S., 2003. Permeation of captan through disposable nitrile glove, Journal of Hazardous Materials, B 100: 95-107.	Experimental (laboratory)	SPE (gloves)	Material performance	n.a.	Results indicate high chemical resistance of the disposable nitrile glove to a highly concentrated aqueous emulsion of captan
11	Raheel, M., Dai, G.X., 2002. Viability of textile systems for hand and body protection: effects of chemical interaction, wear, and storage conditions, Bull. Environ. Contam. Toxicol., 69: 164-172.	Experimental (laboratory)	SPE (gloves and protective clothing)	Material performance	n.a.	Study focused on the effects of chemical interaction and low temperature on various gloves materials; as well as the effects of abrasion that may occur due to repeated wear and laundering, on barrier efficacy of a number of fabrics used as full body protective clothing. Results show that latex, rubber, neoprene, nitrile, and Viton glove polymers showed a highly significant reduction in puncture resistance. However,

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
						there were no significant changes in tensile property of the materials. In general, the woven fabrics allowed much greater penetration of liquids that non-woven and repellent finished fabrics.
12	Shaw, A., Cohen, E., Hinz, T., Herzig B., 2004. Laboratory test methods to measure repellency, retention and penetration of liquid pesticides through protective clothing: Part 2: Revision of three test methods, Textile Res. J. 74: 684-688.	Experimental (laboratory)	SPE	Material performance	n.a.	In this study three test methods (ISO 6350/EN368 gutter test, atomizer test (developed in Germany), pipette method (ASTM)) for screening protective clothing materials against pesticides were modified so they can be used to measure the performance of fabrics based on different exposure conditions. Results are used to determine the level of exposure(s) that the test methods represent while screening materials against liquid pesticides.
13	Shaw, A., Cohen, E., Hinz, T., 2001. Laboratory test methods to measure repellency, retention and penetration of liquid pesticides through protective clothing: Part 1: Comparison of three test methods, Textile Res. J. 71: 879-884.	Experimental (laboratory)	SPE	Material performance	n.a.	Study on three test methods (ISO 6350/EN368 gutter test, atomizer test (developed in Germany), pipette method (ASTM)) for screening protective clothing materials against pesticides. Comparison of these test methods is made on suitability for screening protective clothing materials against liquid pesticides. Results indicate that the evaluation of fabric performance is affected by the test method.
14	You, K.S., Lee, M.H., Park, K.H., 2005. A rat model to evaluate the pesticide permeability and stress effects of protective clothing, Toxicol. Ind. Health, 21 (3-4): 49-55.	Experimental (laboratory)	SPE	Material performance	n.a.	Study to design a rat model to examine pesticide permeability and physiological responses to protective clothing materials. In this study as a comparison also human subjects performed treadmill work with and

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
						without protective clothing (commercial Tyvek) resulting in significantly higher body temperatures for subjects wearing protective clothing compared to regular work suits and significantly increased heart rate responses for subjects wearing protective clothing.
15	Zainal, H., Que Hee, S.S., 2005. Permeation of Telone EC^{TM} through protective gloves, Journal of Hazardous Materials B124: 81-87.	Experimental (laboratory)	SPE (gloves)	Material performance	n.a.	Permeation study on nitrile and multi-layer gloves against Telone EC formulation shows that the multi layer gloves offered about 2.5 times more protection for 8h than nitrile gloves.
16	Acqavella, J.F., Alexander, B.H., Mandel, J.S., Gustin, C., Baker, B., Chapman, P., Bleeke, M., 2004. Glyphosate biomonitoring for farmers and their families: results from the Farm Family Exposure Study, Environmental Health Perspectives, 112, Number 3, March 2004; 321-326.	Exposure study (field biomonitoring)	SPE (gloves)	- Uptake reduction	- 80% reduction uptake	Farmers who did not use rubber gloves during mixing and loading had higher GM urinary concentrations than did other farmers (1- ppb versus 2 ppb)
17	Baldy, I., Lebailly, P., Jean, S., Rougetet, L., Dulaurent, S., Marquet, P., 2005. Pesticide contamination of workers in vineyards in France, summary, Journal Expo. Environ. Epidemiol. Sep 21; 1-10.	Exposure study (field; patches and hand washes)	Not specified	Reduction of contamination	n.a.	Studied the specific dermal and inhalation exposure levels for different tasks in vineyards and determined parameters related to the daily contamination of workers. Results of the study show that the use PPE resulted in a limited decrease of contamination.
18	Fenske, R.A., Birnbaum, S.G., Methner, M.M., Lu, C., Nigg, H.N., 2002. Fluorescent tracer evaluation of	Exposure study (field; fluorescent tracer)	SPE (protective clothing)	Reduction of contamination/reduction of	93-95% reduction of contamination	Chemical protective clothing performance was determined beneath garments for different chemical protective clothing

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
	chemical protective clothing during pesticide applications in central Florida citrus groves, J. Agric. Saf. Health. Aug; 8 (3): 319-331.			exposure loading		regimes (cotton work shirts and work pants, cotton/polyester coveralls, and two non-woven garments) with a fluorescent tracer technique which measured the deposition on skin surfaces. Results show that fabric penetration was detected for all garments: 5-7% of the pesticide ethion measured outside the garments was found beneath the garments.
19	Harris, S.A., Sass-Kortsak, A.M., Corey, P.N., Purdham, J.T., 2002. Development of models to predict dose of pesticides in professional turf applicators, Expo. Anal. Environ. Epidemiol. Mar; 12 (2): 130-144.	Exposure study (field biomonitoring) and survey (questionnaire)	SPE (gloves)	Uptake reduction	n.a.	Although the majority of individuals wore gloves while spraying pesticides, the individuals who did not wear gloves received significantly higher doses. Moreover the use of long gloves (elbow) appeared to provide better protection as compared with short gloves (wrist) and no glove protection. Most individuals (66%) always wore gloves while rolling in the spray hose into the truck and had significantly lower doses as compared to the 27% who never wore gloves. Very few applicators used respirators or wore coveralls over their clothing and almost all wore boots. The use of glasses or hat did not appear to afford better protection. Close to half the applicators in the study wore a short sleeved T-shirt and had significantly higher total and mean doses than those who were wearing long-sleeved shirts (almost al these individuals did not wear gloves also and used other technique).

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
20	Krieger, R.I., Dinoff, T.M., 2000. Captan fungicide exposures of strawberry harvesters using THPI as a urinary biomarker, Arch. Environ. Contam. Toxicol. 38 (3): 398-403.	Exposure study (field biomonitoring)	SPE (gloves)	Uptake reduction	38% reduction	Normal work clothing of female strawberry harvesters was supplemented with rubber latex gloves (new each day) (and facial scarves) to determine whether those measures reduced exposure. Results show that clean rubber gloves reduced absorbed dose by 38%, compared to bare–handed harvesters.
21	Lee, S., Adhikare, A., Grinsphun, S.A., McKay, R., Shukla, R., Zeigler, H.L., Reponen, T., 2005. Respiratory protection provided by N95 filtering face piece respirators against airborne dust and microorganisms in agricultural farms, Int. J. Occup. Environm. Hyg., 2: 577-585.	Exposure study (field) Particle sizes in and outside of respirator	RPE (N95 filtering face piece respirator)	Reduction of contamination	More than 50% of the measured workplace protection factors for micro organisms were less than the proposed assigned protection factor of 10 (90% reduction)	Specific for airborne dust and micro organisms of different particle size ranges
22	Stone, J., Coffman, C., Imerman, P.M., Song, K., Shelley, M., 2005. Cotton liners to mediate glove comfort for greenhouse applicators, Arch. Environ. Contam. Toxicol., 49 (3): 421-428.	field and survey questionnaire	SPE (gloves)	n.a.	n.a.	Applicators reported feeling more comfortable with cotton liners under their chemical resistant gloves than without and that cotton liners were easy to manage and had no difficulties doing their work related to wearing the liners.
23	Berger-Preiβ, E., Boehncke, A., Könnecker, G., Mangelsdorf, I., Holthenrich, D., Koch, W., 2005. Inhalational and dermal exposures during spray application of biocides,	Exposure study (field patches and workplace simulations)	SPE (gloves)	Reduction of contamination	95-99% reduction gloves (2 out of 3 applicators)	Dermal exposure for antifouling applications increased by a factor of about 10 during improper application. Dermal exposure was reduced 95-99% if the operator wore protective gloves during spraying (2 out of 3

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
	Int. J. Hyg. Environm. Health 208: 357-372.					operators).
24	Creely, K.S., Cherrie, J.W., 2001. A Novel Method of assessing the effectiveness of protective gloves - results from a pilot study, Ann. Occup. Hyg., 45: 137-143.	Field trial	SPE (gloves)	Reduction of contamination	>99% reduction gloves (GM)	Geometric mean protection factors were calculated from the ratio of outer and inner sampling glove contamination being obtained from two nitrile and PVC gloves (470, 200, 96). High protection factors probably due to short sampling period of approximately 20 minutes.
25	Marín, A., Martínez Vidal, J.L., Egea Gonzalez, F.J., Garrido Frenich, A., Glass, C.R., Sykes, M., 2004. Assessment of potential (inhalation and dermal) and actual exposure to acetamiprid by greenhouse applicators using liquid chromatography-tandem mass spectrometry, J. Chrom. B, 804: 269-275.	Field trial	SPE (coverall)	- Uptake reduction	80% reduction uptake	In this study the development and validation of an analytical methodology is investigated. Only two applicators (one with PPE and one without PPE) were measured.
26	Brouwer, D.H., de Vreede, J.A.F., Meuling, W.J.A., van Hemmen, J.J., 2000. Determination of the efficiency for pesticide exposure reduction with protective clothing: a field study using biological monitoring in Worker Exposure to Agrichemicals, R.C. Honeycutt, E.W. Day jr. (Eds)., ACS Symposium Series, CRC, Lewis Publishers, Baton Rouge (FL), USA, 63-84.	Intervention study (field)	SPE	- Reduction of exposure loading - Uptake reduction	- Actual exposure of the hands was reduced by 95% for applicators and 87% for harvesters - Median IPP excretion was reduced 42% for applicators and 37% for harvesters	Normal work clothing (jeans and long-sleeved shirt for applicators and jeans and short-sleeved shirt or T-shirt for harvesters) versus protective clothing (Tyvek coveralls with a hood nitrile rubber gloves for applicators and cotton coveralls and stretch-cotton gloves for harvesters)

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
27	Van der Jagt, K., Tielemans, E., Links, I., Brouwer, D., van Hemmen, J.J., 2004. Effectiveness of personal protective equipment: relevance of dermal and inhalation exposure to chlorpyrifos among pest control operators, J. Occup. Environm. Hyg. 1: 355-362.	Intervention (field)	RPE SPE	- Reduction of contamination - Uptake reduction (SPE) - Test performance on improvement of reduction of leakage (RPE)	- 75% reduction SPE** - Lower levels of metabolites in urine after intervention* - Highly significant increase of the fit factor of the respirators (RPE).	Intervention consisted of tight fitting full-face respirator with new A2/P2 filter, fit test prior to measurement, chemical proof boots, long protective gloves, Tyvek hood, instruction video prior to putting on the PPE. Baseline consisted of half face or full-face mask with P2 or P3 filter, fit test prior to measurement, safety shoes and protective gloves.
28	Brouwer, D.H., Marquart J., van Hemmen, J.J., 2001. Proposal for an approach with default values for the protection offered by PPE, under European new or existing substance regulations. Ann. Occup. Hyg., 45 (7): 543-553.	Review	RPE SPE	n.a.	n.a.	An proposal is given for risk assessment purposes to use the following conservative estimates of protection in a tiered approach: In the first tier, *i.e.* for scenarios where no PPE use can be documented, reduction by PPE should be ignored in the process of risk assessment. The second tier will be used if no PPE programme appears to exist, but the use of RPE or SPE can be documented. In this tier the most restrictive assigned protection factor (APF) should be used as a default, *i.e.* APF = 4 for RPE, whereas for chemical resistant gloves a proposed overall default of 6 and personal protective clothing defaults of 2.5 and 6 can be used for one layer and two layers of clothing (including work clothing) respectively. In the third tier the

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
						presence of a PPE program can be documented, or is highly reliable for the exposure scenario's, APFs for RPE should be used as proposed by the BSI (British Standard), since these are, at least partly, derived from Workplace Protection Factor (WPF) field studies according to an 'as is' protocol. For gloves and personal protective clothing no APFs have been set yet, so in this tier no similar approach can be followed and the second tier should be used.
29	Evans, P.G., McAlinden J.J., Griffin, P., 2001. Personal protective equipment and dermal exposure, Appl. Occup. Environ. Hyg., 16 (2): 334-337.	Review	SPE	n.a.	n.a.	Growing evidence from other studies that the theoretical protection afforded by PPE may not be achieved in real use situations but the actual protection is often uncertain and variable
30	Garrod, A.N.I., Phillips, A.M., Pemberton, J.A., 2001. Potential Exposure of Hands Inside Protective Gloves- a Summary of Data from Non-agricultural Pesticide Surveys. Ann. Occup. Hyg., 45 (1): 55-60.	Review	SPE (gloves)	n.a.	n.a.	Reviewed data on contamination by non volatile components of pesticide products inside gloves. Protective gloves are almost always contaminated inside. Data on exposure inside new gloves and data on deposition on outer gloves indicate that in general, gloves provide a reasonable degree of protection to non-agricultural pesticides.
31	Nielsen, J.B., 2005. The Selection and Use of Gloves against Pesticides in Protective gloves for occupational exposure. Edited by Boman, A., Estlander, T., Wahlberg, J.E., Mailbach, H.I, CRC Press, second edition, Chapter 22, 321-333	Review	SPE (gloves)	n.a.	n.a.	Overview of penetration of groups of pesticides through gloves, penetration of pesticides through different glove materials and general information on comfort, use and use after storage, washing or cleaning.

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
32	Carpenter, W.S., Lee, B.C., Gunderson, P.D., Stueland, D.T., 2002. Assessment of personal protective equipment use among midwestern farmers, Am. J. Ind. Med., 42: 236-247.	Survey	Not specified	n.a.	n.a.	Two major factors influenced the decision of farmers to use PPE; 1) a personal desire to avoid injury and 2) current personal health problems.
33	Curwin, B., Sanderson, W., Reynolds, S., Hein, M., Alavanje, M., 2002. Pesticide use and practices in an Iowa farm family pesticide exposure study, J. Agric. Saf. Health, 8 (4): 423-433.	Survey	Not specified	n.a.	n.a.	Questionnaire which included questions on PPE use shows that 6 (24%) farmers wore no PPE at all, while 13 (52% wore gloves), 16 (64%) wore long pants, 7 (28%) wore long-sleeved shirts, 3 (12%) wore rubber boots and 2 (8%) wore goggles. One farmer wore a nitrile apron while mixing/ loading pesticides.
34	Hwang, S., Gomez M.I., Stark, A.D., Lowery St. John, T., Pantea, C.I., Hallman, E.M., May J.J., Scofield, S.M., 2000. Safety awareness among New York farmers. Am. J. Indust. Med., 38: 71-81.	Survey	Not specified	n.a.	n.a.	Training in the use of pesticides was associated with more frequent use of protective equipment
35	Mandel, J.H., Carr, W.P., Hillmer, T., Leonard, P.R., Halberg, J.U., Sanderson, W.T., Mandel, J.S., 2000. Safe handling of agricultural pesticides in Minnesota: results of a country-wide educational intervention, J. rural Health, 16 (2): 148-154.	Survey	SPE (gloves and protective clothing)	n.a.	n.a.	The use of gloves and other protective clothing while handling pesticides, by farmers age 40 or older, increased in the intervention group who got country-wide education. Use of chemically resistant gloves increased from 59% to 71%. Use of other protective clothing increased from 21% to 34%. Improvement was greater for farmers who had used PPE the least before the intervention.

Nr	Reference	Study type	PPE type	Method	Exposure Reduction (%)	Remarks
36	Perry, M.J., Layde, P.M., 2003. Farm pesticides: outcomes of a randomized controlled Intervention to reduce risks, Am. J. Prev. Med., 24 (4):310-315.	Survey	Not specified	n.a.	n.a.	Educational intervention significantly increased PPE use but did not have a significant impact on achieving full PPE label compliance
37	Perry, M.J., Marbella, A., Layde, P.M., 2002. Compliance with required pesticide-specific protective equipment use, Am. J. Indust. Med., 41:70-73.	Survey	RPE SPE	n.a.	n.a.	Full compliance with pesticide-specific protective gear use requirements (based on label) was well below 50% for 12 out of 15 pesticides

* Results unreliable due to different potential dermal exposure between both measurement periods and significant varying metabolite levels between workers before onset of spraying activities

Default reduction factors in predictive exposure models

In Table VII the defaults for exposure reduction provided by PPE are listed as used in different predictive pesticide exposure models.

UK POEM does not explicitly address RPE, but uses the APF (BSI) values (given in Table VIII). EUROPOEM I uses a default for RPE in general. Two types of RPE are distinguished in the German model (filtering half mask and half mask with combination (aerosol/vapor filter) with reduction percentages of 95% (protection factor 20) and 98% (protection factor 50), respectively. A similar approach is observed in PHED Surrogate Exposure Guide (1998), however, much lower defaults for reduction are used, *i.e.* dust/mist respirator reduction 80% (protection factor 5) and 90% (protection factor 10). The latter values are quite similar to the assigned protection factors for the type of RPE as given by ANSI (1992) and BSI (1997).

For reduction of dermal exposure EUROPOEM I distinguish between normal work clothing and SPE, both clothing and gloves, with default reduction of 50% and 90%, respectively. The PHED Surrogate Exposure guide only considers permeable work clothing (long sleeve shirt and long pants or full coverall) with reduction default of 50% and no specific protective garments. The reduction default for permeable clothing used in UK POEM ranges from 80% to 98% depending on the body part and the level of surface contamination. The German model uses two defaults, one for ‘standard protective garment’ (95%) and another for ‘liquid tight protective clothing’ (Type III).

All models use default reduction values for gloves. The UK POEM relates the reduction properties of the gloves to the type of formulation, whereas the German and the PHED Surrogate Exposure guide address one not-specified universal protective glove or chemical resistant glove, respectively. EUROPOEM I does not specify the glove type. The higher reduction defaults used in the German model (99% versus 90%) are based on results of laboratory glove material integrity tests. The same holds for the UK POEM defaults for gloves, however, results from a wide range of glove materials-solvent type breakthrough data were considered.

The Agricultural Handlers Exposure Database (AHED; still under development) permits the user to select SPE or RPE protection values for various types of PPE. The user may select actual data monitored under the PPE of interest or may select a protection value of 90%, 80%, 75%, 50%, or a user defined protection value. AHED makes no recommendations on the most appropriate value and it is the user’s responsibility to justify his selection.

Defaults of reduction show a large variation between the models. The EUROPOEM I model provides no specification of PPE and, consequently, uses conservative defaults for reduction. Conversely the German model provides many specifications and uses the highest defaults, mostly based on laboratory test results.

UK POEM and PHED Surrogate Exposure Guide are in between those two other models with respect of specifications and default value for level of reduction. PHED vales for clothing are mainly based on results of field studies.

EUROPOEM II has provided a large database of literature and other information on mitigation effectiveness, but they have not been interpreted in terms of a possible approach or set of defaults.

Default reduction factors used by regulatory authorities and industry for PPE

Table VIII gives an overview of default reduction values used by regulatory authorities for PPE. In general this is related to the use of the specific model(s) by national authorities, however, in some cases data of the PHED database are (re)analyzed, *e.g.* DPR, US EPA, or additional approaches are included, *e.g.* Cal-DPR, ICPS and PSD.

In exposure estimations for registration purposes, DPR assessments are based on the assumption that any label-required PPE will always be used by all workers. This may not be the case for other regulatory authorities.

DPR and US EPA use the 90th percentile of the permeable clothing penetration factor (resulting in range 58%-94.6% reduction for one layer) for different levels of outer dosimeter loadings. DPR uses in practice a default for a single layer of permeable clothing of 90% protection (see Table IX). PMRA uses a reduction of 75% for a second layer.

Cal-DPR and PMRA also included reduction afforded by chemical-resistant full body protective clothing, with defaults of 95% and 90% reduction, respectively. PMRA considers in addition to this that Tyvek may provide adequate protection for a dry product, but that for liquid formulations, laminated or treated Tyvek is considered necessary.

More details of DPR default values are listed in Table IX. The references as presented in the notes of Table IX are indicated by Cal-DPR, and have not been evaluated in the present project. Both Cal-DPR and PMRA specify RPE with reduction percentages for types of RPE similar to protection factors assigned by ANSI Z88.2 (ANSI, 1992). Different industrial consortiums or Task Forces suggest defaults derived from dedicated studies for specific protection in specific exposure scenarios, *e.g.* cotton work clothing for re-entry exposures (Table X).

The assigned protection factors by ANSI and BSI are listed in Table XI.

Recently, ECPA has been and is still conducting studies (Safe Use Initiative) with emphasis on effectiveness of specially designed PPE for specific climate conditions and in some cases even crops. An initial overview is presented in a brochure (ECPA, 2005).

Tables XIIa,b give an overview of the results of the RISKOFDERM project for control actions as described in Deliverable 48 of that project (Final paper version of Toolkit) (RISKOFDERM, 2002). These data are used by BAuA in their exposure assessments of biocidal products.

Table VII Overview of predictive operator exposure models/ databases and their defaults for % exposure reduction

Name predictive operator exposure model	Default in % exposure reduction	Type of exposure	PPE type or normal work clothing	Defaults in models based on	References
EUROPOEM I*	50%	Dermal exposure	Normal work clothing	These defaults are preliminary estimates due to the complexity of the matter because the degree of protection depends on the amount and location of the contamination and the type of formulation and seams and openings in the clothing. The defaults chosen are more or less based on the used reduction coefficients by authorities (PSD, CTB, BBA, Cal-EPA). In the majority of cases these reduction coefficients are in the range of 0.02 – 0.2 (garments) and 0.01-0.1 (gloves).	The Development, Maintenance and Dissemination of a European Predictive Operator Exposure Model (EUROPOEM) Database, Final report, December 1996.
	90%	Dermal exposure	SPE (including gloves)		
	90%	Inhalation exposure	RPE		
UK POEM*	90%	Dermal hand exposure	Gloves when handling ECs and other formulations containing organic solvents	Transfer has been assumed to be dependent on the main solvent and its concentration. To account for the wide range of gloves materials and the fact that in use the gloves are unlikely to be new, the defaults (% exposure reduction) are derived from the breakthrough time of the solvent through the least effective glove material,	PSD, Predictive Operator Exposure Model (POEM): A Users Guide, 1992.
	95%	Dermal hand exposure	Gloves when handling SCs and other aqueous based formulations		
	99%	Dermal hand exposure	Gloves when handling solids		

Name predictive operator exposure model	Default in % exposure reduction	Type of exposure	PPE type or normal work clothing	Defaults in models based on	References
	Scenario: Vehicle mounted (with cab) hydraulic nozzles: Trunk 95%, Legs 85% Scenario: Vehicle mounted (with cab) rotary disc atomizers: Trunk 95%, Legs 95% Scenario: Vehicle mounted (without cab) air assisted: application volume 500 l/ha: Trunk 98%, Legs 95% Scenario: Vehicle mounted (without cab) air assisted: volume 100 l/ha: Trunk 85%, Legs 80% Scenario: Vehicle mounted (without cab) air assisted (rotary discs): volume 50 l/ha: Trunk 80%, Legs 85% Scenario: Hand held outdoors hydraulic nozzles: low level application: Trunk 80%, Legs, 82%	Dermal body exposure	Permeable clothing	usually natural rubber. The contamination volume on the proportion of dilute spray effects the penetration of clothing. No further explanation is given in the document if the penetration factors are based on experimental studies or something else.	
German model*	99%	Dermal hand exposure	Universal protective gloves	Defaults (% exposure reduction) are derived from laboratory testing (general requirements)	Lundehn, J.R, Westphal, D., Kieczka, H., Krebs, B., Löcher-Bolz, S., Maasfeld, W., Pick, E.D., 1992. Mitteilungen aus der Biologischen Bundesanhalt für Land- und Forstwirtshaft Berlin-Dahlem, Einheitliche Grundsätze zur Sicherung des Gezundheitsschutzes für den Anwender von Pflanzenschutzmitteln (Einheitliche Grundsätze
	95%	Dermal body and feet exposure	Standard protective garment and sturdy footwear		
	100%	Dermal body exposure	Protective clothing against chemicals: type 3 (liquid tight)		
	50%	Dermal face/head exposure	Cap (broad brimmed headgear)		

Name predictive operator exposure model	**Default in % exposure reduction**	**Type of exposure**	**PPE type or normal work clothing**	**Defaults in models based on**	**References**
	95%	Dermal face/head exposure	Hood and visor		Anwenderschutz). Uniform principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection).
	20%	Dermal face exposure	Particle filtering half-mask		
	92%	Inhalation exposure	Particle filtering half-mask		
	20%	Dermal face exposure	Half mask with combination filter		
	98%	Inhalation exposure	Half mask with combination filter		
PHED *	50%	Dermal body exposure	Long sleeve shirt and long pants or full coveralls	Arithmetically estimated protection factors. No further explanation is given in the document	PHED surrogate exposure guide; Estimates of Worker Exposure from The Pesticide Handler Exposure Database Version 1.1, august 1998.
	90%	Dermal hand exposure	Chemical resistant gloves		
	80%	Inhalation exposure	Dust/Mist respirator		
	90%	Inhalation exposure	Organic vapor respirator		

* Agricultural pesticide models

Table VIII Overview of PPE defaults (% exposure reduction) from models, and other PPE defaults (% exposure reduction) used by authorities in Europe, USA, Canada, and California

Authority and country	EUROPOEM defaults*	UK POEM defaults*	German model defaults*	PHED defaults*	Other PPE defaults (% exposure reduction)	References
APVMA, Australia	-	+	-	+	-	
BfR, Germany	-	-	+	-	-	
BAuA, Germany (biocides)	-	-	-	-	50% for summer work clothing used for biocides 90% for heavy work clothing used for biocides	RISKOFDERM Toolkit (deliverable 48)
CTB, Netherlands	+	+	+	-	-	
DPR, California	-	-	-	+	90th percentile clothing penetration factor of the PHED database for dermal (non hand) exposure representing the protection afforded by a single layer of permeable clothing which varies between 58% – 96.4%. The DPR also uses the protection factors presented in table IX.	International harmonization position paper on methodology issues, January 18, 1999. Occupational Exposure Assessment Section, Health Evaluation Division Pest Management Regulatory Agency, Health Canada, Health Effects Division, US Environmental Protection Agency, Worker Health and Safety Branch, Department of Pesticide Regulation, California Environmental Protection Agency
ICPS, Italy	-	+	+	-	95% reduction of dermal body exposure by wearing an impermeable coverall while making handheld applications (derived from HSE data), Regarding respiratory protective equipment the assigned protection factors from the British Standard (BS 4275, 1997) are used	
INRA, France	-	-	-	-	-	
PMRA, Canada	-	-	-	+	75% protection for a second layer of clothing for dermal (non	Internal PMRA Document,

Authority and country	EUROPOEM defaults*	UK POEM defaults*	German model defaults*	PHED defaults*	Other PPE defaults (% exposure reduction)	References
					hand) exposure 90% for chemical resistant non-tear coveralls for dermal (non hand) exposure 90% for chemical resistant gloves for hand exposure 99.99% for air supplied (SCBA/Airline) respirator for inhalation exposure 98% for air purifying (full face) respirator (due to the larger sealing surface of the full face piece, this type of respirator offers a 50-fold reduction). for inhalation exposure 96% for a powered air purifying (incorporates a battery powered blower unit that purifies ambient air and delivers a constant supply to a respirator face piece or helmet. This type of respirator does not depend on a face-to-face piece seal for protection and can be worn by workers that have difficulty obtaining a seal with other types of respirators due to facial hair or face shape) for inhalation exposure 90% for air purifying (half-face) respirator (most common respirator for personal respiratory protection during pesticide uses) for inhalation exposure 80% Single use/Disposable (dust mask) respirator (typically for use against particulate and are not typically available with vapor or gas removing capacity) for inhalation exposure	Recommended protection factors. January 25, 2000.
PSD, United Kingdom	-	+	-	-	95% reduction of dermal body exposure by wearing an impermeable coverall while making handheld applications (derived from HSE data), Regarding respiratory protective equipment the assigned protection factors from the British Standard (BS 4275, 1997) are used	
US EPA, USA (pesticides)	-	-	-	+	90th percentile clothing penetration factor of the PHED database for dermal (non hand) exposure representing the protection afforded by a single layer of permeable clothing. This is instead of the 50%	

Authority and country	**EUROPOEM defaults***	**UK POEM defaults***	**German model defaults***	**PHED defaults***	**Other PPE defaults (% exposure reduction)**	**References**
					reduction default in policy since 1988 (PHED database which varies between 58% – 96.4%).	
US EPA, USA (biocides)	-	-	-	+	50% clothing protection (for one layer); 90% protection by chemical resistant gloves; 80% protection for dust/mist respirator; 90% for an O/V respirator. Since biocides are in many cases industrial chemicals; control regimes have a higher priority than PPE.	

* Agricultural pesticide models

Table IX Default protection factors (% exposure reduction) for PPE, clothing and engineering controls: pesticide handlers (used by Cal-DPR, California)

Protective Item (body regions protected)	**Exposure Reduction (%)** [a]
PPE	
Coveralls (all but head, hands, feet)	90 [b]
Chemical-resistant full-body protective clothing (all but head, hands, feet)	95 [b]
Chemical-resistant apron (chest/stomach, front half of thighs)	95
Chemical-resistant gloves (hands)	90 [c]
Goggles, nonvented (½ of face, or ¼ of head)	95 [d]
Goggles, vented (½ of face, or ¼ of head)	75 [e]
Face shield (face)	75
Chemical-resistant boots (feet)	90 [f]
Non-PPE attire	
Work clothing	
Short-sleeved shirt and short pants (chest/stomach, back, upper arm, thighs)	90 [g]
Long-sleeved shirt and long pants (all but head, neck, hands, feet)	90 [g]
Shoes plus socks (feet)	90
Respirators: Air-purifying particulate and gas/vapor filters	
Dust/mist/fume-filtering respirator (MSHA[h]/NIOSH [i] approval number TC-21C), or a NIOSH-approved particulate respirator with any N, R, P or HE filter [k] (NIOSH approval number TC-84A) in either elastomeric quarter-face, elastomeric half-face or filtering-facepiece configuration.	90 [j]
Half-face respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C), or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with appropriate N, R, P, or HE prefilter (NIOSH approval number TC-84A)	90 [j]
Full-face respirator with an organic-vapor removing cartridge with a prefilter approved for pesticides (MSHA/NIOSH approval number prefix TC-23C) or a canister approved for pesticides (MSHA/NIOSH approval number prefix TC-14G), or a NIOSH-approved respirator with an organic vapor (OV) cartridge or canister with appropriate N, R, P, or HE prefilter (NIOSH	99 [j]

Protective Item (body regions protected)	**Exposure Reduction (%)**[a]
approval number TC-84A)	
Powered Air-Purifying Respirator (PAPR) equipped with a dust/mist/fume filter (MSHA/NIOSH approval number TC-21C) and/or organic vapor cartridge (MSHA/NIOSH approval number prefix TC-23C) in loose-fitting facepiece configuration.	96[j]
Powered Air-Purifying Respirator (PAPR) equipped with a dust/mist/fume filter (MSHA/NIOSH approval number TC-21C) and/or organic vapor cartridge (MSHA/NIOSH approval number prefix TC-23C) in half-face configuration.	98[j]
Powered Air-Purifying Respirator (PAPR) equipped with a dust/mist/fume filter (MSHA/NIOSH approval number TC-21C) and/or organic vapor cartridge (MSHA/NIOSH approval number prefix TC-23C) with full facepiece or helmet/hood.	99[j]
Respirators: Air-supplying	
Airline respirator (MSHA/NIOSH approval number prefix TC-19C) equipped with a full facepiece and operated in a pressure-demand or other positive-pressure mode	99.9[j]
Self-contained breathing apparatus (SCBA; MSHA/NIOSH approval number prefix TC-13F) equipped with a full facepiece or other full-sealing system and operated in a pressure demand or other positive pressure mode	99.99[j]
Engineering Controls	
Closed mixing/loading system	95[l]
Enclosed cab with positive pressure and charcoal air-filtration unit meeting ASAE S525 Standard[m].	98[b]
Enclosed cab	90[n]

Notes for Table IX*:

a	Protection factors (PF) for PPE and clothing are applied to the dermal exposure of the protected parts only. PF for respirators and enclosed cabs are applied to the inhalation exposure. PF for closed systems is applied to the total dermal exposure.
b	Thongsinthusak *et al.* (1991)
c	Aprea *et al.* (1994)
d	Based on assumption that goggle material provides similar protection to that of chemical-resistant apron or suit
e	Based on assumption that aerosols and airborne residues can pass through openings
f	Based on assumption that chemical-resistant boots give same protection as chemical-resistant gloves

g	Based on assumption that protection is similar to coverall
h	MSHA Mine Safety and Health Administration
i	NIOSH National Institute for Occupational Safety and Health
j	ANSI (1992), Bollinger (2004) and U.S. EPA (1998a)
k	U.S. EPA (1998a)
l	Thongsinthusak and Ross (1994)
m	ASAE (1998a,b)
n	Thongsinthusak *et al.* (1994)

* References as indicated by CAL DPR

Table X Overview of PPE defaults (% exposure reduction) from models and other PPE defaults used by industry

Industry	PPE defaults (% exposure reduction)	Based on/Reference	Remarks
AHETF	50%, 75% of 90% defaults can be used for multiple layer of clothing	AHED permits this use of defaults for an estimate under multiple layers of clothing	Preference of the AHETF is to use actual data and not use defaults.
ARTF (Agricultural Reentry Task Force)	80% (AM) for one layer of cotton work clothing for lower arm exposure 87% (AM)for one layer of cotton work clothing for upper arm/torso exposure 92% (AM) for one layer of clothing for lower body exposure (legs).	Baugher, D.G., 2005. Penetration of Clothing by Dislodgeable Foliar Residues of Pesticides During Agricultural Occupational Reentry –Redacted Draft Final, Agricultural Reentry Task Force, LLC.	Based on results of 26 dermal exposure re-entry studies

Table XI Overview of ‘AssignedProtection Factors’ for filtering devices

Mask type	Filter type	BS 4275	ANSI Z88.2	
Filtering half masks	FFP1	4		
	FFP2	10		
	FFP3	20	10	
Half or quarter mask and filter	P1	4		
	P2	10		
	Gas	10	10	
	GasXP3	10	10	
	P3	20	10	
Filtering half masks without inhalation valves	FMP1	4		
	FMP2	10		
	FMGasX	10	10	
	FMGasXP3	10		
	FMP3	20	10	
Valved filtering half masks	FFGasXP1	4		
	FFGasX	10	10	
	FFGasXP2	10		
	FFGasXP3	10	10	
Full face masks and filter	P1	4		
	P2	10		
	Gas	20	100	
	GasXP3	20		
	P3	40	100	
Powered filtering devices incorpoating helmets or hoods	TH1 all types	10	100	
	TH2 all types	20	100	
	TH3 (semi)hood/ blouse	40	1000	
Power assisted filtering devices incorporating full, half or quarter masks	TM1 (all types)	10	50 (Half face)	100 (full face)
	TM2 (all types)	20	50 (Half face)	100 (full face)
	TM3 (half face) particle, gas or combined filters	20	50	
	TM 3 (full face) gas or combined filters	40	1000	

Control Efficiency Class	Potential Exposure (as assessed by applying the toolkit) is multiplied by factor:	Description
4	0	No remaining exposure / risk
3	0.01	Almost complete control of exposure / risk
2	0.1	Considerable effect
1	0.3	Slight effect
0	1	No effect
-1	3 - 10	Unintended higher overall risk after implementation of an improper measure

Table XIIa Efficiency classes of control actions (RISKOFDERM project Deliverable 48)

Table XIIb Control by personal protection (RISKOFDERM project Deliverable 48)

Control Action	Condition	Remarks	Control Efficiency Class
Chemical Protective Clothing (Gloves or Suit)	Special rubber or plastic, the barrier effect is well documented (see special information). Discarded after safe protection time is elapsed. Good handling practice*	Some additional risk from allergens in glove and from occlusion effect	3
	Special rubber or plastic, the barrier effect is well documented (see special information). Discarded after safe protection time is elapsed. Untrained handling.	Some remaining skin exposure by inside contamination, PLUS see above	2
	Special rubber or plastic, the barrier effect is not documented. Discarded max. 5 minutes after first contamination occurred.	Risk of enhanced skin exposure if gloves are not discarded in good time, PLUS see above	1
	Textile or leather, discarded or cleaned immediately after exposure ends.	ONLY true for exposure to dry solids.	1

Control Action	Condition	Remarks	Control Efficiency Class
	Special rubber or plastic, the barrier effect is well documented (see special worksheet). Wearing time is longer than the safe protection time.	Accumulation of contaminants, extended contact, PLUS see above	0
	Special rubber or plastic, the barrier effect is not documented. Worn longer than max. 5 minutes after first contamination occurred	Accumulation of contaminants, extended contact, PLUS see above	-1
	Textile or leather. Worn even after contamination	Accumulation of contaminants, extended contact, PLUS see above	-1
Cleaning of contaminated clothing / gloves	Immediately after each single exposure ends	Does not avoid, but shortens exposure	1
	At every break	Avoids accumulation of contaminants	0
	Once a day	Accumulation of contaminants, extended contact	-1
	Never	Accumulation of contaminants, extended contact	-1
Head Shield, face and eyes	Worn during exposure	Low rating because the protected area is relatively small	2
Protective Glasses, protecting eyes	Worn during exposure	Low rating because the protected area is only small	1
Cleaning of hands with water + soap	Immediately after exposure ends		1
	At every break		0
	Once a day	Accumulation of contaminants	-1

Control Action	Condition	Remarks	Control Efficiency Class
	Never	Extended contact, oral exposure	-1
	Abrasive cleaning	Skin damage	-1
	Solvent cleaning	Skin damage and penetration	-1
Skin Care Creams, applied before work starts. Relevant only if the local effects determine the hazard.	Selected for the specific workplace	Contact of chemical to skin is not excluded - but the skin barrier is fortified	0
	Usefulness for the specific workplace is unclear	Contact of chemical to skin is not excluded, sometimes even expanded	-1
Skin Protection Creams, applied before work starts. Relevant only if the local effects determine the hazard.	Selected for the specific workplace	Contact of chemical to skin is not excluded - but skin is fortified against hazard	0
	Usefulness for the specific workplace is unclear	Contact of chemical to skin is not excluded, sometimes even expanded	-1
	Cream does not help with the chemicals in use	W/O creams with organic solvents, O/W creams with aqueous solutions	-1

Current developments as indicated by respondents

Competent authorities

BAuA (biocides)
In previous projects BAuA observed that compliance is a most important factor for the efficacy of PPE. This reflects compliance of the employee/worker but also of the producer/ distributor. One of the projects showed, however, that with the instruments currently available, exposure and compliance estimates are only possible with partly high levels of uncertainty and it outlines the additional information required (Kliemt and Voullaire, 2000).
BAuA has different other projects planned for the nearby future to determine the state-of-the- art concerning technology and control measures during application of biocides.

Cal-DPR, California

DPR expects to update the protection factors within the next year or two to reflect both more recent equipment and more recent data.

The following guidance applies for using protection factors in exposure assessments:

- The default protection factors are used when no appropriate chemical-specific penetration data are available.
- Chemicals with high vapor pressure may behave rather differently than other chemicals. Therefore the use of default protection factors for these chemicals is discouraged.
- Exposure is estimated assuming the minimum required protection for each scenario.
- The protection factor is applied only to the exposure affected by the protective item, not to the total exposure.

ICPS, Italy

The weaknesses of the models used with regard to national specific working scenarios are well known. Some research has been conducted on a local level to better define scenarios typical of different working areas and tasks. Nevertheless, the activity is quite complex due to technical and economical difficulties in performing such studies. That's the reason why the issue is not yet solved and the perspectives are still unclear.

INRA, France

The INRA is working on this topic at the moment with a subgroup of the French tox committee. No paper is present at the moment. A published study of Baldy *et al.*, 2005 (see Table VI, overview literature), is used as a background document to check the efficacy of PPE in practical use, in comparison to technical references of PPE measures by tests.

PMRA, Canada

At PMRA, although defaults are routinely applied to PHED data, for new chemical-specific exposure studies, it is required that the study be designed to assess exposure according to the PPE anticipated to be required on the product label. This is particularly true for the dermal route of exposure.

PMRA does not recommend PPE for post-application activities and as such would not incorporate protection factors into post-application exposure assessments.

PMRA only incorporates PPE requirements when it is considered known that this is feasible.

PMRA Canada finds the following issues worth considering for future research:

- **Account for differences in formulation type, concentration, body parts, etc.**
- Specify which chemical resistant material is appropriate for specific formulations.
- Possible differences in protection between different cottons.

PSD, United Kingdom (pesticides)

The PSD has the attitude that PPE/RPE on pesticide labels (statutory requirement) should only be recommended when necessary to control predicted exposures to acceptable levels or to protect against local effects. The reasons for this are that ergonomic comfort and avoiding heat stress are important, and to give greater prominence to those circumstances where PPE/RPE is necessary. However the PSD does advocate a general work uniform of protective coveralls, suitable footwear and protective gloves when handling pesticides and contaminated surfaces. In addition, whenever PPE is recommended PSD also requires that technical controls should be considered in addition.

PSD only requires PPE when this is feasible and practicable.

The PSD recommends the following issues worth considering for future research:

- The protection provided by contaminated used equipment, because most information comes from studies based on use of new PPE.
- Pull together information on biologically measured exposure to see if there is sufficient information to compare exposures of individuals who have worn PPE with those who have not, to see what the differences are.
- There seems to be a paucity of information regarding feet exposure, which implies an assumption of 100% protection to feet.

HSE Biocides Section, United Kingdom (biocides)

The UK would always see the use of PPE as being a small component of the hierarchy of control mechanisms and that the eight principles of good control practice, as described in the Control of Substances Hazardous to Health Regulations, would always be an integral component of preventing / controlling exposure.

Instituto Nacional de Seguridad e Hygiene en el Trabajo, Spain

INSHT is aware of the limitations of the default protection factors. There is often a lack of clarity as to how these default values correlate with laboratory test results and requirements of the European Standards on CPC. Despite this fact these protection factors are used as the basis to estimate exposures in the authorisation process. Nevertheless the spirit of the European standards and compliance with PPE Directive (CE marked products) is always the principal reference used for all possible recommendations or use restrictions imposed on the registered pesticide formulation. Special concern is currently given to greenhouse applications where the exposure percentages and protection factors given by models may be not applicable.

Industry

American Chemistry Council

The antimicrobial task force of the ACC is at the moment analysing data of the PHED database on clothing penetration. Results are expected early 2006. This work is carried out by Infoscientific (John Ross)

AHETF

The preference of the AHETF is to have actual data and not use defaults. The position of the AHETF is to collect actual residues under a single layer of clothing to represent normal work attire. For use patterns were an additional layer of clothing is used, such as rain-jackets with hoods for open-cab orchard spraying, the AHETF collects the actual residues under both layers of clothing.

However, there are times where the AHETF must address two layers of clothing. AHETF currently does not have any studies planned to collect residues under two layers of fabric clothing.

AHED (Agricultural Handlers Exposure Database) does permit one to estimate the reduced exposure under multiple layers of clothing from the actual dermal exposure under one layer of clothing. A 50%, 75% or 90% default can be used for upper body or lower body areas. In addition, a user-specified estimate can be made based on analysis of penetration factors or any other source to support a position. The one type of extrapolation that AHED will not permit is to extrapolate from two layers to one or from one layer to no clothing.

ECPA

ECPA is involved in the Safe Use Initiative project (see below). In a provided document ECPA accessed default mitigation figures (used in UK POEM and German model) by comparison with results from studies. Results of studies showed that with an increasing amount of exposure (exposure loading) a significant reduction of transfer occurs. Concluded is that when high end exposure figures are selected for an assessment of potential dermal exposure and, at the same time, high end figures for transfer (as percentage) are used to estimate actual dermal exposure, then two worst cases are multiplied resulting in an error prone exposure assessment of actual dermal exposure. This means in practice that UK POEM and German model already deliver a conservative estimate of actual dermal exposure.

ECPA is presently funding statistical work to cover the relevant issues, carried out by the University of Reading, UK.

Safe Use Initiative - Southern Europe

The Safe Use Initiative Southern Europe (ECPA, and national authorities from Spain (INSHT), Portugal and Greece) started a Safe Use Initiative project. The Spanish project started in 2002, and the Portuguese and Greece ones in 2005. The aim of the project is to reduce on one side the potential exposure of applicators by new application technology, and on the other side to recommend to farmers suitable protective clothing. In the Spanish greenhouse project more than 20 coveralls already marketed have been laboratory tested, 9 were tested with regard to comfort, and 4 with regard to residues on inner cotton dosimeters (representing the skin). Also about 10 pairs of gloves have been inspected. The Spanish project is described in the ECPA brochure ‘The Safe Use Initiative’. An overview is given in the box below.

Background

In Southern Europe label compliance must in general improve. The differences in working conditions in southern and north-western Europe must be recognised. Industry shares with the authorities concern on worker protection. The industry has taken the lead in improving the situation in Southern Europe.

Objective

To help improve worker safety by the selection and correct use of personal protective equipment, best application techniques and minimization of exposure.

Involved countries

- Spain
- Portugal
- Greece
- Italy
- France

Method PPE

- Reduction of dermal operator exposure by suitable PPE
- Search for protective clothing available on the market
- Conditional evaluating testing:
  - Laboratory
  - Field operator comfort
  - Field operator exposure
- Manufacturing and sales by protective equipment manufacturers via dealers

Safe use logo

- Identity for safe use initiative
- Text country specific
- Qualification for PPE, spray/mix equipment, etc.
- Use in training material/media campaign

Major work area PPE and hygiene

- Use of PPEs
  - Coverall, gloves, face masks, protective shield, goggles, boots
- Safety
- Homogenization of the PPEs
- Promotion of the availability
- Maintenance of PPEs
- Hygiene
- Comfort
- In the Spanish greenhouses 4 models of suits are recommended.

Results follow up survey 2005 (after baseline survey 2002)

Factor (in %) of 200 growers observed and interviewed	**2002**	**2005**
Mix/load: gloves worn (observation)	38%	63%
Mix/load exposure unprotected hands	44%	17%
Application: coveralls worn (observation)	58%	75%
Application: boots worn (observation)	62%	77%
Application: exposure of unprotected arms and legs	40%	14%
Use of novel spray technology	23%	32%
Label reading before product use	39%	51%

Academia

University of Maryland Eastern Shore
The University of Maryland Eastern Shore has been involved in the following PPE projects (www.umes.edu/ppe):

- Online module: Online system developed with information on work and protective clothing for agricultural workers with information on physical and performance properties of about 100 fabrics. Penetration through these fabrics has been measured for three pesticide formulations.
- Project in protective clothing for hot climates.
- Development of ASTM and ISO standards to measure penetration of pesticides through textiles materials.
- Project on performance specifications for clothing worn by agricultural pesticide workers.

Other academia
Several papers and references were presented by various academicians which have been integrated in the present project.

DISCUSSION AND CONCLUSIONS

Introduction

An important distinction that should be made between agricultural pesticides and biocides is that many biocides are used in industrial scenarios. Therefore in such cases there might be a higher degree of confidence in compliance with label-prescribed PPE use.

The number of published studies related to PPE and pesticides over the past five years found in the literature (n=37) is not very large, but still substantial. However, only very few studies report quantitative data on PPE use and reduction of exposure to pesticides or on other important aspects of PPE use, *e.g.* ergo-comfort, which indicates that the older data form still the main source of knowledge.

Predictive exposure models or data bases use or provide defaults for effectiveness based on analysis of results of underlying (exposure) studies, laboratory tests, and/or literature.

With respect to the approach proposed in the scoping paragraph it is difficult to differentiate between types of data on effectiveness of PPE. However, data generated in field studies can be distinguished by from data derived from laboratory tests.

Laboratory tests can be done under chosen conditions which have been described using criteria. [An overview is presented in the EUROPOEM II report on mitigation.]

There are many tests for material performance carried out in Europe and North America that are designed for conditions in the chemical industry where the circumstances and the nature of the work may not be all that similar to those occurring in agricultural practice. This issue is for the time being generally not considered by the test criteria required for PPE performance (Shaw *et al*., 2001; 2004).

Another important issue is the methodology to determine skin exposure loading. From the work of Schneider *et al*. (1999) on what is called the conceptual model for dermal exposure, and the recent results of a CEFIC LRI project (Brouwer *et al*., 2005; see paragraph on scoping) it is evident that our current methodology for estimating dermal exposure loading is not adequate enough. For the time being there is, however, no better approach available. One should consider that the current methodology as used in agricultural practice for estimating pesticide exposure is probably overestimating the relevant amount in many cases. This holds at least for the majority of data points that are currently available in the databases underlying the predictive potential exposure models. This is an even more important point when inner and outer dosimeters are compared for assessing the degree of transfer from outer clothing to inner clothing (or even more difficult) to the skin. For estimating external dermal exposure (frequently called potential exposure) frequently a monitoring material is used that absorbs or rather retains the liquid or solid that is to be captured. The use of monitoring materials that leads to run off of the spray may not give the right level of contamination when it is to predict the exposure to a worker without that clothing material. The same holds for the inner dosimeter, meaning that the degree of transfer observed in this way is very dependent on the two monitoring materials used and of course the conditions under which the experiment is carried out, such as humidity and degree of pressure at the two layers. This may of course affect the degree of transfer in both ways when deriving default values that need to describe the efficacy of protection in practice, either under protecting or overprotecting, depending on the actual field conditions for which the default value is meant. This no doubt leads to the conclusion that for relevant

comparisons of inner and outer dosimeters, one needs to consider material that mimick the actual clothing in the fields as much as possible.
It is hoped that in the current approaches by industry (both in North America and in Europe) to derive an approach for setting default values for different clothing attires and use scenarios on the basis of available databases, somehow these issues are taken into account.

Inhalation issues
For RPE some consistency can be observed, since most models and authorities use (ANSI or BSI, listed in Table XI) assigned protection factors. The German model, however, uses reduction factors that are slightly higher than the APF values for the same type of RPE. It should be noted that APF values can be used for users that have been trained and instructed according to a dedicated PPE program. Since agro-exposure scenarios are likely to be 'stand-alone' scenarios (individuals) the existence of a PPE program for an individual agro-worker is in general very unlikely. Some aspects of the relevance of training programmes for the use patterns of PPE are indicated in the section 'dermal issues'. The present default dataset for RPE under these constraints can be used in agricultural settings with respect to pesticides and similarly for biocides. No specific deviation is to be expected between chemical and microbiological pesticides.

Dermal issues
For SPE the overall view is, as indicated, less clear. In general, chemical-resistant or protective garments are distinguished from work clothing and/or permeable garments. The latter can be considered to be either single or double layer garments. Apparently, data on reduction are based on penetration data, thus representing P_{CTNM}. EUROPOEM I and PHED data use 50% for a single layer; Cal-DFR, PMRA and US EPA use or will use an outer loading depending penetration factor, however, the lowest 90th percentile is 58%. PMRA uses a 75% reduction in case of a second (cotton) layer, probably because of low level of challenge of this layer.
For (chemical-resistant) protective clothing (SPE) the range of default reduction values is relatively close, *i.e.* 90% (EUROPOEM I, PMRA) to 95% (German model, Cal-DPR, ICPS). These reduction factors seem to be based on the results of laboratory tests (material integrity and SPE performance tests for permeation and penetration).

Important results of data analysis of comparison of outer and inner dosimeters, representing P_{CNTM}, is the loading (or challenge) dependency of 'migration' through the fabric or garment. Therefore, Cal-DPR, PMRA, US EPA, and UK POEM propose different mitigation or penetration factors for different ranges of 'challenge (loading)' in stead of one single factor for the whole (exposure) range. This approach seems to be scientifically sound; however, it is likely to be only valid for the process of penetration through permeable materials. For non-permeable or chemical-resistant materials default values are derived from laboratory permeation tests (based on breakthrough times).
Both theoretical considerations (Brouwer *et al.*, 2005) and experimental and field data and observations (Garrod *et al.*, 2001; Rawson *et al.*, 2005; Brouwer *et al.*, 2006) show that contamination of skin (or clothing) underneath gloves and protective work clothing is not limited to penetration and permeation processes. SPE-design related deposition and transfer processes are assumed to play a role as well. In addition, the human factor, *e.g.* the way workers put on and take off gloves, determines the overall protection very much. In several intervention type of studies (Van der Jagt *et al.*, 2004, Rawson *et al.*, 2005) it was demonstrated that training and instruction of proper use of PPE decreased

uptake or skin loading. However, surveys on the use of PPE show that overall frequency of use is low, despite observed increase of use after education.
In addition, design factors are important both in acceptance of use and protective performance. Special designs to meet climate conditions seem to be promising with respect to acceptance and frequency of use (SUI, 2005).
Ergo-comfort factors are not addressed very explicitly in studies, with exception of thermo-physiology, although this is also one of the main points of attention in the Safe Use Initiative in Southern Europe (SUI, 2005). No evidence has been found that other factors are considered in the selection of PPE and or included in PPE performance evaluations.

Brouwer *et al.* (2001) proposed a tiered approach for risk assessment purposes where the PPE use or presence of a PPE program can be documented. In case of a scenario where no PPE use can be demonstrated, the default reduction of PPE should be zero, whereas in cases where PPE use can be documented, however no PPE program is present, conservative defaults should be used.

In conclusion it can be stated that a first key factor for the use of default reduction factors of PPE during a risk assessment process is (the frequency of) use by workers.
Information campaigns on awareness and education programs showed to be helpful to increase proper use; however, to stimulate longstanding use PPE type design should be fitted to the exposure scenarios (tasks, environmental conditions).

A second key factor is whether PPE, if used, is used properly. The overall protection afforded by PPE is heavily determined by proper use, *e.g.* by fit, decontamination, or taking off PPE, as well as timely replacement. Both human factors emphasize the need for a PPE program where instruction, training and surveillance of maintenance and replacement are implemented. Since in most agro-pesticide exposure scenarios such a program is lacking, default reduction factors of PPE derived from other sources than field studies will tend to overestimate its protective performance in practice. Nevertheless in a field study (Chester *et al.*, 1990) it was shown that protective effectiveness was quite good, even for cotton clothing, whereas this also provided good comfort according to the users in a questionnaire survey.

The relatively few biomonitoring studies that have been conducted and published on the performance of PPE show that no (mean) decrease of uptake has been observed above 80%. Although reduction of uptake is the result of substance specific properties and PPE interactions, it indicates that assumptions on the level of reduction of exposure based on reduction of contamination (P_{CTNM}) or exposure loading (P_{LOAD}) that exceed 80% are of limited relevance in view of reduction of uptake.
Documentation of use of PPE and or a PPE program seem to be important for the use of a default protection factor. Therefore, user- and exposure scenario should be considered in addition to type of PPE.

Since the use of pesticides in agriculture is not very similar in many cases to the use of chemicals in general and chemical industry, it seems appropriate to consider the development of specific tests for protective clothing and PPE that reflect agricultural use better than what is currently considered appropriate (Shaw *et al.*, 2001; 2004).

Conclusions with respect to PPE and its performance

- Personal Protective Equipment can be defined as “any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards” (EU, 1989). For pesticides, including biocides, both respiratory protective equipment (RPE) and skin protective equipment (SPE) are relevant subgroups.

  - Respiratory protective equipment (RPE) can be divided into filtering devices and air supplied devices. Both types of equipment consist of a face piece and a filtering device (filter or filter cartridge) or air supply unit, respectively.

  - Skin protective equipment (SPE) can be defined as a combined assembly of garments worn to provide protection to the skin against exposure to or contact with chemicals. It includes all barrier systems intimate to individual persons, protective gloves and chemical protective clothing. In Europe, work wear such as permeable coveralls, caps, etc. are only PPE if the European regulations for chemically impervious protective clothing are fulfilled (*e.g.* performance testing in pre-market introduction tests).
- The overall performance of RPE to reduce inhalation exposure during actual use has been tested in specially designed workplace protection studies. Overall statistical evaluation of results of workplace protection factor (WPF) studies for types of RPE has resulted in assigned protection factors (APF), *e.g.* ANSI (1992) and BSI (1997). The APF are considered to be valid for 95% of adequately trained and instructed wearers. Since it is unknown if such WPF studies have been conducted in agricultural settings and since it is unlikely that all agricultural pesticides workers are adequately trained and instructed, APF values should be used with some restrictions.
- Very few data on overall field performance of skin protective clothing (CPC types 1-6) could be found. Most of the data that has been used to derive default exposure reduction vales are related to results (quantitative or pass/fail) of performance standard tests in the laboratory for repellence, retention, and penetration, permeation, or pressure/jet. Only a few intervention types of field studies have been found, indicating lower reduction of exposure or uptake than the defaults used.
- Most of the default reduction factors are for layers of fabric that are worn in addition to normal clothing *e.g.* work clothing, permeable coverall. Retention of the layer or transfer through the layer has been studied by outer/inner dosimeter comparisons, mainly reflecting processes like penetration, permeation and deposition. Meta analysis of large data sets revealed an outer-loading dependency of the penetration (penetration decreases with loading). These studies are currently carried out by industry using new data and/or improved statistical methodology.
- Defaults for performance of protective gloves are generally derived from laboratory (material) integrity test data *e.g.* breakthrough times (BTT). As a basic condition for appropriate protection in practice BTT should exceed duration of actual use when the neat compound is used and the exposure is continuous. These conditions, however, do not happen frequently in practice. Furthermore, it has been demonstrated that the effectiveness of gloves is also, probably even much more importantly, determined by proper design and proper use *i.e.* the human factor. Similar to RPE adequate training and instruction is a basic condition to rely entirely on results of material integrity test results.
- A tiered approach for use of defaults of exposure reduction afforded by PPE might be appropriate. In such an approach the use of the ‘high end of the range’ reduction factors will be limited to those scenarios where adequate training and instruction of users of PPE can be demonstrated/documented.

- Since the use of pesticides in agriculture is very different in many cases to the use of chemicals (including many biocides) in general and in the chemical industry, it seems appropriate to consider the development of specific tests on the effectiveness of protective clothing and PPE that reflect agricultural use better than what is currently considered appropriate (Shaw *et al*., 2001; 2004). Considerable work is in progress (draft ISO TC94/SC 13 N: Protective clothing – Performance requirements for work and protective clothing for horticultural and agricultural pesticide workers). Germany is at the moment the only European country having defined a protective clothing standard (DIN 32781) specifically for agricultural workers handling pesticides.
- The default exposure reduction values currently used by different regulatory authorities vary widely and in many cases it is not clear what scientific or other basis they have. In many cases the default values are linked to generic descriptions of clothing or PPE which do not take into account variations which are practically important, such as use scenario and field performance.

REFERENCES

ACP, Advisory Committee on Pesticides, 2004. Exposure during concentrate handling using mechanical transfer devices, SC 11382 (Meeting of 12 October 2004).

Acqavella, J.F., Alexander, B.H., Mandel, J.S., Gustin, C., Baker, B., Chapman, P., Bleeke, M., 2004. Glyphosate biomonitoring for farmers and their families: results from the Farm Family Exposure Study, Environmental Health Perspectives, 112, Number 3, March 2004; 321-326.

ANSI Z88.2. American National Standard for respiratory protection. American National Standards Institute, New York, 1992.

Baldy, I., Lebailly, P., Jean, S., Rougetet, L., Dulaurent, S., Marquet, P., 2005. Pesticide contamination of workers in vineyards in France, Journal Exp. Environ. Epidemiol. Sep 21: 1-10.

Baugher, D.G., 2005. Penetration of Clothing by Dislogeable Foliar Residues of Pesticides During Agricultural Occupational Reentry –Redacted Draft Final, Agricultural Reentry Task Force, LLC.

Berger-Preiβ, E., Boehncke, A., Könnecker, G., Mangelsdorf, I., Holthenrich, D., Koch, W., 2005. Inhalational and dermal exposures during spray application of biocides, Int. J. Hyg. Environm. Health 208: 357-372.

British Standards Institution (BSI) 1997. BS 4275 Guide to implementing an effective respiratory protective device programme, BSI, London.

Brouwer, D.H., de Vreede, J.A.F., Meuling, W.J.A., van Hemmen, J.J., 2000. Determination of the efficiency for pesticide exposure reduction with protective clothing: a field study using biological monitoring in Worker Exposure to Agrichemicals, H.C. Honeycutt, E.W. Day jr. (Eds). ACS Symposium Series, CRC, Lewis Publishers, Baton Rouge (FL), USA, 63-84.

Brouwer, D.H., Aitken, R.J., Oppl, R., 2005. Skin Protection Strategies: Evaluation of Real and Theorethical Effectiveness of Skin Protection Equipment in Industrial Exposure Scenarios. Summary of Project Results. Final Report LRI-A2.5TNO-0207.

Brouwer, D.H., Aitken, R.J., Oppl, R., Cherrie J.W., 2005. Concepts of skin protection: Considerations for the evaluation and terminology of the performance of skin protective equipment. J. Occup. Environ. Hyg. 2:425-34.

Brouwer, D.H., Marquart J., van Hemmen, J.J., 2001. Proposal for an approach with default values for the protection offered by PPE, under European new or existing substance regulations. Ann. Occup. Hyg., 45 (7): 543-553.

Brouwer, D.H., Verbist, K., Goede, H.A., Tijssen, S.C.H.A., 2003. Aanzet tot de integratie van ergonomie- en comfortfactoren in een selectiesysteem voor beschermende handschoenen. TNO V4932, Zeist, The Netherlands. [Approach for integration of ergonomics and comfort factors in a selection approach for protective gloves]

British Standards Institution (BSI): Guide to implementing an effective respiratory protective device programme BS 4275. London, BSI, 1997

Carpenter, W.S., Lee, B.C., Gunderson, P.D., Stueland, D.T., 2002. Assessment of personal protective equipment use among midwestern farmers, Am. J. Ind. Med., 42: 236-247.

CEN 2006. Workplace exposure-strategy for the evaluation of dermal exposure, C 15278.

Cherrie, J.W., Semple, S., Christopher, Y., Saleem, A., Hughson, G., Philips, A., 2006. How important is advertent ingestion of hazardous substances at work. Ann. Occup. Hyg., 50: 693-704.

Chester, G., Adam, A.V., Inkmann Koch, A., Litchfield, M.H., Tuinman, C.P., 1990. Field evaluation of protective equipment for pesticide operators in a tropical climate. La Medicina del Lavoro 81 (6): 480-488.

Creely, K.S., Cherrie, J.W., 2001. A Novel method of assessing the effectiveness of protective gloves - results from a pilot study, Ann. Occup. Hyg., 45: 137-143.

Curwin, B., Sanderson, W., Reynolds, S., Hein, M., Alavanje, M., 2002. Pesticide use and practices in an Iowa farm family pesticide exposure study, J. Agric. Saf. Health, 8 (4): 423-433.

ECPA, 2005. The Safe Use Initiative. A European project for farmer’s wellbeing. ECPA, Brussels, Belgium.

EUROPOEM I, 1996. The Development, Maintenance and Dissemination of a European Predictive Operator Exposure Model (EUROPOEM) Database, Final report, BIBRA, Carshalton, Surrey, UK.

EUROPOEM II, 2002. The Development, Maintenance and Dissemination of a European Predictive Operator Exposure Model (EUROPOEM) Database, Final report, CSL, York, UK.

EU, European Union Council, 1989. Personal Protective Equipment (EU Directive 89/686/EEC), Brussels, Belgium.

Evans, P.G., McAlinden J.J., Griffin, P., 2001. Personal protective equipment and dermal exposure, Appl. Occup. Environ. Hyg., 16 (2): 334-337.

Fenske, R.A., Birnbaum, S.G., Methner, M.M., Lu, C., Nigg, H.N., 2002. Fluorescent tracer evaluation of chemical protective clothing during pesticide applications in central Florida citrus groves, J. Agric. Saf. Health. Aug; 8 (3): 319-331.

Gao, P., Tomasovic, B., 2005. Change in tensile properties of neoprene and nitrile gloves after repeated exposures to acetone and thermal decontamination, Journal of Occupational and Environmental Hygiene, 2: 543-552.

Garrod, A.N.I., Phillips, A.M., Pemberton, J.A., 2001. Potential exposure of hands inside protective gloves- a summary of data from non-agricultural pesticide surveys. Ann. Occup. Hyg., 45 (1): 55-60.

Garthwaite, D., 2002. A survey of current farm sprayer practices in the United Kingdom. Pesticide survey report, CSL, York, UK.

Goede, H., Tijssen, S.C.H.A., Brouwer, D.H., 2001. Ergonomie en comfortfactoren als onderdeel van een selectiesysteem voor adembeschermingsmiddelen: een aanzet. TNO V3922, Zeist, The Netherlands. [Ergonomy and comfort factors as part of a selection system for respiratory protection means: an approach]

Goede, H.A., Tijssen, S.C.H.A., Schipper, H.J., Warren, N., Oppl, R., Kalberlah, F., van Hemmen, J.J., 2003. Classification of dermal exposure modifiers and assignment of values for a risk assessment toolkit, Ann. Hyg., Nov 2003; 47: 609 - 618

Guo, C., Stone, J., Stahr, H.M., Shelly, M., 2001. Effects of exposure time, material type, and granular pesticide on glove contamination, Arch. Environ. Contam. Toxicol., 41: 529-536.

Harris, S.A., Sass-Kortsak, A.M., Corey, P.N., Purdham, J.T., 2002. Development of models to predict dose of pesticides in professional turf applicators, Expo. Anal. Environ. Epidemiol. Mar; 12 (2): 130-144.

Hayashi, C., Tokura, H., 2000. Improvement of thermo physiological stress in participants wearing protective clothing for spraying pesticide, and its application in the field, Int. Arch. Occup. Environ. Health, 73: 187-194.

Hayashi, C., Tokura, H., 2004. The effects of two kinds of mask (with or without exhaust valve) on clothing microclimates inside the mask in participants wearing protective clothing for spraying pesticides, Int. Arch. Occup. Environ. Health, 77: 73-78.

Hoernicke, E.; Nolting, H.G.; Westphal, D., 1998. Label instructions for the protection of workers re-entering crop growing areas after application of plant protection products; Nachrichtenbl. Deut. Pflanzenschutzd.50 (10), 267 – 269.

Hwang, S., Gomez M.I., Stark, A.D., Lowery St. John, T., Pantea, C.I., Hallman, E.M., May J.J., Scofield, S.M., 2000. Safety awareness among New York farmers. Am. J. Indust. Med., 38: 71-81.

Jain, R., Raheel., M., 2003. Barrier efficacy of woven and non woven fabrics used for protective clothing: predictive models, Bull. Environ. Contam. Toxicol., 71: 437-446.

Kliemt, G., Voullaire, E., 2000. Einfluβ der Regelungstreue (Compliance) beim betrieblichen Arbeitsschutz auf die Exposition gegenüber Gefahrstoffen Teil 1: Entwicklung einer Methode zur Erhebung und Auswertung expositionsrelevanter Indikatoren. F 1659, BAuA, Dortmund, Germany.

Krieger, R.I., Dinoff, T.M., 2000. Captan fungicide exposures of strawberry harvesters using THPI as a urinary biomarker, Arch. Environ. Contam. Toxicol. 38 (3): 398-403.

Krzemińska, S., Szczecińska, K., 2001. Proposal for a method for testing resistance of clothing and gloves to penetration by pesticides, Ann. Agric. Environ. Med, 8: 145-150.

Lee, S., Adhikare, A., Grinsphun, S.A., McKay, R., Shukla, R., Zeigler, H.L., Reponen, T., 2005. Respiratory protection provided by N95 filtering facepiece respirators against airborne dust and microorganisms in agricultural farms, Int. J. Occup. Environm. Hyg., 2: 577-585.

Lee, S., Obendorf, S.K., 2005. Statistical model of pesticide penetration through woven work clothing fabrics, Arch. Environ. Contam. Toxicol., 49: 266-273.

Lundehn, J.R,Westphal, D., Kieczka, H., Krebs, B., Löcher-Bolz, S., Maasfeld, W., Pick, E.D., 1992. Mitteilungen aus der Biologischen Bundesanhalt für Land- und Forstwirtshaft Berlin-Dahlem, Einheitliche Grundsätze zur Sicherung des Gezundheitsschutzes für den Anwender von Pflanzenschutzmitteln (Einheitliche Grundsätze Anwenderschutz). Uniform principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection).

Mandel, J.H., Carr, W.P., Hillmer, T., Leonard, P.R., Halberg, J.U., Sanderson, W.T., Mandel, J.S., 2000. Safe handling of agricultural pesticides in Minnesota: results of a country-wide educational intervention, J. rural Health, 16 (2): 148-154.

Marín, A., Martínez Vidal, J.L., Egea Gonzalez, F.J., Garrido Frenich, A., Glass, C.R., Sykes, M., 2004. Assessment of potential (inhalation and dermal) and actual exposure to acetamiprid by greenhouse applicators using liquid chromatography-tandem mass spectrometry, J. Chrom. B, 804: 269-275.

NAFTA, International harmonization position paper on methodology issues, January 18, 1999. Occupational Exposure Assessment Section, Health Evaluation Division Pest Management Regulatory Agency, Health Canada, Health Effects Division, US Environmental Protection Agency, Worker Health and Safety Branch, Department of Pesticide Regulation, California Environmental Protection Agency.

Nielsen, J.B., 2005. The selection and use of gloves against pesticides in protective gloves for occupational exposure. Edited by Boman, A., Estlander, T., Wahlberg, J.E., Mailbach, H.I, CRC Press, second edition, Chapter 22, 321-333

Nielsen, J.B., Andersen H.R., 2001. Dermal in vitro penetration of methiocarb, paclobutrazol, and pirimicarb: effect of nonylphenolethoxylate and protective gloves, Environmental Health Perspectives, 109, nr 2, February 2001, 129-132.

Perry, M.J., Layde, P.M., 2003. Farm pesticides: outcomes of a randomized controlled Intervention to reduce risks, Am. J. Prev. Med., 24 (4):310-315.

Perry, M.J., Marbella, A., Layde, P.M., 2002. Compliance with required pesticide-specific protective equipment use, Am. J. Indust. Med., 41:70-73

Phalen, R.N., Que Hee, S.S., 2003. Permeation of captan through disposable nitrile glove, Journal of Hazardous Materials, B 100: 95-107

PHED Surrogate Exposure Guide; Estimates of Worker Exposure from The Pesticide Handler Exposure Database Version 1.1, august 1998.

PMRA Internal Document, Recommended protection factors. January 25, 2000.

PPE testing and maintenance in Europe[34]

PSD, Predictive Operator Exposure Model (POEM): A Users Guide, 1992.

---

[34] CEN/TR 15419:2006 Protective clothing. Guidelines for selection, use, care and maintenance of chemical protective clothing, 31-Jul-2006.
Comité Européen de Normalisation (CEN) 1990A Respiratory protective devices - Gas filters and combined filters- Requirements, testing marking. EN 141. CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1990B Respiratory protective devices -Particle filters Requirements, testing marking. EN 141. CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1990C Respiratory protective devices - Definitions. EN 132. CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1990D Respiratory protective devices - Classification EN 133. CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1990E Respiratory protective devices - List of equivalent terms EN 135. CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN). 1992A Respiratory protective devices- AX gas filters and combined filters against low boiling organic compounds- Requirements, testing marking, EN 371, CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN). 1992B Respiratory protective devices- SX gas filters and combined filters against specific named compounds- Requirements, testing marking, EN 372, CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1992C Protective clothing- Protection against liquid chemicals- Test method: Resistance of materials to penetration by liquids EN-368, CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1993A Guidelines for the selection and use of respiratory protective devices. CR 529:1993. CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1993B Protective clothing- General requirements EN-340, CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1993C Protective clothing- Protection against liquid chemicals- Test method: Resistance of materials to permeation by liquids EN-369, CEN, Brussels, Belgium.
Comité Européen de Normalisation (CEN) 1994A General requirements for gloves EN-420, CEN, Brussels, Belgium
Comité Européen de Normalisation (CEN) 1994B Protective gloves against chemicals- Part 1: Terminology and performance requirements. EN374-1. CEN, Brussels, Belgium
Comité Européen de Normalisation (CEN) 1994C Protective gloves against chemicals- Part 2: Determination of resistance to penetration. EN374-2. CEN, Brussels, Belgium
Comité Européen de Normalisation (CEN) 1994D Protective gloves against chemicals- Part 3: Determination of resistance to permeation by chemicals. EN374-3. CEN, Brussels, Belgium
Comité Européen de Normalisation (CEN) 1994E Protective clothing. Protection against liquid chemicals- Test method: Determination of resistance to penetration by a jet of liquid (Jet Test) EN463. CEN, Brussels, Belgium
Comité Européen de Normalisation (CEN) 1994F Protective clothing. Protection against liquid and gaseous chemicals, including aerosols and solid particles- Test method: Determination of leak-tightness of gas-tight suits (Internal pressure test). EN464, CEN, Brussels, Belgium
Comité Européen de Normalisation (CEN) 1994G Protective clothing. Protection against liquid chemicals- Test method: Determination of resistance to penetration by spray (Spray Test) EN468. CEN, Brussels, Belgium
Comité Européen de Normalisation (CEN) 1998 Respiratory protective devices - Nomenclature of components. EN 134. CEN, Brussels, Belgium.
Directive 89/686/EEC
The approximation of the laws of the Member States relating to personal protective equipment
Directive 89/656/EEC
The minimum health and safety requirements for the use by workers of personal protective equipment at the workplace
prEN 14325: 2001. Protective clothing against chemicals – Test methods and performance classification of chemical protective clothing materials, seams, joins, and assemblages.
EN 374-1: 1994. Protective gloves against chemicals and microorganisms
(revision in preparation)– Part 1: Terminology and performance requirements.
General requirements
ISO/DIS 16602: 2002 Clothing for protection against chemicals – Classification, labeling and performance requirements.

Raheel, M., Dai, G.X., 2002. Viability of textile systems for hand and body protection: effects of chemical interaction, wear, and storage conditions, Bull. Environ. Contam. Toxicol., 69: 164-172.

Rawson, B.V., Cocker, J., Evans, P.G., Wheeler, J.P., 2005. Internal Contamination of Gloves: Routes and Consequences, Ann. Occup. Hyg., 49: 535-541.

RISKOFDERM Toolkit (Deliverable 48) TNO Zeist (available through J.J. van Hemmen).

Ross, J.H., Powell, S., Thongsinthusak, T., Haskell, D., Dow, M.I., Worgan, J., 1997. Harmonization of issues involving pesticide exposure assessment in North America. HS-1763, Cal-DPR, Sacramento, CA, USA.

Schneider, T., Vermeulen, R., Brouwer, D.H., Cherrie, J.W., Kromhout, H., Fogh, C.L., 1999. Conceptual model for assessment of dermal exposure. Occup. Environ. Med. 56:765-773.

Shaw, A., Cohen, E., Hinz, T., Herzig B., 2001. Laboratory test methods to measure repellency, retention and penetration of liquid pesticides through protective clothing: Part 1: Comparison of three test methods, Textile Res. J. 71: 879-884.

Shaw, A., Cohen, E., Hinz, T., Herzig B., 2004. Laboratory test methods to measure repellency, retention and penetration of liquid pesticides through protective clothing: Part 2: Revision of three test methods, Textile Res. J. 74: 684-688.

Stone, J., Coffman, C., Imerman, P.M., Song, K., Shelley, M., 2005. Cotton liners to mediate glove comfort for greenhouse applicators, Arch. Environ. Contam. Toxicol., 49 (3): 421-428.

SUI, Safe Use Initiative project, ECPA Brochure, A European project for farmers' wellbeing, 2005.

SUI, Sheets of the Safe Use Initiative project, ECPA Annual Conference, 17th November 2005, Brussels.

Thongsinthusak, T., *et al.*, 1990. Reduction of pesticide exposure by using protective clothing and enclosed cabs, Cal-DPR, Sacramento, CA, USA.

Thongsinthusak *et al.*, 1993. Guidance for the preparation of human pesticide exposure assessment document (HS-1612), Cal-DPR, Sacramento, CA, USA.

Thongsinthusak, T., Ross, J., 1994. Protection provided by the closed system (HSM-94006), Cal-DPR, Sacramento, CA, USA.

Van Hemmen, J.J., van Golstein Brouwers, Y.G.C., Brouwer, D.H., 1995. Pesticide exposure and re-entry in agriculture in Methods of Pesticide Exposure Assessment. Edited by P.B. Curry, S.Iyengar, P.A. Maloney and M. Maroni, Plenum Press, New York, NY, USA. pp. 9-27.

Van Hemmen, J.J., van der Jagt, K.E., Brouwer, D.H., 2005. Generic operator exposure databases in Occupational and Residential Exposure Assessment for Pesticides. Edited by C.A. Franklin and J. Worgan. Wiley, Chichester, UK. pp. 173-208.

Van der Jagt, K., Tielemans, E., Links, I., Brouwer, D., van Hemmen, J.J., 2004. Effectiveness of personal protective equipment: relevance of dermal and inhalation exposure to chlorpyrifos among pest control operators, J. Occup. Environm. Hyg. 1: 355-362.

Whitmyre, G.K., Ross, J.H., Ginevan, M.E., Eberhart, D., 2005. Development of risk-based restricted entry intervals in Occupational and Residential Exposure Assessment for Pesticides. Edited by C.A. Franklin and J. Worgan. Wiley, Chichester, UK. pp. 45-69.

You, K.S., Lee, M.H., Park, K.H., 2005. A rat model to evaluate the pesticide permeability and stress effects of protective clothing, Toxicol. Ind. Health, 21 (3-4): 49-55.

Zainal, H., Que Hee, S.S., 2005. Permeation of Telone EC^{TM} through protective gloves, Journal of Hazardous Materials B124: 81-87.

Zarterian, V., Bhadori, T, Mckone T., 2005. Adoption of an official ISAE glossary. J. Exp. Anal. Environ. Epidemiol. 15: 1-5.

Zeigler, J.P., 2000. Protective clothing: exploring the wearability issue, Occupational Hazards, 62 (9): 81-83.

Appendix 1: Letter sent to authorities/industry/ universities requesting information

Dear colleague,

TNO (the Dutch organization for applied Sciences), specifically the Occupational Hygiene team of TNO Quality of Life has been asked by the Dutch Ministry of Social Affairs and Employment to prepare a document that may be used for discussions in Europe (and elsewhere). The subject is the efficacy of personal protective equipment (PPE) with respect to skin and respiratory protection against exposure to pesticides (agricultural and non-agricultural (biocides/antimicrobials)), with a focus on agricultural pesticides. Also aspects of thermo physiology and ergonomics of PPE will be taken into account.

The document should discuss the findings described in the open (and where possible the grey) literature and should contain (default) approaches taken by regulatory authorities and the agrochemical and biocide/antimicrobial industry in Europe and North America, including the scientific or other evidence on which the approaches (*e.g.* default values) are based.

For getting to such a document to be prepared by my colleagues Derk Brouwer and Rianda Gerritsen and myself, we would like to ask you whether you can present us with the requested evidence which you as a regulatory authority expert or as an industry expert have in possession or know of. We would like to receive the requested evidence and approaches within a month (*i.e.* ultimately November 30), since we try to finish a first draft of the document before the end of the year.

If you (or a colleague) are able to help us with relevant information (copies, references, organizations), we will send you the first draft for consideration early next year, since we would also like your opinion on our overview and conclusions. Your contribution will of course be acknowledged.

We will try to reach you by e-mail and/or telephone in about a couple of weeks to check your willingness to cooperate. If we have your mailing address on our files, we will send you this letter by surface mail. Using e-mail gains time.
If you need further information, do not hesitate to call on us.

Thank you in advance of your cooperation.

Unfortunately, I will be abroad until November 11 and Rianda Gerritsen is on holiday in November. The number below leads you during our absence to our secretary and she may take note of what you need.

Regards,

Joop J. van Hemmen, PhD. TNO Senior Research Fellow in Occupational Toxicology, project leader (vanhemmen@chemie.tno.nl) (+31-30-6944913)
Also on behalf of
Derk H. Brouwer, PhD. Senior Occupational Hygienist, currently on sabbatical leave in South Africa
Rianda Gerritsen, MSc. Occupational Hygienist