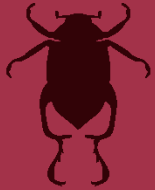


Introduction on Risk Assessment



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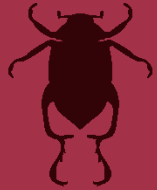
May 2012

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Contents



- Deriving Reference Values
- Dietary data
 - mean intake (50-percentile)
 - large portion (97.5-percentile)

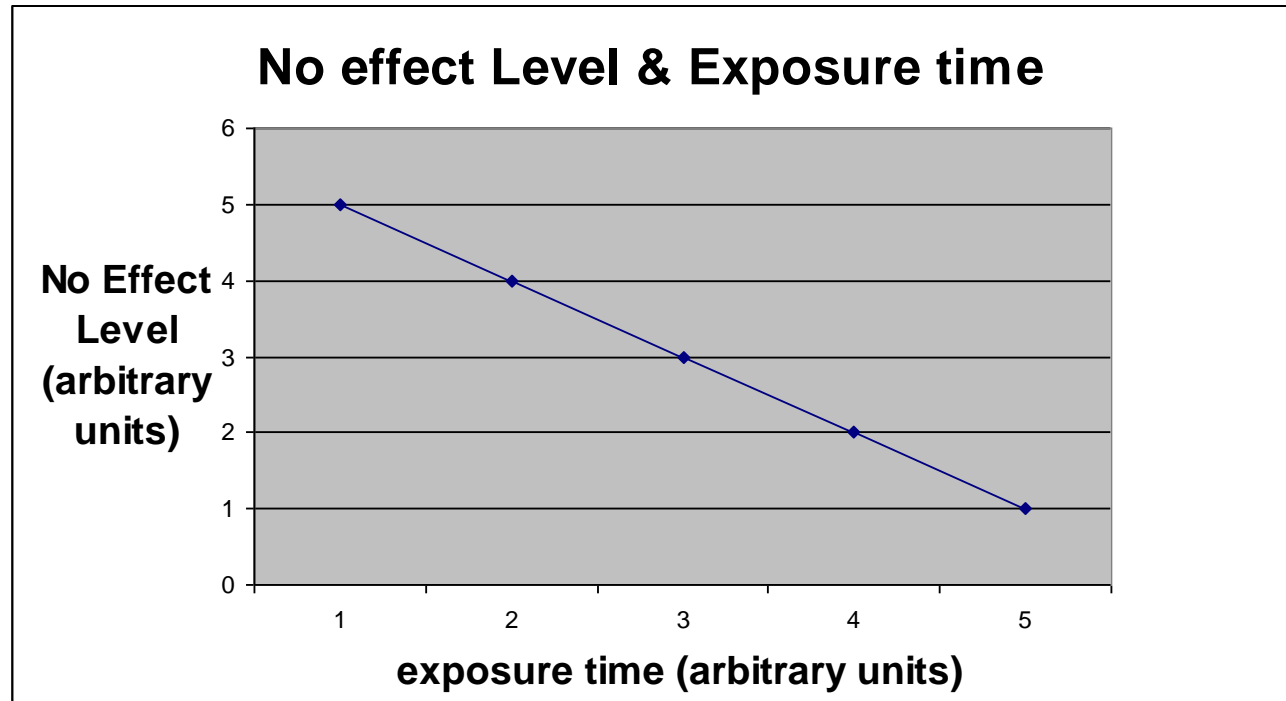


- Choice of population groups
- Residue data
- Calculation/exercises





General principle of toxicology



Conclusion

long term acceptable exposure level is lower,
short-term acceptable exposure level is
higher.



Reference values



ADI

Acceptable Daily Intake: no effect level from long term animal study, divided by 100



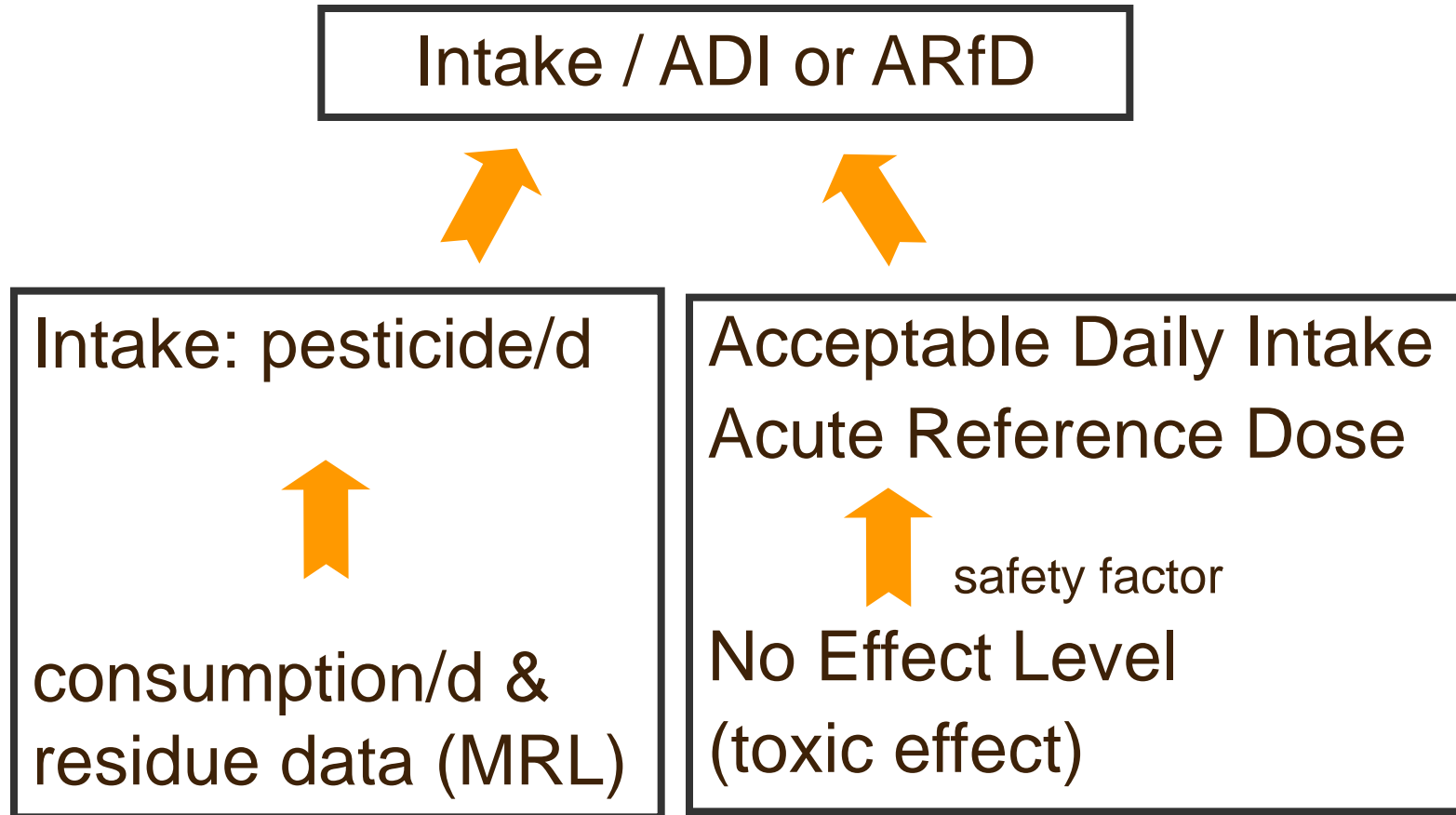
ARfD

= Acute Reference Dose: no effect level from a short term or reproduction animal study, divided by 100



[workshop on operator exposure of Marloes Busschers, 23-26 April]

Consumer risk assessment general



Consumer risk assessment chronic exposure



Input parameters

- MRLs
- *mean* dietary intake data
- during whole course of life

Calculation

Theoretical Maximum Daily Intake, TMDI):

$$\Sigma x,y = (\text{MRL } x,y * \text{intake } x,y)$$

Consumer risk assessment - chronic



- **Chronic intake (TMDI) \leq ADI**
 - Safe use
- **Chronic intake (TMDI) $>$ ADI**
 - *Refinement* of calculation using processing data and median residue values
- **Refined chronic intake $>$ ADI**
 - No safe use, restriction of application needed / authorisation cannot be granted.

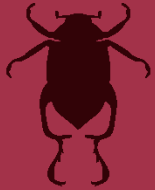
Consumer risk assessment acute exposure



Why is an acute consumer exposure calculation necessary?

- Large portion instead of mean portion
- Variation in residue levels between different units while MRL has been based on composite sample. Compensation by variability factor of usually 3 (JMPPR, 2010).
- For decision making if during monitoring residue level is above MRL.

Consumer risk assessment acute, tiered approach



- **Acute intake \leq ARfD**
 - Safe use
- **Acute intake $>$ ARfD**

Refinement of calculation using:

 - New toxicity studies
 - New residue trials
 - Specific variability factor
 - New/other processing data
 - Other statistic methods
- **Refined acute intake $>$ ARfD**
 - No safe use, restriction of application needed / authorisation cannot be granted.

Consumer risk assessment acute exposure



Input:

- Residue data (MRL)
- Large Portion Dietary Intake data (LP, children, adults, ...)
- Standard variability factor for particular crop (v)
- one time/occasional intake

ESTI = Estimate of Short-Term Intake

Calculation:

$$\text{ESTI} = [U \times \text{MRL} \times v] + [\text{LP-U} \times \text{MRL}]$$

Exercises for workshop participants (paper copy)



thiacloprid

- Derive ADI and ARfD from list of endpoints
- Calculate TMDI and ESTI for apple, cucumber and melon
- Calculate relative risk (% ADI/ARfD)
- Decide on acceptability