



# Proposal for an Approach with Default Values for the Protection Offered by PPE, Under European New or Existing Substance Regulations

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Introduction of personal protective equipment (PPE) in the process of quantitative exposure and risk assessment should be addressed carefully. PPE which have been designed and manufactured according to CE-criteria and have proved to pass relevant test criteria, can be classified as 'proper functioning'. However, test criteria for PPE are not equal to levels of protection which can be achieved in the workplace, because actual workplace exposure scenarios, fit, maintenance and storage may differ substantially from the test conditions.

The proper use of PPE is related to issues which form a part of a PPE-programme. Such a programme should be implemented in a company to ensure selection of proper PPE and information, training and instruction of employees how to wear PPE properly.

Assigned protection factors (APFs) for different designs of respiratory protective devices (RPD) have been introduced to quantify effectiveness of RPD in the workplace. Similar APFs are proposed for dermal protection (gloves and clothing). In general biological monitoring studies show lower reduction of internal exposure than estimated by reduction of external exposure. Therefore, conservative estimates of protection by PPE, i.e. the lowest APFs, are proposed for risk assessment purposes if 'proper use of proper functioning' PPE as part of a PPE-programme cannot be demonstrated. © 2001 British Occupational Hygiene Society. Published by Elsevier Science Ltd. All rights reserved

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## INTRODUCTION

The impact of the use of personal protective equipment (PPE) as part of the exposure assessment of new/existing substances has been addressed by the European Chemicals Bureau (ECB) (Doc. ECB4/32/98) during Technical Meetings, and a proposal has been given for an approach. Key issues related to PPE and protection against exposure to chemicals were identified as being:

- proper functioning, i.e. designed and tested to result in reproducible, quantifiable reduction of exposure.
- proper use, i.e. wearers use PPE according to

guidelines to ensure adequate protection under conditions of use.

This paper is focussed on both issues for inhalation and dermal exposure and aimed at presenting the state of the art on approaches to set defaults for exposure reduction by PPE for both upstream and downstream use of industrial chemicals. The effectiveness of PPE is considered a key issue in such an approach, as was illustrated previously by Evans (1999). The more developed situation for inhalation exposure and personal protection is used as a basis for the development of an approach for protective clothing.

In this paper, for reasons of space, many references to standards and testing procedures have not been made. This information is contained in a report (Brouwer *et al.*, 2000) that may be obtained from the authors.

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## PPE AND RISK MANAGEMENT

Risk management includes both hazard control and exposure control measures to reduce risks due to occupational or consumer/residential exposure to chemicals.

Exposure control measures are classified according to the so called occupational hygienic hierarchy and include process or work method measures: (1) to reduce emission of the chemical, e.g. low emission formulation forms; (2) to reduce transmission, e.g. containment, (local exhaust) ventilation; and (3) to reduce immission, e.g. organizing the work, cabins, and (4) finally measures at a personal level, i.e. the use of personal protective equipment. Essentially, if such measures are identified and implemented, it should result in a refinement of the exposure assessment for specific exposure scenarios. However, exposure reduction measures on the level of processes, technical devices, or organization of the work, are generally accepted as feasible and long lasting (full-shift) risk management tools, whereas no consensus exists on PPE in this field. In the view of some competent authorities in the EU the use of PPE should be time-limited (not full-shift use), temporary, and limited to specified high risk tasks.

In addition to the restraint on the use of PPE as an adequate control measure in risk management, there is another point of concern. This is the variability of the effectiveness of PPE in workplace practice, because it is the result of the interaction of proper design and manufacturing ('proper functioning') and actual fit, maintenance and cleaning, and proper use by the wearer in workplace practice ('proper use').

## PPE MANUFACTURING AND TEST PERFORMANCE SPECIFICATIONS

In 1989 the European Commission introduced Directive 89/686/EEC on personal protective equipment (PPE). The Directive gives the minimum requirements, which are common to all kinds of protectors. Also the Directive and its revisions (93/68/EEC, 93/95/EEC, 96/58/EC) (EEC, 1996) state how PPE can be introduced to the market. For details, the reader is referred to Brouwer *et al.* (2000). These regulations aim to protect the European market against the introduction of unsound designs of protective devices and to classify designs and devices into categories of protection.

CE-marked PPE has been approved according to manufacturing criteria and classified as protective devices in the EU. However, test criteria adopted in this certification process should not be interpreted directly into levels of protection during actual use in the workplace. This will be illustrated by some examples from the area of protective gloves.

First, tests are performed under laboratory conditions which do not mimic actual workplace user

scenarios (which include a wearer) completely. Since the permeability coefficient of protective glove material is affected by temperature according to an Arrhenius relationship, theoretical steady state permeation rates increase and breakthrough times decrease with an increase in temperature (Perkins, 1987). Elevated temperatures — inside the glove the temperature will be about body temperature ( $\pm 35^{\circ}\text{C}$ ) — may enhance permeation and result in shorter breakthrough times compared to the conditions of the formal breakthrough test at  $23^{\circ}\text{C}$ . The same holds for permanent or periodical stretching during use, giving localized thinning of glove membrane (Packham, 1998). Preliminary results of an ongoing study in Germany reveal an impact of the adjustments of test conditions for gloves to real life conditions. Enhanced temperature of the sampling chamber to  $35^{\circ}\text{C}$ , and length stretching by 20% resulted in reduction of break-through times of 10–60% and 10–50%, respectively (Anon, 1999). Moreover, tests are performed with 8 h chemical challenge, whereas in realistic workplace practice short-time and intermittent contacts to chemicals occur (Packham, 1998).

From the results of a laboratory experiment, the effect of glove flexure on (solvent) permeation parameters has been demonstrated, but the authors state that the effect is relatively small in the overall scheme of things. Other variables such as temperature, thickness variability, and intermittent use, would be more important than flexing alone (Perkins and Rainey, 1997).

Raheel (1991) and Yang and Li (1993) demonstrated respectively that mechanisms which occur during the use of permeable protective clothing in practice, such as perspiration and frictional transition, enhance penetration of contaminants.

Second, a single test compound is used, whereas a large variety of chemicals and mixtures can be observed in workplaces. Therefore the selection of a test substance is a key issue in standardization and testing, in particular when the chemical rather than physical properties of chemicals play an important role in protective performance of the device. For example, in filter efficiency testing it is agreed that  $0.4\ \mu\text{m}$  aerosols show the highest penetration and aerosols with this critical diameter are used in standard tests. Permeation through impermeable materials depends very much on the properties of the chemical and all chemicals should be tested separately. However, breakthrough time of mixtures is very complex and depends on similarity of intermolecular forces or polarity of the components of the mixture (Perkins, 1987), which makes it impossible to predict breakthrough time of mixtures from their ingredients' permeation data (Anon, 1999).

Third, standard sizes based on distribution of anthropometrical data do not always result in optimum personal fit. Individual fit has been considered

critical for respiratory protection, therefore qualitative and quantitative fit tests have been developed (Coffey *et al.*, 1998; Mullins *et al.*, 1995) For protective gloves and clothing an inappropriate fit may result in uncovered body parts, or may lead to hazardous situations caused by lack of dexterity.

Fourth, in standard laboratory tests for dermal protection, new unused devices are tested, whereas devices may be re-used in workplace practice. Apart from cleaning and maintenance issues, some material degradation, loss of ability to stretch etc., may have occurred. This may affect fit or resistance properties.

Fifth, last but not least, the protective performance of a device is judged in terms of degree of retainment of a test substance by the device. In view of risk assessment the performance of a device should be judged according to the ability to reduce 'biologically relevant exposure' of the worker. There may be a discrepancy between these two approaches. This will be illustrated later.

The factors given above are related to manufacturing and marking aspects which could be considered to be part of 'proper functioning' criteria. However, 'functioning' relates to workplace performance of the devices. This is addressed by the introduction of workplace protection factors in the next paragraph.

#### PPE AND WORKPLACE PROTECTION

In practice, the effectiveness of PPE will be determined by interaction of the ability of the device to retain workplace contamination and workers' factors related to the use, e.g. actual fit of the device to the worker during the performance of work tasks, instruction and training in use, cleaning and maintenance.

As illustrated before, CE-marked PPE has passed efficacy tests, which are basically standard laboratory tests. Quantitative comparison of the level of contamination 'outside' and 'inside' the protective device assessed in workplace scenarios for an individual worker who uses PPE, enables a better assessment of the 'overall' performance of PPE, i.e. 'the proper functioning' of PPE.

For various designs of RPD, field studies have been conducted to assess workplace protection factors (WPF). Most studies have been conducted in the USA according to a protocol drafted by the AIHA (Guy, 1985; Myers *et al.*, 1995), but the protocol adopted in the UK is on different principles (BSI, 1997).

In WPF-studies according to the AIHA-protocol only workers who are adequately trained and have experience using the respirator design under study, and who have passed a quantitative or qualitative fit test, are included. Prior to the study additional instructions of use are given, and during the study the use of RPD is monitored by investigators. If necessary, additional instructions are given during the study. In the BS 'as is' studies, no additional instruc-

tions are given prior to the study and no intervention by investigators is made. Outside the respirator and inside the mask concentrations of the hazardous chemical are determined. Inside mask concentration measurements may be biased by incomplete mixture of the contaminant in the inside face piece air, so the sampling location related to the location of the mask leakage may determine the outcome of the in-mask measurement very much (Crutchfield and Park, 1997).

ANSI (ANSI, 1992; Nelson, 1996), and BSI (BSI, 1997) have evaluated all WPF-studies available at a certain point in time, to assign protection factors for various respirator designs in the USA and the UK, respectively. The 'assigned protection factors' (APFs) are 'weighted' 5th-percentiles of the (log-normal) distribution of observed workplace factors, and afforded protection to 95% of adequately trained and instructed wearers, who wear proper functioning and well-fitted respiratory equipment. Typical GSDs for AIHA-protocol studies are within the range of 2.3–3.6, however observed GSDs were up to 7.2, indicating large between-wearer variances.

Table 1 summarizes APF-values drafted by ANSI and BSI for some types of filtering respirator designs. Partly due to the non-acceptance of 'as is' designed studies for some types of RPD by ANSI, e.g. full face masks, higher APFs have been derived compared to APFs set by BSI. The nominal protection factor (NPF) is shown in the last column, and clearly illustrates the difference between observed workplace protection and test criteria.

For protective clothing, including protective gloves, assessment of protective properties relies on laboratory test data on penetration and permeation rates and breakthrough times. Forsberg and Keith (1995) classified materials used for gloves and protective clothing according to permeation rate and breakthrough time into classes of permeation indices (0–5 scale), where class 0 indicates highest level of afforded protection and class 5 the lowest level.

Some initiatives are observed to derive 'workplace protection factors' or 'default reduction factors', mainly in the area of pesticide exposure (van Hemmen, 1998). Compared to respiratory protection, determination of workplace protection factors for protective clothing and gloves is much more complex, because of multi-compartment origin of dermal contamination and possibly interference of workers' behaviour. However, the latter parameter does not exclusively apply to dermal exposure. Scheider *et al.* (1999) distinguished several mass transport processes, i.e. emission, deposition (of aerosols) and direct contact transfer from direct sources, air, and surface layer compartments to clothing or skin, whereas respiratory exposure only originates from the air compartment. For (pesticide) spraying activities aerosol deposition may be the dominant process for contamination of clothing. Determination of the penetration of pestic-

Table 1. Examples of assigned protection factors for filtering devices

Mask type	Filter type	BS 4275	ANSI Z88.2	NPF <sup>a</sup>
Filtering half masks	FFP1	4		4
	FFP2	10		10
Half or quarter mask and filter	FFP3	20	10	50
	P1	4		5
	P2	10		12
	Gas	10	10	50
	GasXP3	10	10	50
	P3	20	10	50
Filtering half masks without inhalation valves	FMP1	4		5
	FMP2	10		12
	FMGasX	10	10	50
	FMGasXP3	10	10	50
	FMP3	20	10	50
	FFGasXP1	4		5
Valved filtering half masks	FFGasX	10	10	50
	FFGasXP2	10		12
	FFGasXP3	10	10	50
	P1	4		5
Full face masks and filter	P2	10		16
	Gas	20	100	200
	GasXP3	20		200
	P3	40	100	200
Powered filtering devices incorporating helmets or hoods	TH1 all types	10	100	5/16
	TH2 all types	20	100	16/50
	TH3 (semi)hood/ blouse	40	1000	50/500
Power assisted filtering devices incorporating full, half or quarter masks	TM1 (all types)	10	50 (Half face)	20
	TM2 (all types)	20	50 (Half face)	100
	TM3 (half face) particle, gas or combined filters	20	50	100 (full face)
	TM 3 (full face) gas or combined filters	40	1000	100 (full face)

<sup>a</sup>Nominal protection factor.

ides through clothing in field exposure scenarios is performed by comparison of the contamination of 'outer pads' to contamination of 'inner pads', i.e. small-sized collection media placed against the outside and inside of the clothing, respectively. As with RPD the location of the pads may affect the outcome of measurement very much, since the location of the inside pad is not exactly beneath the outside pad, and contamination of clothing is not homogeneously distributed. Significant progress to derive penetration factors in real life exposure scenarios is made by a meta analysis of pesticide penetration through clothing based on data in the Pesticide Handlers' Exposure Database (PHED) on inner/outer pad comparison, and quantitative data are available (Anon, 1997). Since a decreasing relationship of penetration to outside level was observed, a non-constant estimate for mean penetration was proposed ranging from 1.6 to 50.6% for outside levels of contamination of 60 to 0.00025  $\mu\text{g}/\text{cm}^2$ , respectively.

Studies conducted in non-pesticide exposure scenarios showed substantial exposure to industrial chemicals, e.g. MDA (Boeniger *et al.*, 1992; Hoogendoorn, 1995; Brouwer *et al.*, 1998) and lead (Wheeler and Sams, 1999; Wheeler *et al.*, 1999), for workers who wore protective gloves, e.g. by monitoring gloves or hand washing, showed substantial actual hand exposure. In these processes hand exposure is considered to be determined primarily by hand-contact to contaminated surfaces. In a survey on lead exposure in the battery industry in the UK, Wheeler *et al.* (1999) observed no significant difference in hand contamination between workers wearing gloves and those not wearing gloves, after correction for the average contamination of surfaces in the area where the workers worked. Since processes such as surface transfer and direct contact with the source, e.g. by immersion, dominate deposition in most cases, workers' behaviour when wearing protective gloves may play an important role in determining contamination of gloves. This holds especially for exposure scenarios where sticky or liquid forms of compounds are handled, e.g. MDA-containing resins or wet prepregs. Comparison of contamination recovered from the outside of protective gloves and contamination removed from the inside of the gloves or from the hands of the same individuals may give very high estimates of workplace protection factor, e.g.  $\geq 98\%$  (Hoogendoorn, 1995; Boeniger *et al.*, 1992), but contamination of the outside of protective gloves might be unrealistically high compared to non-glove use exposure.

For pesticide exposure scenarios such designed studies showed mean average reduction of 84% (Nigg and Stamper, 1983), 87% (Chester *et al.*, 1990) and 98% (Maddy *et al.*, 1989). A within-worker comparison study for actual hand exposure revealed median reduction of 95% and 87% for applicators wearing

nitrile gloves and harvesters wearing cotton gloves, respectively (Brouwer and van Hemmen, 1997).

Despite the limitations of the study design, data generated by this type of field study should indicate the reduction by types of clothing or glove design more appropriately than test criteria do. The presence of openings, stretching, bellows effects, etc. may result in a lower exposure reduction than expected. Brouwer *et al.* (2000) contains a summarizing table with 'defaults' used for types of clothing and other skin protective devices which have been set for similar exposure processes by several national authorities for the registration of pesticides. The statistics or rationale which have been used to derive the defaults differ, but are not necessarily the most appropriate (van Hemmen, 1998). Based on a review of the open literature on pesticide exposure Beelen *et al.* (1995) proposed 'reasonable worst case' defaults for clothing layers and gloves in actual practice, i.e. not necessarily good practice. They stated that for one clothing layer, despite of the fabric, an 'assigned protection factor' of 2.5, i.e. 60% reduction, would be possible, where an additional layer would result in an APF of 6.25. For gloves, based on a worst case protection of 85% an APF of 6.7 was proposed. The authors stated that in field practice a mixture of processes, e.g. penetration, permeation, bellows effect, transfer by (cross)contamination during handling contaminated gloves or clothing, etc., will result in transport of pesticide through clothing or gloves.

#### PPE AND 'PROPER USE' CRITERIA

In general, factors which determine 'proper use' in practice are related to (i) awareness of the need to use PPE, (ii) instruction and training, (iii) ability to perform work tasks (ergonomics), and (iv) acceptability based on (dis)comfort. The latter two aspects will determine the duration of use, and therefore the overall effectiveness of PPE to reduce exposure.

The awareness of need to use PPE and instruction and training should be included in a PPE-programme that consists of (Colton *et al.*, 1991):

- an assessment to determine the nature and degree of actual or potential exposure;
- PPE selection by a decision logic system;
- employee information, training and instruction;
- PPE fitting;
- maintenance, cleaning, and storage;
- purchasing and inventory control;
- emergency use planning;
- medical surveillance (optional, depending on PPE-type);
- program evaluation.

#### Selection of PPE

PPE-selection is a key issue in the area of 'proper use', since the selection should be based on the out-

come of a risk assessment, but should also include an evaluation of the ability of the worker to use PPE.

Decision logic systems for respirator selection have been drafted which afford professional occupational hygiene or safety persons to select adequate respiratory protection based on risk assessment (NIOSH, 1987; BSI, 1997). Briefly, decision logic systems evaluate the workplace atmosphere and oxygen concentration, and IDLH-values (Immediately Dangerous to Life and Health) to preselect the category of respirator that can be used, i.e. air purifying types or supplied-air types (low oxygen concentration and/or concentration >IDLH). The next step is comparison of potential inhalation exposure with Occupational Exposure Limits to assess the required protection factors. Within the appropriate category of RPD those designs are selected that have APFs which afford adequate protection.

Similar decision logic systems for skin protection have not been drafted, basically because the lack of Occupational Exposure Limits for dermal exposure limits the assessment of required protection, i.e. to reduce dermal exposure to 'safe levels' and/or the limited possibilities to quantify dermal exposure. Moreover, no sound basis exists to relate level of exposure and local effects, e.g. irritation and sensitization. However, the approach presented by BSI (BSI, 1989) includes a paragraph on risk and danger assessment to determine the need for dermal protection, but the level of required protection has not been quantified.

Recently, an approach has been proposed to select protective gloves for industrial chemicals, products, and or in-house mixtures of chemicals (Schipper *et al.*, 1998). In this approach (systemic) hazardous properties of chemicals related to the dermal route of exposure have been classified using the assigned R-phrases according to the EU-classification system [annex I Dangerous Substance Directive 67/548/EEC (EEC, 1967)]. The categories have been fitted into the target dose 'banding' system proposed for inhalation risks (Brooke, 1998). Skin effects classes were linked to protection classes, where substances that are expected to penetrate the skin at low rates ( $M < 400$ ,  $-1 < \log Pow < 4$ ) fall into lower categories of protection than substances with possibly high penetration rates. The permeation index by Forsberg and Keith (1995) is used to link protection classes to protective materials. Table 2 summarizes this classification system. This approach is useful as a first tier in the selection of protective clothing/gloves, because it indicates the relation between hazardous properties of a substance and surrogate generic 'acceptable' levels of exposure for substances of that class. However, linking the target dose bands to protection classes directly, can be considered a short-cut, since actual workplace exposure scenario, i.e. skin exposure, is not a part of the selection procedure.

For substances with local (skin) effects classi-

fication according to quantitative target doses is not possible (Basketter *et al.*, 1999). In absence of such quantitative classification scheme, concentration limits are used according to the Guideline on Preparations (EEC, 1967).

#### *Job, task and worker related issues*

In addition to the ability to reduce exposure, the use of PPE may limit or make it difficult for the worker to perform the task. For RPD, quantitative data are available that show the limitation of vision of the worker by full face masks by design or by condensation of moisture at the face shield (Baak *et al.*, 1990; Johnson *et al.*, 1992). Air-purifying RPD, self containing breathing air-devices and airline RPD limit the movements of the worker by weight and geometry, and the connecting hose, respectively (CR 529, 1993). These properties may limit performance of tasks which demand good vision or stretching and span of activity and high work speed. Air-purifying RPD will increase breathing resistance, which could affect the performance of tasks that imply high metabolic rates. Air-supplied hoods result in high noise levels and affect the ability of conversation and of hearing acoustic (warning) signals, which may be a part of the task.

For protective clothing, limitations are focussed on reduction of span of activity and work speed (reduction of reach, stretching), whereas for gloves dexterity (finger/hand) reduced by the thickness of the glove is important. The latter illustrates the conflict between effectiveness and ergonomics, since permeation theory indicates that thickness and permeation rate are inversely proportional (Perkins, 1987), but thickness seems to be proportionally related to dexterity reduction determined by standard tests, e.g. Minnesota manual dexterity test, Purdue Peg-board test (Havenith and Vrijotte, 1993).

In addition to ergonomics of PPE, aspects related to comfort will limit its use or the duration of wearing by the worker. Quantitative factors, e.g. heat, moisture (sensation), pressure, breathing resistance and less quantifiable factors, e.g. ease of use and perception of isolation, greatly determine the comfort perception of PPE. These factors differ for type and make of RPD, clothing or glove, and materials and configurations are tested in laboratory settings. For example, for heat and moisture discomfort, laboratory tests are developed for heat and water vapour transport through fabrics (Lamb, 1992), to mimic thermophysiological comfort by skin models (Hatch *et al.*, 1990), or by human volunteer test panels (Havenith and Vrijotte, 1993). Sometimes both physiological and subjective responses were investigated in trials, where volunteers wore personal protection equipment (clothing and/or RPD) adjusted for specific exposure scenarios (White *et al.*, 1989; Rissanen *et al.*, 1991). In addition, comfort factors are evaluated in field practice by questionnaires. For example, Popendorf *et*

Table 2. Recommended level of hand protection (gloves) for hazardous chemicals with systemic effects (Schipper *et al.*, 1998; Brouwer *et al.*, 2000)

Hazard class	Classification of severeness of skin exposure according to target doses based on R-phrases		Protection class <sup>c</sup>	Recommended protective properties of gloves	
	High level of skin absorption can not be excluded <sup>a</sup>	High level of skin absorption is unlikely		Permeation index <sup>d</sup>	Additional requirements
0	R-phrases not assigned	Xn, R20, R22 Xn, R40/20, R40/22	0	Glove not needed	
1	Xn, R20, R21, R22 Xn, R40/20, R40/21, R40/22	T, R23, R25 T, R39/23, R39/25 Xn, R48/20, R48/22	1	≤4	None
2	T, R23, R24, R25 T, R39/23, R39/24, R39/25 Xn, R48/20, R48/21, R48/22	T+, R26, R28 T+, R39/26, R39/28 T, R48/23, R48/25	2	≤2	Break trough time > duration of direct, contact with the compound
3	T+, R27, R28, R26 T+, R39/26, R39/27, R39/28 T, R48/23, R48/24, R48/25		3	≤1	Break trough time > duration of exposure, i.e. period of time with occasional contact
b	Carcinogenicity: T, R45 (Cat 1 and 2); Xn, R40 (Cat 3); T, R49 (Cat 1 and 2); Mutagenicity: T, R46 (Cat 1 and 2); Xn, R40 (Cat 3); T, R49 (Cat 1 and 2); Reproductive toxicity: T, R60, R61; Xn, R62, R63 No toxicological data given	Carcinogenicity: T, R45 (Cat 1 and 2); Xn, R40 (Cat 3); T, R49 (Cat 1 and 2); Mutagenicity: T, R46 (Cat 1 and 2); Xn, R40 (Cat 3); T, R49 (Cat 1 and 2); Reproductive toxicity: T, R46 (Cat 1 and 2); Xn, R40 (Cat 3) Reproductive toxicity: T, R60, R61; Xn, R62, R63 No toxicological data given	4	≤1	Break trough time > duration of exposure, i.e. period of time with occasional contact

<sup>a</sup>Criteria: skin-notation and/or M < 400, en of -1 < log Pow < 4.

<sup>b</sup>Compounds with non-quantitative R-phrases cannot be categorized, since a no-observed-adverse-effect-level can be derived and accordingly no threshold limit value for effect classes can be derived. Additional toxicological data are warranted.

<sup>c</sup>Protection class: combination of permeation index (requirements for protective glove material) and additional requirements for use.

<sup>d</sup>Permeation index, i.e. a combination of permeation rate and break trough time, according to Forsberg and Keith (1995).

*al.* (1995) evaluated acceptability among agricultural workers for three types of RPD according to a 10 point scale for 11 parameters, ranging from breathing ease to overall comfort. Ojanen *et al.* (1992) used a five point scale for 45 variables to evaluate the subjective wearing comfort of protective clothing among herbicide sprayers in forestry.

To select optimum PPE these factors should be integrated in a decision logic which is illustrated in a generic form in Fig. 1. It is recognized that ergonomic and (thermal) comfort factors influence the acceptability and thus the 'proper use' of PPE by the worker very much. Generally, these issues are addressed in more general terms. In 'Guidelines for selection and use of respiratory protective devices' (CR 529, 1993) interference of RPD to movements, restriction of vision distorting of speech transmission are mentioned, but only briefly discussed. BSI (1997) includes 'suitability' and 'compatibility' in the selection of RPD. Suitability is discussed in general terms of inhalation resistance and work rate, wear duration, stooping and bending or work in confined spaces, or work in hot, humid or cold environments, whereas 'compatibility' has been addressed in terms of interaction of PPE such as hearing protection with RPD. Perkins (1987) addressed these items in recommendations for selection of protective clothing by industrial hygienists. BSI (1989), and in particular the proposed 1999 revision, addresses protective clothing related to comfort and mobility in more details, but still in qualitative terms.

At present, no system has been published to classify tasks related to the ergonomic and (thermal) comfort needs to perform these tasks. Participation of the potential users of PPE in selection process could partly overcome this problem, for example by offer-

ing use and testing of several types of PPE that have been selected in the first tier of the decision logic and that should offer adequate protection. Workers can try all of them and select the most appropriate type individually.

#### EXPOSURE REDUCTION AND PROTECTION

PPE are designed and used to offer protection of the wearer by reduction of external exposure. However, reduction of (external) exposure is not always linearly related to increase of protection.

Firstly, it should be realized that dimensionless, fixed point, reduction 'factors' presume a proportional reduction of exposure over a large range of exposure levels and time. This may not always be a proper assumption, since retention of contamination by PPE or the barrier function, e.g. air purifying filters for RPD and non-, semi- and, permeable materials for clothing and gloves, is determined by (mass) capacity and a time factor. This can be illustrated by the permeation process of substances through materials. After a period of initial contact of the contaminant with the protective material (layer/fabric) a breakthrough will be observed. Prolonged contact will result in increase of the permeation rate and finally a steady state permeation will occur. Increase of the capacity (weight per m<sup>2</sup>) of the material will show both a prolonged breakthrough time and lag time; however the steady state permeation rate will be similar. The process of penetration of contaminants, driven by pore sizes of the fabric in combination with the diameter of the aerosol and pressure differences, has been physically described. However, the loading may effect the pore sizes of the fabric, e.g. by swelling of the membranes

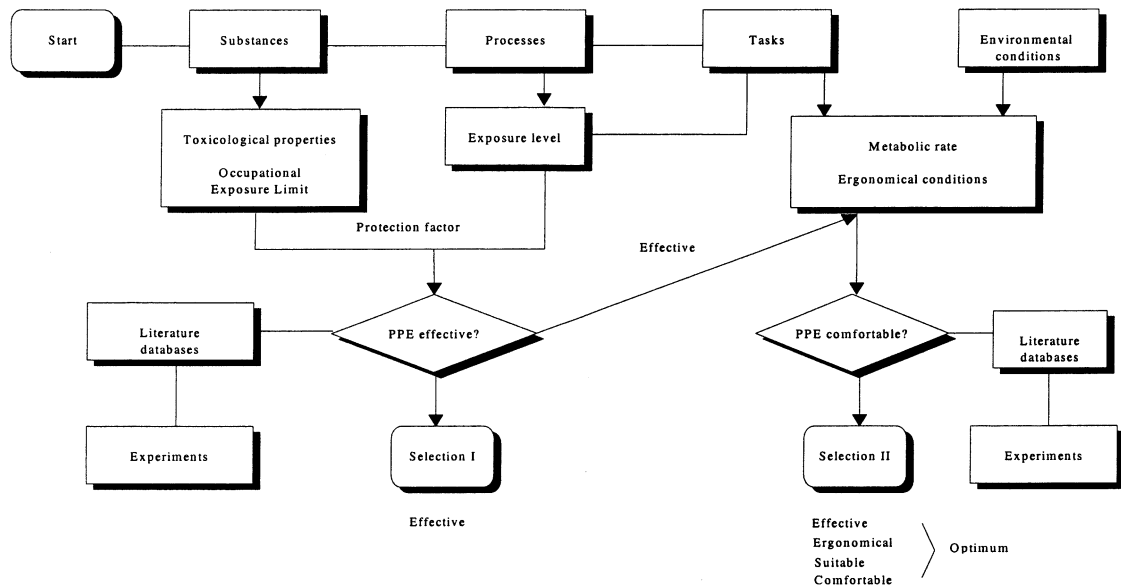


Fig. 1. Generic decision logic to select optimum personal protection equipment for chemical hazards.

by absorption of liquid. An example is shown by Brouwer *et al.* (2000) in a figure where much lower reduction factors, i.e. higher percentage of penetration, were observed for lower levels of contamination of the fabric (cotton coverall) compared to high levels of contamination. It shows the difficulty of deriving a fixed reduction 'factor' from these data and the influence of the statistics that are used. From a thorough analysis of inner- and outer patch analyses available in the PHED-database, an estimate of the mean penetration was proposed by linear regression, where the percentage penetration is an exponential function of the loading of the outer patch (Anon, 1997).

Secondly, reduction of external body exposure is not always linearly related to reduction of internal exposure. Especially for dermal exposure scenarios, the use of reduction factors may oversimplify the process of reduction for dermal exposure and absorption. This is described in detail by Bos *et al.* (1998).

In an intervention study by Brouwer and van Hemmen (1997), where actual dermal exposure and internal exposure (biological monitoring) to a pesticide was assessed for a group of greenhouse applicators and harvesters for conditions of using normal clothing and protective clothing, it has been shown that reduction of actual exposure by protective clothing was high (approximately 90%), but the reduction was rather small (approximately 40%) for the internal exposure. The authors suggested that dermal uptake of the pesticide (propoxur) for conditions of protective clothing may be enhanced by the increase of skin moisture content, as observed in the study. Meuling *et al.* (1997) confirmed this hypothesis by an experimental human volunteer study where a linear relationship between increase of skin moisture and increase of dermal uptake was observed.

In general biological monitoring studies show lower reduction of internal exposure than estimated by reduction of external exposure. Chester *et al.* (1990) observed in a field study on pesticide applicators an average reduction of actual hand exposure by protective gloves of 87%, whereas urinary excretion data showed a reduction of approximately 80%, whereas Nigg and Stamper (1983) observed 24% reduction in urinary excretion among pesticide applicators who wore protective coveralls which showed a reduction of actual exposure of 79%. For non-pesticide exposure scenarios, van Rooij *et al.* (1993) observed among creosote workers a reduction of urinary excretion of 1-hydroxy-pyrene of approximately 50%, whereas skin contamination of pyrene had been reduced by approximately 60%.

## CONCLUSIONS AND RECOMMENDATIONS

Utilization of PPE under conditions of 'proper functioning' and 'proper use' can reduce actual external exposure and internal exposure substantially.

However, these conditions will only be met if a good PPE-programme is implemented in the workplace. Evidence exists that such programmes are not effectively implemented in small and medium sized enterprises and in downstream user scenarios for industrial chemicals. For example, Burgess and Mashingaidze (1999) demonstrated by qualitative fit tests that fewer workers failed the fit test in medium sized companies with a structured RPE training programme compared to companies with non-structured or no RPE training programme.

If issues related to acceptability of PPE by users, e.g. ergonomics and comfort, are not included in the decision logic system for the selection of PPE, the overall effectiveness of PPE to reduce exposure in real workplace practice may be overestimated.

Quantified prediction of exposure reduction by adopting preset performance classification criteria that meet product liability (CE marking) will overestimate workplace protection substantially. The use of assigned protection factors as set by Standardization Institutes or expert panels based on workplace protection studies results in more reliable estimates of external exposure reduction. A fixed point reduction factor, despite a reasonable worst case approach (95 percentile) which addresses between worker variances, ignores a possible variance of reduction performance over exposure levels and duration.

Biological monitoring results suggest a lower actual reduction of internal exposure compared to predicted reduction based on the results of reduction of external exposure.

For risk assessment purposes conservative estimates of the protection can be made according to the following proposed 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 RPD or protective clothing can be documented, e.g. by an Industrial and Safety Management System. In this tier the most restrictive APF should be used as default, i.e. APF = 4 for RPD, 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, according to Beelen *et al.* (1995) and Brouwer and van Hemmen (1997).

In the third tier the presence of a PPE programme can be documented, e.g. by an Industrial and Safety Management System, or is highly reliable for the exposure scenario, APFs for RPD should be used as proposed by the BSI, since these are, at least partly, derived from 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.

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