

# **Risks at the Workplace that will influence Annex I - Inclusion**

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# Biocidal product directive RL 98/8/EC

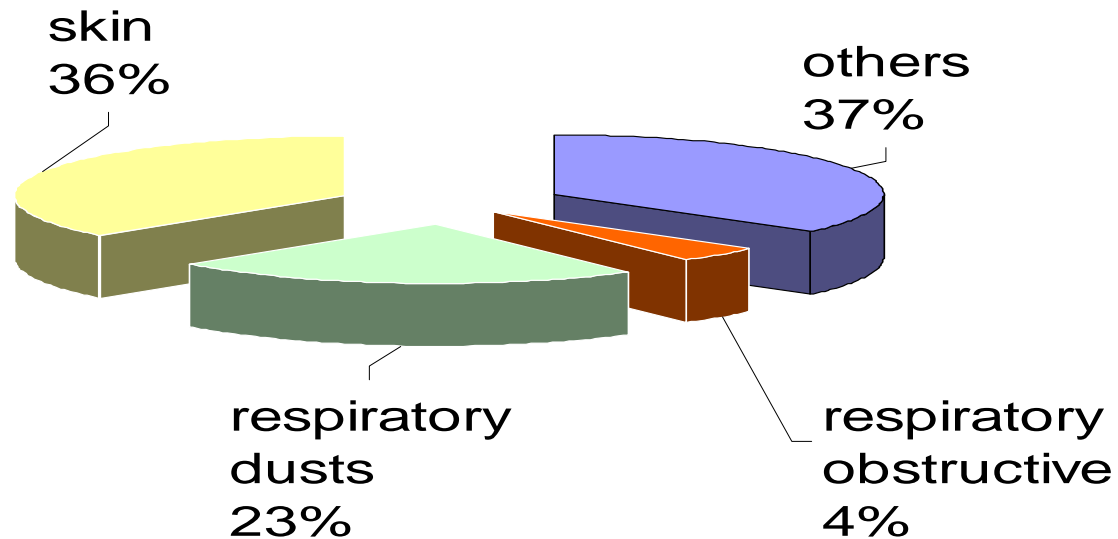
In accordance with Article 5(1)(b) of the Directive  
Member States  
shall only authorise a biocidal product if ...

**... the product**

**has no unacceptable effects on human  
or animal health directly or indirectly ...**

# Occupational diseases Germany 2004

23.600 recognised (1)



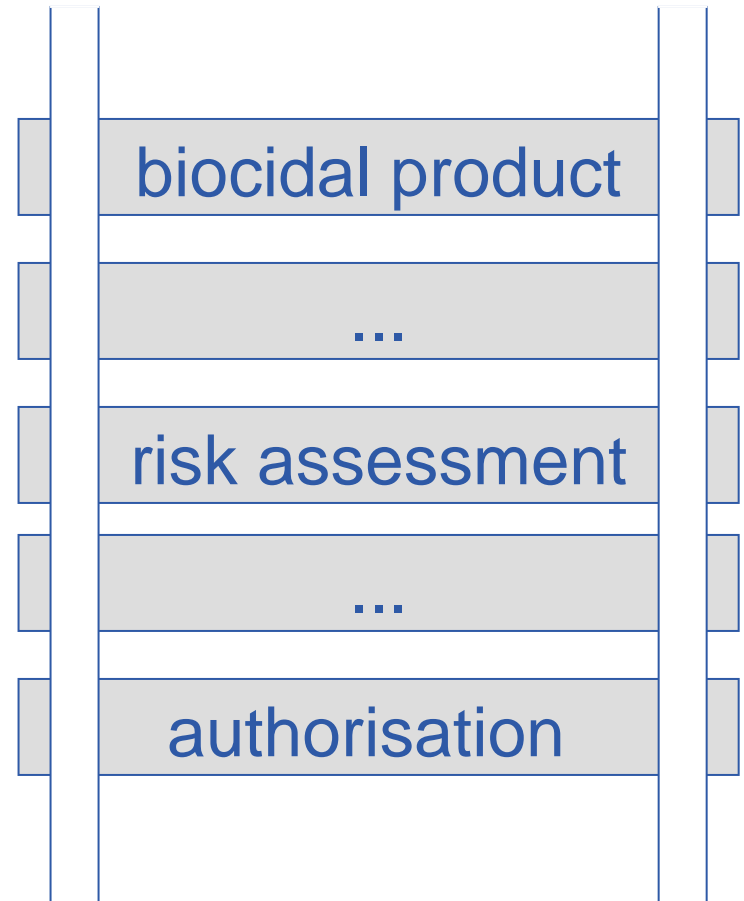
(1) for comparison ~ 60.000 notified

# Professional use of biocides

registered products in Germany	~ 13.000
active substances	~ 300
active substances: professional use only (1st list)	20 of 41
products used by non-professionals	~ 10 %

**„workers are the first  
and often the only ones to be directly exposed“**

# Positive list



# Existing active substances

## Priorities for the evaluation

### product type

1. wood preservatives  
rodenticides
2. disinfectants, ...
3. insecticides, ...
- ⋮

### professional use (e.g.)

carpenter,  
pest control operator

nurse, butcher

gardener, farmer

# Examples of workplaces



# Prerequisites for Annex I- Inclusion



- all relevant data available
- efficacy
- one safe use





# Safe use

**exposure < reference value: no concern**

**exposure > reference value: concern**

**in case of concern:**

- **protection measures**
- **restrictions**

# Topics

- **exposure assessment**      potential ↔ actual
- **reference value**              OEL ↔ AOEL
- **risk reduction**              already applied ↔ additional

- **common understanding**
- **identification of problems**
- **ideas for a way forward**

# Exposure data provided

dermal

inhalation

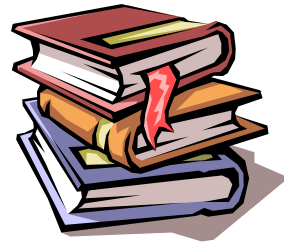
mg/cm<sup>2</sup>

- level of exposure
- duration
- frequency

mg/m<sup>3</sup>

mg/person/day

# Source of exposure information



literature

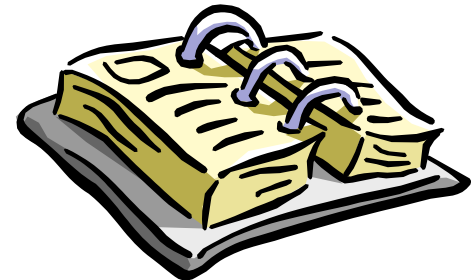


models



tools

field studies



information participant

# Example for field studies



# Actual exposure

e.g. dermal exposure of potassium sorbate  
(szenario bathing or dipping)

## potential

7.300 mg/p/d

- mixing loading: 90 % PPE
- application: 70 % clothing  
45 % footwear
- post-application + disposal: 70 % clothing  
90 % PPE hand

## actual

2.140 mg/p/d

## Specific questions ❄ exposure ❄

- **how to bridge missing information (defaults) ?**
- **which uncertainties exist?**
- **which model is applicable?**
- **how to derive actual exposure?**

# Reference value

**NOAEL**



Safety factors

interspecies  
intraspecies



**AOEL**

acceptable operator  
exposure level



# Different Technical Guidance

	interspecies	intraspecies
TNsG (AOEL)	10	10
TGD (MOE)	2.5 x metabolic rate	5 (worker)

# Additional considerations

## Internal / external value

- absorption data
- route specific toxicity
- combined exposure

## Different exposure length

- acute reference dose
- short-term reference dose
- long-term reference dose

## Specific questions ❄ reference values ❄

- **different reference values from the same data ?**
- **how to calculate internal values?**
- **shall reference values refer to exposure duration ?**

# Risk reduction measures ...

**... already applied**



good practice  
safety data sheet  
regulations  
personal factors



**... decide on actual exposure**

# Example



# Additional measures

**potential exposure**



measures as already applied

**actual exposure**

if concern

**additional measures  
to reduce exposure**

**S**ubstitution  
**T**echnique  
**O**rganisation  
**P**ersonal protection

# Conditions as result of concern

- **no annex I listing** (Diamin)
- **(specialised) professional use only** (Anticoagulants)
- **to be used with applicator** (Al-phosphide)
- **intermittent period necessary** (Sulfurylfluoride)
- **daily change of gloves** (Dichlofluanid)

## Specific questions ❄️ measures ❄️

- **which measures are already applied?**
- **which protection factors shall be assigned?**
- **how to deal with compliance?**
- **which additional measures appear feasible?**
- 
- 
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# Benefits for occupational safety and health

**pool of information**

available for practical use  
at the workplace

**substance regulation**

classification/ OEL  
comparative assessment  
restrictions

**product development**

inherently safe products 😊