Food and Agriculture Organization of the United Nations

FMM/RAS/298: Strengthening capacities, policies and national action plans on prudent and responsible use of antimicrobials in fisheries Final Workshop in cooperation with AVA Singapore and INFOFISH

12-14 December, Concorde Hotel, Singapore

AMR in Codex Alimentarius Commission and country responsibilities

Iddya Karunasagar

Iddya.Karunasagar@nitte.edu.in

CODEX ALIMENTARIUS
International Food Standards

World Health Organization

Food and Agriculture Organization of the United Nations

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Codex Standards

All Codex texts are publicly available from this website:

All standards, guidelines, codes of practice and advisory texts that compose the Alimentarius are available from the List of standards.

The numerical Codex standards for food additives, veterinary drugs maximum residue levels and pesticide maximum residue levels, can also be accessed via databases that facilitate their use.

Thematic compilations of Codex texts can be downloaded or ordered here.

Type of Text	EN	FR	ES	AR	ZH	RU
Codes of practice	53	51	50	36	12	31
Guidelines	78	77	74	51	47	35
Misc	4	3	3	1	0	1
MRLs	1	1	1	1	1	1
Standards	213	209	202	104	161	118
TOTALS	**349**	**341**	**330**	**193**	**221**	**186**

Updated on: 10-10-2017

Latest news

Safer Food Training for effective participation in Codex
11 Oct 2017 - Bangkok October 11 2017 In some ways the premise is very simple: build stronger Codex coordination [...]

Codex standards for safe food and access to trade
2 Oct 2017 - Experts meet in Kampala to discuss standards for fresh fruits and vegetables Kampala, 2nd October 2017 [...]

FAO and EU to intensify collaboration on AMR
30 Sep 2017 - The Director-General of the Food and Agriculture Organization of the United Nations (FAO), José Graziano [...]

As a group we have much to achieve
27 Sep 2017 - As the Executive Committee of the Codex Alimentarius Commission began its three-day meeting in Rome, [...]

ISO: open minded for change
22 Sep 2017 - Open minded, Open for Change Foresight activities, attracting new experts, cooperation with other organizations and the [...]

News archive

Tweets by @FAOWHOCodex

Codex Alimentarius @FAOWHOCodex

#MustSee The State of Food and

SANITARY AND PHYTOSANITARY MEASURES: TEXT OF THE AGREEMENT

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

Members,

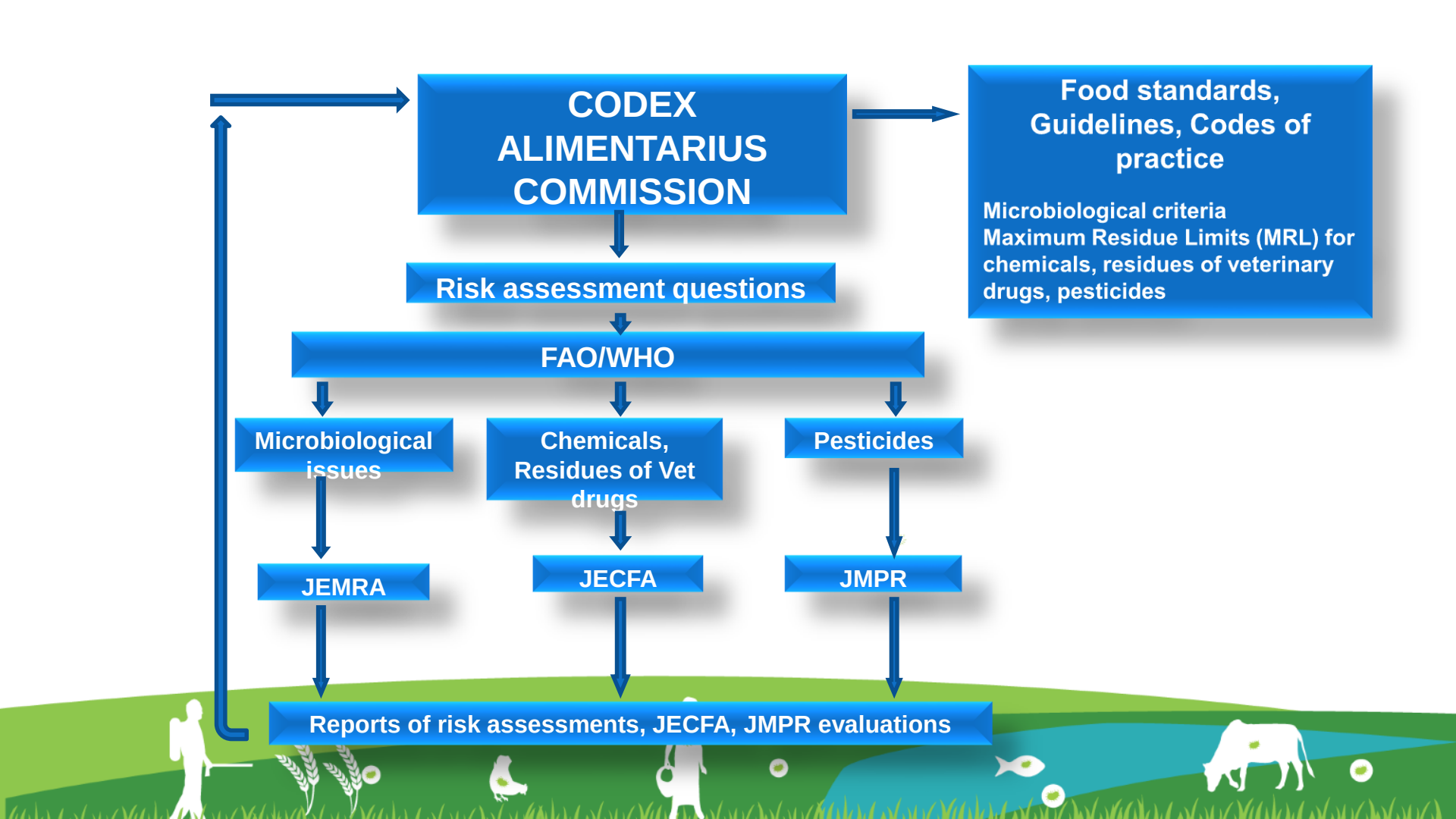
Reaffirming that no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade;

WTO SPS Agreement
International Standard-Setting Organisations
(the '3 sisters')

food safety
CODEX

Animal health/ Zoonoses
OIE

plant health
IPPC


CODEX ALIMENTARIUS COMMISSION
Food standards, Guidelines, Codes of practice
Microbiological criteria
Maximum Residue Limits (MRL) for chemicals, residues of veterinary drugs, pesticides
Risk assessment questions
FAO/WHO
Microbiological issues
Chemicals, Residues of Vet drugs
Pesticides
JEMRA
JECFA
JMPR
Reports of risk assessments, JECFA, JMPR evaluations

HAZARDS ASSOCIATED WITH ANTIMICROBIAL USE IN AQUACULTURE

- Residues of antimicrobials in aquatic products
- Antimicrobial resistance in aquatic microorganisms –
  - pathogens of aquatic animals,
  - aquatic bacteria,
  - zoonotic pathogens associated with aquatic environment.

CODEX ALIMENTARIUS
INTERNATIONAL FOOD STANDARDS

Food and Agriculture Organization of the United Nations
World Health Organization

E-mail: codex@fao.org - www.codexalimentarius.org

MAXIMUM RESIDUE LIMITS (MRLs) AND RISK MANAGEMENT RECOMMENDATIONS (RMRs) FOR RESIDUES OF VETERINARY DRUGS IN FOODS

CAC/MRL 2-2017

Updated as at the 40th Session of the Codex Alimentarius Commission (July 2017)

CHLORTETRACYCLINE/OXYTETRACYCLINE/TETRACYCLINE (antimicrobial agent)

JECFA Evaluation: 45 (1995); 47 (1996); 50 (1998); 58 (2002)

Acceptable Daily Intake: 0-30 µg/kg body weight (50th JECFA, 1998). Group ADI for chlortetracycline, oxytetracycline and tetracycline.

Residue Definition: Parent drugs, singly or in combination.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	200	26th (2003)	
Cattle	Liver	600	26th (2003)	
Cattle	Kidney	1200	26th (2003)	
Cattle	Milk (µg/l)	100	26th (2003)	
Fish	Muscle	200	26th (2003)	Applies only to oxytetracycline.
Giant prawn (*Paeneus monodon*)	Muscle	200	26th (2003)	Applies only to oxytetracycline.

DELTAMETHRIN (insecticide)

JECFA Evaluation: 52 (1999); 60 (2003)

Acceptable Daily Intake: 0-10 µg/kg body weight (1982). Established by the 1982 JMPR.

Residue Definition: Deltamethrin.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Cattle	Muscle	30	26th (2003)	
Cattle	Liver	50	26th (2003)	
Cattle	Kidney	50	26th (2003)	
Cattle	Fat	500	26th (2003)	
Cattle	Milk	30	26th (2003)	
Chicken	Muscle	30	26th (2003)	
Chicken	Liver	50	26th (2003)	
Chicken	Kidney	50	26th (2003)	
Chicken	Fat	500	26th (2003)	
Chicken	Eggs	30	26th (2003)	
Salmon	Muscle	30	26th (2003)	

EMAMECTIN BENZOATE (antiparasitic agent)

JECFA Evaluation: 78 (2013)

Acceptable Daily Intake: ADI of 0–0.5 µg/kg body weight established by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 2011, based on an overall no-observed-adverse effect level (NOAEL) of 0.25 mg/kg body weight per day for neurotoxicity from 14- and 53-week studies in dogs, supported by an overall NOAEL of 0.25 mg/kg body weight per day from 1- and 2-year studies in rats. An uncertainty factor of 500 was applied to the NOAEL, which includes an additional uncertainty factor of 5 to account for the steep dose–response curve and irreversible histopathological effects in neural tissues at the lowest-observed-adverse-effect level (LOAEL) in dogs, as used by JMPR and confirmed by the current Committee (78th JECFA, 2013).

Estimated Dietary Exposure: 11 µg/person per day, which represents approximately 37% of the upper bound of the ADI (78th JECFA, 2013).

Residue Definition: Emamectin B1a.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Salmon	Muscle	100	38th (2015)	
Salmon	Fillet	100	38th (2015)	Muscle plus skin in natural proportion
Trout	Muscle	100	38th (2015)	
Trout	Fillet	100	38th (2015)	Muscle plus skin in natural proportion

TEFLUBENZURON (insecticide)

JECFA Evaluation: 81 (2015)

Acceptable Daily Intake: 0-5 µg/kg body weight on the basis of a lower 95% confidence limit on the benchmark dose for a 10% response (BMDL10) of 0.54 mg/kg body weight per day for hepatocellular hypertrophy in male mice observed in a carcinogenicity study, with application of an uncertainty factor of 100 to account for interspecies and intraspecies variability. (81st JECFA, 2015).

Estimated chronic dietary exposure (GECDE): The EDI is 42.9 µg/person per day, on the basis of a 60 kg individual, which represents approximately 14% of the upper bound of the ADI. The GECDE for the general population is 1.6 µg/kg body weight per day, which represents 31% of the upper bound of the ADI. The GECDE for children is 2.1 µg/kg body weight per day, which represents 43% of the upper bound of the ADI. The GECDE for infants is 0.9 µg/kg body weight per day, which represents 18% of the upper bound of the ADI. (81st JECFA, 2015)

Residue Definition: Teflubenzuron.

Species	Tissue	MRL (µg/kg)	CAC	Notes
Salmon	Muscle	400	40th (2017)	
Salmon	Fillet	400	40th (2017)	Muscle plus skin in natural proportion

Risk Management Recommendations (RMR) for Residues of Veterinary Drugs

Carbadox

Chloramphenicol

Chloropromazine

Dimetridazole

Furazolidone

Ipronidazole

Malachite Green

Metronidazole

Nitrofural

Olaquindox

Ronidazole

Stilbens

CHLORAMPHENICOL (antimicrobial agent)

JECFA evaluation: 12th (1968), 32nd (1987), 42nd (1994) and 62nd (2004) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of chloramphenicol or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of chloramphenicol in food. This can be accomplished by not using chloramphenicol in food producing animals.

FURAZOLIDONE (antimicrobial agent)

JECFA evaluation: 40th (1992) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of furazolidone or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of furazolidone in food. This can be accomplished by not using furazolidone in food producing animals.

NITROFURAL (antimicrobial agent)

JECFA evaluation: 40th (1992) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions, although insufficient data were available or there was a lack of data to establish a safe level of residues of nitrofural or its metabolites[1] in food representing an acceptable risk to consumers, significant health concerns were identified. For this reason, competent authorities should prevent residues of nitrofural in food. This can be accomplished by not using nitrofural in food producing animals.

[1] Semicarbazide is not a unique indicator of nitrofural use and low levels can be associated with other legitimate sources.

MALACHITE GREEN (antifungal and antiprotozoal agent)

JECFA evaluation: 70th (2008) JECFA

CAC37 (2014)

Recommended risk management measures

In view of the JECFA conclusions on the available scientific information, there is no safe level of residues of malachite green or its metabolites in food that represents an acceptable risk to consumers. For this reason, competent authorities should prevent residues of malachite green in food. This can be accomplished by not using malachite green in food producing animals.

CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.**codex**alimentarius.org

Agenda Item 6.2

CX/RVDF 18/24/6
December 2017

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON RESIDUES OF VETERINARY DRUGS IN FOODS

Twenty-fourth Session

PROPOSED DRAFT MRLs FOR AMOXICILLIN (FINFISH FILLET, MUSCLE); AMPICILLIN (FINFISH FILLET, MUSCLE); FLUMETHRIN (HONEY), LUFENURON (SALMON AND TROUT FILLET), MONEPANTEL (CATTLE FAT, KIDNEY, LIVER, MUSCLE)

At Step 3

PROPOSED DRAFT MAXIMUM RESIDUE LIMITS (MRLS) FOR VETERINARY DRUGS

(at Step 3)

AMOXICILLIN (antimicrobial agent)

Microbiological Acceptable Daily Intake (mADI)	0–0.002 mg/kg body weight (bw) based on the effects of amoxicillin on the intestinal microbiota.
Acute Reference Dose (ARfD):	0.005 mg/kg bw based on microbiological effects on the intestinal microbiota
Estimated Chronic Dietary Exposure (GECDE):	0.14 µg/kg bw per day (for the general population), which represents 7% of the upper bound of the mADI
Estimated Acute Dietary Exposure (GEADE):	1.4 µg/kg bw (for the general population), which represents 28% of the microbiological ARfD.
	1.6 µg/kg bw (for children), which represents 31% of the microbiological ARfD.
Residue Definition:	Amoxicillin

Species	Tissue	MRLs (µg/kg) recommended by the 85th JECFA	Step	JECFA
Finfish[a]	Fillet[b]	50	3	85
	Muscle	50	3	85

[a] The term “finfish” includes all fish species.

[b] Muscle plus skin in natural proportion.

AMPICILLIN (antimicrobial agent)

Microbiological Acceptable Daily Intake (mADI)	0–0.003 mg/kg bw based on a no-observed-adverse-effect level (NOAEL) equivalent to 0.025 mg/kg bw per day for increase in population(s) of ampicillin-resistant bacteria in the gastrointestinal tract in humans, and using a safety factor of 10 (for the variability in the composition of the intestinal microbiota within and between individuals).
Acute Reference Dose (ARfD):	0.012 mg/kg bw based on the microbiological end-point.
Estimated Chronic Dietary Exposure (GECDE):	0.29 µg/kg bw per day (for the general population), which represents 10% of the upper bound of the ADI.
Estimated Acute Dietary Exposure (GEADE):	1.9 µg/kg bw per day (for the general population), which represents 16% of the ARfD. 1.7 µg/kg bw per day (for children), which represents 14% of the ARfD
Residue Definition:	Ampicillin.

Species	Tissue	MRLs (µg/kg) recommended by the 85th JECFA	Step	JECFA
Finfish[a]	Fillet[b]	50	3	85
	Muscle	50	3	85

[a] The term "finfish" includes all fish species.

[b] Muscle plus skin in natural proportion.

Note: The 85th JECFA recommended an MRL of 50 µg/kg for ampicillin in finfish muscle and in finfish muscle plus skin in natural proportion, the same as that recommended for amoxicillin, because the modes of action, the physicochemical properties and the toxicological and pharmacokinetic profiles of amoxicillin and ampicillin are very similar.

Codex Guidelines on Veterinary drugs and AMR

- Code of Practice for fish and fishery products – CAC/RCP 52-2003.
- Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005.
- Guidelines for the design and implementation of regulatory national food safety assurance programme associated with the use of veterinary drugs in food producing animals – CAC/GL 71- 2009.
- Guidelines for risk analysis of foodborne antimicrobial resistance – CAC/GL 77-2011.

Code of Practice for fish and Fishery Products

- Section 6: Aquaculture
- 6.3.2 Veterinary drugs
- Gives general guidance on use of veterinary drugs (should be approved), should be based on diagnosis, prescribed by authorised person, follow withdrawal time, maintain records.

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- **Aims and objectives**:
- Protection of consumer by ensuring safety of foods of animal origin.
- Prevent or reduce as far as possible of the direct and indirect transfer of resistant microorganisms or resistance determinants within animal populations or from animal to human pathogens.
- Prevent the contamination of animal derived food with residues of antimicrobial drugs.
- Comply with ethical obligation and economic need to maintain animal health.

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- Encourages the regulatory authorities to:
- Assess the impact of antimicrobial use in accordance with national and international guidelines.
- Conduct research on resistant microorganisms in the environment and the magnitude of transfer of resistance determinants among microorganisms in the environment.

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- **Responsible use of veterinary drugs in food producing animals:**
- Is controlled by veterinarians or other professionals with required expertise.
- Is part of good veterinary practice and good animal husbandry and considers disease prevention by vaccination and improvements in husbandry conditions.
- Aims to limit the use of antimicrobial agents to their approved and intended uses and takes into consideration on farm sampling and testing of isolates from food-animals during production and making adjustments to treatments when required.

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- Responsible use of veterinary drugs in food producing animals:
- Should be based on resistance surveillance and monitoring as well as clinical experience.
- Should not use antimicrobials for growth promotion.

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- Responsibilities of the regulatory authorities
  - Develop appropriate guidelines for data requirement for drug approval;
  - Assessment of efficacy by preclinical trials including pharmacodynamic (mode of action, spectrum, MIC, MCC, intrinsic resistance) and pharmacokinetic (bioavailability, conc at site, distribution, metabolism, excretion) studies
  - Evaluation of application should include assessment of risk to animal and human health;
  - Provide guideline on product labeling (target animal species, pathogen, dosage and administration route, incompatibilities, withdrawal period, shelflife, operator safety) on conditions that minimise resistance
  - Ensure use only on prescription by trained professional

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- Responsibilities of the regulatory authorities
  - Ensure quality and concentration until expiry,
  - Assessment of potential to select resistant microorganisms (degree of cross resistance within the class of antimicrobials and between classes; pre-existing resistance in human pathogens), ,
  - Establishment of ADI, MRL, withdrawal period,
  - Surveillance,
  - Control of advertising,
  - Training of drug users
  - Promoting research
  - Collection and destruction of unused veterinary drugs.

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- Responsibilities of the pharmaceutical industry
  - Submit information required for providing marketing authorisation, ensure quality of information;
  - Marketing and export as per national and international regulations,
  - Training
  - Research

Code of Practice to minimise and contain antimicrobial resistance – CAC/RCP 61-2005

- Responsibilities of whole sale and retail dealers (dispense only on prescription, support responsible use)
- Responsibilities of veterinarians (support improvement of husbandry practices, follow prudent use guidelines, off-label use, recording, training)
- Responsibilities of the producers (implementing good husbandry practices, follow prudent use guidelines, maintain records)

Guidelines for the design and implementation of National Regulatory Food Safety Programme associated with the use of veterinary drugs in food producing animals

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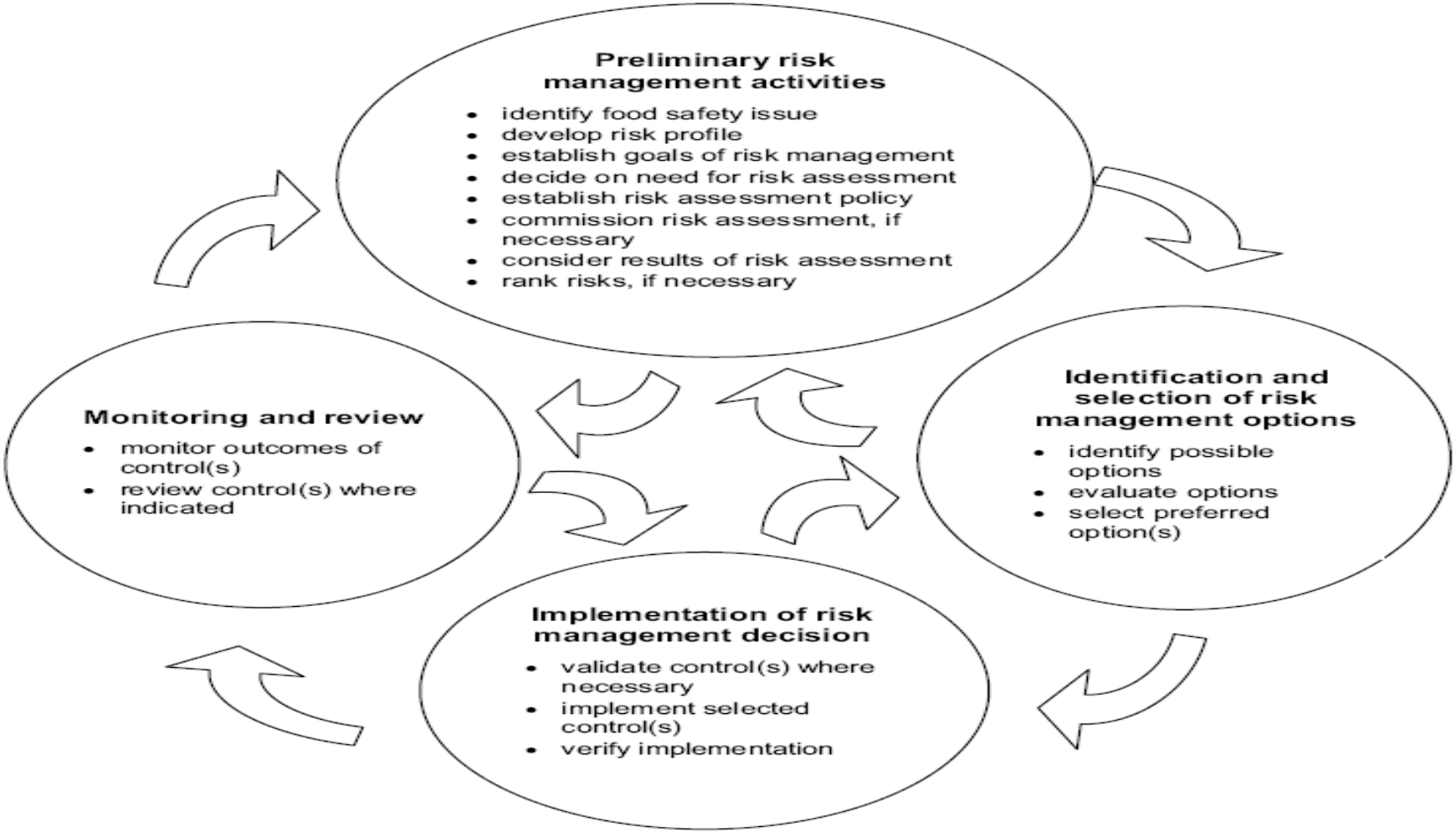
Attributes of analytical methods for residues of veterinary drugs in foods

Guidelines for risk analysis of foodborne antimicrobial resistance

- Hazard: a biological, chemical or physical agent in, or condition of, food with potential to cause an adverse health effect.
- Risk: A function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food.
- Risk Analysis: A process consisting of three components: risk assessment, risk management and risk communication.

STRUCTURE OF RISK ANALYSIS

Figure 2.1. Generic framework for risk management



Identification of food safety issue – sources of information

- Surveillance data
- Epidemiological reports
- Case reports
- Studies on interaction of the microorganisms with the environment through food production to consumption continuum
- Studies on dissemination of AMR determinants in the environment
- Science based expert opinion

AMR risk profile

- Description of AMR food safety issue

(AMR hazard of concern, antimicrobial agent to which resistance is expressed, food commodity with which AMR is associated)

- Information on AMR microorganism(s) and/or determinant(s)

(source, transmission route, pathogenicity, virulence, linkage to resistance, growth and survivability, inactivation in foods, distribution, frequency and concentration in food chain;

Characteristics of resistance – mechanism, location, cross-resistance, co-resistance, transferability between microorganisms)

AMR risk profile

- Information on the antimicrobial agent(s) to which resistance is expressed

(Class, non-human uses, purpose, sector, routes of administration, frequency, potential for extra-label use, potential role of cross- and co-resistance on food production, trends in use, trends in relation between use and occurrence of AMR)

- Information on food commodities

(source-domestic, imported, volume of production, frequency and volume of consumption, description of food production to consumption continuum, characteristics of food that may impact risk management – pH, $a_{W,}$ cooking)

AMR risk profile

- Information on adverse public health effect

(Characteristics of the disease, frequency, severity, susceptible population, risk factors, epidemiological patterns, regional, seasonal, ethnic differences, consequences of AMR on disease outcome,, loss of treatment options, increased frequency, severity of infection, prolonged duration, hospitalisation requirement)

AMR risk profile

- Risk management information

(identification of management options to reduce AMR hazard in food production to consumption continuum, measures to reduce the risk of selection and dissemination of AMR, measures to minimise contamination, cross-contamination with AMR microorganism, effectiveness of current management practices bsed on surveillance or other data)

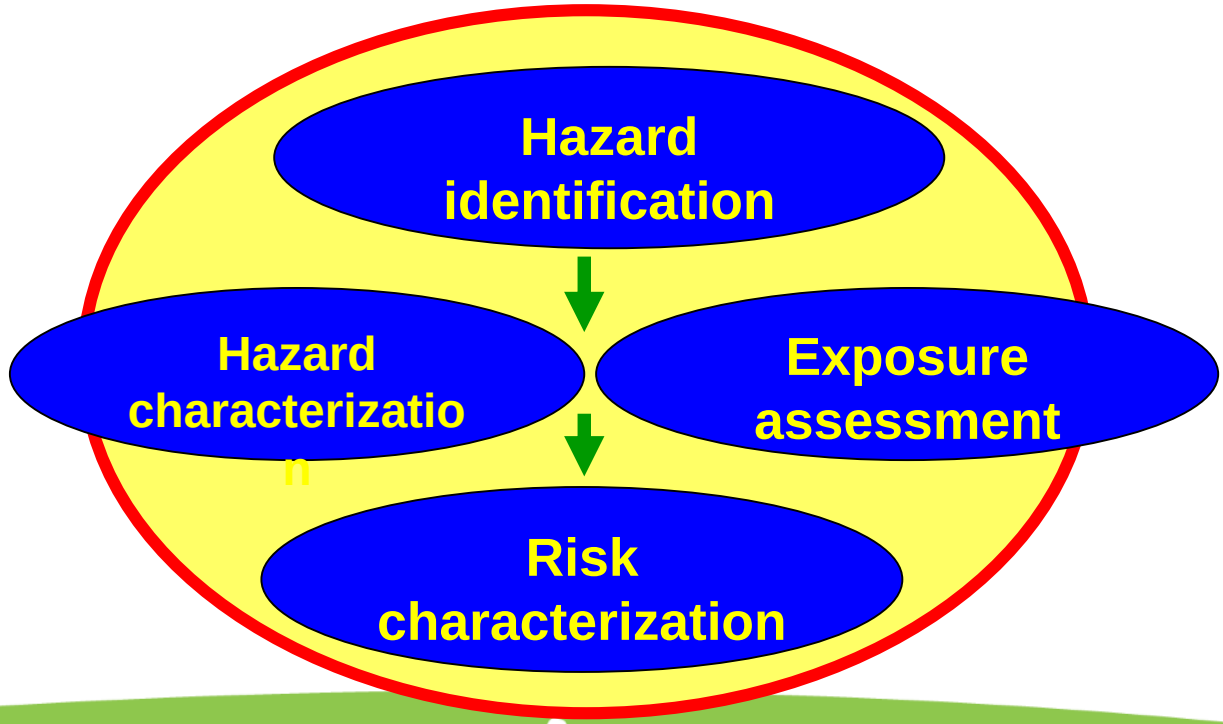
- Evaluation of available information and major knowledge gaps

(uncertainty in available information, identification of knowledge gaps)

Next steps after development of risk profile

- Ranking of food safety issue and setting priorities for risk assessment and management
- Establishment of preliminary risk management goals
- Establishment of risk assessment policy
- Commissioning risk assessment

Risk Assessment - components



Hazard Identification

MICROORGANISMS AND RESISTANCE

- Potential human pathogens likely to acquired resistance
- Commensals with AMR determinants
- Mechanisms of AMR, frequency of transfer and prevalence
- Co- and cross-resistance and importance of other antimicrobial agents
- Pathogenicity, virulence and their linkage to resistance

ANTIMICROBIAL AGENTS

- Description antimicrobial agent
- Class
- Mode of action
- Pharmacokinetics
- Potential human and non-human uses of the antimicrobial agent

Hazard Characterization

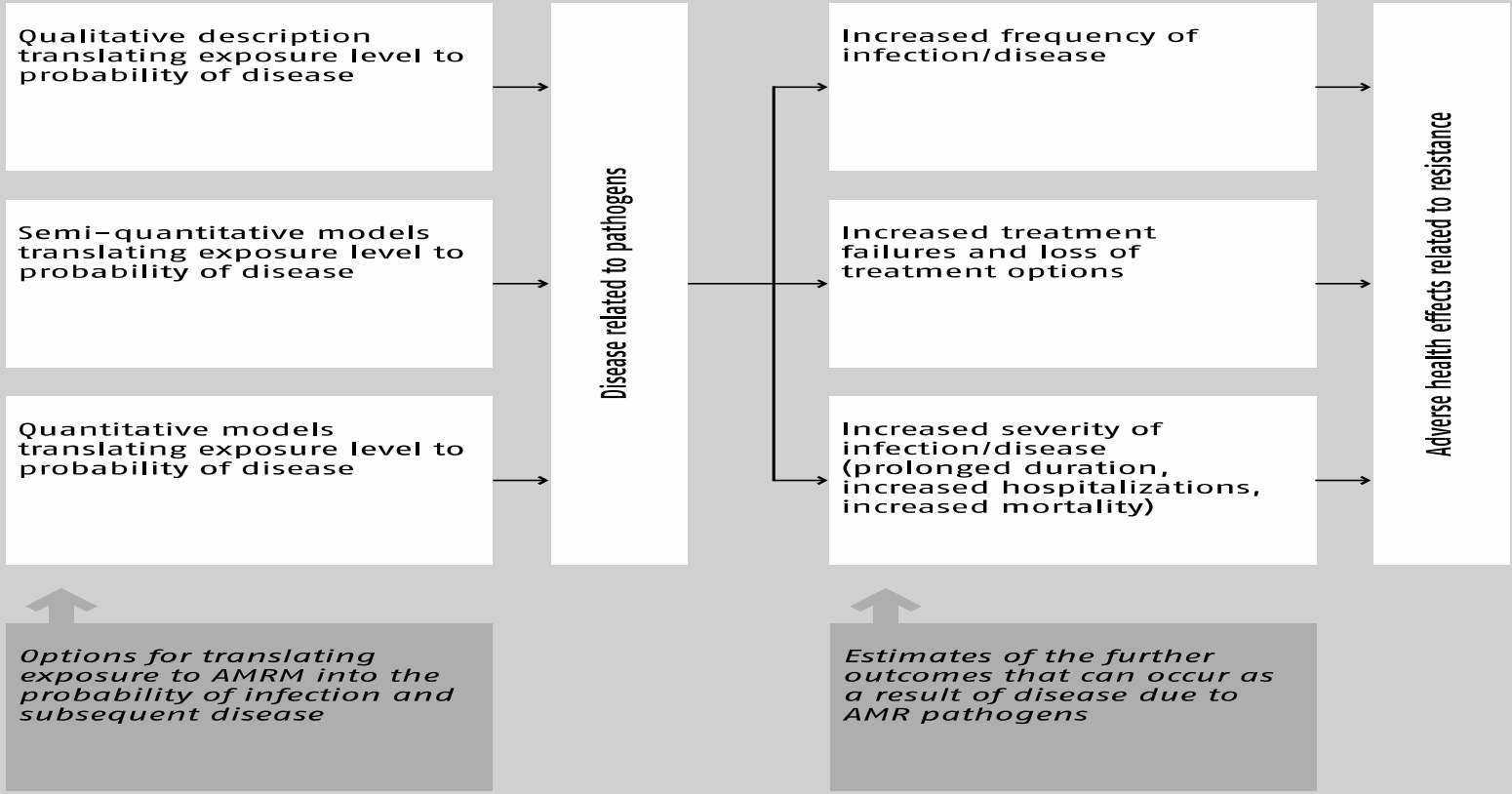
Human host and adverse health effects

- Nature of the infection, disease
- Diagnostic aspects
- Epidemiological pattern (outbreak or sporadic)
- Antimicrobial therapy and hospitalization
- Increased frequency of infections and treatment failures
- Persistence of hazards in humans

HAZARD Characterisation

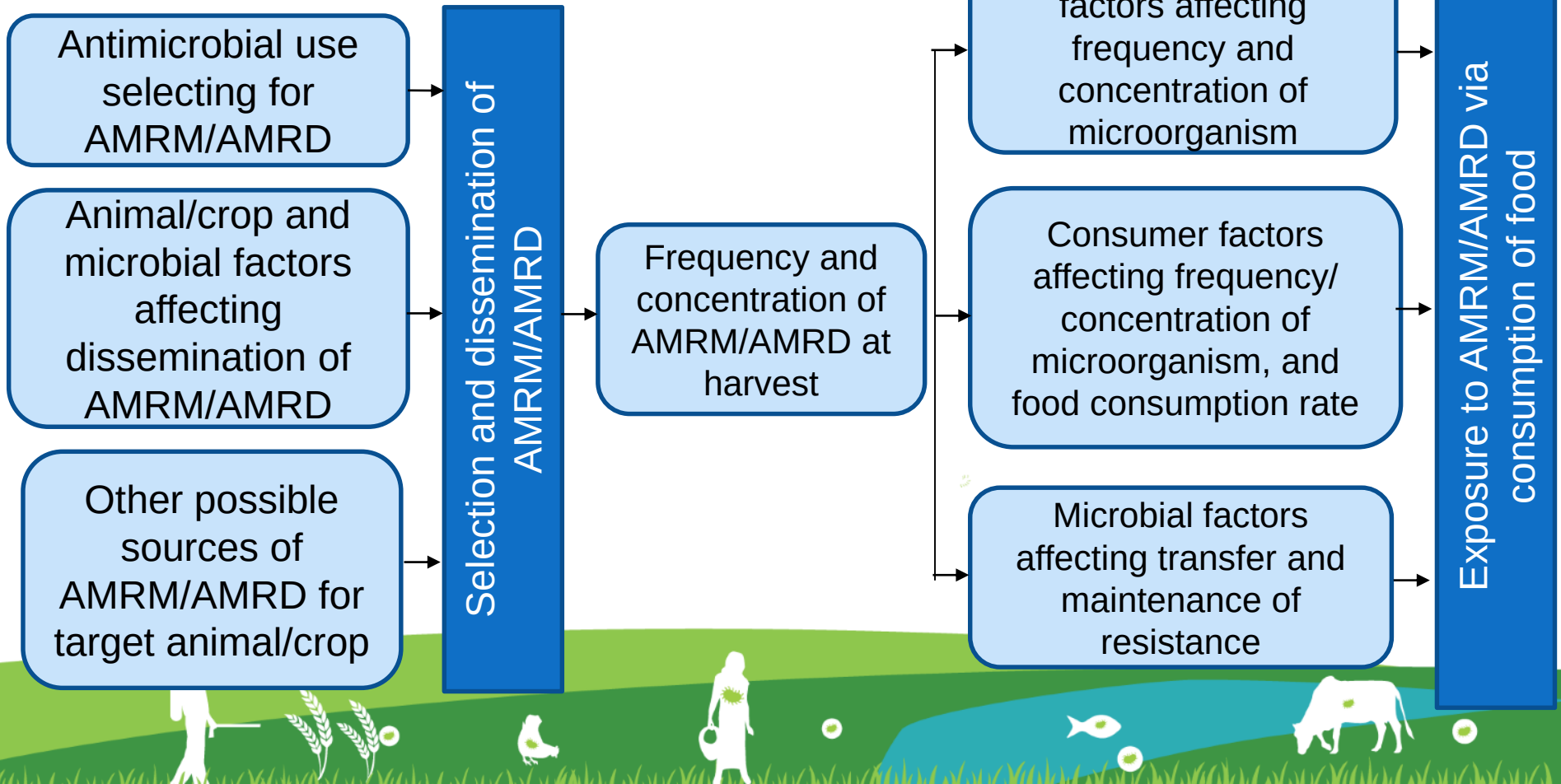
- Food matrix related factors that can influence the survival of the microorganisms while passing through the gastrointestinal tract
- Dose-response relationship: mathematical relationship between the exposure and probability of adverse outcome (e.g. infection, disease and treatment failure)

Figure 2b. Considerations for Hazard Characterization in a Foodborne AMR Risk Assessment



The objective is to arrive at an estimate of the adverse health effects related to resistance conditional on disease and infection with an AMRM.

Exposure Assessment



Exposure Assessment Scoring

- **Qualitatitive Risk assessment**

Negligible (0) – Virtually no probability that exposure to the hazard can occur;

Moderate (1) – Some probability for exposure to occur;

High (2) – Significant probability for exposure to occur.

Risk characterization

- Number of people falling ill
- Microorganisms attributable to a foodborne source
- Frequency of infections, treatment failures
- Duration of infectious disease
- Deaths
- Therapeutic alternatives
- Comparison of public health burden before and after interventions

Risk Characterization Scoring

No Additional Risk: Value of 0

Some Additional Risk: Value between 1 and 2

High Additional Risk: Value between 3 and 4

Very High Additional Risk: Value between 5 and 6

Risk management options

- Animal production:
  - implementation of GAP, biosecurity
  - Support disease diagnosis and susceptibility testing
  - Dissemination of prudent use guidelines
  - Restrict extra-label use
  - Implement surveillance
  - Promote use of alternatives for disease control
- Animal feed: Implement programmes to minimise use of feed or ingredients that could be source of AMR

Risk management options

- Waste treatment
- Ensure far, sewage and waste treatment
- Postharvest measures
- Reprocessing
- Recall procedures

Ongoing work in Codex Ad-hoc Intergovernmental Task Force on Antimicrobial Resistance

- Revision of Codex Code of Practice to minimise and contain antimicrobial resistance (CXC 61-2005)- EWG led by USA, Chile, China, Kenya, UK.
- Drafting of Guidelines on integrated surveillance of antimicrobial resistance (EWG led by Netherlands, Chile, China and New Zealand)

THANK YOU