FOOD SAFETY – CAPACITY BUILDING ON RESIDUE CONTROL

Risk Analysis and MRLs

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Antoine Kabwit Nguz

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Content

- Food Safety
- Risk Analysis
- Process of setting MRLs
- Good practices and MRLs
- Conclusion

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Food Safety

- Food Safety is an « essential » quality factor
- Food Safety
  - Presence of undesirable constituents with adverse effect to human health
  - Relationship Food – Health
- Risk Analysis
  - The basic principle of Food Safety

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Risk Analysis

- A structured and multidisciplinary approach to identifying and where possible, to reducing risk
- Zero risk not achievable
- Hazards-Risks
  - long list of hazards
  - but is there a risk?

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Hazard and Risk

- **Hazard**
  - A biological, chemical and physical agent in, or condition of a food, with the potentials to cause an adverse health effect
- **Risk**
  - A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard in food

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Hazards

- **Biological**
  - pathogenic bacteria (Salmonella, Campylobacter), mycotoxins, viruses, prions
- **Chemical**
  - contaminants: dioxins, PCB's, heavy metals, PAH's, POP's endocrine disruptors, pseudo-estrogens,
  - residues: antibiotics, other veterinary drugs, pesticides
- **Physical**
  - glass, metal, plastic

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Risk Assessment

- **Hazard identification**
  - **What can the product do at any dose?**
- **Hazard characterisation**
  - **What is the dose response?**
  - **What is the «safe» dose for humans?**
- **Exposure/Intake assessment**
  - **What is the intake?**
- **Risk characterisation**
  - **What the risk associated with the intake?**

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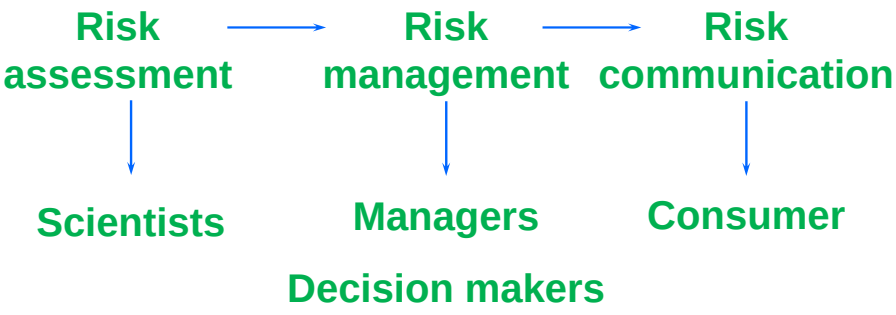
Risk Analysis



Hazard Characterisation

Non Threshold effects

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Theoretical risk exist at any level

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Mutagenicity

Genotoxicity

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WOULD NOT BE APPROVED

Threshold effect

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Low level of intake exist without risk

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Most forms of toxicity

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ANALYSE TOXICITY DATABASE AND DEFINE A SAFE INTAKE

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Hazard Characterisation

- Threshold effect
  - Analyse dose-response data to define the most sensitive toxic effect
  - Define the daily dose that do not produce that effect (NOAEL= non-observed-adverse-effect-level)
  - Divide the experimental dose by a safety factor to take into account interspecies extrapolation and human variability.
  - The safety or uncertainty factor varies between 100 and 1000.
  - ADI= NOAEL/100
  - ADI is the acceptable daily intake that can be consumed daily over a life time without effect

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Determining Acceptable Daily Intake (ADI)

- Adverse systemic effect
- Reproduction and developmental effect
- Mutagenic effect
- Carcinogenic effect
- Effect on human intestinal flora
- Immunologic effect
- Pharmacological effect
- Endocrine effect

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Food Additives

- Hazard Identification
- Hazard Characterisation
  - Establishment of heath-based exposure limit (ADI)
- Establish permitted levels such as projected intake are below health-based limit
- Risk characterisation

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Veterinary Drugs

- Hazard Identification
- Hazard Characterisation
  - Establishment of heath-based exposure limit (ADI)
- Establish maximum permitted residues levels MRLs such as projected intake are below health-based limit
- Risk characterisation

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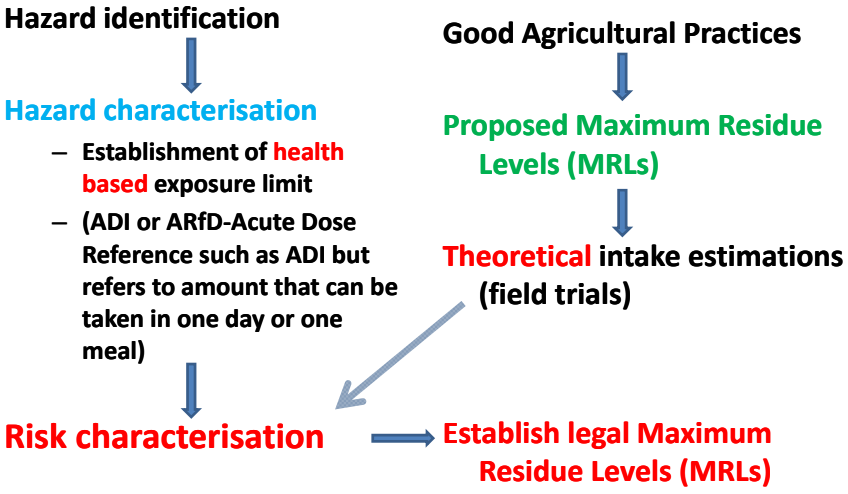
Theoretical Maximun Daily Intake (TMDI)

- The TMDI is the sum of residue present in a food basket (daily consumption)
- The safe concentration of drug and its metabolites that could be consumed by individual eating the animal products
- Safe concentration= ADI x Body weight/Food Consumption Factor
- Example: 0,3kg of meat, 0,1kg of liver, 0,05kg fat,0,05kg kidney, 1,5kg milk, 0,01kg eggs, 0,02kg honey.

Pesticides residues



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Issues with pesticides residues

- Maximum Residues Levels are establish based on controlled field trails
  - Under Good Agricultural Practices
  - At the required application rate
  - At the expense of the applicant
- If theoretical predicted intake is above safety limit the product is not approved for use under those conditions
- Additional trials with lower but effective dose or longer withdrawal period before harvesting
- Approval - Pesticide must be effective at applied level and give residues below health based exposure limit

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Conclusion

- The marketing labelling and the establishment of MRLs in the should be based on scientific assessments and is a multidisciplinary process
- Guidelines for the Registration of Veterinary Drugs within the SADC Region are under development to harmonise the registration process and will include also the establishment of MRLs
- Consumption patterns also vary according to cultural practices in different countries or part of the SADC Region.
- Therefore this fact should be taken into account in the establishment of MRLs

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Conclusion

- Therefore, while efforts are made to harmonize when possible, their conclusions may result in establishing different MRLs
- The implementation of the guidelines will ensure the safety of food supply including animal products and the proper use of additives, drugs and pesticides sold in the SADC Region

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Thanks for your attention