



# Risk Assessment of veterinary Drug Residues in Edible Animal Food: Role of International Agencies

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# Use of vet drugs



- \* 1. Specific therapy
- \* 2. Prophylaxis
- \* 3. Modification of cell, tissue, organ and system functions



## Edible tissues or products from food animals



- \* Drugs can be retained in the following edible tissues as shown below

\*

\* **Food animal**

**Edible by products/s**

\*

- |               |   |
|---------------|---|
| * Cattle      | Muscle, liver, kidneys, fat, milk and offal |
| * Sheep/goats | Muscle, fat, liver, offal and milk          |
| * Chicken     | Meat, eggs                                  |
| * Pig         | Muscle, fat, liver                          |
| * Salmon      | Muscle                                      |



# RISK ANALYSIS – Food safety



## What is risk?

- This is defined as the probability of an adverse outcome when unsafe food is consumed

## What is a hazard?

- This is the probability of adverse outcome from intrinsic toxic properties of a compound

## What is risk analysis?

- This is a relatively new paradigm for formal decision making in the area of food safety.
- It is an interactive process between risk assessment and risk management
- The process has to be science-based, open and transparent



# Risk analysis components



- 1. Risk assessment – Science based
- 2. Risk management
- 3. Risk communication

## **What are the features of risk assessment?**

- Hazard identification (what are the dangers)
- Hazard characterization (dose – response)
- Exposure assessment (assessment of human exposure)
- Risk characterization (description of the nature and magnitude of human risk – drugs)



# Risk for vet drug residues



- Veterinary drugs and acaricides – used for treatment, prevention or supportive agents in food animals.
- Residues (metabolites) of drug/pesticide compounds can contaminate edible tissues above permitted threshold levels
- Safe food of animal should contain only accepted residue levels in order to conform to WTO Sanitary and Phytosanitary (SPS) measures for international trade.
- Countries and high institutions should train personnel in risk analysis on food safety to ensure free trade among countries.
- Drug/acaricide residues can cause some risks to consumers unless they conform to SPS measures.



## Public health risks from drug residues



- \* 1. Anaphylaxis/food allergies
- \* 2. Reproductive disorders e.g. birth malformation, genotoxicity
- \* 3. Development of antimicrobial resistance (AMR) through food chain,
- \* 4. Long term effects – e.g. carcinogenesis



# International regulation



- FAO and WHO in 1987 mandated JECFA (established 1956) to assess the safety of veterinary drug and food additives in food.
- **JECFA**- Joint FAO/WHO Expert Committee on Food Additives
- Assesses safety of veterinary drug residues in edible food of animal origin
- **JMPR** – Joint FAO/WHO Meeting on Pesticide Residues
- Assesses safety of pesticide in edible food of animal origin and edible crops.





## What is JECFA?



- It is an independent scientific peer review body that advises FAO and WHO
- Advises the Codex Alimentarius Commission and Member states
- Advises on risk factors associated with consumption of edible animal tissues containing small amounts of veterinary drug and pesticide residues.
- Establishes ADI and sets MRL for the various drugs and pesticide residues in food.
- MRL set by JEFCA and JMPR become adopted as standards by the Codex Alimentarius Commission
- WTO's SPS Agreement recognizes the Codex standards as reference for international trade for food products.
- Countries and public health scientists should adopt and implement the Codex standards to ensure free trade among themselves and even export the balance



# Procedures for Risk assessment



- Industry submits a battery of data on acute, sub acute, sub chronic and long term toxicological studies on veterinary drugs to WHO's JECFA experts to review and establish an ADI
- Industry submits residue data to FAO team to review metabolic pathways to enable establishment of MRL
- **ADI** - amount of residues of foreign substance (drug/pesticide /food additive) which is recognized as safe and can be consumed daily by human being throughout life time.

**Unit:** amount of residue (mg/person/day)

**Basis:** daily diet (derived from animals)

**Purpose:** reference value for consumer safety



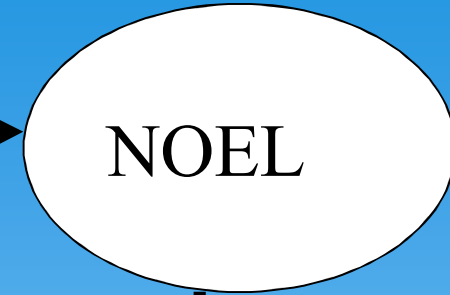
# Establishing an ADI



- \* 1. Lab animals are often used for toxicological studies to establish a NOEL
- \* 2. **NOEL**- (No observed effect level) This is the dose (mg/kg) of a drug that does not produce any adverse effects in animal studies. It can be derived from either sub acute, sub chronic or long-term studies
- \* 3. Identify the most appropriate NOEL from either toxicological, pharmacological or microbiological end point
- \* 4. Apply a safety factor of 1 x10, 100, 200, 500 or 100 to the NOEL to obtain ADI
- \* 5. Establish MRL from ADI based on the following criteria:
  - \* - Standard diet consumption
  - \* - Total residue depletion studies
  - \* - Selection marker residue
  - \* - Analytical methodology usefulness and metabolism studies



Toxicological, pharmacological  
or microbiological end point



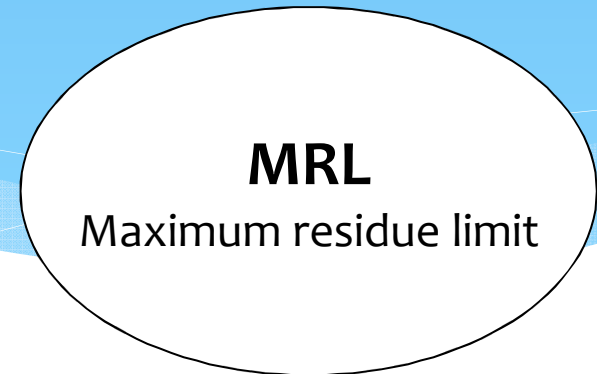
Safety factors e.g. 1x10, 10x10, 200, 500,  
1000, 2000



Why and how  
MRL's are  
established

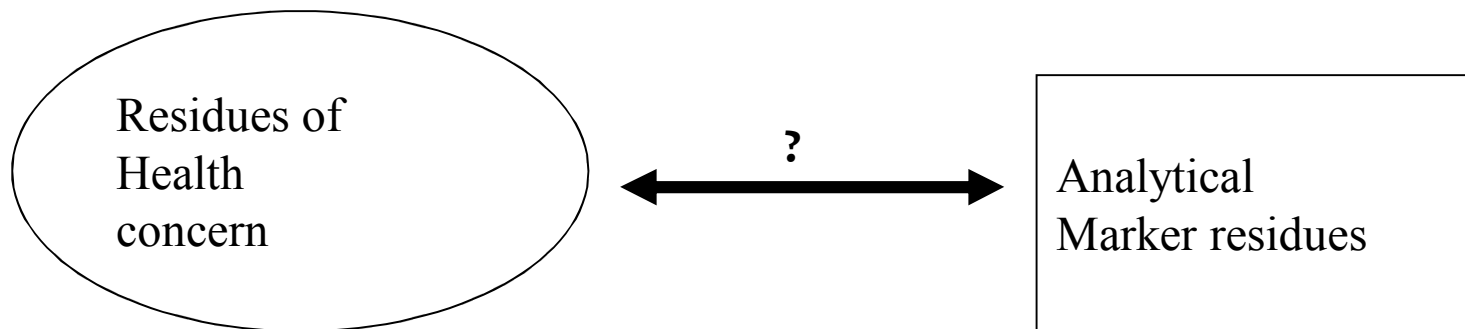
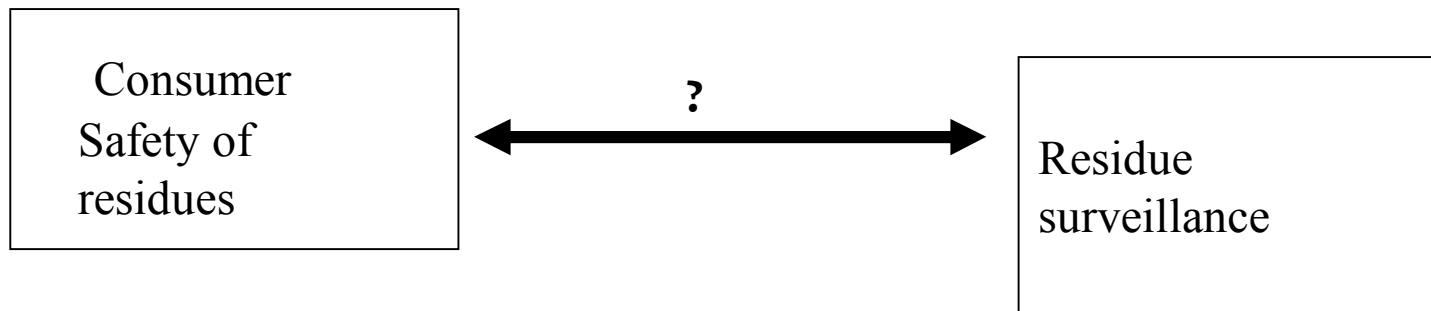
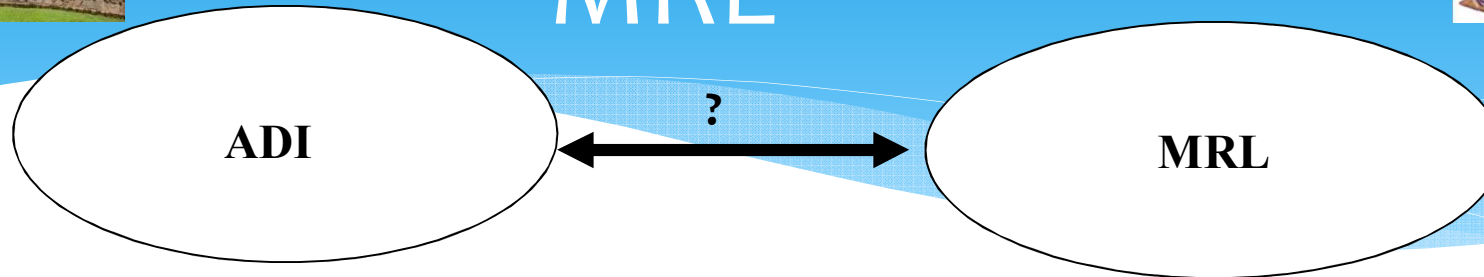


- Standard diet consumption
- Total residue depletion Studies
- Selection of marker residue
- Analytical usefulness
- Metabolism studies





# Properties of ADI and MRL





# What is MRL?



This represents the concentration of a veterinary drug , pesticide or food additive residue in individual food items which is permitted/recognized as safe.

**Unit:** Concentration of residue (mg/kg)

**Basis:** Single target tissue (e.g liver, muscle)

**Purpose:** Reference values for analytical residue control



# MRL cont..



- \* -JECFA establishes MRLs for various drugs which become adopted by CACVDR
- \* -Once adopted these MRLs become residue food standards
- \* - WTO Sanitary and Phytosanitary Measures (SPSS) enforce these standards for fair international free trade



# Risk management



## What is the goal?

- To protect the public by controlling risks by implementation of appropriate measures for instance **regulatory** ones
- These should be managed at national level by making appropriate decision.
- Management in the region should focus on both availability of food and its safe level
- Measures which hinder free and adequate food supply may not be appropriate.
- Each member country should formulate its laws concerning distribution pattern of food





# Risk communication



Interactive exchange of information concerning hazards and risks.

It can originate from either:

- Industry
- Consumers
- Risk assessors
- Risk managers
- Academic community or
- Other internal parties (citizens)

Publications- local media, educational material, labelling are examples of communicating risk



# Applications of SPS measures



- Each member country should adopt and implement the Codex Alimentarius Commission Food Standards to fulfil SPS Measures.
- Countries setting regulations when no international standards do not exist (either stricter than the Codex standards, should base it on scientific risk assessment (for instance EU and FDA may be stricter than the Codex standards))



# Conclusions



- \* 1. International agencies provide technical advise to Member States on food safety
- \* 2. Fair and free trade among Members States is facilitated
- \* 3. Consumer protection