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Risk Analysis and Science in Codex

FAO/IAEA International Symposium on Food Safety and Quality: Application of Nuclear Techniques

Vienna, 10-12 November 2014

ANNAMARIA BRUNO

SECRETARIAT, CODEX ALIMENTARIUS COMMISSION

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Content

- Introduction to Codex
- Role of science and risk analysis in the work of Codex
- Main work of Codex on risk analysis
- Conclusion: Trends and challenges of risk analysis in Codex

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Codex Alimentarius Commission

Intergovernmental food standards-setting body established by FAO and WHO

Members: 185 Member countries and 1 Member Organization (EU)

Observers: 224 IGOs & INGOs including UN Agencies

Objective → Development of worldwide food quality and safety standards to:

Protect consumers' health and

Ensure fair practices in the food trade

Codex food safety standards → benchmark standards under the WTO/SPS Agreement

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History

Codex has been implementing risk analysis since its creation in 1961-63, then came …

1991 FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade

1980s Uruguay Round of the Multilateral Trade Negotiation and creation of WTO (1995) and the SPS Agreement

Sanitary measures applied by WTO members should be based on scientific principles (art. 2.1) and on risk assessments (art. 5.1)

Sanitary measures conforming to international standards (as defined in Annex A) are deemed necessary to protect human health (art. 3.2)

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Role of science

"The ... Codex Alimentarius shall be based on the **principle of sound scientific analysis** and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply." (CAC decision 1995)

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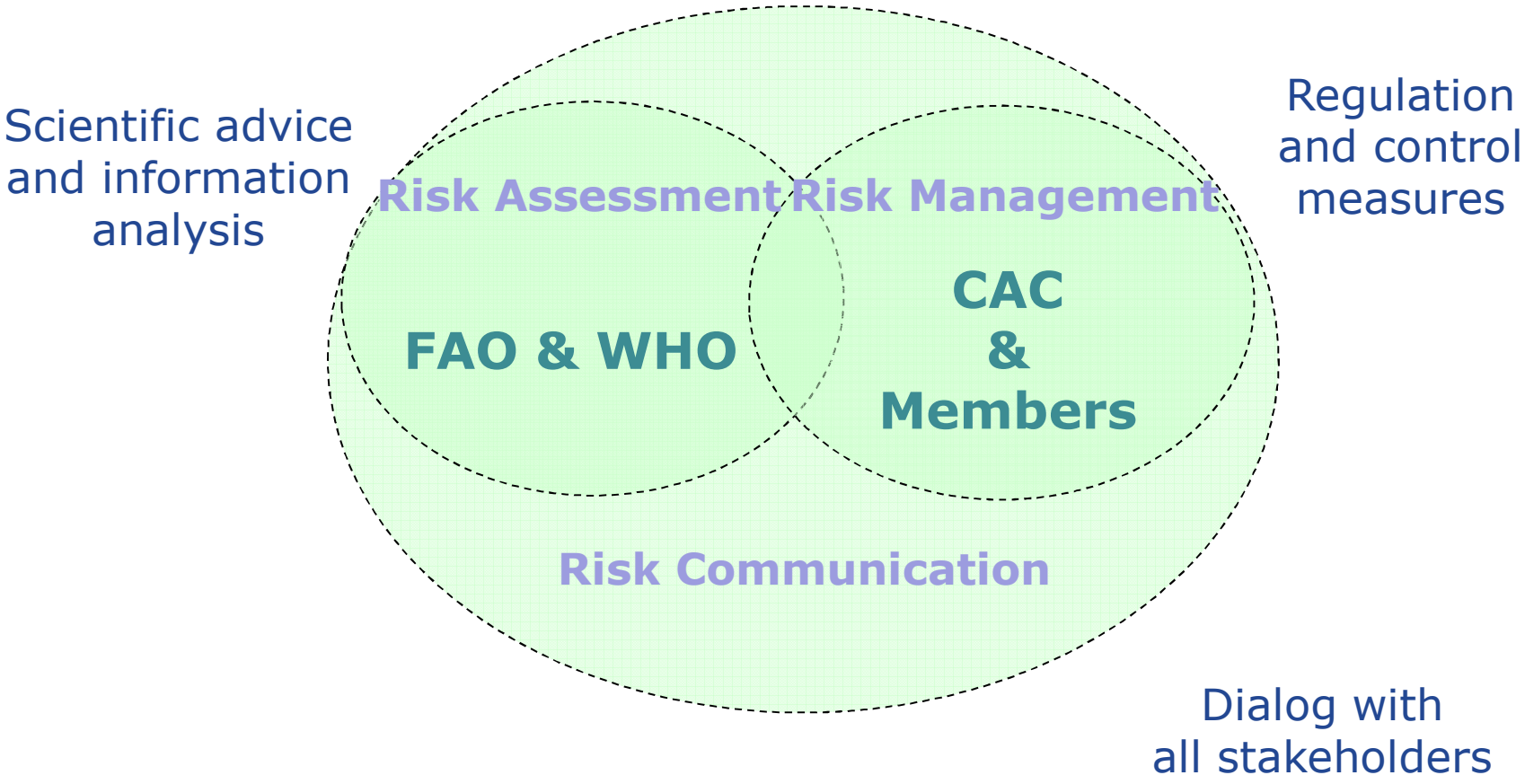
Risk analysis paradigm



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Sound scientific basis and evidence

Risk assessment:

- Provides the scientific basis to underpin risk management actions
- A tool to assist risk managers with independent scientific advice related to food and feed safety with respect to public health issues
- Provides a transparent scientific basis to underpin development of standards and regulations
- Enables comparative assessment of different options before implementation

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Food Safety Risk Assessment (four steps)

Hazard Identification – What is the agent?

Hazard Characterization – What harm will it do?

Exposure Assessment – How much will a given population be exposed to it?

Risk Characterization – What will be the harm to a given population

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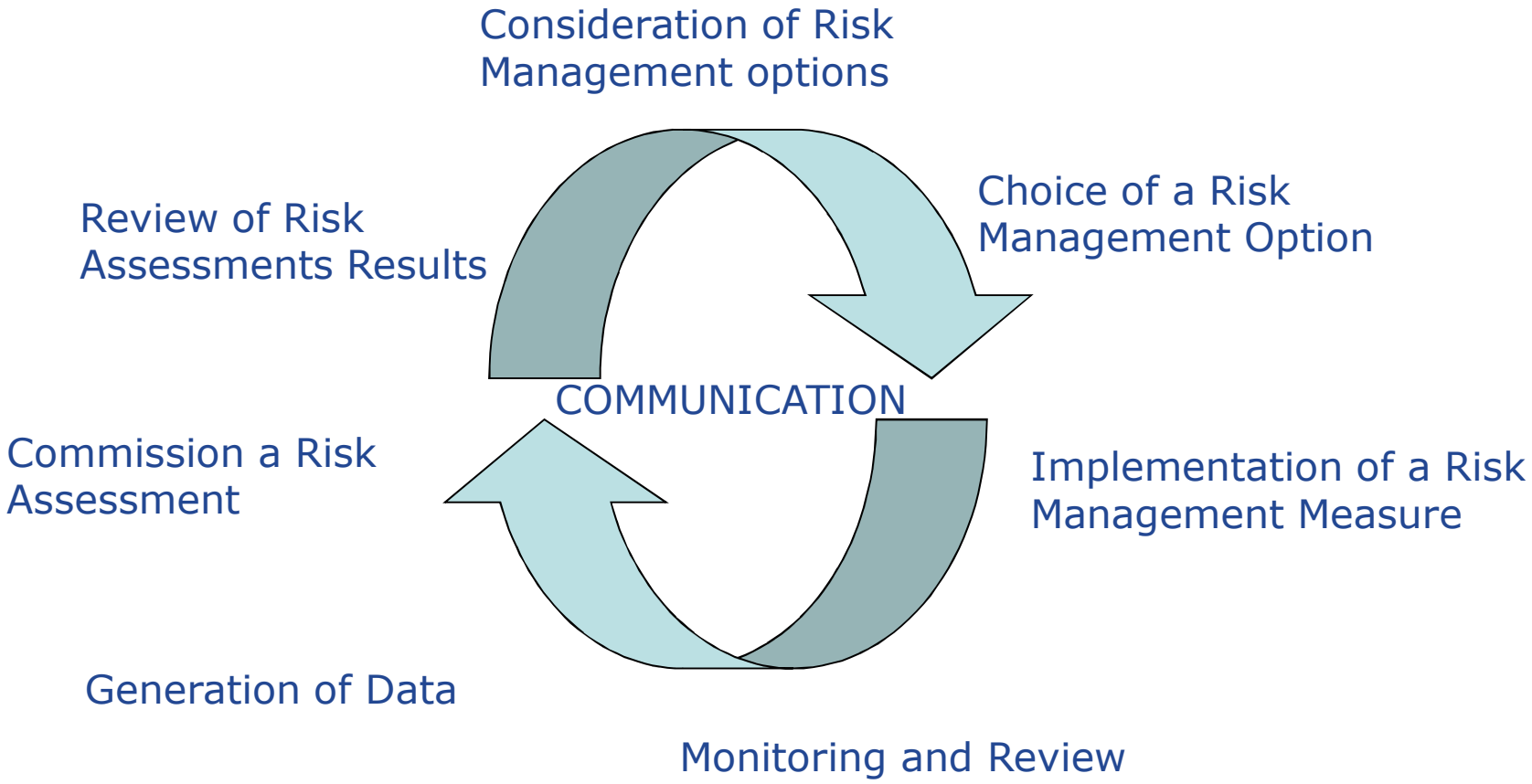
Risk Management Activities



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Risk Communication

Between risk assessors and risk managers

- Clear definition of the issues to be addressed
- Clear definition of the process
- Transparent and documented procedure

Between risk managers and other relevant stakeholders (including consumers)

- Transparent decision process
- Communicating uncertainties
- Providing immediate communication in case of emergency

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Precaution/Uncertainty analysis

- Precaution is an inherent element of risk analysis.
- The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis.
- The risk management options should reflect the degree of uncertainty and the characteristics of the hazard.

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Other legitimate factors

- Should not affect scientific basis of risk analysis
- Should be accepted on a worldwide basis
- Some legitimate concerns of governments are not generally applicable or relevant worldwide

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Integrating Risk Analysis into the Codex process

- Role of science and other factors in the Codex process (1995)
- Role of food safety risk assessment (1997)
- Risk analysis terms related to food safety (1997)
- Criteria for the consideration of "other factors" (2001)
- Working principles for risk analysis for application in the framework of the Codex Alimentarius (2003)

Specific risk analysis principles/policies:

- Food additives
- Contaminants
- Residues of veterinary drugs in foods
- Pesticide residues
- Nutrition
- Hygiene

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International Level

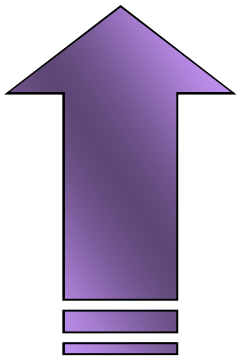
Regional/National Level

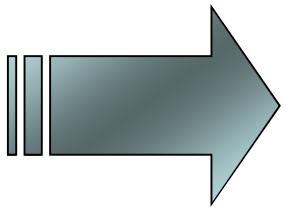
FAO/WHO Expert Body

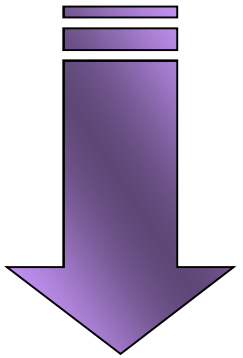
Risk Assessment

Codex Standard

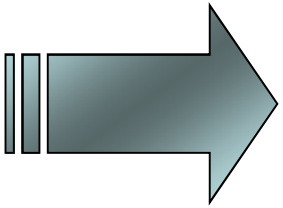
Risk Management







Risk Assessment



Risk Management

Regional/National Risk Assessment

Regional/National Regulation

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Scientific Advice to Codex

International 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 emerging issues (e.g. Nanotechnologies in agri-food sector)**

Requests for advice, risk assessment

Scientific advice

International Risk Management

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JECFA Activities

Residues of veterinary drugs in food

- Elaborates principles for evaluating their safety
- Establishes ADIs and recommends Maximum Residue Limits (MRLs) when products are administered to food-producing animals in accordance with good veterinary practices
- Determines criteria for the appropriate methods of analysis for detecting and/or quantifying residues in food

JECFA

Joint FAO/WHO Expert Committee on Food Additives

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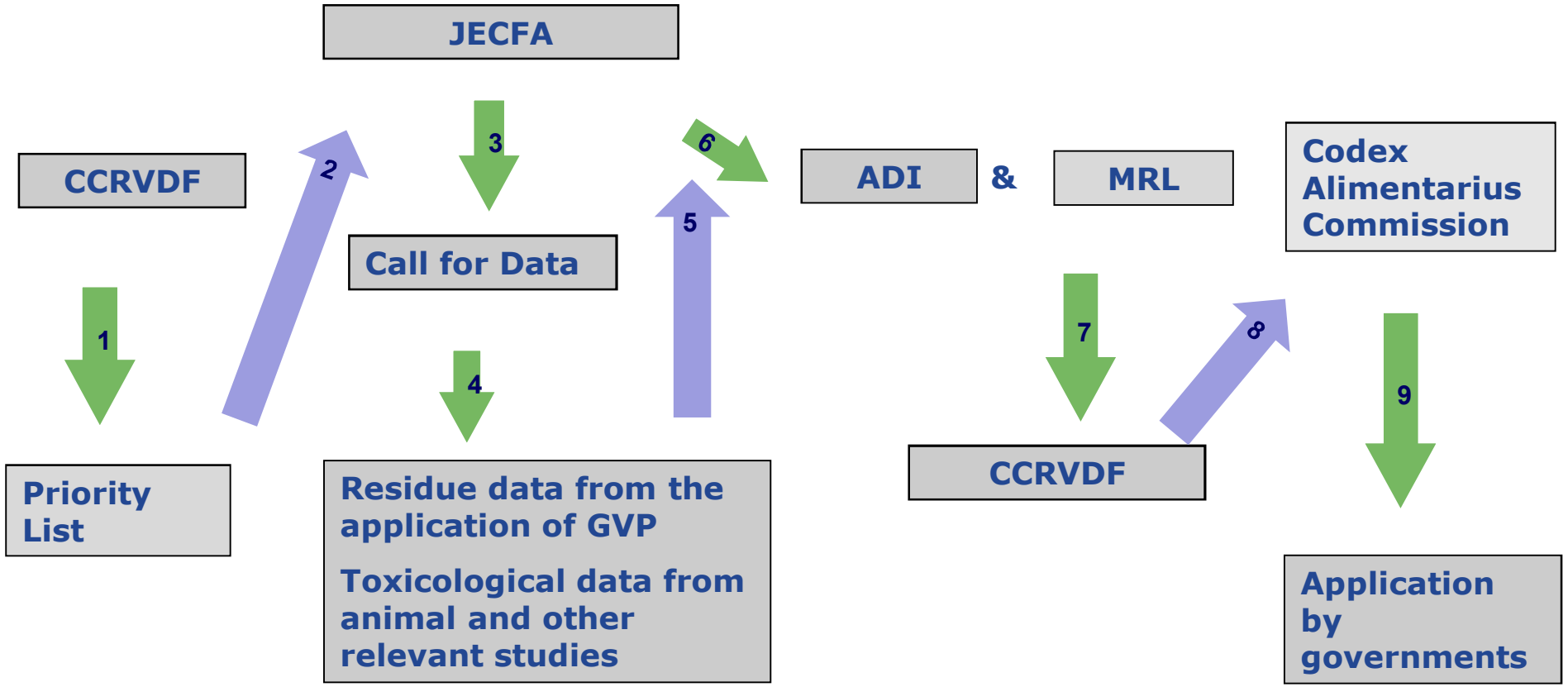
Development of MRLs for veterinary drugs



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FAO/WHO Food Standards

ENGLISH | FRANÇAIS | ESPAÑ

CODEX alimentarius

Veterinary Drug Residues in Food

Updated up to the 35th Session of the Codex Alimentarius Commission (2012)

VETERINARY DRUG DETAI

Narasin

Functional Class

- Antimicrobial agent

Search JECFA
Click the above link to access the relevant JECFA residue monograph(s)

Maximum Residue Limits for Narasin

Species	Tissue	MRL	Year of Adoption	e
Cattle	Liver	50 µg/kg	2012	
Cattle	Kidney	15 µg/kg	2012	
Cattle	Fat	50 µg/kg	2012	
Cattle	Muscle	15 µg/kg	2012	
Pig	Muscle	15 µg/kg	2011	
Pig	Fat	50 µg/kg	2011	
Pig	Kidney	15 µg/kg	2011	
Pig	Liver	50 µg/kg	2011	
Chicken	Liver	50 µg/kg	2009	
Chicken	Muscle	15 µg/kg	2009	
Chicken	Kidney	15 µg/kg	2009	
Chicken	Fat	50 µg/kg	2009	

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Trends in risk analysis

Risk management

- Clear problem formulation
- Indication of how advice is to be used
- Significance and urgency of the work
- Availability of scientific knowledge and data
- Availability of resources to perform the work
- Cost/benefit analysis

Risk assessment

- Best science available
- Independent advice
- Transparency in the assessment
- Systematic review
- Weight of evidence approach
- Combined exposure to multiple hazards
- Comparison of options

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Challenges

- To identify priorities at international level
- Definition of possible scope of the work and use to be given to results
- Harmonization of risk assessment methodologies based on the Codex principles for risk analysis
- Periodic review of old risk assessment
- Availability and quality of data
- Resources

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Thank you for your attention