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

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Integrating Safety and Nutrition Research along the Food Chain,
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• Type of Project: **Integrated Project**
• Project title:

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

• Coordinators:  Dr. H. A. Kuiper and Dr. H.J.P. Marvin

• Total budget: **14,5 €**
• EU contribution: **11,4 €**
• Number of partners: **32**
• Number of countries involved: **17**

www.safefoods.nl
## Participants SAFE FOODS

1. **DLO-RIKILTRIKILT** - Institute of Food Safety, Netherlands  
2. **SCRI** - Scottish Crop Research Institute, United Kingdom  
3. **TUM** - Technical University Munich, Germany  
4. **UKU** - University of Kuopio, Finland  
5. **IHAR** - Plant Breeding and Acclimatization Institute, Poland  
6. **ISS** - National Institute of Health, Italy  
7. **CSIR** - Council for Scientific and Industrial Research, South Africa  
8. **BiOSS** - Biomathematics and Statistics Scotland Research Institution, United Kingdom  
9. **ICGR** - Institute of Crop Germplasm Resources, China  
10. **NFC** - National Food Center, Ireland  
11. **UNICATT** - Catholic University of Piacenza, Italy  
12. **LFC** - Latvian Food Center, Latvia  
13. **CFRI** - Central Food Research Institute, Hungary  
15. **BfR** - Federal Institute for Risk Assessment, Germany  
16. **BAG** - Swiss Federal Office of Public Health, Switzerland  
17. **NFA** - National Food Administration, Sweden
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<tr>
<th>Number</th>
<th>Institution</th>
<th>Location</th>
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<td>18</td>
<td>NINFS National Institute of Nutrition and Food Safety, China</td>
<td>China</td>
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<td>19</td>
<td>DFVF Danish Institute for Food and Veterinary Research, Denmark</td>
<td>Denmark</td>
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<td>20</td>
<td>NIPH National Institute of Public Health, Czech Republic</td>
<td>Czech Republic</td>
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<td>21</td>
<td>WU Wageningen University, Netherlands</td>
<td>Netherlands</td>
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<td>22</td>
<td>IFR Institute of Food Research, United Kingdom</td>
<td>United Kingdom</td>
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<td>23</td>
<td>KVL Royal Veterinary and Agricultural University, Denmark</td>
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<td>24</td>
<td>DIA DIALOGIK gGmbH, Germany</td>
<td>Germany</td>
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<td>25</td>
<td>AUA Agricultural University of Athens, Greece</td>
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<td>UoS University of Sussex, United Kingdom</td>
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<td>27</td>
<td>UM University of Maastricht, Netherlands</td>
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<td>28</td>
<td>UGOT University of Göteborg, Sweden</td>
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<td>29</td>
<td>KCL King’s College London, United Kingdom</td>
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<td>ISB Institute of Sociology at the Hungarian Academy of Sciences, Hungary</td>
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<td>31</td>
<td>CEIS Centre for International Studies on Economic Growth, University of Rome, Italy</td>
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<td>32</td>
<td>EUFIC European Food Information Council, Belgium</td>
<td>Belgium</td>
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<tr>
<td>33</td>
<td>IRAS Institute for Risk Assessment Science, University of Utrecht, Netherlands</td>
<td>Netherlands</td>
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State of the Art

- Broad public concern about the safety of the European food supply
- BSE, dioxin, E. coli 0157, GM food crops……
- Low public trust in how food crises were handled
- Low trust in the Regulatory System in Europe
The Food Debate!

ADMINISTRATORS

POLITICIANS

EXPERTS

MEDIA

SCIENTISTS

INDUSTRY

ACTION GROUPS

CONSUMERS
Strategic Objectives

• To design a European working-procedure for early identification of emerging risks in food production chains in an expanding European market.

• To develop comparative safety assessment approaches for foods produced by different breeding and production practices, using modern profiling techniques.

• To investigate consumers confidence/preferences in risk analysis practices for foods.
Strategic Objectives

- To understand differences in food risk perceptions of consumers, experts, and decision makers.
- To investigate the new role of institutions across Europe involved in risk assessment and management taking a broader impact of food production on environment, animal welfare, sustainability, and socio-economic consequences into account.
- To design a new risk analysis approach for foods, integrating scientific principles, societal aspects and effective public participation.
European Thematic Network on Safety Assessment of Genetically Modified Food Crops

Dr. H.A. Kuiper
RIKILT, the Netherlands

- 65 Participants from 13 EU countries
- 5 RTD projects
- 4 Working Groups on Safety Evaluation and Assessment
- Project duration: 01-01-2000 to 01-01-2003

European Food Safety Network (EFSN)
RIKILT / RIVM

29 government-related research institutes from 21 EU countries (including 7 pre-accession countries)

Promoting Food Safety through a New Integrated Risk Analysis Approach for Foods (SAFE FOODS)
SAFE FOODS

Risk Analysis Framework

Risk Assessment
- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

Risk Management
- Assess policy alternatives
- Select and implement appropriate options

Risk Communication and Stakeholder Involvement
Interactive exchange of information and opinions

Increased transparency = increased credibility?

Incorporation of societal “values” to create an integrated framework

(after WHO, 1998)
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Comparative Safety Evaluation of Breeding Approaches and Production Practices Deploying High - and Low- Input Systems

Early Detection of Emerging Risk Associated with Food and Feed Production

Quantitative Risk Assessment of Combined Exposure to Food Contaminants and Natural Toxins

Investigation of the Role of Regulatory Institutions in Risk Management

DESIGN OF A NEW INTEGRATED RISK ANALYSIS APPROACH FOR FOODS

Management, Coordination and IPR

Dissemination and Training

Consumer Confidence in Risk Analysis Practices Regarding Novel and Conventional Foods
Major Deliverables

- First comparative databases for profiling of foods produced by different breeding approaches and production systems.
- Development of a working procedure for identification of new emerging chemical and microbial risks in food production chains.
- New approaches for risk modelling of food contaminants and natural toxins, and criteria development for comparative risk analysis.
- Analysis of food safety risk perceptions of experts, regulators, consumers and other stakeholders regarding novel and conventional foods.
Major Deliverables

• Analysis of uncertainties in risk assessment and identification of best practice in communicating risk uncertainty with the public.

• Identification of consumers preference for risk analysis strategies for foods across Europe.

• Guidance for evaluation and governance of systemic food risks.

• Recommendations for improvement in risk management procedures and institutional structure.

• New Risk Analysis Approach for foods that integrates risk assessment, risk management, consumer preferences and values, as well as impact analysis of socio-economical aspects.
Characteristics of the New Risk Analysis Model

- Integration of assessment of human health aspects of foods with consumer preferences and 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.
Promoting Food Safety through a New Integrated Risk Analysis Approach for Foods
WP1: “Comparative Safety Evaluation of Breeding Approaches and Production Practices Deploying High- and Low- Input Systems”
Objectives:

• To identify risks associated with specific breeding approaches.
• To compare risks inherent in high- and low- production systems.
• To explore profiling methods to differentiate risks.
• To develop comparative databases for risk assessment of foods produced in the different systems.
• To evaluate and define the compositional variation of raw materials in the context of a “history of safe use”.
• To actively make use of completed and currently on-going research.

Selected crops: Potato (Solanum tuberosum) and Maize (Zea mays)
What are we already eating
Existing variation: trait spectra
  Natural resistance to pests and pathogens
  Known composition variation e.g. carotenoids
  Baseline data

Does the way we develop new varieties matter
Non GM
Effects of chromosome doubling
Mutations
Somaclonal variation
  Protoplast fusion
  Tissue Culture
In vivo haploid production
GMO: virus resistance, Bt, modified metabolism

What about crop production practices
High and low input systems
  (organic: cf S Africa and Europe)
Storage practices
Site/Climate effects (common varieties?)

Importance of appropriate Controls
WP2: Early Detection of Emerging Risks Associated with Food and Feed production
WP2 - Objectives

• To establish a working procedure for the early detection and assessment of emerging microbial and chemical hazards in food

• To provide information and data on the development (potential and otherwise) of emerging ‘super bugs’

• To provide data on chemical residues in food with particular focus on Central and Eastern Europe

• To develop research proposals on the above and related areas with a particular emphasis on research capacity building in eastern European countries.
WP2 - Tasks

• Develop a database of European experts on microbial and chemical food safety

• Develop a rapid predictive alert system for microbial hazards in the food chain.

• Development of a training module on microbial and chemical hazards identification, risk assessment and risk management (GMP, HACCP, etc)

• Prepare a report predicting emerging microbial pathogens in the food chain.
WP2 - Tasks

- To prepare a report on chemical food contamination (PCB’s, pesticides and mycotoxins) with particular focus on Central and Eastern European countries.

- To prepare a proposal for future research on:
  • predictive modelling for emerging pathogens
  • novel chemical residue / contaminant detection methods
  • standardisation of microbiological and chemical residue detection methodologies
  • food safety identification/assessment training (capacity building Central/Eastern European countries)
WP3: Quantitative Risk Assessment of Combined Exposure to Food Contaminants and Natural Toxins
Limitations of Current Risk Assessment Approaches

- Comparison of results within Europe not always possible
- Variation and uncertainty in residue and consumption levels are not always taken into account
- One chemical at a time (no cumulative exposure assessment)
- What is short-term and what is long-term exposure?
- EU needs to harmonize the risk assessment procedures are not harmonised
WP3 - Objectives

• Develop probabilistic risk modelling
  – exposure, toxicity of food contaminants and natural toxins.

• Develop Pan-European risk modelling based on
  – different national food consumption databases
  – including vulnerable groups

• Evaluate uncertainties in risk assessment
  – exposure, adverse effects, susceptibility.
WP3 - Objectives

- Perform uncertainty analyses
  - uncertainty in data
  - different risk models
  - assumptions made on assessment variables
- Develop criteria for comparative risk analysis
- Develop probabilistic models
  - the risk of combined exposure of contaminants and natural toxins
  - validate the statistics
  - take into account nutrition and labelling aspects
Mycotoxins, pesticides and natural toxins

Both effect modelling (e.g. Benchmark Dose) and exposure modelling resulting in a distribution of Margin of Exposures (MoE)

Criteria for comparative risk assessment (reversible or irreversible effects, DALY, cumulative exposure)

Partners Denmark, Sweden, The Netherlands, Italy, Czech Republic, Switzerland and China
Electronic Platform of Databases

MCRA-software
Training

- Harmonisation of consumption data
- Harmonisation of residue data
- Harmonisation of database structure (MS Access)
- Bench Mark Dose modelling
- Nearby future
  - Query language between databases organised on national websites and probabilistic software
  - New models regarding multi-route exposure and combined exposure to different chemicals
  - Integration effect and exposure modelling
WP4: Consumer confidence in risk analysis and communication practices
Public Perceptions and Attitudes: What are the Key Questions?

• What is driving consumer perceptions of risk and benefit?
• Who trusts whom to inform and regulate? How does this relate to consumer confidence in the food chain and associated science base?
• Are there cross-cultural and intra-individual differences in perceptions and information needs?
• How might the wider public be involved in the debate about risk management and technological development?
• How do related factors (ethics, wider value systems) relate to perceptions of risk?
• How do the public react to information about risk uncertainty and risk variability, and emerging risks?
Specific Objectives (1)

- To identify determinants of public and stakeholder perceptions and attitudes towards food risk analysis for the three food chains under consideration.

- To understand differences and similarities in the social representations of different affected groups (consumers, scientists, policy makers, industry) regarding the implementation of current risk management practices.

- To assess cultural and individual differences in attitudes, perceptions and beliefs regarding optimal risk management practices.
Specific Objectives (2)

- To develop best practice in communication about food risk uncertainty
- To test the effectiveness of the new integrated risk analysis framework.
- To develop a gender policy
  - differences in consumer issues between genders (and interactions across cultures)
  - active inclusion of women in the research process
Methodologies

• Focus groups in Denmark, UK, Greece, Slovenia, Germany

• Social representation studies in each country: (scientists, consumers, stakeholders, and decision-makers and follow-up interviews with individual members)

• Cross-cultural survey based on input focus groups

• Case studies and qualitative interviews with expert representatives

• Stakeholder analysis
WP5: Investigation of the Institutional Changes and Solutions to Systemic Risk Management
Risk Characteristics
Three Challenges of Risk Management

• **Complexity** in assessing causal and temporal relationships

• **Uncertainty**
  – variation among individual targets
  – measurement and inferential errors
  – genuine stochastic relationships
  – system boundaries (endpoints, methods)
  – ignorance

• **Ambiguity** in interpreting results (value differences, symbolic associations, fairness)
Issues of Interest

• Handling of uncertainty, complexity, and ambiguity

• **Structure of Governance**
  – Framing of “issue” (protective goals)
  – Early warning system
  – Division of labor
  – Link between assessment and management
  – Rationale of risk reduction (precaution, risk-benefit, political pressure)
  – Transparency of process
  – Involvement of actors (economic, science, civil society, general public)
  – Monitoring of food behavior and impacts
  – Monitoring of compliance

• Dynamic development of risk governance

• Confidence and trust in regulatory institutions
Tasks

- Development of a common analytic framework and a protocol for the empirical research
- Review of national regulatory styles and processes (UK, France, Germany, Sweden, Hungary, EU)
- Integrated analysis of institutional practice
- Analysis of risk management needs in view of systemic risks
- Suggestions for improving risk management
Structure of Protocol

• Production modes
  – conventional
  – GMOs
  – organic

• Case study classes
  – Microbiological/pathogens (traditional, new)
  – Chemical additives (essential, cosmetic)
  – Other contaminants (such as Acrylamide)
  – Nutritional risk such as obesity
  – Interactions among the above
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NEW RISKS IN EXPANDING MARKETS
CAPACITY BUILDING
PROBABILISTIC/DETERMINISTIC RISK ASSESSMENT
COMPARATIVE ASSESSMENT QUANTIFY UNCERTAINTIES
INTEGRATED SCIENCE-BASED SYSTEMIC RISK ANALYSIS MODEL

COMPARATIVE PROFILING ANALYSIS
HISTORY OF SAFE USE
NEW APPROACHES FOR SYSTEMIC RISK ANALYSIS
NON-STATIC PROCESS ADAPTATION

CONSUMER CONFIDENCE/PREFERENCE VALUE JUDGEMENT RISK ACCEPTABILITY PRECAUTION
STAKEHOLDERS DIALOGUE COMMUNICATION TRAINING
Workpackage 6: Integrated Risk Analysis Approach for Foods
Objectives

- To integrate the outcomes of the different research tasks of the IP into a new risk analysis approach for foods

- To develop scientific, social, and economic criteria for risk analysis of foods

- To develop a New Risk Analysis Approach for foods that integrates risk assessment of quantitative and qualitative human health aspects, consumer preferences and values, and analysis of socio-economical aspects
Objectives

- To provide mechanisms for active stakeholder participation in risk assessment and risk management processes.

- To develop strategies for optimal risk communication throughout the whole process of risk analysis.

- To contribute to an internationally accepted approach for risk analysis of foods.

- To actively make use of completed and currently on-going research carried out in related EU research and other programmes.
Inclusion of New Quality of Life Criteria in the Risk Analysis Process

- Human physical and psychological health
- Animal welfare
- Environmental impact
- Benefit considerations
- Acceptability, cultural attitudes
- Socio-economical impact
- Essential part of the risk assessment or in addition?
Characteristics of the New Risk Analysis Model

- Integration of assessment of human health aspects of foods into a broader socio-economical context.

- Active stakeholder participation in the various stages of the risk analysis process.

- Improved functional and structural risk management procedures.

- Improved risk communication with stakeholders throughout the process of risk analysis.

- Pan European applicability.
Verification and Implementation of the Model

- Testing of the New Risk Analysis Framework by:
  - EU DG Health and Consumer protection
  - EU DG Agriculture
  - EU DG Enterprise
  - EUDG Research
  - EFSA, National Food Authorities
  - FAO/WHO/OECD
  - BEUC, ILSI...

- Platform, interactive Workshops, interviews
Acknowledgements

SAFE FOODS participants