



Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit



Protection of human health

Risk management

Risk management in the area of health

- **concerns consumers, operators, workers and bystanders**
- **includes toxicology/metabolism, residue behaviour and classification/labelling of active substances and preparations**
- **might lead to risk mitigation measures**

Risk management in the area of health

- **Advice to**
 - **notifiers**
 - **Industry**
 - **Official Bureaus of Plant Protection of the Länder**
 - **Ministry counselling**
- **Co-ordination of the establishment of maximum residue levels (MRLs)**

Protection of human health

- **Data requirements**
- **Evaluation criteria**
- **Risk mitigation measures**

In the authorisation procedure for plant protection products

Data requirements

- **Active substances**
 - Regulation (EU) No 283/2013
 - List of test methods and guidance documents 2013/C 95/01
- **Plant protection products**
 - Regulation (EU) No 284/2013
 - List of test methods and guidance documents 2013/C 95/02
- **Sections**
 - Toxicological studies
 - Residues in or on treated products, food and feed

Toxicology - data requirements

		Active substance	Preparation
Acute toxicity	Oral, dermal, inhalation	x	x
	Irritating to eyes	x	x
	Irritating to skin	x	x
	Sensitisation by skin contact Phototoxicity	x x	x
Chronic toxicity	Subacute toxicity	poss.	
	Subchronic toxicity	x	
	Chronic toxicity	x	
Specific & irreversible toxicity	Toxico-kinetics	x	
	Skin penetration	x	x
	Genotoxicity	x	
	Carcinogenicity	x	
	Reproduction toxicity (fertility/development)	x	
	Neurotoxicity	x	
	Further examinations	poss.	
Medical data		x	x

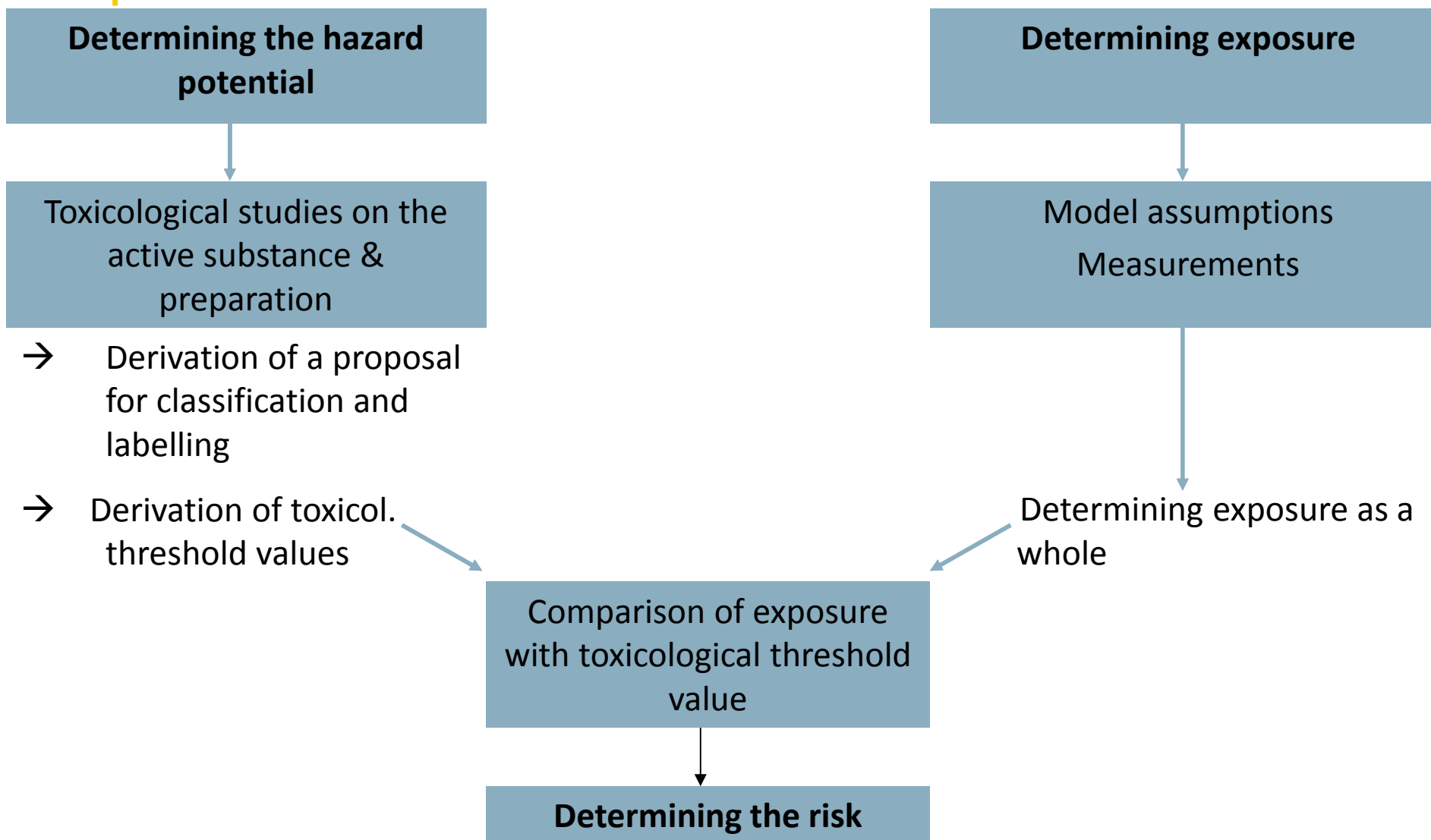
Toxicological assessment - outcome

- **Subsequent proposal for classification and labelling**
 - Hazard designations (e.g. toxic)
 - Warning statements (risk phrases)
 - Safety advice (safety phrases)
- **Derivation of toxicological threshold values for acute, medium term and long term exposure**
 - ADI Acceptable Daily Intake (intake over a whole lifespan)
 - AOEL Acceptable Operator Exposure Level (repeated intake)
 - ARfD Acute Reference Dose (single intake)

Residue behaviour

- **How high are the expected residues after normal use?**
- **Observance of the established Maximum Residue Levels**
- **Determining Maximum Residue Levels**
- **Check of expected and tolerable exposure (toxicological threshold values for acute and long term exposure)**
- **Commodities with residues below established Maximum Residue Levels are safe for the consumer**

Health assessment – risk-based approach



Protection of human health

- Data requirements
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In the authorisation procedure for plant protection products

Evaluation criteria

- **Article 4 of Regulation (EU) No 1107/2009**
- **Annex II of Regulation (EU) No 1107/2009**
- **Uniform principles: Regulation (EU) No 546/2011**
- **Prerequisites for authorisation:**
 - No harmful effects on human health
 - Animal testing to be minimised
 - No data on humans to lower the safety margin resulting from tests or studies on animals
 - No unnecessary suffering and pain to vertebrates to be controlled

Authorisation not possible where

- **exposure of special groups of persons exceeds the relevant toxicological threshold value and there is no (further) risk mitigation possible**
- **an active substance, safener or synergist is or has to be classified in accordance with Reg (EC) No 1272/2008 as mutagen category 1A or 1B**
- **(A) co-formulant(s) of a ppp is/are included in Annex III of Reg (EC) No 1107/2009**

Authorisation not possible where

- **an active substance, safener or synergist**
 - is or has to be classified in accordance with Reg. (EC) No 1272/2008 as carcinogenic category 1A or 1B, toxic for reproduction category 1A or 1B...
 - is considered to have endocrine disrupting properties that may cause adverse effect in humans, ...

unless the exposure to humans ... under realistic proposed conditions of use, is negligible...

Protection of human health

- Data requirements
- Evaluation criteria
- **Risk mitigation measures**

In the authorisation procedure for plant protection products

Risk mitigation measures

- **additional to proper use according to good agricultural practice**
- **Specific advice to fulfil the ALARA principle (as a result of a special classification/labelling of a ppp according to DPD or CLP)**
- **required where standard risk assessment shows no acceptable risk to reduce exposure**
- **Implemented with the authorisation decision**
- **have to be part of the label**
- **have to be enforceable (controlled by plant protection service)**

Risk mitigation measures

- **Limitation of**
 - application rate
 - number of applications
 - time of use
 - maximum content of certain impurities
- **Restrictions regarding**
 - timing of application
 - certain application techniques
 - certain categories of users -> professionals vs. non-professionals
 - certain areas (not on areas for the public, not on home and allotment garden areas, closing ways/areas beside treated areas (e. g. for pedestrians), buffer zones)
- **Monitoring after use (residues, groundwater metabolites)**

Risk mitigation measures

- **Pre-harvest interval for**
 - each relevant crop
- **Re-entry periods for**
 - humans to crops, buildings or spaces treated
 - livestock to areas to be grazed
- **Withholding periods for**
 - animal feeding stuffs
 - post-harvest use
- **Waiting period between**
 - application and handling treated products
 - last application and sowing or planting succeeding crops

Risk mitigation measures

- **Personal protective equipment (operator, worker)**
 - Head protection
 - Eye/face protection
 - Hand protection
 - Body protection
 - Respiratory protection

Risk mitigation measures

- certain application techniques/device – reduction of spray drift by using drift reducing equipment
- The Federal Research Centre for Cultivated Plants (JKI) has tested sprayers for their drift-reducing ability in relation to the German basic drift values
- The sprayers are allocated to drift classes of at least 50 %, 75 % or 90 % drift reduction
- A list of drift reducing sprayers is available from the JKI

Thank you for your attention!

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