
Comparative research of measurement methods used to quantify the effectiveness of personal protective equipment against dermal exposure

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Background and methods

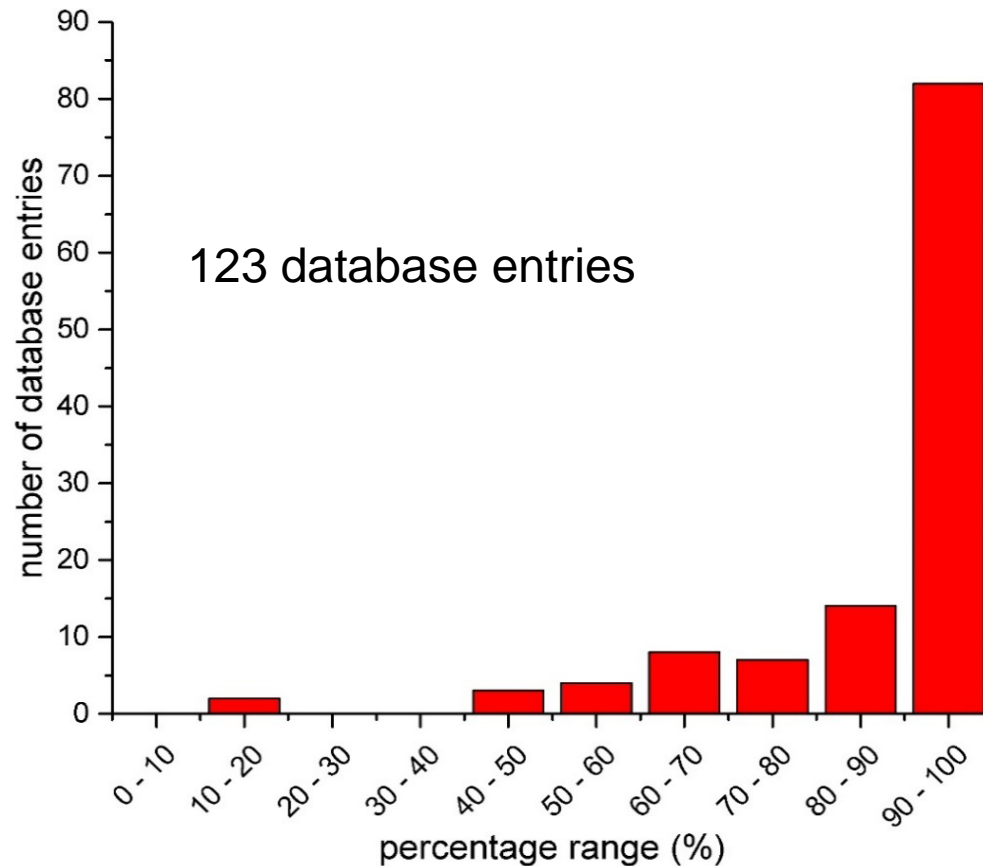
- PPE often used to reduce dermal exposure
- Default efficiency suggestions under REACH (ECETOC TRA) and for biocides (HEEG opinion 9 (default protection factors for protective clothing and gloves)
 - based only on limited experimental data

Project aims:

- gather quantitative efficiency data (dosimetry, biomonitoring)
 - Excel database
 - Information about methodological aspects and influencing factors

➔ Literature search + cross references resulted in **526 publications**

Example: Efficiencies of gloves (dosimetry)

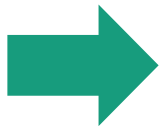


High variability:

- Different baselines
- Different industry areas
- Different glove materials
- Different substances

But at the same time

- Database biased towards certain areas
- Key information often missing



Large range of efficiencies possible, but specific reasons for high or low values can rarely be identified

Results and conclusion

- No standardized methodology
 - Only few high quality studies were found, especially for biomonitoring
 - In vitro studies / penetration models exist, but have limited value concerning conclusions about workplace performance
 - No statistical evaluation possible due to heterogeneity of the collected data
- + Information about single aspects available;
general impression of PPE efficiencies
- no complete understanding; no comparison of PPE groups;
need for research in specific areas (e.g. user behaviour / training)

For the forthcoming final report please visit:

<http://www.baua.de/en/Publications/Publications.html>

Thank you very much for your attention!



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Introduction

In the course of risk assessments under REACH or the biocides regulation, personal protective equipment is often specified as an additional measure to ensure safe use. Suggestions for compensating exposure reduction efficiencies exist, as an example, in the commonly used ECOTOC TRA tool for occupational exposure assessment under REACH and in HEBE version 3 (surface protection factors for protective clothing and gloves) for biocides. However, these suggestions are only supported by limited experimental data. Therefore, the Federal Institute for Occupational Safety and Health (BAuA) opened a project with the aim to gather quantitative efficiency data for various types of dermal protective equipment as well as information about influencing factors (e.g. user training, challenge, carrier substance) and methodological aspects of efficiency derivation.

Materials and Methods

Information was gathered via literature searches in the commonly known databases PubMed, Scopus and Web of Science, resulting in 308 references of potential relevance which were amended by cross references and information found in internet sources, which led to 428 documents of potential interest.

Excel-Database with experimental dosimetry / biomonitoring data

Quantitative information found in dosimetry and biomonitoring studies was collected in an Excel database. The database contains information about PPE, workplace / occupational conditions, substance, dosimetry and the efficiency. A scoring approach was developed describing transparency and sampling method.

193 publications resulting in 1084 data entries (mean 11 efficiencies below 0 or below the level of detection). These have been derived from summary tables.

- 12 entries biomonitoring, 337 entries
- Large efficiency range (0-100%): What is the cause of these differences?

Workplace	Substance	Efficiency	Sampling method
...

Dosimetry: Methodological information

Very different study designs and sampling techniques were identified, although certain techniques were found more often than others:

- Cross sections vs. intervention vs. **simultaneous sampling** vs. laboratory
- Sampling vs. interview vs. **in situ methods**

Hardly information on the influence of these factors on efficiency could be identified although it is known that different exposure results for different sampling techniques can be obtained. Often there is a tendency to capture all exposure (e.g. via cotton pads). There is no standardized evaluation of data.

- Different exposure units (mass per area, mass per area and time etc.) may lead to different results
- Efficiency for each individual vs. efficiency from average exposures

These equations for efficiency derivation are commonly used:

$$Eff (\%) = 100(1 - \frac{D_{PPE}}{D_{no PPE}})$$

$$Eff (\%) = 100(1 - \frac{D_{PPE}}{D_{no PPE}}) \rightarrow \text{Simultaneous sampling, PPE used as dosimeter}$$

$$Eff (\%) = 100(1 - \frac{D_{PPE}}{D_{no PPE}}) \rightarrow \text{Patch sampling, independent / cross-sectional studies}$$

Dosimetry: Quantitative information

A comparatively large number of dosimetry studies with quantitative efficiency information could be identified, covering a large range of efficiency values. The most common types of PPE are gloves (such as glove length or age was found) and gowns (38-76% exposure reduction; new gloves >50%, long gloves instead of old 40-60% reduction). However, this information is based on the patchy old data and other limited quantitative information. Particularly very high efficiency values for barrier gloves and coveralls were found, although these materials are not chemical resistant.

Material	Efficiency	Number of studies
Apriori (4 database entries): 0-88%	Barrier equipment (27 entries): 0-100%	1
Barrier Gown (3 entries): 60-88%	Barrier clothing (18 entries): 4-88%	1
Boots (1 entry): 84%	Respiratory equipment (1 entry): 48%	1
Coveralls (13 entries): 4-100%	Coveralls: whole body garments (147 entries): 38-100%	1
Hand (8 entries): 48-88%		

Biomonitoring

After a screening of the evaluated literature 42 studies of potential relevance were identified. However, only 6 of these studies could be used for the derivation of efficiency values. Several reasons for the limited number of usable biomonitoring studies were identified. As an example, many studies only capture the current situation in a workplace without comparing situations with and without PPE. Other non-usable studies are evaluations of other exposure routes such as inhalation. The following efficiencies were found:

- Gloves (11 database entries): 0-88%
- Barrier Gown (3 entries): 60-88%
- Whole body coveralls (1 entry): 100%

In vitro studies

Some studies were identified that describe exposure reduction by using in vitro studies including PPE materials mounted on skin. Efficiencies derived from these studies vary (0-100%). They depend on material, substance and the experimental setup and no general conclusion based on these studies can be made. Furthermore, their relevance for workplaces is questionable, since substance / material combinations are rarely used or recommendations for the workplace, but instead on purely scientific criteria, and workplace conditions such as surface stress or user behavior are not reflected.

Mathematical models

Mathematical models describing the penetration through materials are able to provide suggestions concerning relevant parameters, which may influence the efficiency result. Relevant parameters are as an example the surface tension difference between PPE and substance and material thickness. Underlying experimental studies can be evaluated separately, leading to the following efficiencies for protective clothing:

- All data sets (n=23): 0% efficiency
- Protective clothing with a thickness of more than 5 mm (n=7): 0% penetration

Again, the relevance of these values for real workplaces is questionable.

Comparison with defaults

By using some assumptions, database entries were assigned to HEBE categories (HEBE option 3). Entries without matching baseline were removed and the results were compared with HEBE default suggestion.

A comparison with default efficiencies commonly used under REACH (ECOTOC TRA) was not possible as this categorization is based on different levels of user training and no sufficient information could be extracted from the evaluated studies.

The distribution of measured efficiencies shows maxima at high efficiency values, but also some lower values. Reasons for a very high or very low efficiency are rarely completely reproducible with the available information.

Conclusions / suggestions for further research

Within this project a number of publications containing information about exposure reduction efficiencies were evaluated. However, despite the large number of evaluated studies only the high quality studies were found. The content of the PPE efficiency database is based towards certain industry areas (pesticides), PPE types (gloves, whole body garments) and other parameters, which complicates the comparison of the results within the database. Even within one PPE category variability is still large concerning efficiency values and scenario parameters. Key information (e.g. glove thickness, material) is often missing and it is usually not known, if a certain type of PPE is applicable for the situation in question (e.g. mapping usually not reported). Furthermore, due to the heterogeneity of the collected data no statistical evaluation was possible.

Overall the identified information can therefore provide a general impression of possible protection factors, some influencing factors and available methodological research. However, no clear recommendation how a certain efficiency may be reached is possible. Three aspects of high priority were identified for which further research is suggested. These are the influence of carrier substance, the influence of behavior and user behavior, and the influence of the challenge. In general only the biomonitoring studies were identified. These points need to be evaluated by the means of high quality, transparent studies.