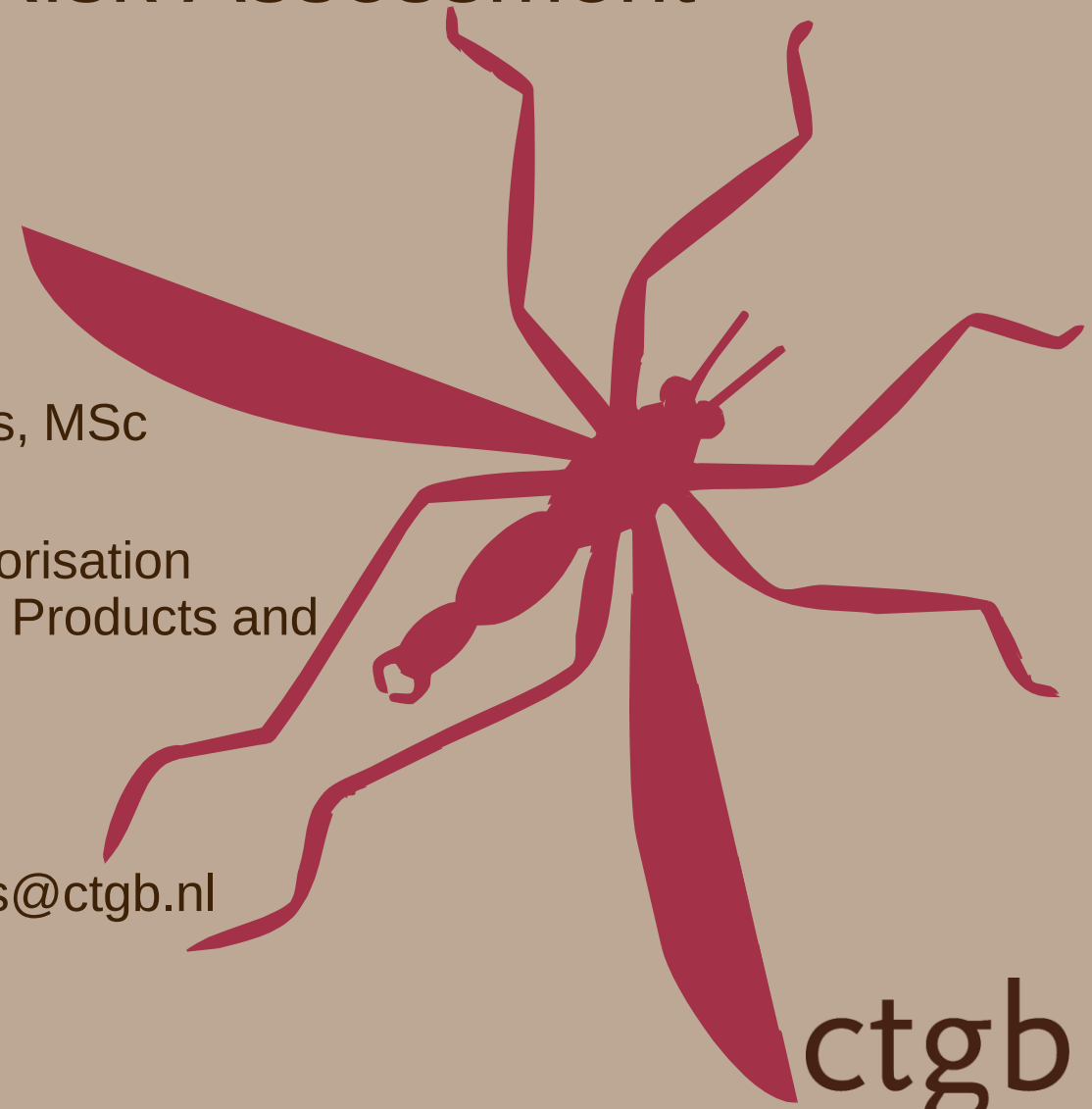
Pesticide Risk Assessment



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Workshop PRRP Toxicology

Monday: introduction, data requirements and reference values

Tuesday: exposure models including practical exercises

Wednesday: discussions on applicability to Ethiopia (break-out groups)

Thursday: AOB, summary, next steps

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Plant Protection Products
Legal Aspects

Formulations which protect plants or products of crop origin like:

Insecticides, herbicides, fungicides, compounds influencing metabolism of plants, growth regulators (e.g. plant hormones) and protection of supplies

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Plant Protection Products
Legal Aspects

No direct or indirect harmful effects on human or animal health via drinking water, food, feed or any other way

No unnecessary repeats of tests on vertebrates

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Pesticide composition

- One or more active substances

  - full evaluation of all aspects within pesticide regulations
- Other formulants

  - evaluation within other regulations like Reach (usually)
- Complete formulation

  - limited toxicological evaluation

  - Risk Assessment

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Pesticide, EU risk assessment

- Active substance(s):

  Evaluation by EU (EFSA and MS) for inclusion in a positive list
  - RMS writes Draft Assessment Report (DAR)
  - MS comment on DAR of RMS
  - MS participate in (expert) meetings
  - Advise government on national position
- National authorisations
  - Evaluation of active substance and plant protection product, detailed risk assessment

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Risk assesment aspects

Aspects

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

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Plant protection products
Risk assessment

<u>Risk Assessment in basic is a simple method, based on two values:</u>

1. Health-based acceptable exposure level (reference dose)

2. Estimated or measured exposure

Acceptable Exposure Level ≥ Exposure

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Essential knowledge

- Toxicological profile
- Population(s) exposed
- Exposure scenario
  - Route
  - Duration
  - Frequency
  - Level of exposure

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Acute studies, active and PPP

	Rat	Rabbit	Guinea pig
Acute oral	R		
Acute dermal	R		
Acute inhalation	R		
Skin irritation		R	
Eye irritation		R	
Skin sensitisation			R

R = Required
CR = Conditionally required

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Repeated dose toxicity, active

		Rat	Dog	Mouse	Rabbit
Short-term	28-day	CR			
	90-day	R	R		
	1-year		CR		
Long-term	Chronic	R			
	Carcino	R		R	
Repro	2-generation	R			
	Developmental	R			R

R = Required
CR = Conditionally required

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Acceptable exposure levels

Can have several definitions

For Risk assesment of pesticides the following Acceptable Exposure levels are important:

ADI: Acceptable Daily Intake (by consumption)

ARfD: Acute Reference Dose (accidental high consumption)

AOEL: Acceptable operator exposure level

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Exposure assessment

Tiered approach:

Basis: Generic or specific models

- DE, UK, NA-PHED, Europoem I and II
- Glasshouse models

Refinement:
Measurement of actual exposure for the application under consideration

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Exposure assessment

Who to protect?

- Operator
- Worker
- Bystander
- Resident

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Which model to select?

- Depends on type of application:
  - Indoors vs outdoors
  - Manual vs mechanical
  - Upwards vs downwards

- No consensus on which model to use for which situation.

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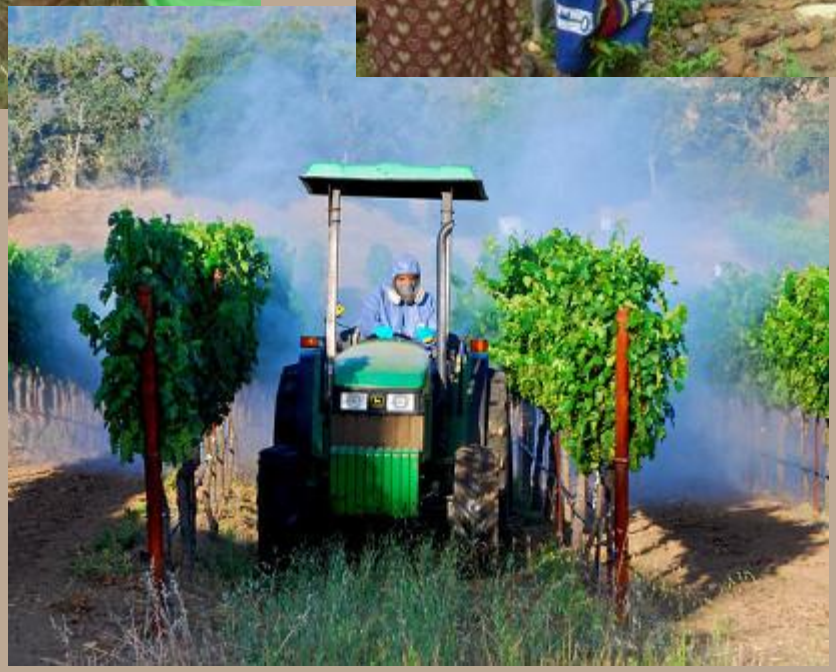

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