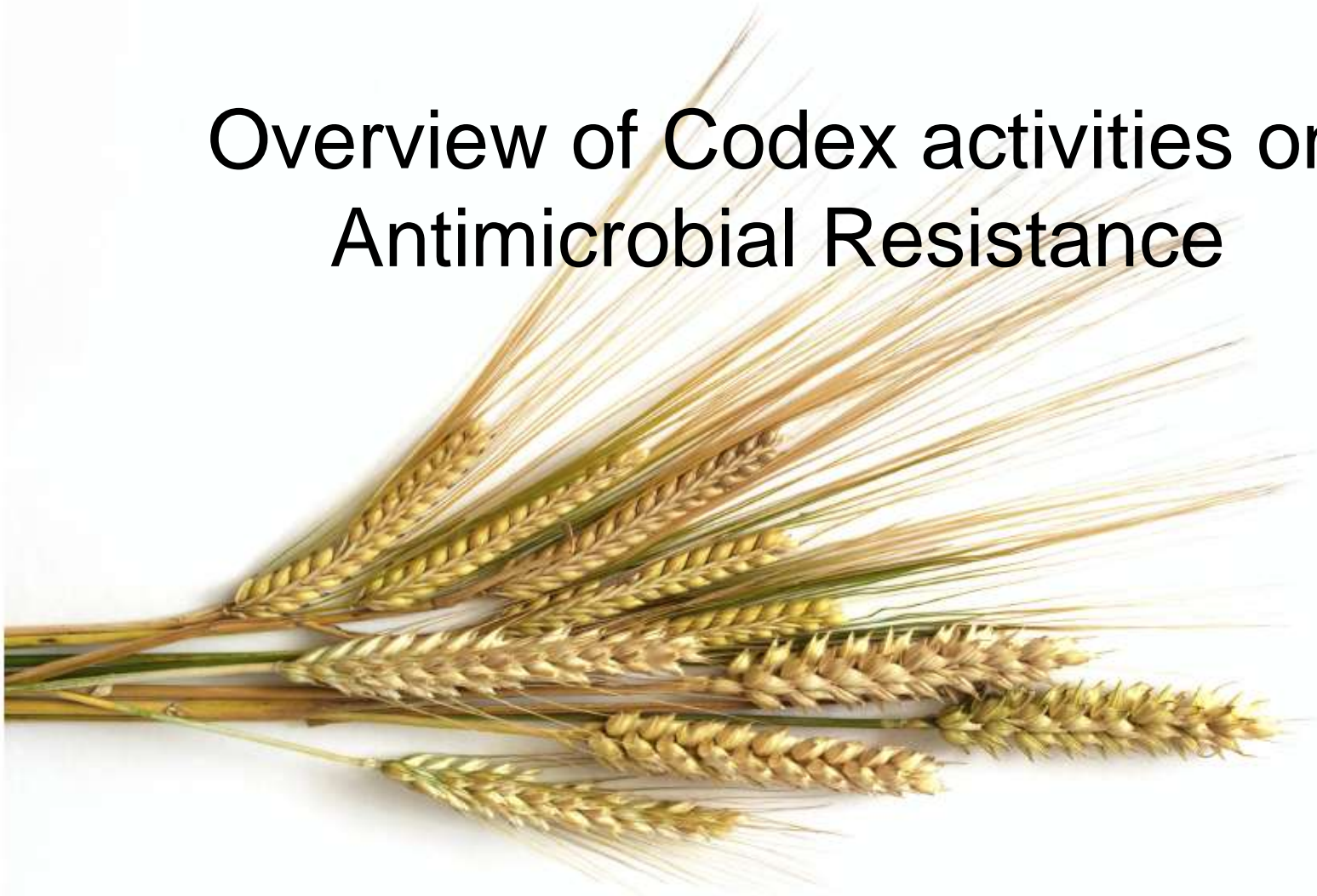


Overview of Codex activities on Antimicrobial Resistance



C O D E X A L I M E N T A R I U S

International Food Standards



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Codex Alimentarius Commission

Work, Standards and Guidelinee related to:

✦ **Antimicrobial resistance**

✦ **Use of antimicrobials in**

✦ **agriculture**

✦ **animal health**

✦ **and food production and processing**



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Codex Alimentarius Commission

- ❖ Intergovernmental food standards-setting body, established by FAO and WHO in 1961/63
- ❖ 184 Member Countries + 1 Member Organization (European Union)
- ❖ 200+ International observer organizations (e.g. OIE)



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Objectives of the Codex Alimentarius

- ✦ Dual objective:
 - Protecting the health of consumers
 - Facilitating fair practices in food trade
- ✦ Promoting coordination of all food standards work undertaken by international governmental and non governmental organizations



Codex Alimentarius Standards

- ✦ Non-mandatory in nature
- ✦ Codex standards and related texts are international benchmarks for harmonization under the SPS and TBT Agreements of WTO
- ✦ Referenced by policy-maker and regulators
- ✦ Used by countries in their work to improve food control systems



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Standards need to be based on science and be implemented and useful to governments and food chain operators

International Food Standards



www.codexalimentarius.net

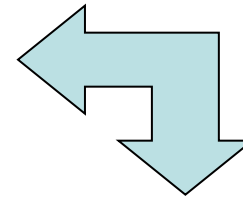


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Codex Alimentarius - Based on science

Liaison & Separation

Codex Alimentarius (***Risk management***)



FAO/WHO Expert Scientific Advice (***Risk assessment***)

- ✦ JECFA – food additives, veterinary drug residues, contaminants in food
- ✦ JMPR – pesticide residues in food
- ✦ JEMRA – microbiological hazards in food
- ✦ *ad hoc* Expert Consultations (for antimicrobial resistance, biotechnology, biotoxins, etc)



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Provision of scientific advice

- FAO and WHO have a long history of providing scientific advice on food safety issues to the *Codex Alimentarius* Commission and its subsidiary bodies and to Member Countries.
- The purpose is to help risk managers, policy makers and others in decision making
- The advice assist in identification and choice of points for most effective risk measures
- Recently the need for scientific advice has increased, also because food safety has emerged as a priority issue in many countries.

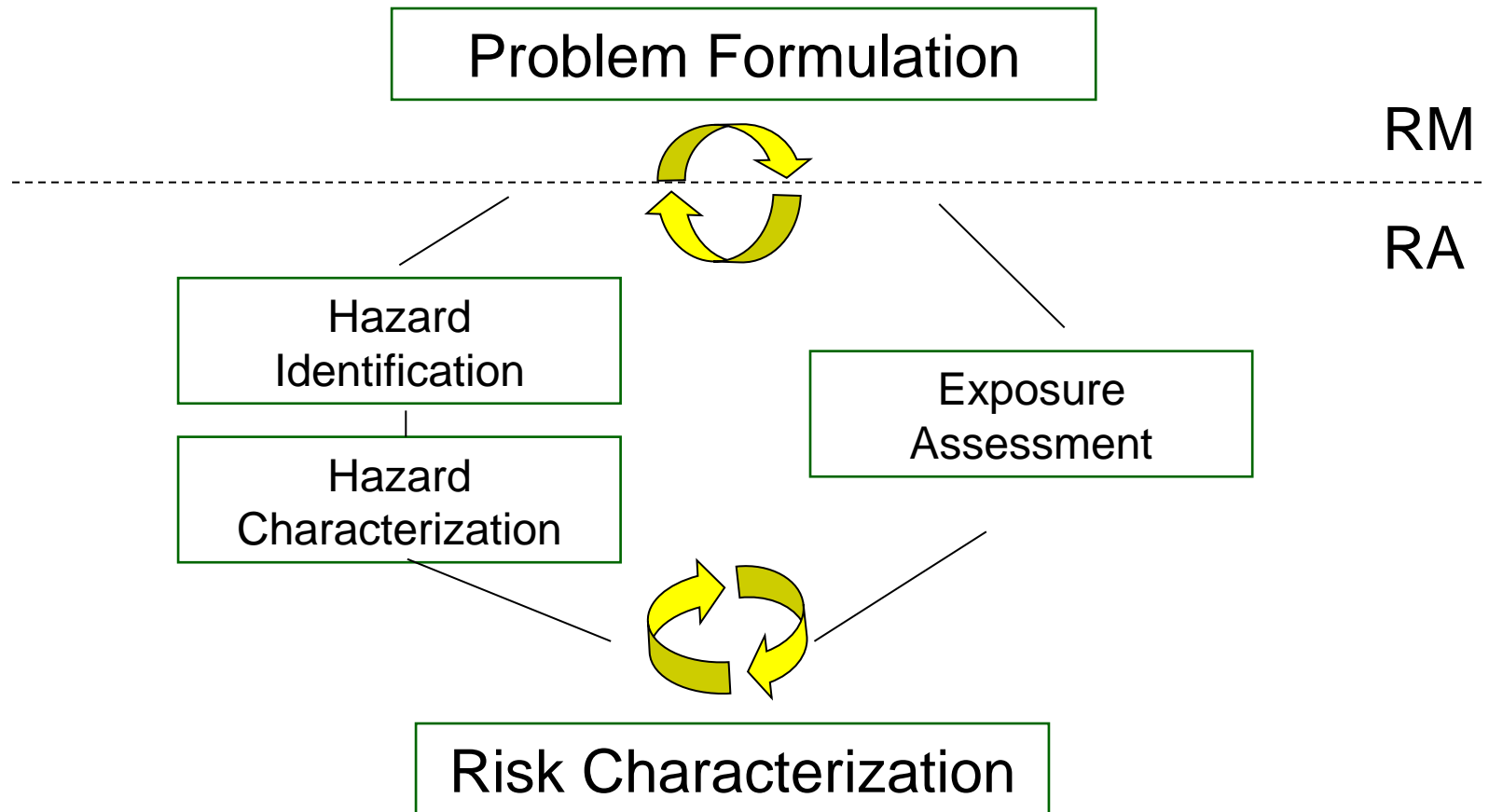


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Risk Assessment: A Scientific Process



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Risk Assessment Methodology – antimicrobial drugs 1(3)

- JECFA began of the assessment of antimicrobial drug residues at the 47th meeting in 1996
- Specific guidance on the data requirements and a detailed decision tree approach for the determination of microbiological ADIs (acceptable daily intake) has been developed and was adopted at the 52nd meeting in 1999
- The decision tree for the establishment of a microbiological ADI includes elaboration on
 - the potential for the drug in question to develop antimicrobial resistance in the human gut microflora, and
 - including the mechanism for resistance development



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Residues of antimicrobial veterinary drugs

- **Determination of the most sensitive adverse effects on the human intestinal microflora**
 - including selection of drug-resistant populations
 - disruption of the barrier to colonization
 - changes in the metabolic activity of the microflora which has been linked to adverse effects on human health
- **If emergence of drug resistant populations is the concern**
 - In vitro or in vivo tests to determine absence of selection in human fecal material
- **If disruption of the colonization barrier is the concern**
 - Determination of MIC values for the most sensitive microorganism
 - Formula for the calculation of ADI including safety factors
- **If changes in enzyme activities is the concern**
 - In vitro or in vivo tests to determine the No-Effect-Level (NOEL)
 - Use this NOEL in the calculation of the ADI



Residues of antimicrobial veterinary drugs

- This guidance on the microbiological ADI was harmonised at the 66th meeting of JECFA with the guidance adopted by VICH (Veterinary International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products) VICH GL36
- Thus, the risk assessment framework for residues of antimicrobial veterinary drugs has been developed and is used on the international as well as on a national and regional level.



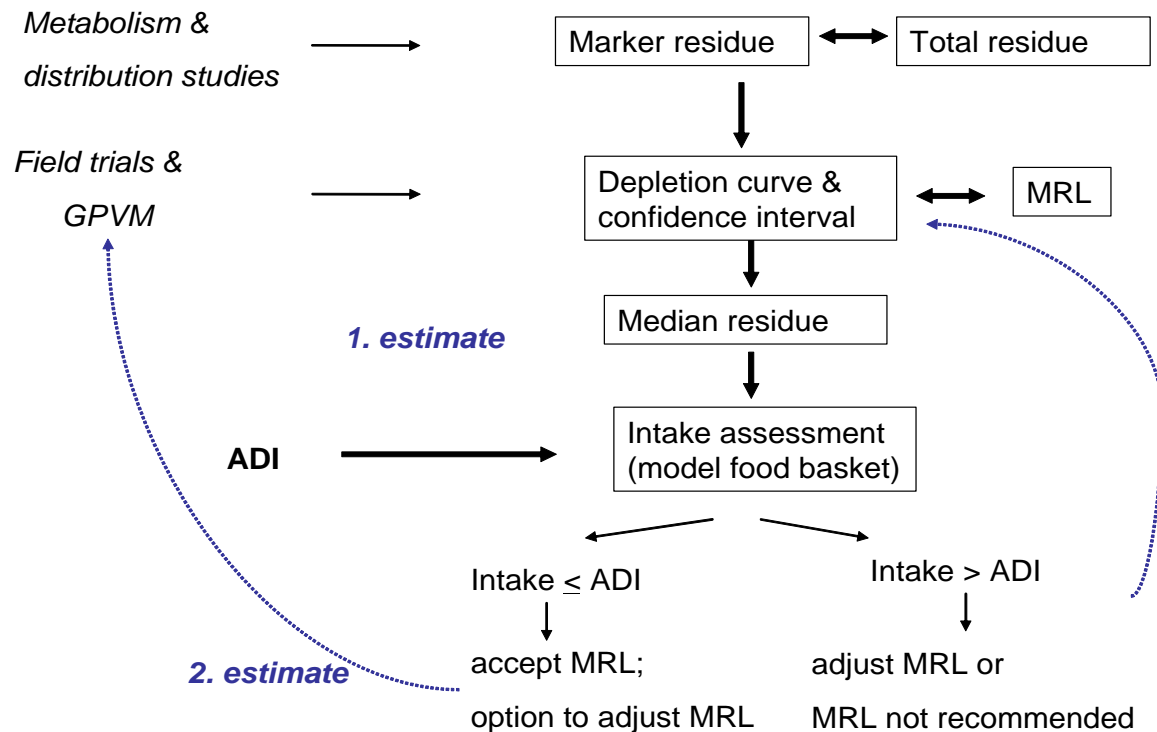
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Residues of veterinary drugs in foods-MRLs

JECFA Residue Evaluation



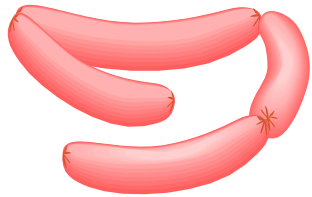
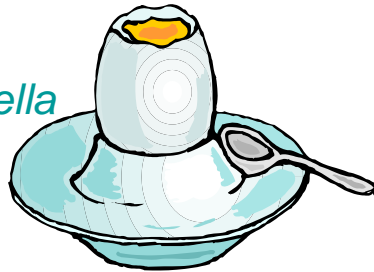
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Microbiological Risk Assessment (MRA)

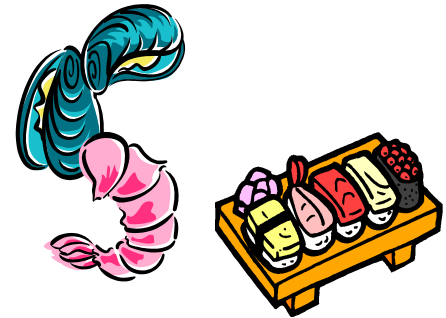
Salmonella



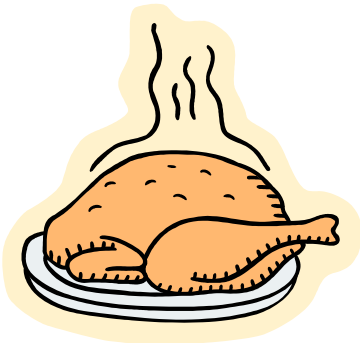
Listeria monocytogenes



Escherichia coli O157



Vibrio parahaemolyticus



Campylobacter

Microbiological risk assessment is performed for pathogen/food combinations that are associated with food-borne illness (single pathogen, one product type, whole chain)



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CODEX and Antimicrobial Resistance

Issues related to antimicrobial resistance considered by:

- ✦ Codex Committees on Residues of Veterinary Drugs in Foods (safety of residues)
- ✦ Task Force on Antimicrobial Resistance (guidance on risk analysis on AMR)
- ✦ Food Hygiene (microbiological risk profiles)
- ✦ By other Committees / Task Forces (to a limited extent)



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CCRVDF and Antimicrobial Resistance

Aspects considered

- ✦ work/activities in other Codex committees and international organizations
- ✦ research and gathering needs
- ✦ prudent use of antimicrobials in livestock and aquaculture
- ✦ better international cooperation in the field on non-human use of antimicrobials
- ✦ development of a Code of Practice for the Containment of Antimicrobial Resistance



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CCRVDF and Antimicrobial Resistance

Relevant texts

- ✧ Code of Practice for Control of the use of Veterinary Drugs (CAC/RCP 38/1989) – Cautious use of anticomocidal, antibacterial or anthelmintic products which may favour the development of antimicrobial resistance
- ✧ Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61/2006) – originated from OIE texts



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Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) (1/2)

Objectives

- ✦ Protect consumers health by ensuring the safety of the food of animal origin
- ✦ Prevent / reduce direct and indirect transfer of resistant microorganisms or resistant determinants
- ✦ Prevent contamination of food with residues exceeding established MRLs
- ✦ Comply with the need to maintain animal health



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Codex Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) (2/2)

- ✦ Highlights the importance of controlled, effective and safe use of antimicrobial agents
- ✦ And the importance of the veterinary sector in this regard
- ✦ Describes the role of competent authorities and others involved in authorization, production, control and distribution of antimicrobial agents
- ✦ Does not address environmental /ecological aspects
- ✦ Consistent with OIE relevant texts on prudent use of antimicrobial agents



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Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011)

1(2)

- ✦ Developed by the Task Force on Antimicrobial Resistance (now completed) with the objectives to:
- ✦ Provide science-based guidance on processes and methodology for risk analysis and its application to foodborne resistance related to non human use of antimicrobial agents
- ✦ Assess the risk to human health associated with the presence and transmission of antimicrobial resistance microorganisms and determinants



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Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (CAC/GL 77-2011) 2(2)

The document provide guidance on activities related to :

- ✦ Preliminary risk management (*risk managers*)
- ✦ Risk assessment (*risk assessors*)
- ✦ Risk management (*risk managers*)
- ✦ Risk communication (*risk managers, risk assessors and other interested parties*)

Does not address issues related to residues, markers genes in recombinant-DNA plant and microorganisms, starter cultures

Other Codex Committees and Task Forces

Codex Committee on Food Hygiene

- ✦ Discussion on development of risk profile of antimicrobial resistant bacteria (potential dissemination in various steps of the food chain)

Task Force on Animal Feeding

- ✦ *Codex Code of Practice on Good Animal Feeding* (CAC/RCP 54-2004)
Section 4.5.1 “feed additives and veterinary drugs used in medicated feed”

Codex Committee on Fish and Fishery Products

- ✦ *Codex Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)
Section 6 “Aquaculture production”

Codex Committee on Pesticide Residues

- ✦ Discussion on Codex priority list of pesticides - inclusion of ***streptomycin*** and ***oxytetracycline***



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CCFH and Antimicrobial Resistance

CCFH has been considering antimicrobial resistance issue since its 31st Session (1998)

- ✦ Due to its recognized expertise in food hygiene in general and in food microbiology in particular, has the specific duty to propose any measures likely to improve the microbiological quality of animal-derived food
- ✦ Also prioritizes pathogens or pathogen-commodity combinations, including antimicrobial-resistant pathogens, for microbiological risk assessment



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CCFH and Antimicrobial Resistance

Risk Profile on Antimicrobial-Resistant Bacteria in Food

- ✦ Antimicrobial-resistant bacteria represent a public health risk via food due to the potential dissemination of resistant genes
- ✦ Antimicrobial-resistant bacteria in food is related to the use of antimicrobials in food production and in humans as well as the transmission of bacteria in various steps of the food chain and environmental spread
- ✦ Strategies: hygienic measures, prudent use of and others measures to reduce overuse and misuses of antimicrobials



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Task Force on Animal Feeding

- ✧ First active 1999-2004 with mandate to address all issues relating to animal feeding
- ✧ Including food safety aspects related to toxic substances, pathogens, *microbial resistance*, new technologies
- ✧ Code of Practice on Good Animal Feeding (CAC/RCP 54-2004)
- ✧ New Task Force will be established in 2012 to consider
 - ✧ Guidelines on the application of risk assessment methodologies in animal feeding for use by Governments
 - ✧ A prioritized list of hazards related to animal feed

