

## 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, produced by different breeding approaches and production practices deploying high- and low-input systems, based on qualitative and quantitative inputs from risk assessment.
- To develop scientific, social, and economic criteria for risk analysis of foods taking into account both qualitative and quantitative aspects of the risk assessment.
- To develop a mechanism for regular update of risk assessment criteria based on scientific developments.
- To develop cost-effective and easy to implement policy recommendations for optimal risk management practices across food chains associated with different production processes taking into account labelling and nutrition issues as well as the identification of emerging risks.
- To provide mechanisms for active consumer participation in risk assessment and risk management processes.
- To develop cost-effective and easy to implement strategies for optimal risk communication throughout the whole process of risk analysis.
- To develop a New Risk Analysis Approach for foods that integrates consistent risk assessment of human quantitative and qualitative health aspects, consumer preferences and values, and analysis of socio-economic, aspects, informed by quantitative and qualitative research
- To contribute to an internationally accepted approach for risk analysis of foods.
- To systematically identify, where applicable, information relevant, to nutrition and labelling derived from WP1-5, and include this in the approach development.
- To actively make use of completed and currently on-going research carried out in related EU research and other programmes

### Co-ordinator

Partner 1, RIKILT

### Partners

1	RIKILT (Inst. Food Safety; NL)
2	SCRI (Scott. Crop Res. Inst.; UK)
10	NFC (Nat. Food Cent.; IRL)
17	NFA (Nat. Food Admin.; SE)
21	WU (Wageningen Univ.; NL)
24	DIA (D)
31	CEIS (Univ. Rome; I)
19	DFVF (Inst Food Saf. Toxicol.; DK)

### Contribution

Project co-ordination
Use of profiling methods for safety assessment
Early risk identification
New approaches in risk modelling
Consumer confidence in risk analysis practices
Changes in institutional role in risk management
Integration economic aspects in risk analysis
General risk assessment aspects

### Deliverables

- Review of current risk analysis approaches applied to foods produced by different practices in European and other countries.
- Report describing the integration of scientific, societal, and economic criteria for risk analysis and how the risk analysis process can be made more responsive to progress in science, and to changing societal norms and values. Besides safety issues, this will also cover labelling- and nutrition- issues, where applicable.
- Document describing responsibilities and conditions for active participation of the different stakeholders in the different elements of the risk analysis process.
- Report describing successful, cost-effective and easy to implement risk communication strategies with stakeholders.
- New Risk Analysis Approach for foods based on integration of scientific principles, consumer concerns and preferences, and societal values taking into account among others advances in scientific assessment tools, qualitative and quantitative, results of risk assessment, institution building, labelling- and nutrition-issues and systemic risk evaluation.
- Report with recommendations for application of the precautionary principle to the introduction of foods produced by different production practices.
- Report on how to assess and evaluate the societal and economical impact of the implementation of the new integrated risk analysis approach.
- Platform and workshops to evaluate the newly developed risk analysis Approach in collaboration with representatives of the various stakeholders groups

This Research Task will generate a new qualitative and quantitative approach for risk analysis of foods, produced by different production practises and different breeding technologies, taking at the same time new scientific developments, social and economical aspects into account when analysing the impact of risks and benefits of the introduction of foods in its broader sense. Stakeholders participation in the various steps of the risk analysis process will be worked out, as well as preferred changes in the role of regulatory institutions in the risk analysis process and strategies for risk communication with the different stakeholders.

### **6.1 Integration of results from Research Tasks 1-5**

The development of comparative, user-friendly and interoperable databases containing metabolite profiles of foods produced by different production practices and different breeding approaches, as performed in WP 1, provides the risk assessor with a more detailed insight in the composition of raw materials and foods and feed and inherent variations, defining the concept of 'history of safe use' of foods against a background of natural variations. Easy implement and cost –effective guidance will be given how profiling data should be interpreted with respect to impact on human health, addressing also nutrition aspects and possible consequences for labelling, and how these data could actually be used for risk assessment. The predictive power of the profiling approach and its limitations for risk assessment will be indicated, and in case of identified differences in composition profiles, strategies for further targeted toxicological assessment will be indicated. Experience built up in ENTRANSFOOD with GM foods, FOSIE, PASSCLAIM, and the Consumer Consensus Workshops will be used to further develop procedures for improved safety testing of whole foods. Results of WP 1 will be communicated to WP 4 and 5 in order to test consumer attitudes towards the use of new profiling methods for safety assessment, and in order to examine the consequences of insertion of these new technologies into risk assessment policies at the institutional level including labelling and nutrition aspects.

The design of working procedures in Europe in order to identify new emerging chemical and microbial risks in food production chains in an early phase as carried out in WP 2, addresses some of the consumers concerns regarding food safety assurance. Proposals will be developed on how to insert these activities into the risk analysis process on a regular basis, and how a permanent structure for risk identification can be build in the light of EFSA activities. In connection with WP 4 consumers perceptions of (new) risks will be analysed, and with WP 5 institutional integration of newly identified risks in the risk management process. Moreover attention will be paid to the socio-economical impact of newly identified risks.

The new probabilistic approaches for the assessment of cumulative effects of food contaminants and natural toxins taking actively into account the newly developed prevention strategies for natural toxins and other undesirable substances, as developed in WP 3, and the use of specialised databases on food contamination and food consumption will be examined for their suitability in the risk assessment process in particular with respect to identifying and estimating risks for vulnerable groups in the society. In co-operation with WP 4 and 5 uncertainties in risk assessment will be characterised, quantified, communicated, and evaluated for risk management purposes including labelling and nutritional aspects. This will yield further easy to implement and cost-effective guidance for the application of the precautionary principle. Furthermore qualitative and quantitative criteria will be developed for comparative risk assessment of mixtures of food contaminants and natural toxins taking actively into account the newly developed prevention strategies for natural toxins and other undesirable substances.

Research on consumer confidence/preferences for risk analysis practices associated with food safety as performed in WP 4, will be used to design a new risk analysis approach building upon the results of earlier EC-supported research activities such as TRUST IN FOOD, TRUST, Consumer Consensus Workshops. In particular, factors which are likely to develop and maintain consumer confidence in consumer protection activities, and effective communication strategies to the public and other stakeholders on risk uncertainty, high-risk groups within the population will be considered for inclusion in the new approach. Proposals for easy to implement and cost-effective

changes in the role and structures of regulatory institutions across Europe as developed in WP 5, will be brought into the new risk analysis approach, in order to accommodate the new requirements for risk management in the broad context of socio-economic consequences including labelling and nutrition aspects.

Partners SCRI, NFC, NFA, WU and DIA will deliver input based on the results obtained in the different WPs. Partners RIKILT, DFVF will concentrate on integration aspects.

## 6.2 Design of the new risk analysis approach

This research task concentrates on integrating the various elements of risk assessment, management and communication into a framework which based on up to date scientific developments, societal values and economical qualitative and quantitative criteria, characterised by a high level of active participation of stakeholders, and transparent communication.

Among the elements to be included in the risk analysis process are:

- Risk assessment policies; qualitative and quantitative criteria and easy to implement and cost-effective strategy development for risk assessment including nutritional aspects.
- Risk assessment; integration of new concepts for safety evaluation, taking progress in analytical, toxicological and molecular-biological sciences into account.
- Systemic risk evaluation; embedding the risk assessment of specific food safety issues into a broader socio-economical context.
- Risk management options; identification of options, uncertainty analysis, risk prioritisation, application of the Precautionary Principle and the role of regulatory institutions including labelling and nutritional aspects.

Among others the following questions will be addressed:

- What are current risk analysis approaches in Europe and other countries, including their strength/limitations?
- How should early identification and evaluation of emerging risks associated with food production in different food chains be included in the new risk analysis framework?
- How should scientific risk assessment policies be developed and who are the stakeholders?
- How should consistency in risk assessment of different food safety issues be accomplished?
- How will scientific developments (genome research, probabilistic modelling) be embedded in the risk assessment process?
- Can a functional separation between risk assessment and risk management be realised, *i.e.* to what extent should risk assessment/risk assessment policies be shaped by political, or socio-economical conditions?
- What is the role and responsibility of risk assessors, risk managers, regulatory institutes, consumers and other stakeholders in the various risk analysis elements and how do they interact
- How can transparency in risk analysis procedures for foods be accomplished
- How should communication be organised throughout the entire process of risk analysis
- What are the best ways of testing the validity and societal impact of the new approach
- How can the new approach be implemented at the pan-European level.

These and other relevant issues will be addressed by partners RIKILT, SCRI, NFC, NFA, WU, DIA, CEIS, DFVF while partners RIKILT, DFVF are in particular responsible for addressing overarching aspects and integration of the various elements for risk analysis.

## **Verification and implementation of the model**

The new proposed risk analysis framework will be tested by users. Representatives from regulatory bodies ( Different Commission Services (e.g. DG Health and Consumer Protection; DG Agriculture; DG Enterprise; etc.), FAO/WHO, OECD, etc.), Food Authorities (EFSA, National Food Authorities), scientific bodies (ICSU, ILSI Europe/USA, etc.), food industry (CIAA, etc.), and consumer organisations (BEUC, EUROCOOP, National, etc.) will be invited to participate in a Platform to evaluate the proposed new approach for risk analysis of foods with respect to scientific robustness, and societal and economical impact. For this purpose interviews and two interactive Workshops will be held. RIKILT and Wu will be responsible for the organisation of the Platform and Workshops. All partners will participate in interview activities, input in Workshops and in reporting.