



Summary

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Board for the Authorisation
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Biocides (Ctgb)

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ctgb



Hazard x Exposure = Risk



Hazard is based on dossier:



- Efficacy
- Human toxicology
- Ecotoxicology
- Fate en behavior in environment
- Physical-chemical properties and analytical methodes





Dossier active substance

- Toxicokinetics
- Acute toxicity
- Short-term toxicity
- Sub-chronic toxicity
- Genotoxicity testing
- Long-term toxicity and carcinogenicity
- Reproductive toxicity
- Delayed neurotoxicity studies
- Other toxicological studies
- Medical data



Quality check



Studies should be performed according to:

- standard test protocol (e.g.OECD=validated)
- GLP (Good Laboratory Practice)



Public (peer reviewed) literature often does not fulfill standard requirements, but can give additional information





Reference values



- ADI: Acceptable Daily Intake
(by consumption)



- ARfD: Acute Reference Dose
(accidental high consumption)



- AOEL: Acceptable operator exposure
level



Deriving an AOEL



- Step 1: select relevant NOAEL
- Step 2: determine oral absorption value
- Step 3: define the safety factor
 - Standard factor: 100
- Step 4: derive the AOEL



$$\text{AOEL (mg/kg bw/day)} = \frac{(\text{NOAEL} \times \text{oral absorption})}{\text{safety factor}}$$



Deriving an ADI

= The amount of a substance that can be consumed on a daily basis over a lifetime without appreciable health risk.

- Step 1: select chronic NOAEL
- Step 2: define the safety factor
 - Standard factor: 100
- Step 3: derive the ADI

$$\text{ADI} = \text{NOAEL}_{\text{chronic}} / \text{safety factor (100)}$$

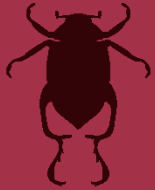


ARfD



- “An estimate of a chemical substance in food (or drinking water), expressed on a bodyweight basis, that can be ingested over a short period of time, usually during one meal or one day, without appreciable health risk to the consumer.”

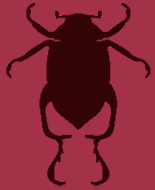




Deriving an ARfD

- Step 1: select (sub)acute NOAEL
- Step 2: define the safety factor
 - Standard factor: 100
- Step 3: derive the ARfD

$$\text{ARfD} = \text{NOAEL} / \text{safety factor (100)}$$



Exposure

- Population(s) exposed
 - Operators
 - Workers
 - Bystanders, including flagman
 - Residents
- Exposure scenario
 - Route
 - Duration
 - Frequency
 - Level of exposure

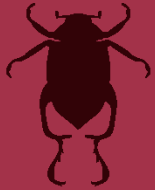


Exposure assessment



Tiered approach:

Tier 1: Models



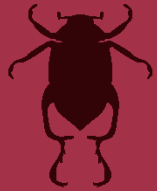
Tier 2 Refinement:

Measurement of actual exposure for the application under consideration





Which model to select?



- Different model, some specific for 1 scenario (indoors: NL greenhouse model), some have different scenarios (field crop high low, tractor and handheld: UK POEM and German model)
- Basic work clothing (= without PPE) differs for models (UK POEM: long sleeves + trousers; German model: short sleeves and shorts)

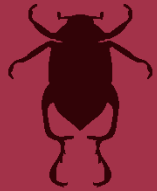




Evaluation report on models



EFSA Project to assess current approaches and knowledge with a view to develop a Guidance Document for pesticide exposure assessment for workers, operators, bystanders and residents.



<http://www.efsa.europa.eu/en/scdocs/doc/26e.pdf>



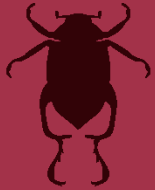


Input data in the models



Dermal absorption

- Based on physical/chemical properties (MW, log Pow)
- Based on dermal absorption studies
 - *in vitro* (rat and/or human skin)
 - *in vivo* (rat)



Defaults

- Body weight
- Time of exposure
- Area treated



Risk assessment



Risk Assessment in basic is a simple method, based on two values:

1. Reference value (AOEL)
2. Exposure (estimated or measured)

Safe use = $AOEL \geq$ Exposure

