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Institute for Health and Consumer Protection
Chemical Assessment and Testing

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HEEG opinion

Default protection factors for protective clothing and gloves

INTRODUCTION

The default protection factors of coveralls and gloves were discussed in TM II 2009, and it was agreed that the current situation is not sufficiently clear to provide harmonized and reliable values for risk assessment.

It was concluded that the values of default protection factors given in the TNsG on Human Exposure (June 2007) are ambiguous due to missing data that is being referred to. In this TNsG, the table on default protection factors (Table 2 on p. 19) includes the following footnote: "*It is recommended to await the results of the development of guidance for Risk Management Measures (RMMs) under REACH, since for the development of 'safe' Exposure Scenarios, RMMs are essential, and thus their alleged protective effectiveness.*" The RMM library cited has no real exposure data and is therefore not usable for the purpose foreseen in the TNsG. It has therefore not been clear whether the values presented should be used, or whether it would be better to use the old guidance of 2002.

It was agreed in TM II 2009 that the situation needs to be discussed within the HEEG, after which a proposal clarifying the situation will be brought to the TM for endorsement.

The aim of this paper is to put into logical context the default protection factors which have been included in the previously peer-reviewed TNsGs (the Technical Notes for Guidance on Human Exposure to Biocidal Products, June 2002, the User Guidance version 1 dated June 2002 and the TNsG dated 2007). It is not the intention of this paper to re-review the default protection factors which have already been peer reviewed. Nor is it the intention of this paper to link protective clothing type categories to the different protection factors or compare these default protection factors with those used to assess plant protection products. It is of note that challenges experienced by the operator during application of plant protection products, often by tractor-mounted sprayers, will differ from those posed during biocide applications (e.g. application by knapsack sprayer).

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PROPOSAL

The basis of the proposal is Table 2 (p. 19) of TNsG 2007. It was seen as a weakness that the table only gives one default protection factor value for dry cotton coveralls, in addition to the values for impermeable coveralls, gloves and minimal clothing for a non-professional.

Using all the information available it can be concluded that several coverall subcategories can be defined with different default protection factors assigned to them.

We concluded that current knowledge supports the default protection factors given in Table 2 of TNsG 2007, but in addition, we assigned default protection factors for double coveralls (99 % protection) and coated coveralls (90 or 80 % depending on use). All proposed values are given in Table 1 below, with references and background information on why these were chosen.

For coated coveralls, two different default protection factors are proposed because of the following considerations:

(a) Complete protection of the operator is not possible since some applied product can get around the coverall and onto the skin; for example at the wrists and the neck of the coverall. Protection thus depends on the nature of the challenge.

(b) With insecticides applied by spray, exposure will be to the spray itself and the spray mist which will be able to enter under PPE via the cuffs/neck of the coverall.

(c) For wood preservatives, the challenge is from the coverall coming into contact with the preservative wet surface; the lack of spray mist would mean there is less substance getting under the coverall via the wrists/neck of the coverall.

(d) Penetration of biocide through the material of the coverall. As the level of challenge increases, the efficiency of protective clothing sometimes increases (i.e. the more in-use product that lands on the coverall, the less penetrates through the coverall to the skin).

When considering the proposed values, it should be noted that the degree of protection afforded by protective clothing and gloves will be dependent on the behaviour of the operator in correctly fitting, removing and maintaining the protective clothing/gloves.

It may be necessary to change these default protection factors in the future, if/when the REACH RMM library (or other relevant data) becomes available.

Table 1. *Default protection factors.*

Description	Default Protection Factor (%)	Source/Reference	Notes
No PPE, gloves or clothing which could afford protection	0	TNsG, January 2008, p. 27	The TNsG informs that Tier 1 human exposure assessments 'must not take account of exposure reduction measures such as personal protective equipment'.
Double coveralls	99	TNsG 2002, Part 3, p. 60	Usually this is for the professional spraying of antifoulants where the spraymen often wear two sets of coveralls, one over the other. In practice this is a long-sleeve, long-leg cotton coverall with a second coverall with a hood worn over the cotton coverall. With exposure to wet paint, spray mist or solvents, this outer coverall should be chemically resistant.
Impermeable coveralls	95	TNsG 2007, Table 2, p. 19 TNsG 2002, Part 2, p. 36 TNsG 2002, Part 3, p. 60	The actual penetration figure is 4 % (TNsG 2002, Part 3, p. 60). The protection is 95 % where a challenge is "considerable" (i.e. at or above 200 mg in-use product/minute) on the whole of the body - not including the hands (TNsG 2002, Part 2, p. 36). 'Impermeable' coveralls should provide a high degree of protection against heavy contamination by being relatively resistant to the penetration of the biocide through the material of which the coverall is made.
Coated coveralls (coveralls designed to protect against spray contamination such as chemical protection clothing of type 6)	90	TNsG 2002, Part 2, p. 36 User Guidance, version 1, 2002, p. 42	This value was used in a worked example for vacuum-pressure/double vacuum impregnation of a wood preservative. A 90 % protection factor has been generally used for wood preservatives where the main challenge is from contact with preservative wet wood. Body exposure occurs mostly through the coverall material. This is usually so for PT 8, post-application exposure, but this is not necessarily the case for other PTs.
	80	TNsG 2002, Part 2, p. 36 For insecticide assessment: TNsG 2002, Part 3, p. 71	The protection is 80 % where a challenge is "light" (i.e. less than 200 mg in-use product/minute) on the whole of the body - not including the hands (TNsG 2002, Part 2, p. 36). An 80 % default protection factor has been generally used for insecticides where they are applied by spray. Body exposure occurs through the coverall material, but may occur also through seams and at the wrist and neck. This is usually so for PT 18, exposure during application, but other scenarios are possible for other PTs.

Uncoated cotton coveralls (dry)	75	TNsG 2007, Table 2, p. 19	Only for dry substances. Cotton coveralls may offer little or no protection from wet substances and may lead to increased rather than reduced dermal exposure if the challenge is from a wet substance by absorbing the liquid challenge and holding it next to the skin.
Protective gloves: For use of protective gloves, it is assumed that the worker has a good occupational hygiene approach in his/her behaviour and uses, where appropriate, gloves with long sleeves to prevent exposure via the openings around the wrists. It is also assumed that gloves are taken off carefully, without touching the outside of the contaminated gloves with bare hands.			
Protective gloves	90 for challenges by a liquid	TNsG 2007, Table 2, p. 19 HEEG opinion agreed at TM I 2008	1) When **potential hand exposure data** are available, a factor of 10 (90 % reduction of exposure by gloves manufactured from appropriate material) can be used as a reasonable and conservative default value to convert the potential to actual hand exposure when using appropriate gloves. 2) When only **actual hand exposure data** are available, it should not be attempted to convert it to potential hand exposure. The data for actual hand exposure can be used for the exposure assessment with the provision that the users will have to wear gloves. This approach needs to be followed in the case of products that cause skin irritation and/or sensitisation and warrant the wearing of gloves. If there is a justified need to convert actual hand exposure data to potential hand exposure (e.g. when the same scenario needs to be used for assessing a less toxic substance or no gloves can be used) a multiplication factor of **100** should be used for the conversion of actual to potential hand exposure. This multiplication factor of 100 is conservative in order to take into account uncertainties over the nature of the gloves to be worn, e.g. permeability of the glove material and glove design. In cases where there are data available in the model with respect to the use of new gloves, a lower percentile and the data on new gloves may be used. This will be a case-by-case decision.
Protective gloves	95 for challenges by a solid	Draft EFSA Guidance	
Protective gloves – new gloves for each work shift	95	TNsG 2002, Part 2, p. 194 Annals of Occupational Hygiene 45 (1): 55-60, 2001 (Table 1, p. 59)	Using new gloves reduces hand-in-glove exposure to approximately half (arithmetic mean factor of 0.52). Therefore, for professional users where new gloves are changed at the beginning of each work shift, the default protection factor of 95 % can be used for the gloves.
Non-professionals wearing long-sleeved shirt and trousers or skirt with shoes – no gloves worn	50	TNsG 2007, Table 2, p. 19 TNsG 2002, Part 2, p. 34 – Options for exposure reduction and personal protective equipment (PPE) and quoted on p. 71 of Part 3	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).