

MODALITIES AND PROTOCOL FOR FIXATION OF MRLs IN MILK AND MILK PRODUCTS INCLUDING RISK ASSESSMENT

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CONTENTS

What is a residue?

How it comes in milk?

Establishing MRLs

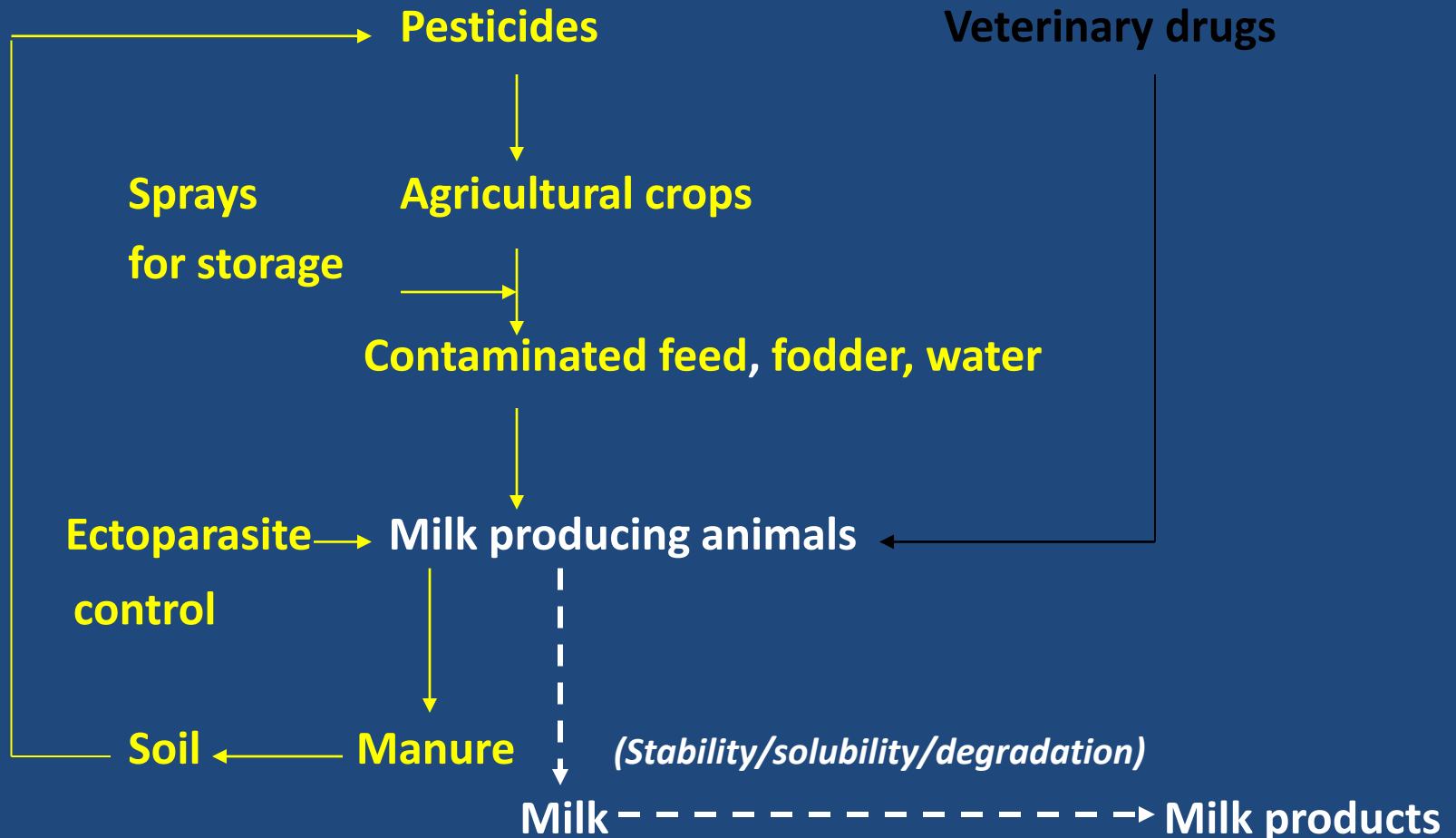
- Risk Assessment (RA)
- Protocol for RA Steps
- Modalities
- National
 - Harmonization with Codex
 - Challenges
 - Further action

WHAT IS A RESIDUE?

- Undesirable chemical
- **Intentional use**
 - Ongoing
 - Past
- Enters food
- Contaminant (***unintentional presence***)
- Examples
 - Plants : Pesticides - Excludes fertilizers, plant nutrients, feed additives
 - Animals : Veterinary drugs
- Parent compound, metabolite, toxic impurity

HOW DOES IT COME IN MILK?

Major Routes



ESTABLISHING MRLs: RISK ASSESSMENT

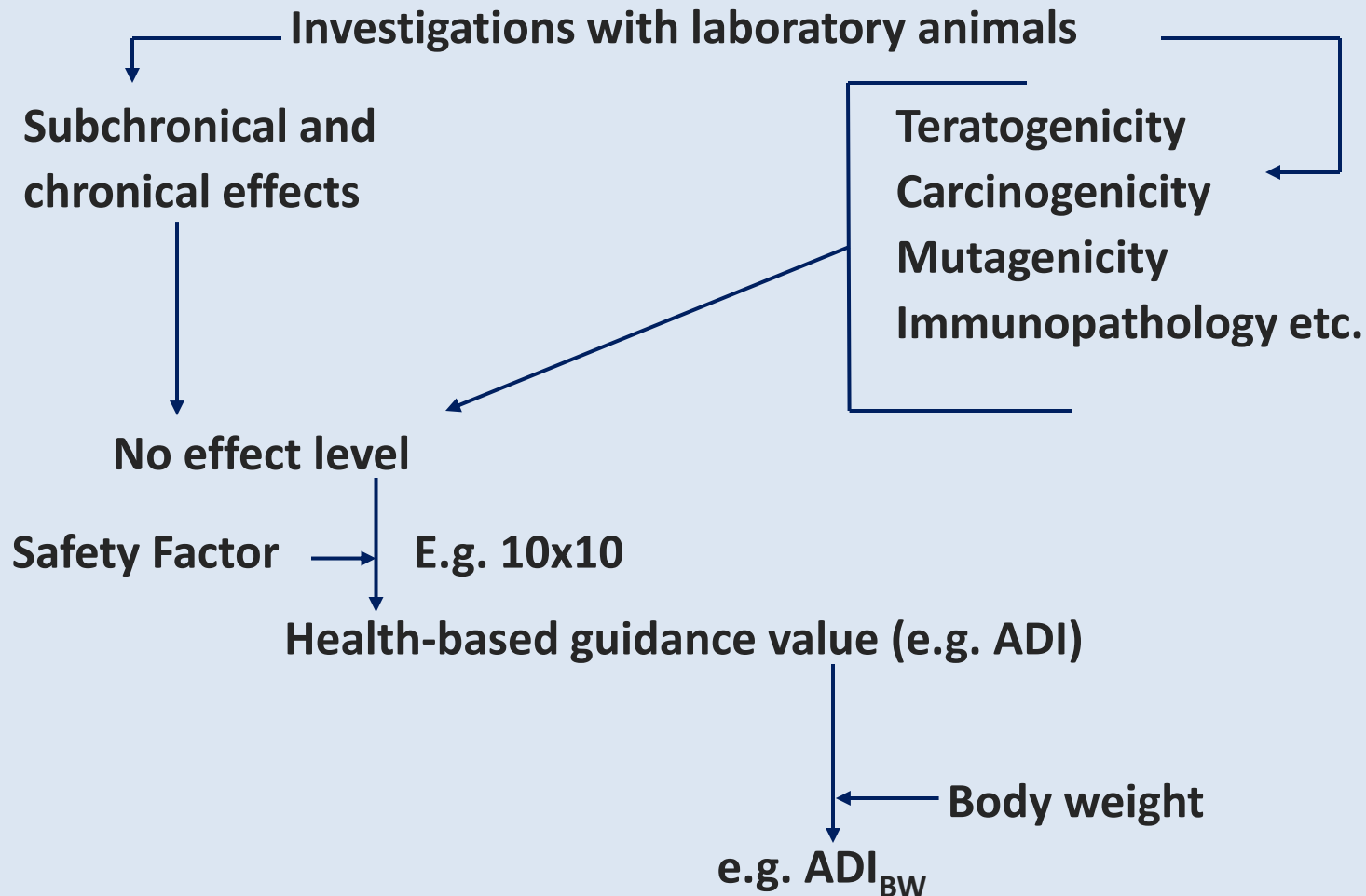
- Risk = $f(\text{Hazard} \times \text{Exposure})$
- Risk assessment
 - Hazard identification
 - Hazard characterization
 - Exposure assessment
 - Risk characterization

ESTABLISHING MRLs: RISK ASSESSMENT

Hazard Identification <ul style="list-style-type: none">– Registered for use– Data availability (FAO manual on the submission and evaluation of residue data for the estimation of maximum residue levels in foods and feed, 2002)– Results in residue in food	HI
Hazard Characterization <ul style="list-style-type: none">– Data adequacy assessment– Health-based guidance value (ADI/ARfD)	HC
Exposure Assessment <ul style="list-style-type: none">– Chronic/Long term: GEMS/National diets data x STMR (Pesticides) Theoretical food basket x STMR (VD)– Acute/Short term : Large portion x HR (Pesticides)	EA
Risk Characterization <ul style="list-style-type: none">– Comparison of exposure with health-based guidance value– Recommendations	RC

RISK ASSESSMENT: PROTOCOL

HC

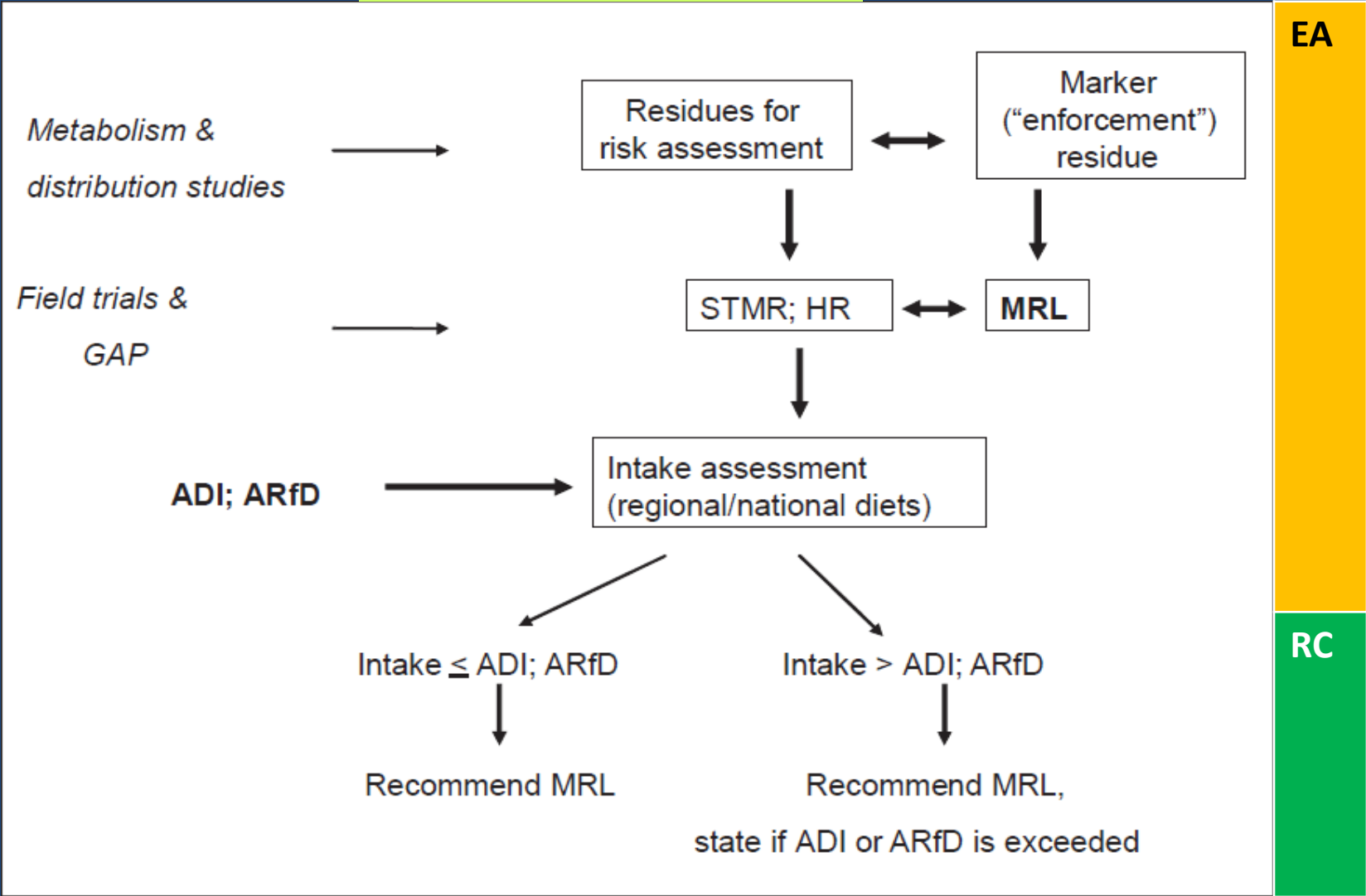


HEALTH-BASED GUIDANCE VALUE

- A numerical value derived by dividing a point of departure (e.g. no-observed-adverse-effect level) by a composite uncertainty factor to determine a concentration that can be ingested over a defined time period (e.g. lifetime or 24 hours) without appreciable health risk.
- **ADI=Acceptable Daily Intake:** The daily dosage of a chemical which, during an **entire lifetime**, appears to be without appreciable health risk
- **ARfD=Acute Reference Dose:** The estimate of the amount of a substance that can be ingested in a **period of 24 hours** or less without appreciable health risk.

RISK ASSESSMENT: PROTOCOL

PESTICIDES

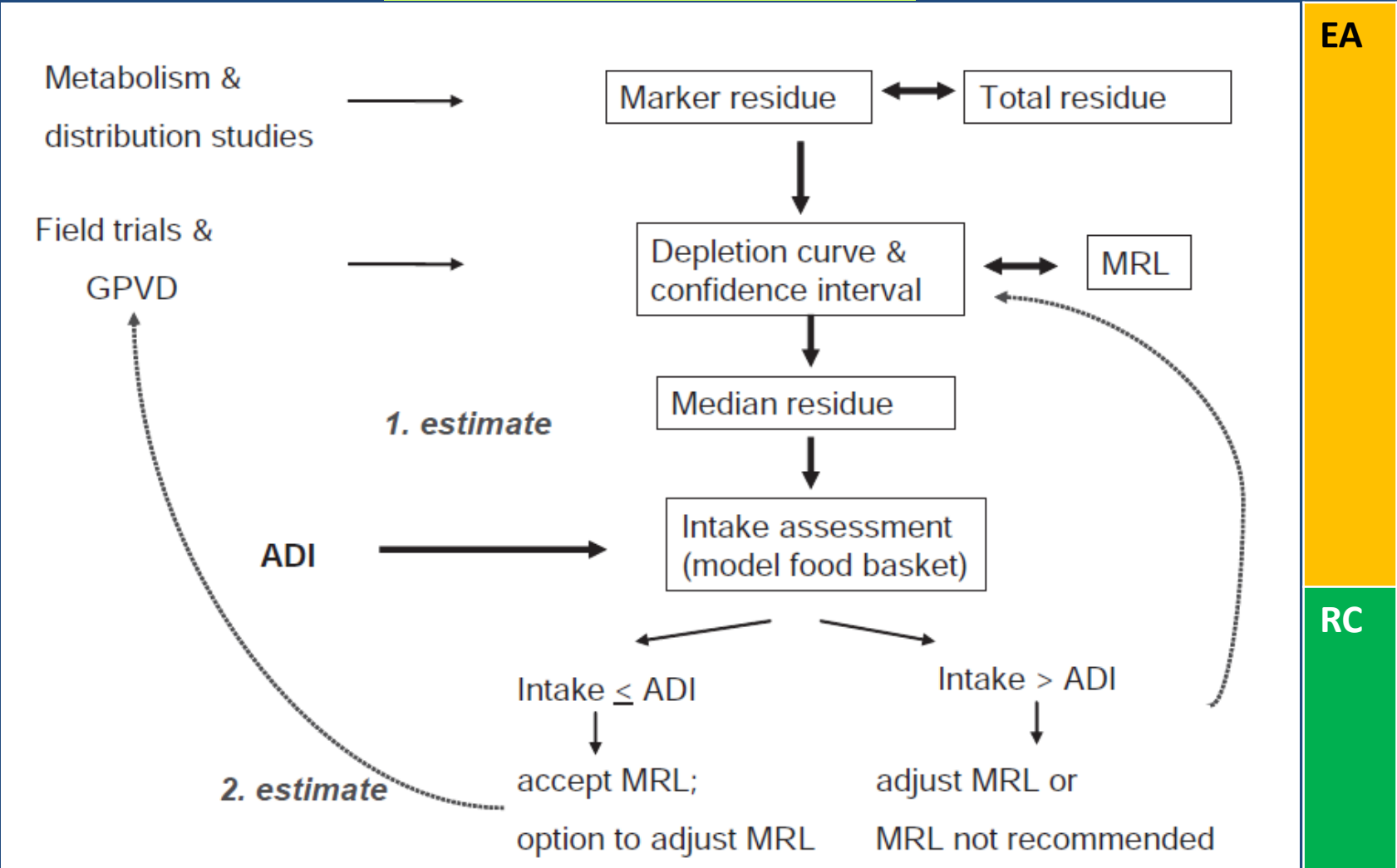


EA

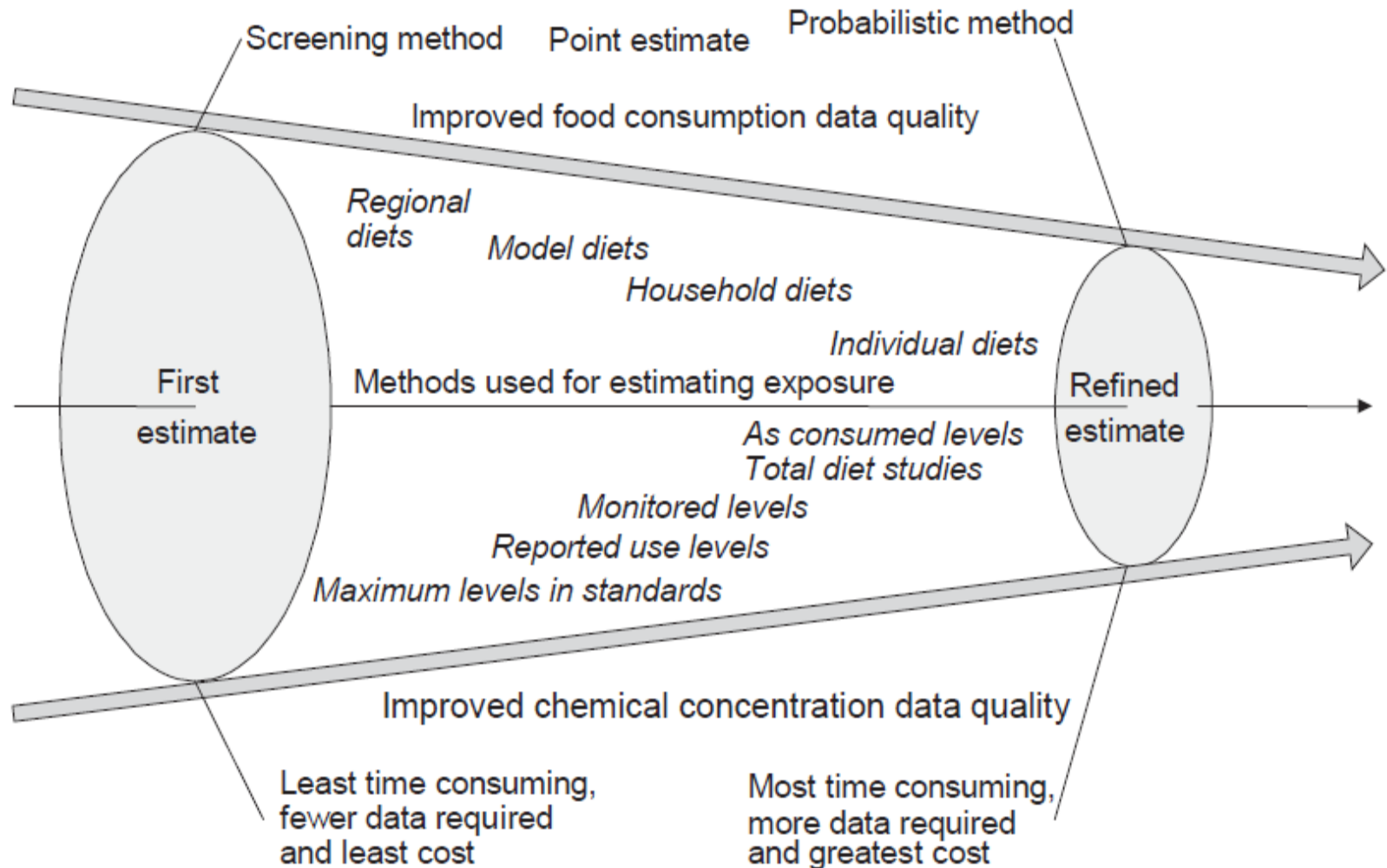
RC

RISK ASSESSMENT: PROTOCOL

VETERINARY DRUGS



REFINING EXPOSURE ESTIMATE



EXAMPLE

Pesticide	ADI(mg/kg body Weight)	ADI per person (mg/person of 50 kg) (ADI*50)	Food Commodity	Residue generated under supervised trials mg/Kg	Waiting period (days)	Food Consumption (g/person)	TMDI (mg/person/day)(Col 3xCol 5/1000)	ΣTMDI (mg/person/day)	% ADI	Codex MRL	Proposed MRLs mg/kg	Methodology	Rem
XYZ	0.01	0.5	Cotton seed seed	0.05		10	0.0005	0.05081	10.162				
			Rice	0.05		270	0.0135						
			Apple	0.5		30	0.015						
			Tea	0.05		10	0.0005						
			Sugarcane	0.03		17	0.00051						
			Milk and milk products	0.15		104	0.0208				0.2	GC-MS	

STMR

MRL

ESTABLISHING MRLs: RELATED MODALITIES

General

- Scientific uncertainties/variability
- Residue definition
- Food/commodity definition/description
- Prevailing residue levels
- Banned chemicals (Negative List)
- Non-registered chemicals and import
- EMRLs (Pesticides)
- Antimicrobial resistance (Antimicrobials)
- Analytical methods
- Periodic review

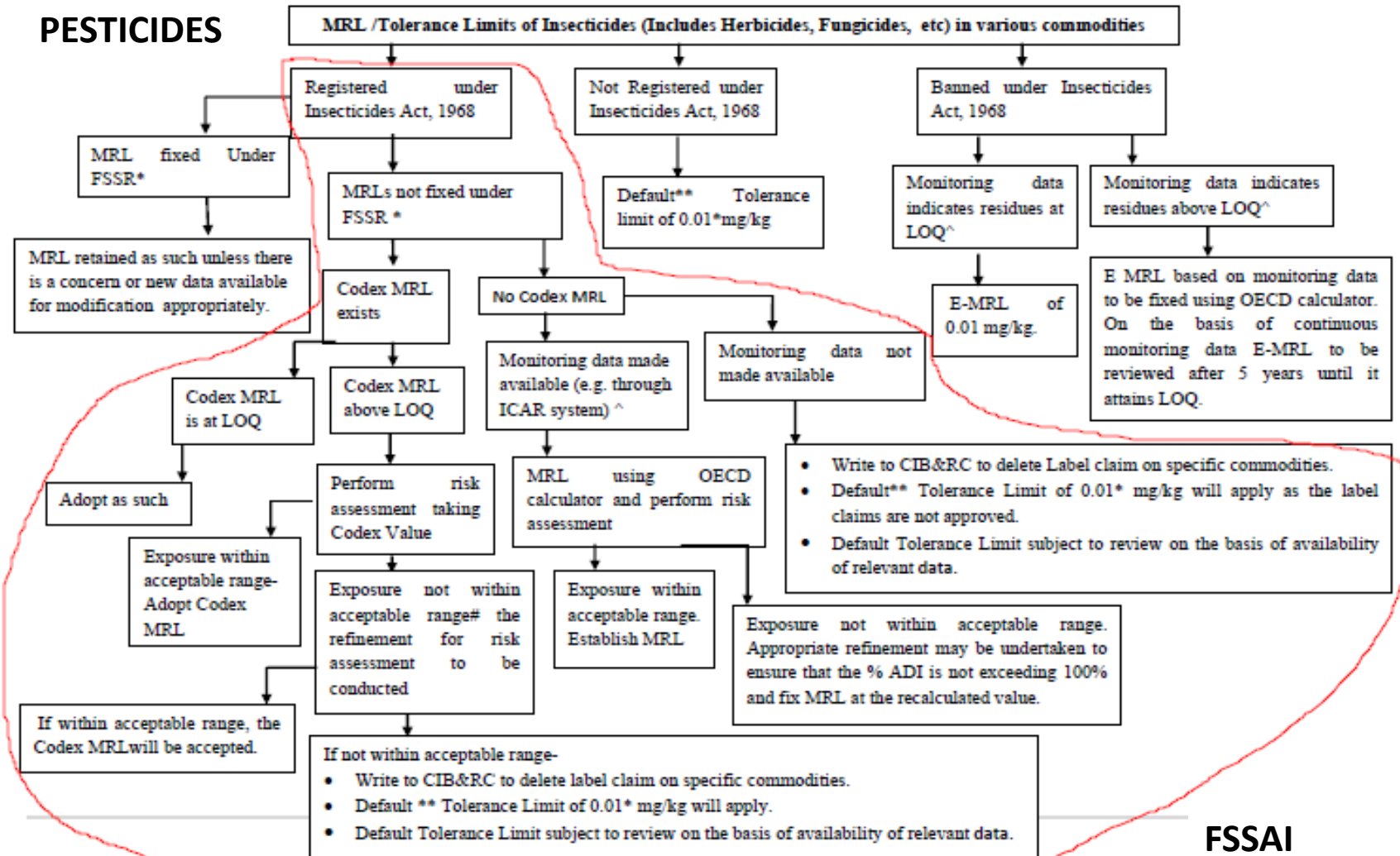
ESTABLISHING MRLs: RELATED MODALITIES

Milk

- Susceptible population: Milk consumed by children
- Biological filtration by animal
- Withdrawal period (Veterinary drugs)
- Partitioning of residue (Pesticides)
 - Identify as 'fat soluble': MRL applies to whole milk
(For a "milk product" with a fat content less than 2%, the MRL applied should be half those specified for milk. The MRL for "milk products" with a fat content of 2% or more should be 25 times the maximum residue limit specified for milk, expressed on a fat basis.)
 - Establish MRL for milk and fat separately

NATIONAL: HARMONIZATION WITH CODEX

PESTICIDES



‘HARMONIZATION’ IS NOT SIMPLE ‘ADOPTION’

ESTABLISHING MRLs: CHALLENGES

- Data availability and adequacy
- Availability of expertise
- Functional separation in the roles of risk manager and risk assessor
- Documentation and follow-up actions
- Assessing cost vs. level of accuracy

ESTABLISHING MRLs: FURTHER ACTIONS

- Collaborate with relevant institutions for planned data generation/sharing
- Training to develop expertise
- Emphasis: Effective documentation of risk assessment/management activities
- Sustained follow-up to address data gaps and uncertainties identified
- Periodic review

THANK YOU

IMPLICATIONS

- Health hazards to consumers
 - **Adverse effects:** toxicity, teratogenicity, carcinogenicity, mutagenicity etc.
 - **Microbiological risks:** favouring resistant or pathogenic microorganisms in the intestine, development of drug resistant strains
 - **Immunopathological effects:** allergies
- Technological problems to food processor – culture failures

IMPLICATIONS

- Proper use- beneficial
- Excessive / improper use- presence in food in unsafe amounts

Safe food- primary concern

RESIDUE LEVEL VS. LIMIT

Level

- Amount of chemical (pesticide) estimated to be present in food with attendant uncertainties
- Relevant good practices (GAP)
- Comparison with health-based guidance value like '*Acceptable Daily Intake (ADI)*'

Limit

- Amount of chemical (pesticide or veterinary drug) allowed to be legally present in food
- Relevant good practices (GAP, GPVD)
- Foods complying with 'limit' are toxicologically acceptable

Level

(Risk Assessment)

Limit

(Risk Management)



PESTICIDES AND ITS RESIDUE

Pesticide means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.

PESTICIDES AND ITS RESIDUE

- **Pesticide Residue** means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.

VETERINARY DRUG AND ITS RESIDUE

- **Veterinary Drug** means any substance applied or administered to any food producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour.

VETERINARY DRUG AND ITS RESIDUE

- **Residues of Veterinary Drugs** include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the veterinary drug concerned.