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# SIST-TP CEN/TR 15278:2006

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**Izpostavljenost na delovnem mestu – Strategija vrednotenja dermalne izpostavljenosti kože**

Workplace exposure - Strategy for the evaluation of dermal exposure

Exposition am Arbeitsplatz - Strategie zur Beurteilung der Hautbelastung



Exposition sur les lieux de travail - Stratégie pour l'évaluation de l'exposition dermique



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# Workplace exposure - Strategy for the evaluation of dermal exposure

Exposition sur les lieux de travail - Stratégie pour l'évaluation de l'exposition dermique

Exposition am Arbeitsplatz - Strategie zur Beurteilung der Hautbelastung

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## Foreword

This Technical Report (CEN/TR 15278:2006) has been prepared by Technical Committee CEN/TC 137 “Assessment of workplace exposure to chemical and biological agents”, the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

# Introduction

Dermal exposure assessment explores the dynamic interaction between environmental contaminants and the skin. In contrast to inhalation exposure assessment, the assessment of dermal exposure remained a nascent field of scientific research and applied occupational hygiene for most of the twentieth century, although multiple fatalities and occupational skin diseases due to dermal exposure have been described in literature.

During the last decade, dermal exposure has received more attention, and one of the important results was the development of a conceptual model for dermal exposure (see [1]). The model systematically describes the transport of contaminant mass from exposure sources to the surface of the skin. The model provides a structure for evaluating dermal exposure both qualitatively and quantitatively.

The purpose of evaluating dermal exposure can differ substantially, as exposure analysis (to give guidance to control), risk assessment, and evaluation of exposure control can all be objectives to undertake assessments. In order to give guidance and to harmonise basic concepts and actions a strategy for evaluation of dermal exposure is proposed.

# 1 Scope

This Technical Report gives guidance on approaches for awareness and evaluation of dermal exposure in workplaces.

This Technical Report describes strategies to evaluate exposure of the skin to chemical and biological agents qualitatively and quantitatively, e.g. to analyse exposure, as part of the risk assessment process, to investigate associations between exposure and diseases, and to evaluate control measures.

The definitions and procedures given in this document are primarily related to dermal exposure to chemical substances.

The specifications given in this Technical Report are not applicable to microbiological skin contaminants.

# 2 Terms and definitions

For the purposes of this Technical Report, the following terms and definitions apply.

NOTE The definitions are based on the implementation of exposure terminology by IPCS (see [2]) and the conceptual model (see [1]), see also Annex A.



**2.1**
**agent**
any chemical or biological entity on its own or admixed as it occurs in the natural state or as produced by any work activity, whether or not produced intentionally and whether or not placed on the market



NOTE Adapted from EN 1540.

**2.2**
**dermal contact volume**
volume containing the mass of the agent that contacts the exposure surface

NOTE 1 The dermal contact volume is given in litres (l).

NOTE 2 The dermal contact volume is equivalent to the volume of the skin contaminant layer, and for practical reasons it is defined by the mass in kilograms (kg) of all substances contained in this compartment.

**2.3**
**dermal exposure**
process of contact between an agent and human skin at an exposure surface over an exposure period

**2.4**
**dermal exposure concentration**
exposure mass divided by the dermal contact volume or the exposure mass divided by the mass contained in the skin contaminant layer

NOTE The dermal exposure concentration is expressed in grams per liter (g/l) or grams per kilogram (g/kg) respectively.

**2.5**
**dermal exposure loading**
exposure mass divided by the exposure surface

NOTE For practical reasons it can be expressed as the time-averaged mass divided by area-averaged skin contaminant layer surface area in grams per square centimetre ($g/cm^2$).

**2.6**
**dermal exposure mass**
mass of agent present in the dermal contact volume

NOTE 1 For practical reasons it is defined by the amount of agent in grams (g) present in the skin contaminant layer.

NOTE 2 The outcome of the process of dermal exposure, i.e. the contact, can be expressed by different parameters of exposure.

**2.7**
**dermal exposure surface**
skin surface area where an agent is present

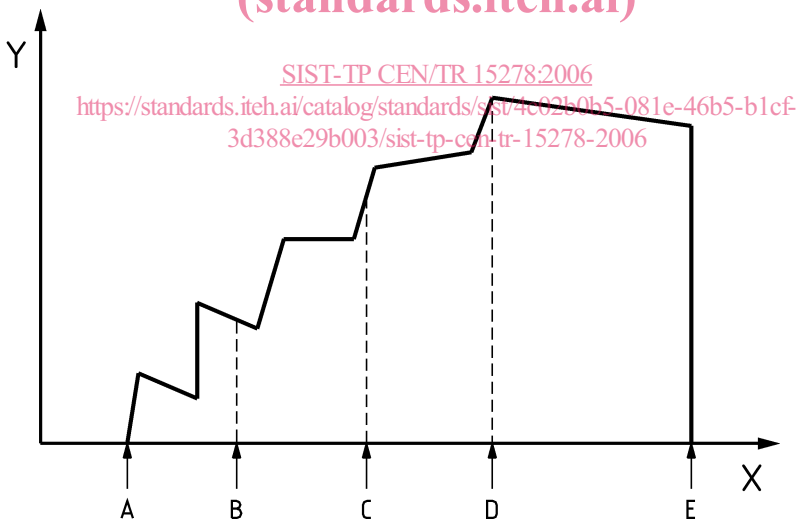
NOTE For practical reasons this is represented by a two dimensional representation of the skin contaminant layer in square centimetres ($cm^2$).

**2.8**
**exposure period**
time the agent is present in the skin contaminant layer, i.e. contact time

NOTE 1 The process by which an agent crosses an outer exposure surface of a target is called intake. In case of the concentration driven transport from the skin contaminant layer into the skin, i.e. crossing the (exposure surface) interface between skin contaminant layer and the stratum corneum as an absorption barrier, the process is called uptake. Therefore, relevant for uptake would be the time- exposure concentration profile for an identified area of the skin contaminant layer over a defined period of time.

NOTE 2 Other relevant types of time intervals, e.g. sampling time (B-C), immission or loading time (A-D), and post emission time (D-E), are illustrated in Figure 1.






**Key**
X time
Y exposure loading
A-E exposure/contact time
A-D immission/loading time

D-E post immission time
B-C sampling time

**Figure 1 — Different types of time intervals relevant in view of dermal exposure**

**2.9**
**immission**
transport of an agent from a defined source to the skin or outer clothing contaminant layer compartment

**2.10**
**potential dermal exposure mass**
mass retrieved from (outer and inner clothing contaminant layer and exposure mass, i.e. mass retrieved from the covered and uncovered by clothing) parts of the skin contaminant layer compartment

NOTE For practical reasons related to sampling methodology and strategy the term potential exposure mass has been introduced. It refers to the agent mass that has the *potential* the reach the skin (contaminant layer) since it has landed on the clothing and the agent mass that has actually reached the skin. The conceptual model distinguishes between outer and inner clothing contaminant layer compartment, respectively, and characterises the clothing itself as a buffer layer.

**2.11**
**skin contaminant layer compartment**
compartment on top of the stratum corneum of the human skin

NOTE The skin contaminant layer compartment is formed by sebum lipids, sweat and additional water from transepidermal water loss, rest products from cornification and unshed corneocytes, and is given by its three dimensional volume.

**2.12**
**workplace**
the defined area or areas in which the work activities are carried out

[EN 1540:1998, 3.36]



# 3 Assessment of dermal exposure

## 3.1 General



Sampling strategies provide general guidelines to approach dermal exposure issues systematically. This approach is according to the conceptual model illustrated in Figure A.1. The conceptual model structures the process of dermal exposure to chemicals and assists in evaluating the performance of sampling methods. Basically, the model systematically describes the transport of contaminant mass from the source onto the surface of the skin. Six compartments, i.e. three environmental compartments (air, surface and source) and three personal compartments (outer and inner clothing, and skin contaminant layer) and eight mass transport processes onwards and from the compartments are distinguished and their mutual relationship is outlined.

## 3.2 Objectives

In general, five objectives for assessing dermal exposure can be distinguished:

a) evaluation of exposure processes and pathways

Evaluation of exposure processes and pathways is an important tool for selecting an adequate sampling strategy and for effective risk management.

b) evaluation of exposure control measures or interventions

Evaluation of control measures is relevant in view of effectiveness of exposure reduction and post-intervention surveillance.

c) risk assessment

Results for risk assessment purposes should be linked to results of hazard assessment. Hazardous agents that show local effects are distinguished from hazardous agents that show systemic health effects after uptake (see [3]). For the first group of agents, quantitative exposure assessment seems to be very difficult, however some data are available on effect and dosage and duration.

d) epidemiological investigations

To investigate possible associations between exposure and health effects by epidemiological investigations estimates of relevant parameters of exposure are needed.

e) compliance

Compliance sampling is relevant in case exposure limits have been set. At the present time no such limits have been set by National Authorities or other International Bodies. However, in-company exposure limits are used as action levels or references for compliance. Such limits may be at the level of any parameter of dermal exposure, i.e. exposure mass, exposure loading, exposure surface area, or at the level of determinants of exposure, e.g. surface contamination in case of transfer, or at the level of intake by aggregated exposure routes including the dermal route, e.g. biological monitoring limit values. The last two types of limit values, however, are beyond the scope of this document.

## 3.3 Models and semi quantitative estimates

### 3.3.1 Objectives

Most models provide estimates of the likelihood of skin exposure or skin contamination that can be used as a first tier in exposure assessment processes. Application of the models is analogous to the first two steps, i.e. initial appraisal and basic survey, of a tiered approach as given for airborne contamination by EN 689. The estimates provided by the models can be used for an initial evaluation of the exposure process, initial exposure assessment in view of risk assessment processes, and estimation of exposure levels for epidemiological studies. Moreover, the results will be helpful to select an appropriate sampling strategy for quantitative exposure assessment and to prioritise control measures.



### 3.3.2 Methods



Categorical estimates, e.g. ever-never, yes-no or exposure classes (low, medium, high) can result from human expert approaches. More structured approaches in combination with computer or human expert systems can provide semi-quantitative estimates of dermal contamination. Basically, structured approaches use identified or assumed determinants of exposure (or contamination). Examples of such approaches are EASE (Estimation and Assessment of Substance Exposure, see [4]) and the semi-quantitative DREAM (DeRmal Exposure Assessment Method, see [5]).

The decision logic of EASE is outlined in Annex B. According to EASE three key selections are made:

a) compound-specification physical state;

b) pattern-of-use one (range from non to wide dispersive use;

c) selection of level of contact.

The end-points of the decision logic (five boxes) are linked to ranges of exposure levels (see [6]).

DREAM consists of an inventory and an evaluation part. The inventory part comprises a hierarchically structured questionnaire with six modules: company, department, agent, job, task and exposure (see Table C.1). Information is obtained by observations and interviews. The modules address general information as well as possible determinants of exposure as identified by the conceptual model and by evaluating literature. In the DREAM model evaluation of exposure takes place on the level of tasks. A summary of the evaluation module is given in Figure C.1. Examples of determinants of dermal exposure are identified (see [7]) and given in Annex D.

For an initial systematically description of dermal exposure situations in different industry sectors, so called dermal operation (DEO)-units can be used, as developed by the RISKOFDERM project (see [8]). The DEO-units handling of contaminated objects, manual dispersion, hand tool dispersion, spray dispersion, immersion, and mechanical treatment include several task-groups or scenarios.

In the RISKOFDERM project a so-called toolkit for dermal exposure assessment and management has been developed (see [9]). The toolkit provides some first estimates to determine the risk associated to dermal exposure to hazardous substances. Default values for potential exposure loading per unit time for hands and body for the DEO-units were derived from literature (see [10]). In addition, the magnitude of the effect of determinants or modifiers of exposure was estimated (see [11]).

Semi-deterministic models or mixed subjective (semi-) deterministic models have been developed for specific exposure scenario's, e.g. paint spraying (see [12] and [13]), and non-industrial pesticide application, and re-entry work (see [14]), and biocides (see [15]).

## 3.4 Measurements to quantify dermal exposure

### 3.4.1 Objectives and sampling strategy

For the objectives for assessing dermal exposure (see 3.2), the following should be taken into consideration:

a) for evaluating exposure processes and pathways and in view of the conceptual model it is relevant to know mass transport rates from different compartments to the skin contaminant layer and how the different transports contribute to total contamination;

b) to evaluate exposure control measures it would be appropriate to measure compartment agent (contaminant) mass;

c) for risk assessment it would be relevant to measure the concentration/time profile in the skin contaminant layer;



d) for compliance measurements the definition of the exposure limit would prescribe what should be measured;



e) for epidemiological investigations the mechanisms of the health effect or other considerations will determine the relevant parameters of exposure.



Developing an appropriate sampling strategy related to the sampling objectives should include the selection of the relevant:

— agent;

— workplace;

— population/ jobs/ tasks;

— sample size;

— time of sampling;

— sampling duration;

— frequency of sampling;

— body locations;

— sampling method(s).