Design of a New Integrated Risk Analysis Approach for Foods

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Safe Foods Meeting

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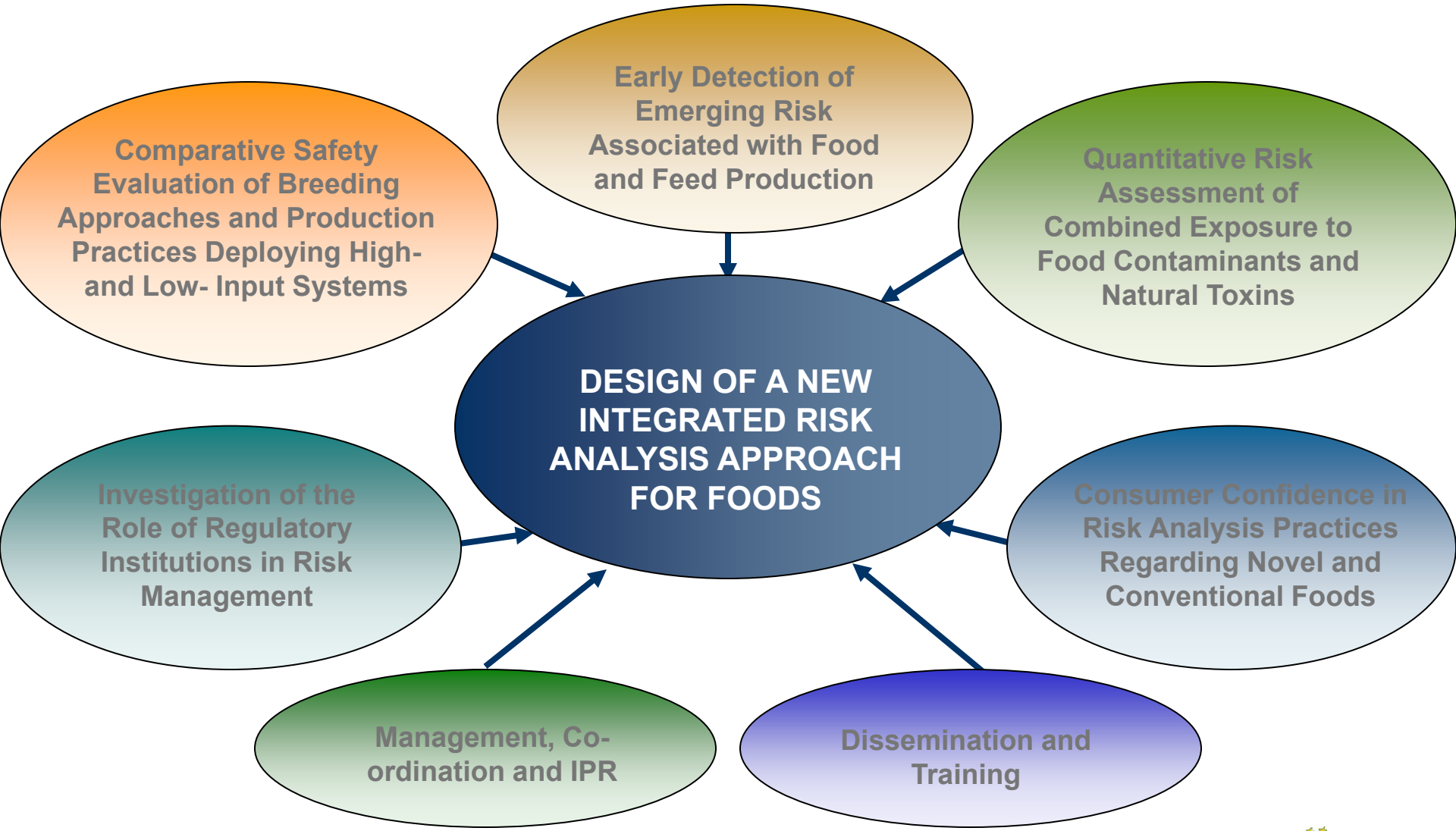
CONTENT

- **To report on the activities carried out within Work Package 6**

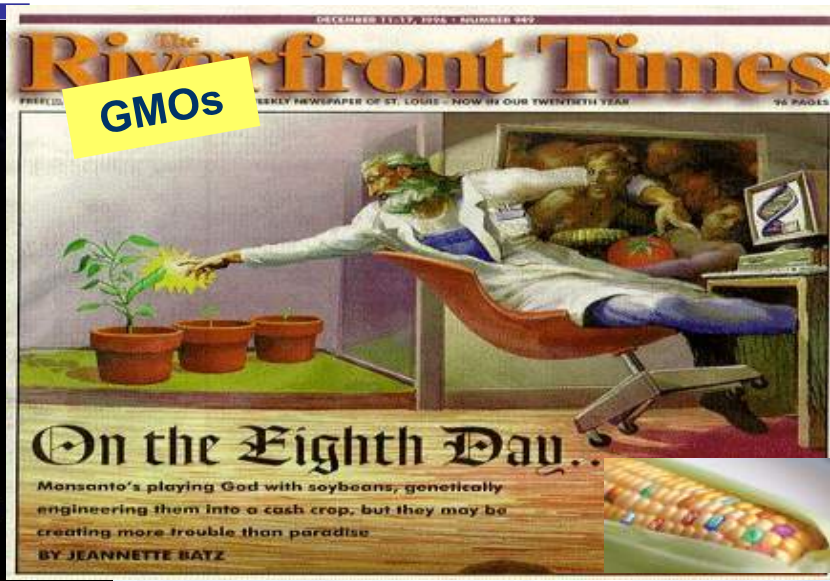
- **A New Integrated Risk Analysis Framework with:**
  - **Risks and benefits evaluation**
  - **Health, environmental, economic, social and ethical impacts assessment**
  - **Improved methods for food safety and benefit assessment**
  - **Greater transparency, accountability and increased participation of stakeholders**

WP6 Members

SAFE FOODS


Early Detection of Emerging Risk Associated with Food and Feed Production
Comparative Safety Evaluation of Breeding Approaches and Production Practices Deploying High- and Low- Input Systems
Quantitative Risk Assessment of Combined Exposure to Food Contaminants and Natural Toxins
DESIGN OF A NEW INTEGRATED RISK ANALYSIS APPROACH FOR FOODS
Investigation of the Role of Regulatory Institutions in Risk Management
Consumer Confidence in Risk Analysis Practices Regarding Novel and Conventional Foods
Management, Co-ordination and IPR
Dissemination and Training

Public Concern and Low Trust in Food Risk Management in Europe



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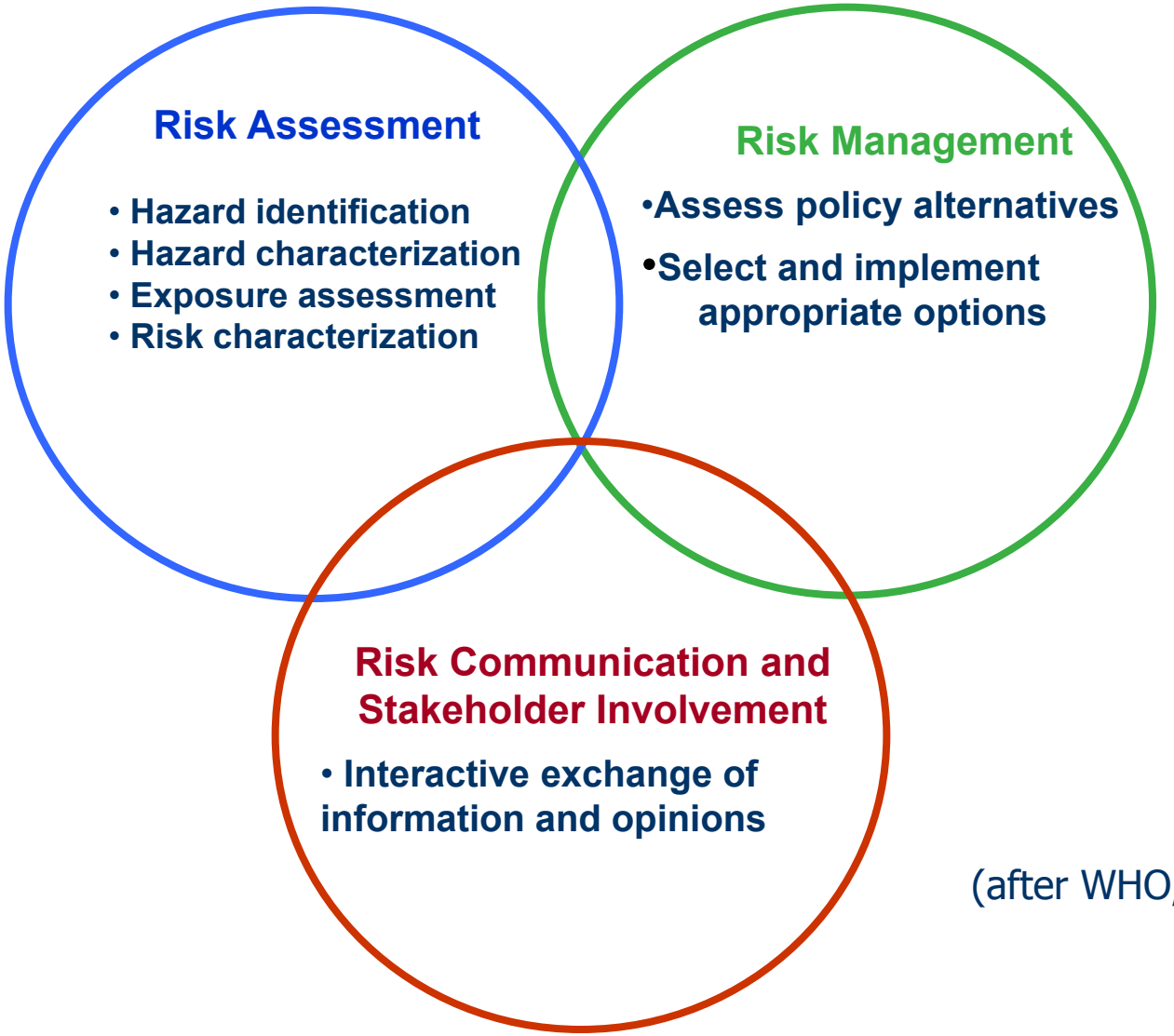
European Commission Actions

- EU White Paper on Food Safety
  - Establishment of the European Food Safety Authority (EFSA) in 2002
  - “Farm to Fork” approach in EU legislation
  - Defining responsibilities for food safety
- General Food Law (Regulation 178/2002)
- Rapid Alert System for Food and Feed (RASFF)
- Precautionary Principle
- Traceability and Transparency

- *Has this resulted in an increased consumer confidence?*

Safe Foods

Risk Analysis Framework

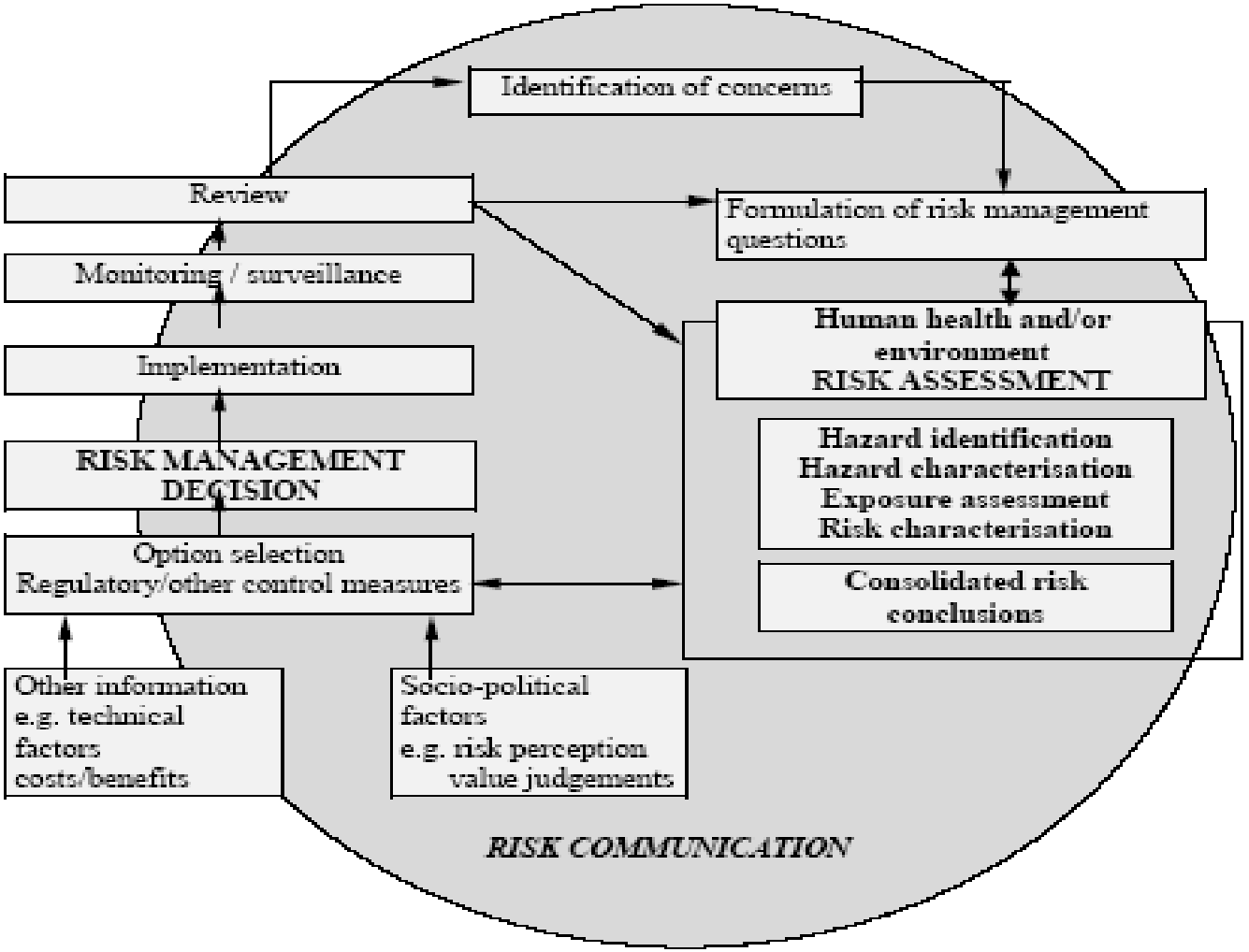


(after WHO, 1998)

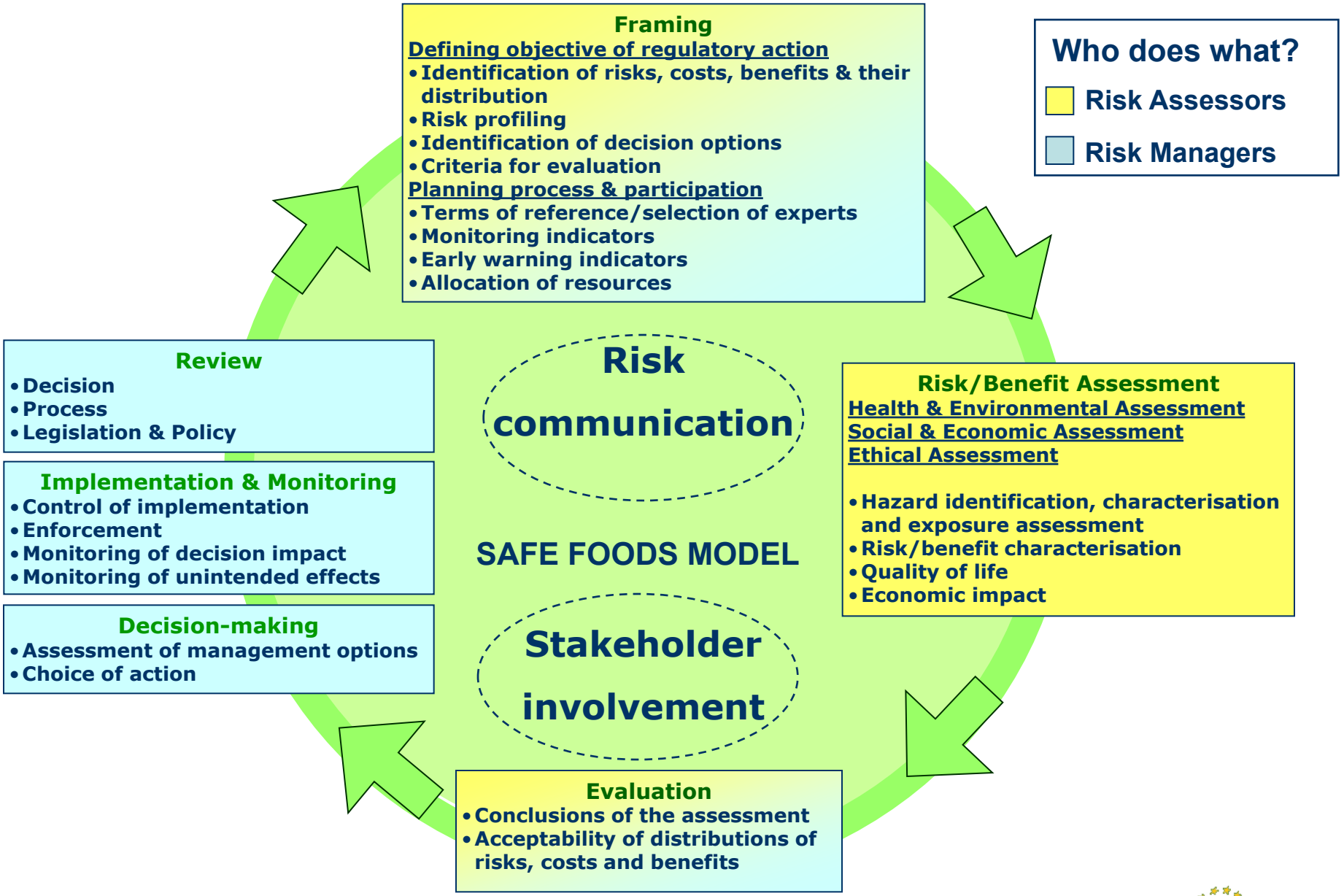
Need for Improvement of Risk Governance

- Current system primarily focused on evaluations of technical aspects e.g. Single Risk Issues
- Responsibilities of different stakeholders?
- Process of risk governance not transparent
- No systematic considerations of potential benefits, economical consequences, and social values and attitudes
- Process of risk governance not transparent
- No formal participation of representative stakeholders

The Risk Cycle: Components of Risk Analysis



EU Scientific Steering Committee, 2000


Framing
Defining objective of regulatory action
• Identification of risks, costs, benefits & their distribution
• Risk profiling
• Identification of decision options
• Criteria for evaluation
Planning process & participation
• Terms of reference/selection of experts
• Monitoring indicators
• Early warning indicators
• Allocation of resources
Who does what?
Risk Assessors
Risk Managers
Review
• Decision
• Process
• Legislation & Policy
Risk communication
Risk/Benefit Assessment
Health & Environmental Assessment
Social & Economic Assessment
Ethical Assessment
• Hazard identification, characterisation and exposure assessment
• Risk/benefit characterisation
• Quality of life
• Economic impact
Implementation & Monitoring
• Control of implementation
• Enforcement
• Monitoring of decision impact
• Monitoring of unintended effects
SAFE FOODS MODEL
Decision-making
• Assessment of management options
• Choice of action
Stakeholder involvement
Evaluation
• Conclusions of the assessment
• Acceptability of distributions of risks, costs and benefits

Novel Elements SF Model

- Formal Framing Phase and Evaluation Phase
- Risk and Benefit Assessment
- Improved and new tools for risk-benefit analysis
- Economical, Social and Ethical Impact Analysis
- Transparency in decision-making

Overarching Report WP 6 SAFE FOODS
Ariane König et al.

- A. Introduction on risk analysis and food safety in the EU
- B. The Safe Foods Framework
- C. Safe foods contributions to improve food safety governance
- D. Compatibility of the Safe Foods Framework with risk analysis principles of the Codex Alimentarius Commission and the EU institutions, policies and laws
- E. Conclusions
  - Annex a. Glossary
  - Annex b. Methodology for development of the Safe Foods Framework
  - Annex c. Summary of the ethical matrix approach
  - Annex d. European Commission Guidelines on Impact Assessment

Impact Assessment Papers

- **Economic Assessment of Food Standards: Costs and Benefits of Alternative Approaches**

  W. Bruce Traill and Ariane König

- **Methods and Approaches to Assess Social Impact and Risk-Benefit Perceptions of Food Safety Issues**

  Shannon Cope, Lynn Frewer, Marion Dreyer, Ellen van Kleef and Ortwin Renn

- **Exploring the Social Impact of Food Safety Issues: Including Social Impact Assessment in Food Safety Governance**

  Marion Dreyer, Ortwin Renn, Shannon Cope, Ellen van Kleef, Meike Wentholt and Lynn Frewer

- **Considering Ethics in the Risk Analysis of Foods: a Structured Approach**

  Matthias Kaiser & Ariane König

FRAMING PHASE

DEFINING THE ISSUES

- Risk/benefit profiling
- Identification of risks, costs, benefits
- Defining the scope of economical, social and ethical assessment
- Setting the risk assessment policy, ownership, prescriptive
- Application of the precautionary principle?
- Defining objective of regulatory action

PLANNING THE RISK ANALYSIS PROCESS

- Planning process, time limits
- Who should participate where and when
- Selection of experts
- Monitoring indicators
- Early warning indicators
- Allocation of resources

FRAMING STATUS QUO and SAFE FOODS APPROACH

STATUS QUO

- EU-Commission → EFSA → EFSA Panels
- EU Advisory Committee on the Food and Feed Chain
- EU Stakeholders Dialogue Group
- EFSA Advisory Forum
- Ad-hoc Internet-based questionnaires (Internet- Forum)
- No formal input stakeholders from industry, NGO's

SAFE FOODS PROPOSAL

- Formalization of the framing procedure
- Early warning signal handling
- Transparent public reporting: Framing Report
- Internet Forum for dissemination and deliberation
- Interface Advisory Forum with flexible composition
- For which cases?
  - Not for routine analysis
  - Particular challenges, generic issues, new technologies
  - Nanotechnology, next generation GMOs, synthetic biology

RISK-BENEFIT ASSESSMENT PHASE

- **Health and Environment Assessment**
  - Not only hazards and risks, also potential health and nutritional benefits

- **Economic, Social and Ethical Impact Analysis**
  - Economic impact assessment to estimate private and public costs and benefits
  - Anticipate impacts of decisions on diverse societal groups
  - Consider ethical issues as perceived by different interest groups that shape people's attitudes and beliefs

Health and Environmental Assessment

Risk-Benefit Assessment Paradigm

1. Hazards and potential benefits identification
2. Characterization of adverse effects and benefits
3. Exposure assessment
4. Combined risk-benefit characterization
    - Type of risks and distribution
    - Potential benefits, efficacy
    - Ranking/balancing, “safety first”
    - Uncertainties, variability

- Broadening of expertise needed
- Power and limitation of new methods

NEW TOOLS FURTHER DEVELOPED IN SAFE FOODS FOR RISK- BENEFIT ASSESSMENT

- Genomics, proteomics, metabolomics
  - Food composition
  - Thresholds for adverse/ beneficial effects
  - Metabolic pathway regulation/linkage
- Probabilistic measurements of exposure, toxicity
- Aggregate exposure assessment
- Health impact prioritization
  - Risk-risk
  - Risk-benefits
- Validation, databases
- Adaptation and use for routine risk assessment

Economic Impact Assessment

- SAFE FOODS paper: “Economic Assessment of Food Standards: Costs and Benefits of Alternative Approaches” by W. Bruce Traill and Ariane König
- Economic tools can help to structure the analysis of costs and benefits at the aggregated level
- Impact of regulatory actions on costs by firms/sector/governments
- QUALYs (Quality Adjusted Life Years) to convert effects on health endpoints, using utility scales:
  - Decrease measured in functioning, productivity, life expectancy etc
- Damage perceived by affected group to be expressed in monetary terms?
- Inequities from distribution of risks, costs and benefits between different societal groups are difficult to capture

Social Impact Assessment

- Social impact assessment characterizes differences between different societal groups with diverse sets of values
  - Views on risks, risk perceptions, risk management, costs, benefits and associated uncertainties
- Three stage approach proposed: *preliminary framing, concern assessment, social impact appraisal*
- Methods used to provide insights in concerns and expectations that individuals and groups of different cultures may link to the hazards or cause of hazards:
  - Focus groups consultations
  - Large scale quantitative surveys
  - Expert Delphi procedures
  - Hearings with relevant social groups

Ethical Impact Assessment

- Increased awareness that food production and consumption are associated with ethical values including equity, dignity, fairness, and integrity relating to humans, animals and the natural environment
  - Focus on changes in governance of food to improve the social legitimacy of decisions on food safety
  - The use of an *ethical matrix approach* to gain insight in diverse ethical concerns
  - Separation of risk and benefit issues (if possible)

Value Matrix –New Technologies in Food Production

	Absence of harm	**Do some good**	**Dignity/Identity**	**Fairness**
Treated organism	Animal welfare	Improved disease resistance	Behavioural Freedom	Respect for telos
Producer	No economic loss	Economic gain	Address a social need / Socially responsible products	Level field for competition
Consumer	No harm to health	Health benefit Added pleasure	Choice Autonomy	Equal access/distribution
Environment	No harm and no depletion	Planting new trees Clearing up past mess	Respect of systems interactions and legal standing	Equal chances for future generations

Kaiser and König, 2008

EVALUATION PHASE

- New intermediate stage between risk-benefit assessment and the decision-making phase
- A participatory process to evaluate the assessment outcomes
  - compare risks, costs, and benefits and their distribution
  - Ranking of options
- To understand possible differences in views held by interested parties

EVALUATION PHASE

- Outcome of the Evaluation Phase:
  - Areas of (dis)consensus on outcomes of risk-benefit assessment
  - Acceptability of consequences of the risk-benefit characterisation
  - Ranking of options
  - Requirements for risk management measures
- Different procedural options (WP5)
  - Internet Forum
  - Advisory Committee
  - Steering Committee
- Decision-makers part of this?

Risk Management

- **THREE DISTINCT PHASES WITH FORMAL REPORTING**

Decision-making

- Assessment and selection of management options
- Choice of action
- Accountability by risk manager

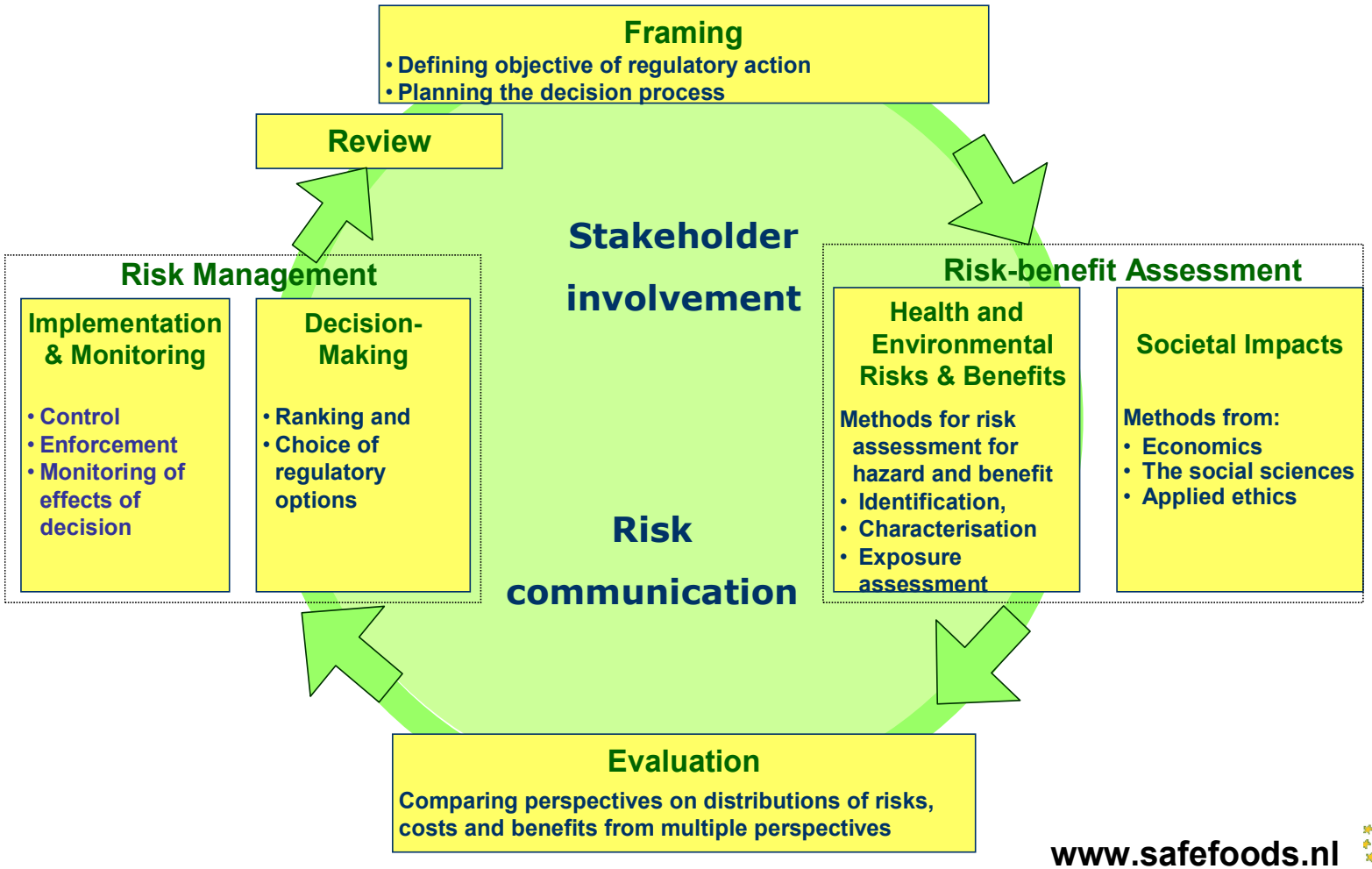
Implementation & Monitoring

- Final selection of a risk reduction or risk mitigation option
- Enforcement and control
- Monitoring plans, suitable indicators
- Monitoring of (un)intended effects

Review

- Decision-making process
- Impact of the decision
- Iteration?

SF Model



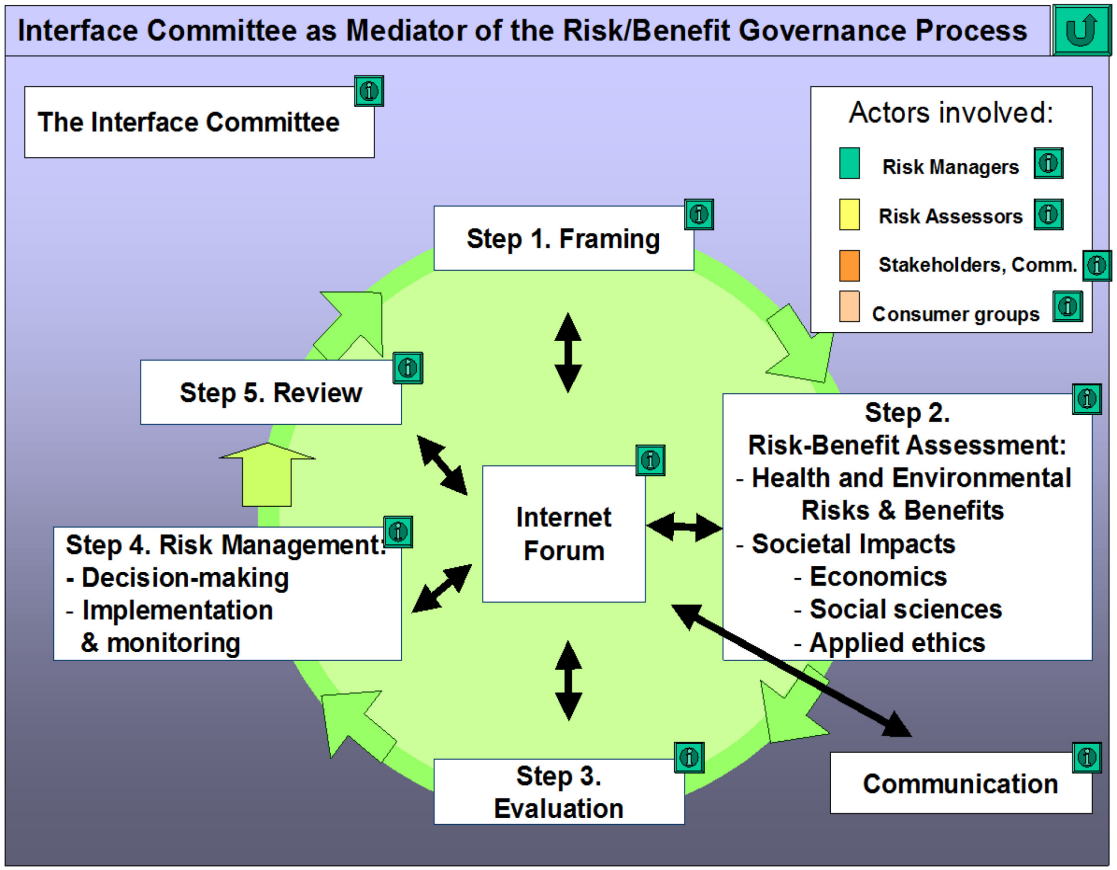
www.safefoods.nl

Running the Model: Suggestions for Institutional Reforms (WP5)

Preferred option

- **An Internet Forum in combination with and Interface Advisory Committee**
  - Internet Forum for dissemination of information and mutual exchange of views
  - Interface Advisory Committee (IAC) to adopt ***advisory opinions*** on the terms of reference and on the evaluation of cases addressed to the Commission.
  - The IAC is ***flexible*** with its composition depending on the case
  - The IAC involved in particular challenges to be decided by the Commission).

Further Suggestions for Running the Model



Ib Knudsen draft paper

When does the Model apply?

- For generic issues and particular challenges
  - Next generation of food/non-food GM crops
  - Alternative modification methods
  - Nanotechnology
  - Synthetic biology
- Not in emergencies, crises

Suggestions for Broadening the Risk-Benefit Assessment

- EFSA's assessments restricted to technical risk-benefit assessments
- Other groups should be involved in economic, social and ethical impact assessment, among them:
  - European Economic and Social Committee (EESC)
  - European Group on Ethics in Science and New Technologies (EGE)
  - EU Group of Advisors on Ethical Implications of Biotechnology

SAFE FOODS Approach Compatible with the European and International Setting for Food Safety Governance?

- Are SF stages of framing and evaluation and engaging stakeholders in line with EU Treaty and EU food law provisions?
- Compatibility with Codex and WTO?

SAFE FOODS Approach Compatible with the European and International Setting for Food Safety Governance?

- Current EU system for risk evaluation is basically *technocratic* but in transition:
  - more account of public concerns (BSE, GM crops),
  - greater transparency in risk management decisions and procedures

- Stakeholders play more and more an important role within the EU:
  - Regular consultations by the European Commission, Member States and European Parliamentarians
    - framing of issues, draft policies and proposals for legislation

SAFE FOODS Approach Compatible with the European and International Setting for Food Safety Governance?

- Safe Foods recommendations needs further implementation in the EU legal system,
- The distribution of power between EU Commission, Member States and EU Institutions should be taken into account
- SAFE FOODS proposals come at the right moment

SAFE FOODS Approach Compatible with the European and International Setting for Food Safety Governance?

- Compatibility with Codex and WTO
  - EU endorses principles for risk analysis as set forth under Codex Alimentarius Commission rules
  - Level of protection of consumers?
  - Application of the Precautionary Principle?

Steps in Implementation of Proposed SF Changes in the Risk Analysis Procedure

- Actions for Implementation of the SF Model:
  - Establishment of Formal Framing and Evaluation Steps in Risk Analysis and Stakeholders Participation

    Consultation Workshops with Commission Services, Member States, other stakeholders
  - Establishment of Economic, Social and Ethical Impact Guidance

    Workshops Commission Services, Member States, Experts
  - Further Development of New Risk Assessment Methodologies

    Research Investments and Formation of Platforms (DG Research) for
    - Genomic and profiling methods
    - Probabilistic exposure and effect measurements
    - Set up of databases

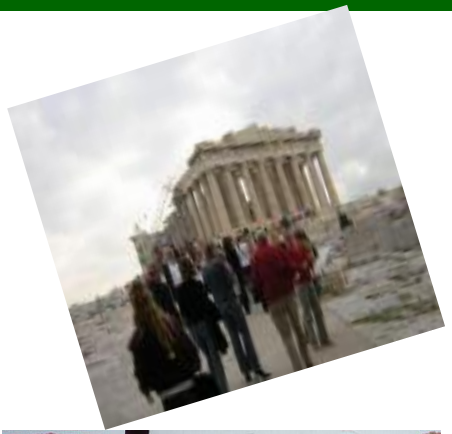
Case Studies to Test the SF Model

- BSE Pascal and König
- Acrylamide Busk et al.
- GMO's Kuiper and Davies

Conclusions

- **SAFE FOODS Model for Risk Analysis presents a number of innovations:**
  - A framing and evaluation phase in current risk analysis procedures
  - A scientific assessment, not only including risks but also benefits and an evaluation of the economic, social and ethical impacts
  - Insertion in the risk assessment of new technologies of holistic nature
  - Recommendations for improved communication on risk management and risk assessment (uncertainties)
  - Recommendations for institutional rearrangements and for management of the new Risk Analysis Model, including specific participation of stakeholders
  - Enhancement of transparency, openness and accountability of the risk analysis process

SAFE FOODS AN ENJOYMENT





THANK YOU ALL