European Food Safety Authority

Discussion Paper on preliminary results about "Prospective project on Quantitative Microbiological Risk Assesment at European Level"

NOTE FOR THE ADVISORY FORUM

Background

The General Food Law requires food legislation to be based on "risk analysis" except where this is not appropriate for the circumstances or the nature of the measure. There is no specific requirement on the nature of the risk assessment and regulations can be based on qualitative as well as quantitative assessments. Currently, opinions of the BIOHAZ panel are based on qualitative or semi-quantitative assessments. The panel aims to structure its opinions according to the established risk assessment framework, as initially defined by FAO, WHO and the Codex Alimentarius Commission, with four stages: hazard identification, hazard characterization, exposure assessment and risk characterization. Due to the qualitative nature of the reports, they can also be considered as risk profiles. The panel does not currently have the capacity to develop QMRAs due to a lack of resources and time. The panel could peer-review reports on QMRA and base conclusions and recommendations on such reports.

EFSA Initiatives

1. In September 2004, EFSA launched a project tender to formulate a strategy for Quantitative Microbiological Risk Assessment (QMRA) at European level. The project will be finalised by May 2005. Several European experts expressed their interest in providing a proposal for a strategy. Following the appropriate selection procedures the project was awarded to Dr Arie Havelaar from RIVM (The Netherlands).

   The task was defined by EFSA as the elaboration and structuring, together with relevant EFSA staff, of:
   a. a strategy on how to address the QMRA at the European level,
   b. the specification of EFSA's role in this activity,
   c. the assessment of the resources needed to set up the activity within EFSA.

   The project awarded consists of several phases:

   Phase 1. Exploring the options
   In this phase, the needs for QMRA at the European level were to be explored, with specific emphasis on the position of EFSA, the available resources (expertise, data) in Europe and the organization of QMRA outside Europe. The key questions to be answered in this phase were:

What are EFSA's mission and tasks in QMRA and how do they support the broader goals of EFSA?

- What is expected of EFSA's QMRA activities by:
  a. The European Commission
  b. The European Parliament
  c. The Member States?

- What resources for QMRA are available at the European and national level, and how are they organized? Under which conditions are they available? Here the term resources is used in the dual sense of professional expertise and availability of data and (modules of) QMRA models.

- What lessons can be learned from experiences outside Europe?

For this purpose, enquiries were sent to the major clients and resources of EFSA and interviews were held with representatives from the European Commission, DG SANCO and the US Food and Drug Administration.

Phase 2. Defining strategies
The collected information will be used to define options for strategies for implementation of co-ordinated QMRA at the European level and EFSA's position therein. The support for each strategy will be assessed, and strengths and weaknesses will be defined. Attention will also be given to potential pitfalls when implementing these strategies.

Phase 3. Making recommendations
Based on the information collected in phases 1 and 2, recommendations for a preferred strategy will be made. The necessary resources for this strategy will be defined in more detail, focusing on the roles of EFSA's Science Department, the Scientific Committee and the BIOHAZ Panel and the interaction with specialized institutes at the national level in Member States. Recommendations will also be made on the collection of data to support QMRA and the organization of these data at an international level. Strengths and weaknesses of the recommended strategy will be described, based on consultation of the Chair and Vice-chairs of the BIOHAZ panel, DG SANCO (Interface Unit) and scientists from different countries with QMRA experience.

2. Preliminary results of Phase I of the project (**Exploring the options**) are presented below.

In order to support the formulation of a strategy, information was sought on what is expected from EFSA's QMRA activities by the European Commission, the Member States and European scientists by circulation of a questionnaire.

The European Commission was represented by DG SANCO (Interface, Health Threats, Biological Risks and Animal Health Units). The Member States were represented by the members of EFSA's Advisory Forum and the Chief Veterinary Officers. European scientists were represented by the members of the BIOHAZ panel and the WHO European Centre for Environment and Health (Rome, Italy). Addressees were encouraged to

advance a copy of the questionnaire to other interested parties if considered appropriate. In total 97 questionnaires were sent and 44 answers (45%) were received.

Summary of responses to questionnaire on the need for QMRA at the European level

	European Commission	Member States	Scientists*
Number of completed questionnaires	1	28	15
QMRA is considered necessary at the European level	1	27	15
Do you consider QMRA to be#			
..- well developed		1	4
- a promising development	1	24	10
- unsure of its use			5
- not useful			
Who should conduct QMRA			
- EFSA	1	25	13
- National Food Safety Authorities		11	7
- National Research Institutes		13	7
- Universities		8	7
- WHO/FAO		12	1
Should EFSA invest in			
- a European network for QMRA	1	23	11
- harmonization of QMRA	1	23	8
- do actual modeling	1	13	6
- develop and manage databases	1	26	11
- develop new methods for QMRA	1	13	5
Should QMRAs at the national level be coordinated by EFSA	-	14	3
Should economic analysis be included in the scientific advice by EFSA	-	19	5
Who should be involved in peer review			
-EFSA		12	6
- National Food Safety Authorities	1	15	4
- National Research Institutes		16	5
- Individual scientists	1	17	13
- Supranational organisations (such as WHO, FAO)		18	1

* 13 BIOHAZ, 2 other

Some respondents ticked more than one box

- All respondents except one Member State agreed that QMRA is necessary at the European level.
- One Member State indicated that the differences between European countries were so large that the national level was considered most appropriate for QMRA.
- Almost all Member States considered QMRA to be a promising development.
- Most Member States and scientists see a role for EFSA in conducting QMRAs at the European level with varied opinions about the involvement of other parties. Scientists

see a more important role for universities and a less important role for FAO/WHO than Member States.

- Respondents and Member States in particular, clearly see three important tasks for EFSA:
  - creating a network of European institutes for QMRA,
  - harmonising QMRA and
  - developing and managing databases.

- There is not much support for coordination of national QMRA projects by EFSA but it was frequently mentioned that EFSA should base its work on existing national QMRAs, and could develop a clearing house for such studies. Furthermore, EFSA could provide a mechanism for Member States to peer-review their national QMRA studies, and to promote the resolution of conflicting conclusions between such studies.
- Furthermore, most respondents (Member States and scientists alike) expected 1-2 questions per year that would benefit from full farm-to-fork QMRA at the European level but other frequencies ranging from 0 to >5 questions per year were also mentioned frequently. QMRA studies of specific stages of the food chain were anticipated more frequently.

There were many expected *benefits* from QMRA at the European level. Some of these benefits are common to all quantitative assessments; others are particular for the European dimension considered in this report. Sometimes, food safety questions cannot be reduced to whether pathogens are present or are not, but the level of occurrence has to be taken into account.

- Many respondents expected a more solid basis for common and more objective, science-based criteria for food safety across Europe.
- QMRA at a European level would strengthen the position of the EU in the Codex Alimentarius Commission and in the World Trade Organization. The quantitative analyses would also support national food safety risk management and help to evaluate the possibilities of different risk mitigation options that might be used by different Member States to reach common targets.
- The increased transparency of a quantitative approach was expected to improve risk communication between professionals and to help building trust among stakeholders. A European approach was also recommended because it enables the sharing and optimal use of available data and resources. This would be more efficient, and avoid duplication of work between Member States.
- Less experienced countries expected a European approach to be helpful in building up their capacities for risk based food safety management and stressed the need for the promotion and development of harmonised models and databases. A possibility of improved financing at the Community level was also mentioned.
- Ultimately, QMRA may lead to a more transparent, systematic and efficient risk management process including improved risk communication, resulting in reduced consumer exposure to microbial hazards.

The respondents also identified several *drawbacks* of QMRA at the European level:

- A concern shared by many was the problem to account for regional differences. QMRA may be too general, overemphasizing similarities, and

deemphasizing the risks of local foods, the importance of regional consumption habits, differences in pathogen occurrence etc.

- It was frequently mentioned that QMRA is a time and resource intensive activity to which many Member States cannot yet contribute.
- There is a risk of duplication of other international work, e.g. by FAO/WHO and in the United States, Canada etc.
- Data quality and data availability including the current lack of data quality control were repeatedly mentioned as obstacles for QMRA. Specifically, the poor availability of dose-response data was considered to be a problem.
- It was emphasised that risk managers need training in order to become aware of the potential benefits of QMRA, to be able to ask the right questions and to interpret the results of QMRA.
- The increased transparency that QMRA may evoke was also considered problematic by some: differences between Member States may become too obvious and a common ALOP for all Member States may not be realistic as they differ in their abilities to adopt certain measures. This might result in the assessment to become politicized and to invoke a conflict of interest.

Many *recommendations* to facilitate the introduction of QMRA at a European level were made. A critical review of the current success of QMRA could reveal its potential to improve decision making.
EFSA was strongly advised to define its strategy with respect to QMRA with high priority because other international and national bodies have already been active in this field for several years. EFSA should assure sufficient funding and support for teams of scientists involved in the risk assessments and should provide well defined questions to these teams, while assuring open communications with all relevant stakeholders.
When presented with the preliminary results of this enquiry, the BIOHAZ panel (in its meeting of 27 January 2005) confirmed the need for the development of quantitative approaches at the European level, but also indicated the complexity of the task.

Way forward

In the coming weeks the report will be finalized identifying the advantages and disadvantages of possible strategies, and recommendations will be made for a preferred strategy on QMRA at European level.