

**Recommendation no. 8**  
**of the BPC Ad hoc Working Group on Human Exposure**

**Consumer use of biocidal product and protection  
from typical clothing**

**(Agreed at the Human Health Working Group IV on 17 September 2015)**

## 1. Introduction

In the Technical Notes for Guidance (TNsG) 2007, for non-professional users it is stated that *"Consumers will not normally use PPE unless it is convincingly recommended by the manufacturer and provided with the product. As a result only typical clothing should be assumed when carrying out consumer exposure assessments"*.

In the HEEG Opinion 9<sup>1</sup> on "Default protection factors for protective clothing and gloves" and based on the TNsG 2002 and 2007, a protection factor of 50% is given for non-professional wearing long-sleeved shirt and trousers or skirt with shoes and no gloves. This protection factor is indicated with the following restrictions: *"This is a general protection factor that is used for non-professionals applying a dry substance. This protection value can also be used for challenge by a liquid formulation where contamination is judged to be relatively light (e.g. from using an aerosol canister or application by a trigger spray)"*.

In the dossiers assessed for substances or product authorization, for a same use discrepancies were identified in the application of this protection factor, depending on the Member States (MS) assessing the dossier. Some MS apply this protection factor considering that consumers will wear long-sleeved shirt and trousers during use due to common sense and/or due to the instruction of use. Others consider that this factor is not applicable because it is not possible to rely on common sense of general public and the application of uses. Furthermore, the protection factor is not supported by any justification or references in the guidance documents.

## 2. Aim of the recommendation

The aim of this recommendation is to address the following three main questions:

- 2.1 What is typical clothing in the frame of a reasonable worst case scenario?
- 2.2 How to assess the protection factor provided by clothing?
- 2.3 How to integrate the protection factor in the models from the TNsGs?

Please note that this recommendation concerns only protection from typical clothing and does not cover the use of gloves.

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<sup>1</sup> The HEEG Opinion 9 is available at [http://echa.europa.eu/view-article/-/journal\\_content/title/support-biocides-heeg-opinions](http://echa.europa.eu/view-article/-/journal_content/title/support-biocides-heeg-opinions)

## 3. Discussion

### 3.1 - What is typical clothing in the frame of a reasonable worst case scenario?

#### A. BPR guidance documents

In the TNsG 2002 and 2007, the following assumptions can be found about typical clothing of consumers:

- [TNsG 2002 part 1, Glossary](#)

*Household 'protective' equipment such as washing-up or gardening gloves may be advised in the method for consumer use of a biocidal product, (but their presence cannot be assumed, and account should not be taken of this advice in terms of exposure estimates).*

*Non-professional users are the general public - consumers - who may or may not read a product label. There is an expectation - but little guarantee - that non-professionals will comply with instructions for use of a product. They have no access to controls or formal PPE.*

- [TNsG 2002 part 2 page 34](#) and [TNsG 2007 page 17](#)

#### Residential environment

*While residents may wear coveralls, gardening or kitchen gloves, or even a dust mask, such usage cannot be assured and must not be assumed in exposure estimation. For example, amateur users wearing sandals and shorts when applying antifoulants to leisure craft is the rule rather than the exception in warm weather. At the most, a user may be expected to wear a long shirt, long trousers and footwear, irrespective of any label stipulation.*

#### B. Guidance documents others than BPR

- [US EPA Standard Operating Procedures \(SOPs\) for Residential Exposure \(2012\)](#)

*Residential handlers are assumed to be wearing shorts and short-sleeve shirts, shoes, and socks. This assumption differs from occupational handler assessments which assume handlers are wearing at least long pants, long-sleeved shirts, shoes, and socks.*

*Personal protective equipment (PPE) is not considered a mitigation option for residential handlers because users are not trained and compliance would not be expected.*

- [Guidance on information requirements and chemical safety assessment - Chapter R.15: Consumer exposure estimation](#)

*Effective risk management measures for consumers are usually product-integrated measures (e.g. concentration limits, package size). For RMMs that are consumer instructions, the efficiency is difficult to evaluate in a quantitative sense. Consumer instructions are usually not expected to be highly effective, unless consumer behavioural data provide evidence that a sufficient degree of implementation can be assumed. The issue of adherence to instructions is fundamentally different for consumers than in occupational settings where operational conditions are more controlled.*

*Therefore consumer RMMs that depend on instructions should as a general rule only be introduced to show that risks are controlled when the use of such RMMs can be shown to*

*effective, necessary and well adhered to by consumers. In principle, for quantitative considerations in the exposure estimation only those RMMs should be applied which can be controlled by the manufacturer of the product. This means that RMMs are either considered by changing one or more operational conditions or product composition, e.g., maximal concentration used or maximal amount of product used. There are very limited circumstances for consideration of personal protective equipment (PPE) in consumer exposure, because people will not necessarily use PPE even though recommended by the manufacturer. Even when PPE is provided with the product (e.g., gloves with a hair dye), this will not ensure that consumers will use it.*

### **C. Health Canada**

Health Canada was consulted on the subject with the following questions:

- Do you in Canada consider a protection from classical clothing against liquid or solids for consumer use?
- If yes what is the basis of this parameter? Was it built from studies or experimentation or expert judgment?

Their response was:

*In the Existing Substances Risk Assessment Division of Health Canada, the standard approach is not to use clothing permeation (or clothing protection) values. The algorithms for most consumer product application scenarios assume only uncovered skin areas are exposed (e.g. parts of hands, forearms). In the case of post-application exposure for products such as laundry detergent, there may be assumptions regarding the % of residue deposited on clothing/fabric that may transfer to the skin.*

*In the case of pesticide products, please note that the Pest Management Regulatory Agency (PMRA) of Health Canada may incorporate clothing protection factors into their professional applicator scenarios to represent protection offered by a second layer of clothing (e.g. coveralls), chemical resistant coveralls and gloves. In the case of domestic (consumer/non-professional) use of pesticide products, no clothing permeation factor is applied, as it is assumed that they do not wear additional layers of clothing beyond a short sleeved shirt and shorts.*

*Background on Clothing Protection Factors for PMRA: PMRA's protection factors for clothing are based on the amount of chemical that could penetrate through the layers of clothing and reach the skin. Values were determined from the default values used by the United States Environmental Protection Agency (US EPA) and California's Department of Regulation (DPR), as well as data from the literature, and are used for all formulation types. These values are used with exposure data from pesticide handler studies and are applied to those areas of the body where the additional clothing would be worn (e.g. to the hands for gloves). As the percent of product penetrating the material is dependent on the concentration of product on the outside of the material, the protection factors used by PMRA are only applied to scenarios where someone is handling a pesticide product and not to other scenarios, such as when contacting a treated surface. It has been observed in pesticide handler data that percent penetration decreases as outside deposition increases, therefore a single percentage value for penetration understates actual penetration at low levels of outside deposition while overstating it at high levels.*

- *The clothing protection values used by PMRA are: 50% long sleeve shirt and long pants*
- *75% for cotton coveralls*
- *90% for chemical resistant coveralls 90% for chemical resistant gloves*

#### **D. Conclusion**

The different guidance documents are on the same lines considering that there is no warranty that non-professional users will follow the labelling and will take particular care to protect them.

Therefore, the typical minimal clothing should be shorts and short-sleeve shirts, shoes, and socks, unless there is a real particularity of the product, for example being applied in winter outdoor.

The use of long sleeves shirt and trousers can only be a risk mitigation measure and the applicability should be discussed on a case by case basis, also taking into account the product type.

### **3.2 How to assess the protection factor provided by clothing?**

The review of the guidance documents about protection factor provided by clothing was done for typical clothing and extended to any kind of protection provided by one layer of fabric including occupational guidance documents.

#### **A. Guidance documents**

- **HEEG Opinion 9 based on TNsG 2002 and TNsG 2007**

A protection factor of 50% is given for non-professional wearing long-sleeved shirt and trousers or skirt with shoes and no gloves. This protection factor is indicated with the following restrictions: "*This is a general protection factor that is used for non-professionals applying a dry substance. This protection value can also be used for challenge by a liquid formulation where contamination is judged to be relatively light (e.g. from using an aerosol canister or application by a trigger spray)*".

All protection factors from the TNsG 2007 are from a paper by Gerritsen-Ebben et al.2007.

- **TNO report: Effective Personal Protective Equipment: default setting of PPE for registration purposes of agrochemicals and biocidal pesticides (Gerritsen-Ebben 2007)**

This report made by TNO is an extensive review of protection factor of PPE from the models and guidance used in 2007 for chemicals at European and member of the OECD level.

The use of the protection factor of 50% for one layer of fabric is observed in a lot of guidance and models, such as Riskofderm dermal toolkit (different from the Riskofderm dermal model), the US EPA Pesticide Handler Database and EUROPOEM I. However, no reference justifying this factor is identified.

- [US EPA Standard Operating Procedures \(SOPs\) for Residential Exposure \(2012\)](#)

The usual 50% for one layer of fabric is used for construction of non-professional user exposure based on professional data:

*"Dermal exposure was measured using clothing the individuals wore, thus representing applicators not wearing any clothing. To estimate exposure representative of applicators wearing shorts, short-sleeve shirt, shoes, and socks, a penetration factor of 50% was used for exposure measurements to the torso, upper arms, and upper legs."*

The document refers to the US EPA Pesticide Handler Exposure Data (PHED) for the factor.

- [US EPA PHED pesticide handler unit exposure surrogate reference table \(2013\) page 11](#)

*"Single layer" body exposure calculated from available "total deposition" body exposure data by dividing by 2 (i.e., an additional layer of clothing is assumed to reduce body exposure by 50%).*

However, no justification for the derivation of this factor is provided.

- [US EPA PHED SURROGATE EXPOSURE GUIDE \(1998\) page 11](#)

In the default PPE protection factor chapter, the following warning is given:

*Arithmetically estimated protection factors are sometimes used when data for handlers wearing the specified PPE are not available. In the following exposure mitigation table is a list of estimated protection factors (agreed to by USEPA/OPP/HED Science Peer Review Committee). These protection factors should be considered interim measures only.*

EXPOSURE MITIGATION TABLE		
PPE	% reduction in exposure	NOTE
Long sleeve shirt and long pants or full coveralls	50% reduction in exposure to covered parts	This estimate is being reviewed by EPA, Health Canada and CADPR. The percent reduction in exposure afforded by coveralls may be increased in the future. Please verify this protection factor before proceeding. As of January, 1998, HED=s policy is 50%.
Chemical resistant gloves	90% reduction in exposure to hands	
Dust/Mist respirator	80% reduction in inhalation exposure	
Organic vapour respirator	90% reduction in inhalation exposure	
Enclosed Cabs	98% reduction in both dermal and inhalation exposure	

## B. Conclusion

As highlighted in the TNO report (2007), many guidance documents recommend the 50% protection factor but no justification for this value was found in them. It seems to be an expert judgment from the US EPA review committee.

The protection factor represents the capacity of the cloth to reduce exposure for the covered part as for a PPE from the HEEG Opinion 9. It does not represent the area of skin covered by cloth.

It can be acknowledged that clothing will provide a minimum level of protection for covered skin areas.

The restriction of use from the HEEG Opinion 9 is to apply this factor only for dry substance and for challenge by a liquid formulation where contamination is judged to be relatively light (e.g. from using an aerosol canister or application by a trigger spray). However, there is a need for a better definition of light challenge.

### 3.3 How to integrate the protection factor in the models from the TNsG?

Skin contamination is expressed in two ways in the TNsGs:

- a) Body and hands
- b) Hands/forearms and legs/feet/face

#### **For typical clothing, short sleeves shirt and shorts**

In case a) contamination of body and hands, in order to apply the correction factor, the repartition of contamination between covered parts and uncovered parts (head, forearms, upper arms and legs) should be known. Contamination is not often homogenous, especially if there is no aerosol. Considering only the surface area of the different parts of the body or applying the protection factor to the whole body contamination can lead to underestimation.

In case b) contamination of hands/forearms and legs/feet/face, the skin area covered by the cloth is already out of the contamination areas from the models. Therefore, the protection factor is of no help and should not be used in this case.

#### **For long sleeves shirt and trousers**

The 50% protection factor can be applied to reduce the exposure in both case a) and b), if the risk mitigation measure is considered applicable.

## 4. Conclusion

A protection factor of 50% can be assumed for one layer of clothing against dry contamination or light liquid contamination.

In case of liquid contamination with challenge higher than light, no protection has to be assumed by cloth.

Considering short sleeves shirt and shorts, there is an inadequacy between the protected surface area and the TNsGs models inputs and therefore no protection factor should be

used.

An application of the protection factor for non-professional wearing long-sleeved shirt and trousers or skirt with shoes and no gloves can be considered if this mandatory clothing is integrated as a risk mitigation measure. The applicability of such measure should be discussed on a case by case basis, also taking into account the product type, as no warranty is given that consumers will wear such clothes.

## 5. References

- Gerritsen-Ebben MG, Brouwer DH, and Hemmen van JJ, Effective Personal Protective Equipment (PPE): Default setting of PPE for registration purposes of agrochemical and biocidal pesticides, TNO Report V7333 (2007)
- [Guidance on information requirements and chemical safety assessment - Chapter R.15: Consumer exposure estimation](#)
- [HEEG Opinion 9 on Default protection factors for protective clothing and gloves](#)
- [PHED Exposure Surrogate reference table, US EPA, March 2013](#)
- [PHED Surrogate Exposure Guide; Estimates of Worker Exposure from The Pesticide Handler Exposure Database Version 1.1, US EPA, August 1998](#)
- [SOPs Standard Operating Procedures for Residential Exposure, US EPA October 2012](#)
- [Technical Notes for Guidance on Human Exposure to Biocidal Products, 2002](#)
- [Technical Notes for Guidance on Human Exposure to Biocidal Products, 2007](#)

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