
The Role of Scientific Experts in Risk Regulation

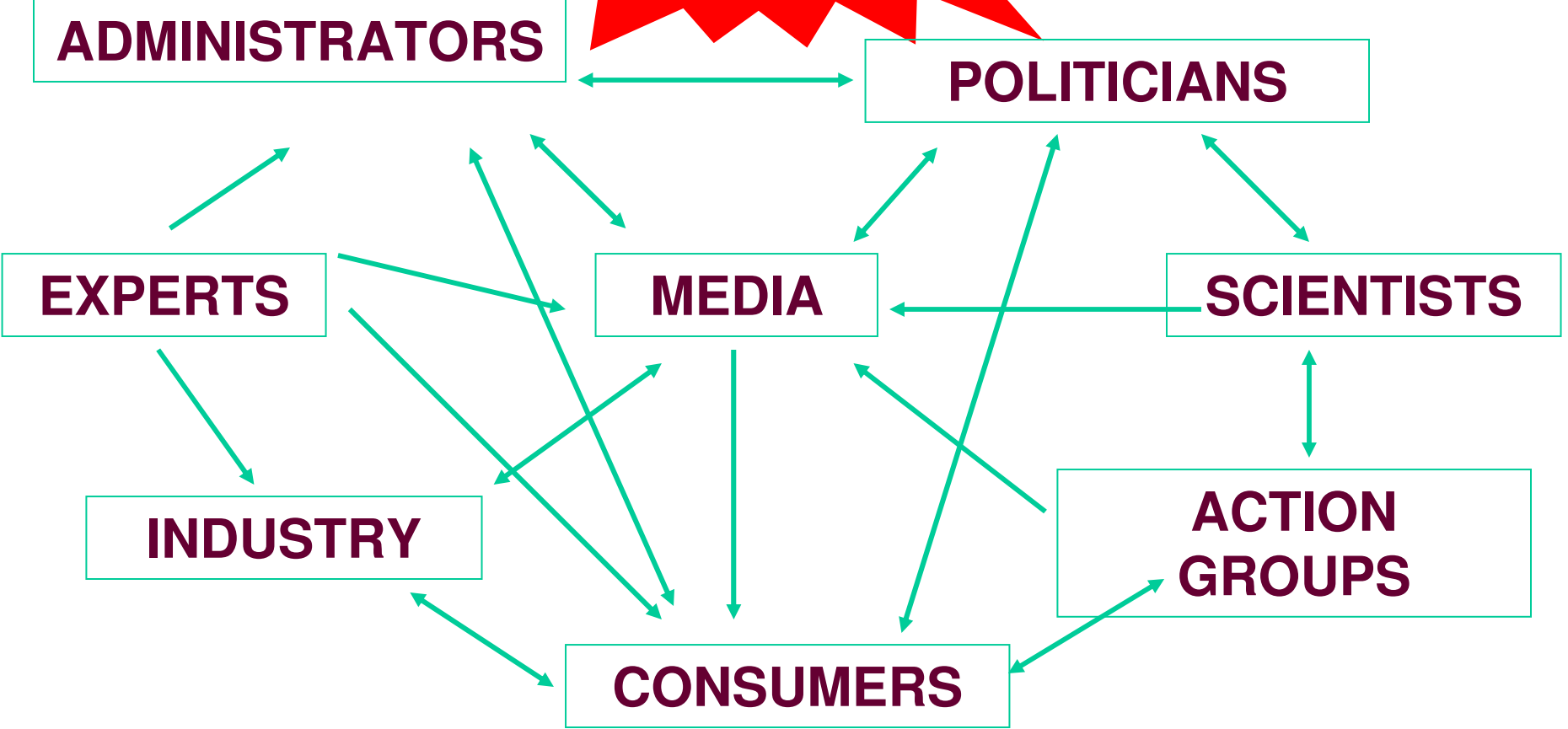
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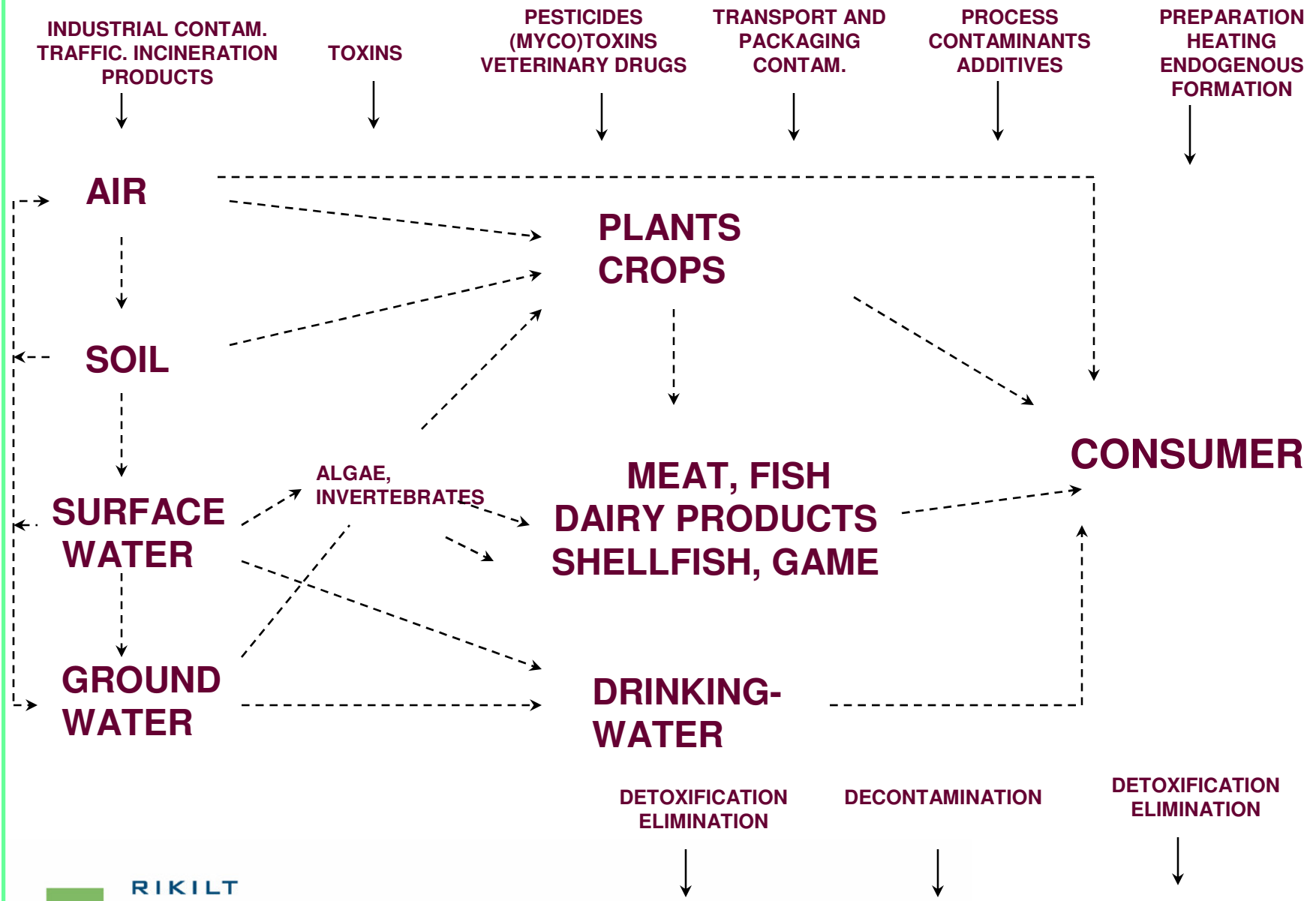
Workshop Maastricht Uncertain Risks Regulated

February, 11-12, 2005

The Food Debate!



Complexity of Food Chains



Issues

- Risk Analysis: Integration of scientific and social aspects
- Different Phases in the Risk Analysis Process
- Role of the scientific expert (risk assessor) in the Risk Analysis Process
- Interactions with stakeholders
- IP SAFEFOODS

Serious Consumers Concerns about Food Safety

- **Public concern about the safety of the European food supply:**
 - **BSE, dioxin, *E.coli* 0157, GM food crops...**
 - **Long-term adverse effects on humans and the environment**
- **Low public trust in how food crises were handled**
- **Low public trust in the Regulatory System in Europe**

EU Commission Wake Up to Consciousness

- **EU White Paper on Food Safety (COM (1999), 719 final)**
- **General Food Law (Regulation 178/2002)**
- **Establishment (2002) of the
EUROPEAN FOOD SAFETY AUTHORITY (EFSA)**
<http://www.efsa.eu.int>

Tasks of EFSA

- Risk Assessment
- Risk Communication
- *Not* Risk Management
- Risk assessment divorced from risk management
- EFSA is not part of the Commission nor answerable to it

EFSA Objectives in Risk Assessment

- Taking forward the science of risk assessment
- Greater transparency of the Risk Assessment process including timeframes
- Authoritative views respected across Europe and beyond
- Increase stakeholder confidence in the Risk Assessment Process

EFSA Scientific Panels

- Panel on contaminants in the food chain
- Panel on food additives, flavourings, processing aids and materials in contact with food
- Panel on dietetic products, nutrition and allergies
- Panel on biological hazards
- Panel on additives and products or substances used in animal feed
- Panel on genetically modified organisms
- Panel on animal health and welfare
- Panel on plant health, plant protection products and their residues

EFSA Accomplishments

- Scientific Panels have produced more than 230 Opinions on a wide range of food safety issues put forward by the Commission, Member States, or on own initiative.
- Strategic Guidance Documents on risk assessment of food safety issues have been produced
- First evaluation of EFSA by stakeholders is positive, but EFSA has still to gain as an independent authority

Further Developments

- Broad support to install an EFSA Stakeholders Consultative Committee (Stakeholders meeting November 2004, Berlin)
- EFSA should become more involved in work on nutrition and obesity
- *Stronger collaboration between EFSA and the European Commission for a more coherent risk communication and risk management*
- Network between EFSA and Member States need further strengthening

Criticism of EFSA Activities



**Friends of
the Earth
Europe**

THROWING CAUTION TO THE WIND

A review of the European Food Safety Authority
and its work on genetically modified foods and
crops.

November 2004

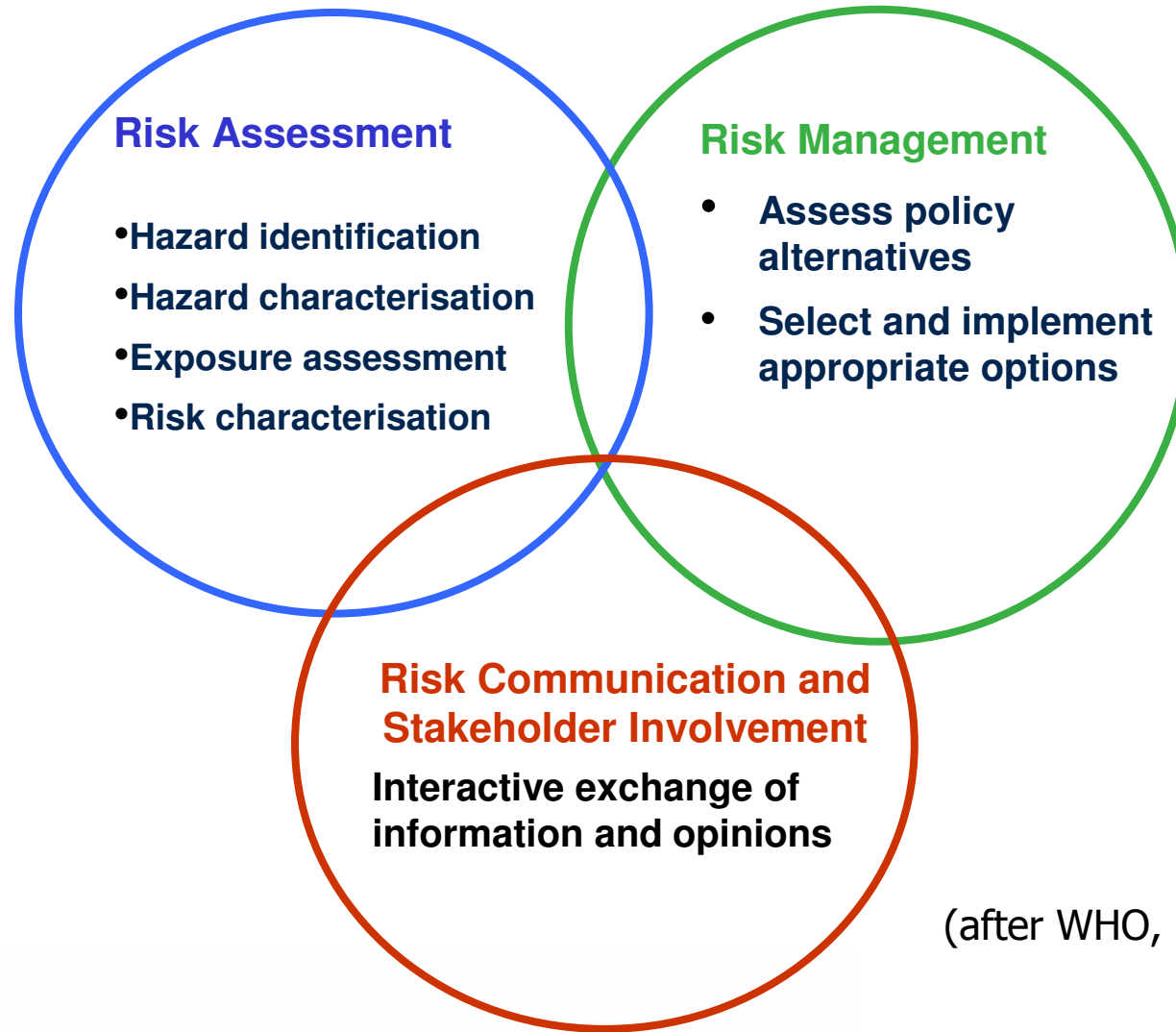
CONCLUSIONS FoE REPORT

1. The GMO Panel of EFSA has not made a good start. It has published twelve scientific opinions, virtually all favourable to the biotechnology industry.
2. Some of the scientists on the GMO Panel are known to have pro-GM views.
3. Nearly a third of the Panelists are involved in the approval of GMOs at a national level and so have to remove themselves from decision making. This includes the Chair.
4. Some of the Panelists have been involved in an EU funded project (ENTRANSFOOD) with the biotechnology industry to agree safety assessment, risk management and risk communication procedures that would “facilitate market introduction of GMO’s in Europe”.

CONCLUSIONS FoE REPORT

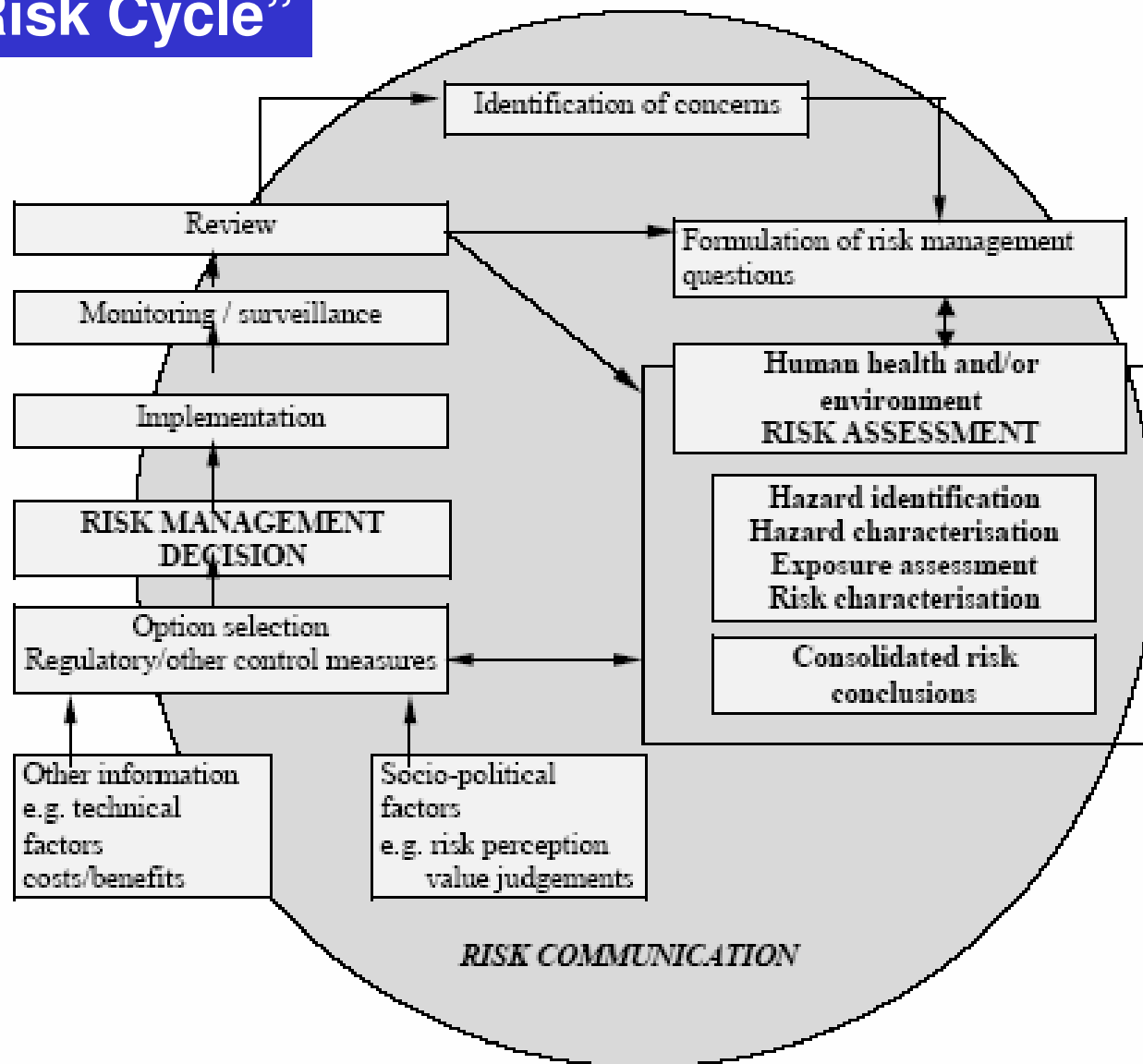
4. When considering applications for new GM foods or feeds, the GMO Panel has consistently dismissed the concerns of other scientists. It appears to be less precautionary than Member States
5. The Panel ignores EU requirements to identify the level of uncertainty in its assumptions, and fails to take in legal requirements that regard is given to the long term effects of eating or growing GM foods.

Risk Analysis Framework



(after WHO, 1998)

The "Risk Cycle"



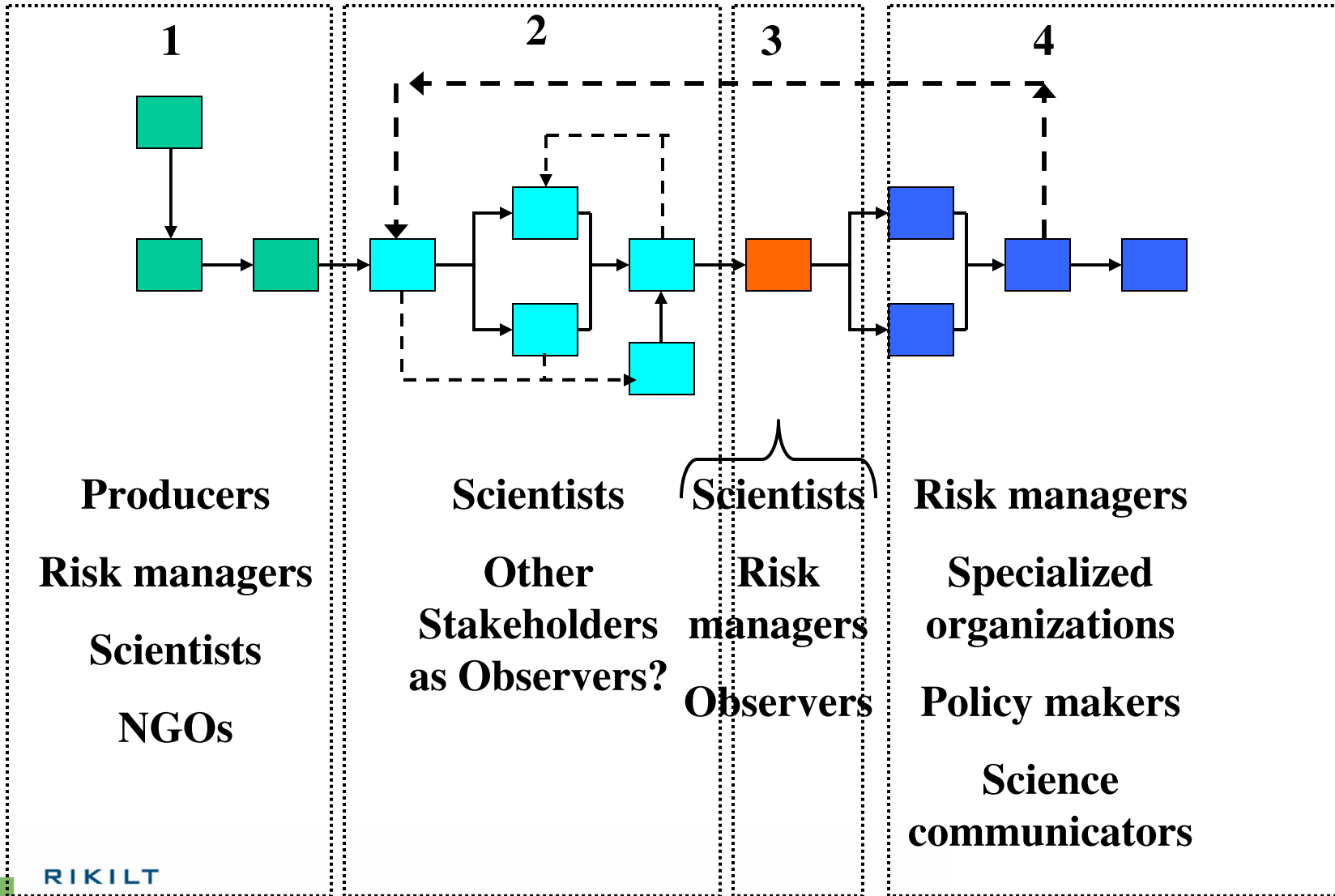
European Commission, 2003

Food Risk Analysis Process

**Hazard Alert
Phase**

Risk Characterization

Risk Management



Risk is more than a number

- Risk evaluation is more than determining numbers, i.e. chances of occurrence and magnitudes of harmful effects
- Social/psychological factors and individual values play a role in risk perception (voluntary character of the risk, manageability, distribution among the population, special vulnerable groups etc)

The New Role of Science

- “ Science is a creative enterprise in which ethics and values of individuals and societies play an increasingly important role” (*ICSU 2004, New Genetics, Food & Agriculture*)
- Science must be active in alerting the public early on new developments and consequences for the society
- Characterise Risks, Uncertainties, Benefits and provide Choices

Social Context of Risk Analysis

- Risk analysis should also take account of the *social* context in which people perceive the quantitative risks and uncertainties, such as community identity, equity and aesthetic issues
- Dread associated with a risk may be a relevant stress factor for groups/individuals in the society which may impair health
- Quality of life issues should be considered from the beginning of the risk assessment process, in the scoping phase of the problem.
- Differences between expert assessment and the way people view it should be addressed and if possible be minimized

EU Scientific Steering Committee, 2000, 2003

A Broader Framework for Risk Analysis

Need to include:

- Human physical and psychological health
- Animal welfare
- Environmental impact
- Benefit considerations
- Acceptability, cultural attitudes
- Socio-economical impact
- How to include them: essential part of the risk assessment or in addition??

Challenges in Risk Assessment

Complexity?
What is known?
Uncertainties?

Causal relationships
between exposure to multiple
agents and effects?
(Low level pollution)

New methods
Genomics
Proteomics
Metabolomics

Modeling adequate/
non-selective?
Extrapolation?

Data handling
Interpretation of
Significance of Effects?
(Hormesis)



Uncertainty Analysis is a Key Element in Risk Assessment

- Variability in measurements in data points (systematic and random errors)
- Methodological uncertainties (models, presumptions, extrapolations valid?)
- Significance of test parameters
- Assumptions for extrapolation (sensitivity humans-animals, sensitive groups)
- Biological significance of observed changes
- Fundamental ignorance: how does the system work??
- Numerical/language description

Role of Scientific Experts in a Broader Concept of Risk Analysis

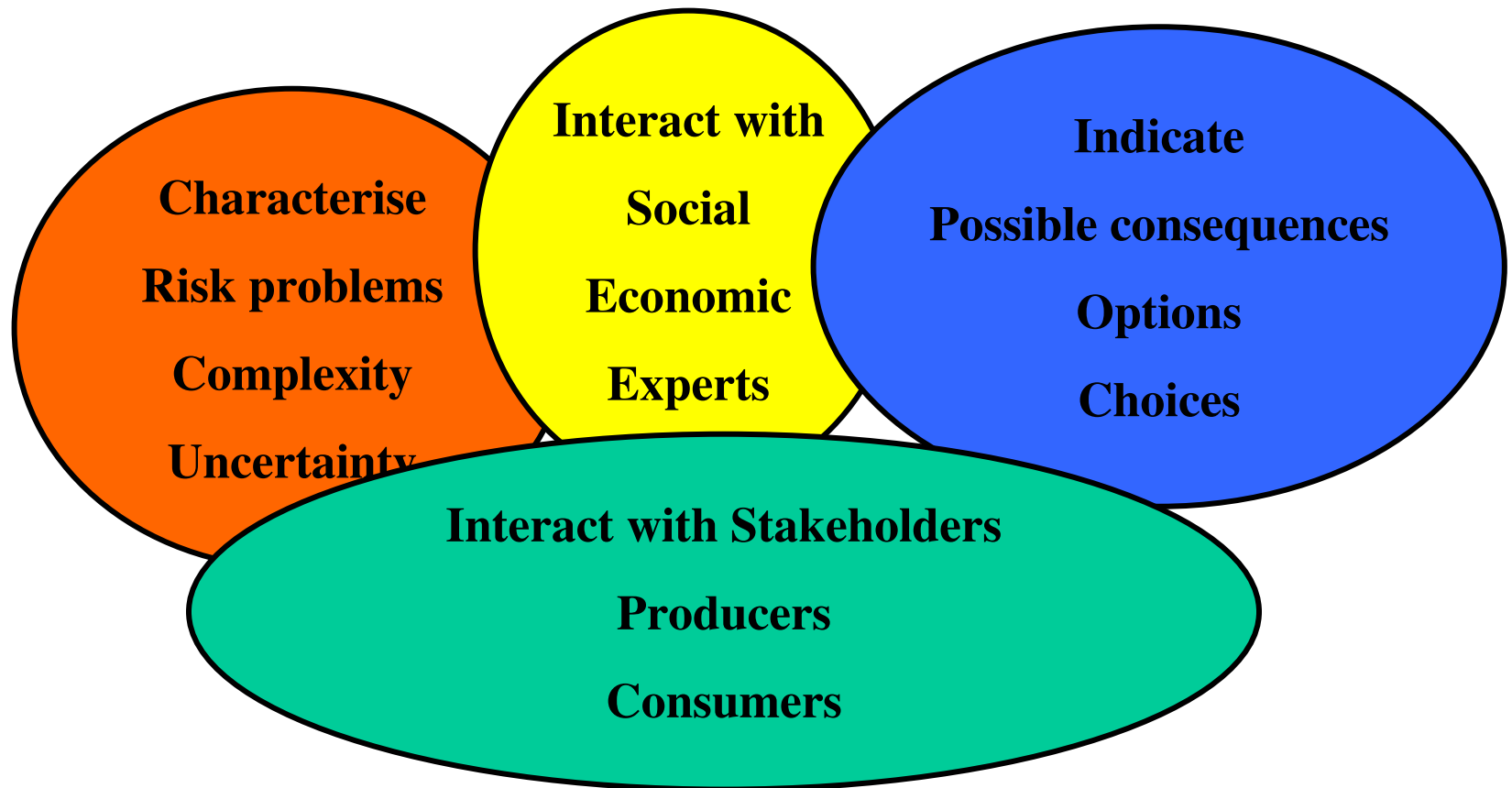
- Identify potential risks in an early phase
- Describe risks, as quantitative as possible:
 - Type and severity,
 - Reversibility/irreversibility
 - Acute/long- term effects on human/animal health and the environment
 - Who will be affected
 - Options for risk handling and control
- Present comprehensive risk assessments, taking all available information into account

Role of Scientific Experts in Risk Analysis

- Describe uncertainties in risk assessment
- Demonstrate the conservative (precautious) character of the assessment
- Provide post-market surveillance and monitoring scenario's and options
- Give guidance for comparative evaluation of (other) risks
- Address public concerns
- Use laymans language for the risk characterisation

Role of the Scientific Expert

Scientific Advisor, Facilitator and Mediator



Precaution in Risk Analysis: Task for Risk Assessors, Risk Managers and other Stakeholders

- The precautionary principle is an essential approach (*attitude*) throughout the whole Risk Analysis Process
- Scientific experts should always apply caution in their assessment of scientific data (quality and uncertainty)
- Risk managers and other stakeholders should consider what is an “acceptable” level of risk for the society

Precaution in Risk Analysis: Task for Risk Assessors and Risk Managers

- Risk assessment should highlight the **unknowns** (uncertainty analysis)
- The Precautionary Principle should be applied in case potential effects could be significant, but chances of occurrence would be impossible to predict
- With increased complexity of risk problems, uncertainty about risks increases, and thus **proportionally** the extent of precaution in risk assessment and risk management
- Risk assessors and risk managers should closely work together within their own responsibilities

Involvement of Stakeholders in the Risk Analysis Process

- Participation of stakeholders in the Risk Analysis Process depends on the nature of the risk problem?
 - Simple problems: routine analysis by experts
 - Complex problems: intensive participation of different stakeholders (observers role, hearings, consultations, workshops)

Involvement of Stakeholders in the Risk Analysis Process

- **Problem identification and formulation**
 - Scientific Experts, Producers, Risk managers, NGOs
- **Risk assessment of specific problems**
 - Scientific Experts
 - Producers as information providers
 - Other stakeholders (Consumers as observers?)
 - Communication specialists

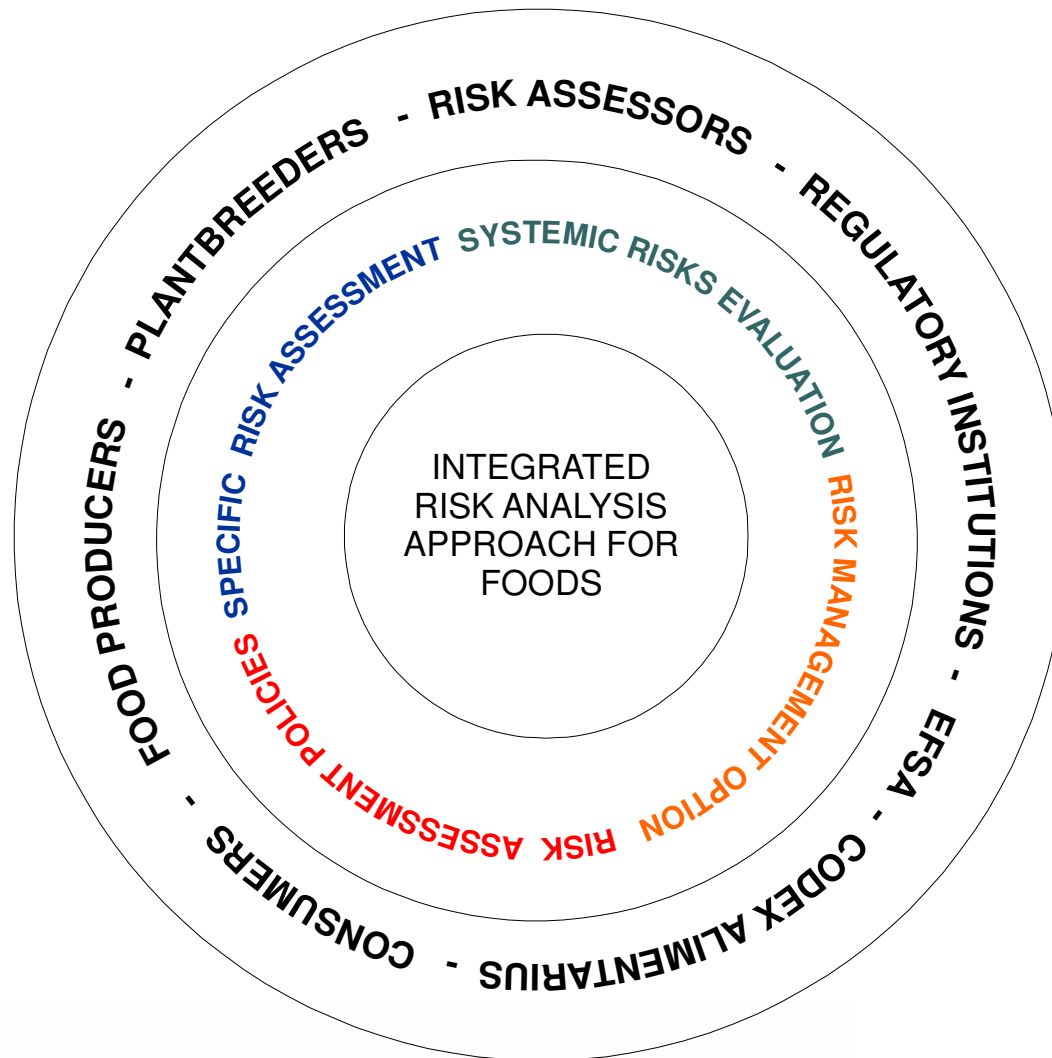
Involvement of Stakeholders in the Risk Analysis Process

- **Overall Risk Characterisation**
 - Scientific Experts
 - Experts of social and economical sciences
 - Risk managers and other stakeholders (Consultations)
 - Communication specialists
- **Assessment of Generic Issues and New Technologies**
 - All stakeholders (Consultations, Workshops, Hearings)

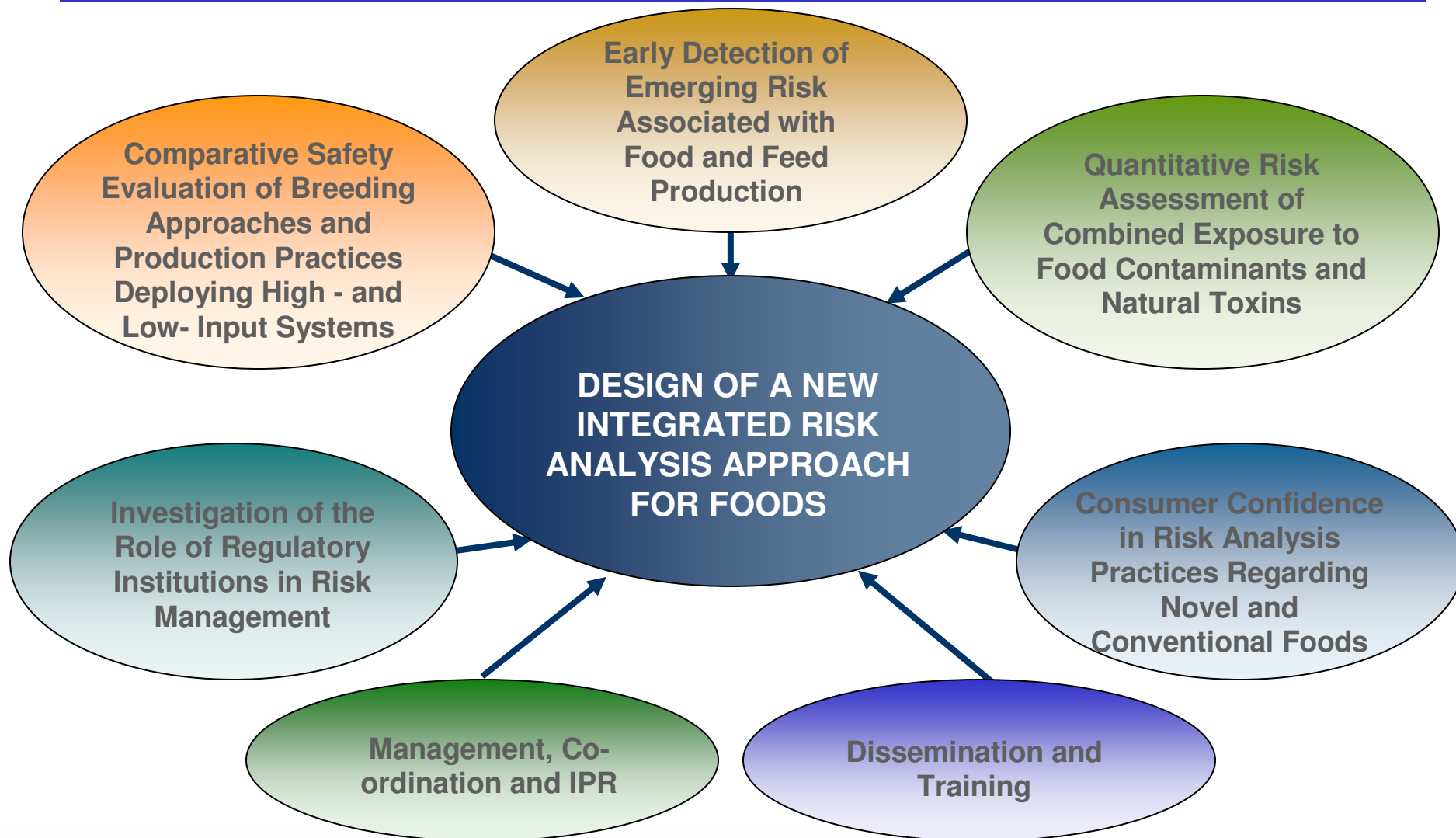
Involvement of Stakeholders in the Risk Analysis Process

- **Risk management/decision-making**
 - Risk managers,
 - Specialized organizations including NGOs,
 - Policy makers,
 - Communication specialists
- Tools: Hearings, Workshops, Consultations etc
- How to handle non-consensus?

Promoting Food Safety through a New Integrated Risk Analysis Approach for Foods



SAFE FOODS



The New Risk Analysis Model in Scaffolding

Characteristics of the New Risk Analysis Model

- Integration of the scientific assessment of human health aspects of foods with consumer values.
- Active consumer participation in the various stages of the risk analysis process.
- Improved functional and structural risk management procedures.
- Improved risk communication with consumers throughout the process of risk analysis.
- Pan European applicability.



SAFE FOODS

**New Integrated Risk
Analysis Approach**



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WAGENINGEN UR

Further Reading

- EU Scientific Committee First and Second Report on the Harmonization of Risk Assessment Procedures, 2000, 2003
- EU Scientific Committee Final Report on Setting the Scientific Frame for the Inclusion of New Quality of Life Concerns in the Risk Assessment Process, 2003
(http://europe.eu.int/comm/food/fs/sc/ssc/outcome_en.html)
- A. Klinké and O. Renn, Risk Analysis 2002;22:1071-94