



World Health
Organization



International Food Safety Authorities Network (INFOSAN)

4 September 2007

INFOSAN Information Note No. 05/2007 - Microbiological Risk Assessments

USE OF MICROBIOLOGICAL RISK ASSESSMENTS IN RISK MANAGEMENT

SUMMARY NOTES

- In recent years, a number of microbiological risk assessments (MRAs) have been undertaken at both national and international level. MRA provides the means to link food control measures to the actual impact on the health of the consumer. As food safety management moves towards a risk-based approach there is a strong desire to use such tools. However, risk managers have difficulties in making the best use of them in elaborating risk-based interventions.
- This note summarizes new guidance from FAO and WHO in this area and addresses:
 - The role of MRA in food safety risk management.
 - The establishment of public health goals and using quantitative microbiological targets to achieve them.
 - The impact of the choice of MRA type on management options.
 - Future directions in this area.

Introduction

In recent years “risk-based” approaches, based on the best available scientific information, have been recognized as a means of enhancing the ability of food safety risk management to meet its primary goal of protecting public health, as well as ensuring access to an adequate food supply and facilitating trade. Such an approach implies that actions, regulations, guidelines and standards are constructed and formulated according to specific knowledge of “risks” to life and health. The practical aspects of developing and implementing a “risk-based” standard introduce new challenges.

Microbiological risk assessment (MRA) is now well recognized as a risk management decision-support tool. When properly designed, an MRA is an objective, systematic evaluation of relevant scientific knowledge to help the risk manager make an informed decision about how to reduce the risk posed by a food safety issue. It is a particularly useful tool in enabling the risk manager to consider and compare risk management options and derive efficient food safety control measures. Together with other tools, for example epidemiology based tools and economic analysis, it can provide a sound scientific foundation for “risk-based” management systems and control measures.

In 1999 the Codex Committee for Food Hygiene (CCFH) adopted the *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*¹. Since then, FAO and WHO have jointly developed a range of pathogen:commodity microbiological risk assessments². In addition, microbiological risk assessments (MRAs) have been undertaken at national level. In order to facilitate the use of these MRAs and their outputs FAO and WHO have convened several expert meetings to provide additional guidance on the interaction between assessors and managers of microbiological hazards³ and incorporation of microbiological risk assessment in the development of food safety standards⁴.

Much progress has been made, particularly in the elaboration of risk assessments and defining those risk management areas which would benefit from MRA. Yet the uptake of the MRA outputs is still limited and often a clear understanding on how to use MRA in elaborating risk management decisions has proven difficult. On the other hand, over the last two years there has been particular focus at the international level on the use of MRA to establish and/or implement quantitative risk-based microbiological targets. Targets are measures of frequency or concentration of a microorganism in a commodity (e.g. % of chickens infected with *Salmonella* or concentration of *Salmonella* in 100g of chicken). Such targets can be used to relate a public health goal (e.g. a 50% reduction in cases of Salmonellosis from chicken) with the degree of stringency of the food safety measures to be employed (e.g. recall of all consignments of chicken with a higher frequency of salmonella than 5%). The need to effectively and efficiently use MRA to lower disease burden has highlighted the need to revisit this area in more detail and look at the experiences in countries and regions that are using MRA, with the objective of developing practical guidance.

In April 2006, FAO and WHO organized an Expert Meeting on the Development of Practical Risk Management Strategies Based on Microbiological Risk Assessment Outputs⁵. This INFOSAN Information Note summarizes and presents the main outcomes of this meeting.

Role of MRA in Food Safety Management

MRA is a tool that can be used in isolation or combined with others such as epidemiology based tools (e.g. source attribution, attributing disease to food source through typing methods) and economic analysis. The role of MRA in food safety risk management is varied and the way in which an MRA is developed should directly relate to the needs of risk managers, as far as possible according to data or resource limitations. Taking this into consideration FAO/WHO is investigating the role of MRA in the development of quantitative risk-based microbiological targets or *metrics*.

Public Health Goals and Quantitative Targets (Metrics)

Public health goals are set to inspire action to improve the public health status and reduce disease burden. In doing so, the goals should take into consideration feasibility of available control measures to achieve the goal. Goals are usually set by government with a varying degree of input from stakeholders. When a public health goal is established as a risk reduction target, a well designed MRA can establish the magnitude of risk reduction that would need to be achieved by changes in control measures in order for the public health goal to become the Appropriate Level of Protection (ALOP). For example, to achieve the goal of reducing Salmonellosis' incidence from chicken from 50 per 100 000 consumers per year to 10 per 100 000 consumers per year, you would need to reduce the frequency of *Salmonella* in chicken down to 20% of previous level⁶. In this example, 10 per 100 000 consumers per year would be the Appropriate Level of Protection decided by the country in question. Typically, different scenarios of choices of control measures are considered during an MRA and a range of associated risk outcomes calculated.

An important aspect of the establishment of quantitative risk-based microbiological targets or metrics is the possibility to link them to public health outcomes and in that way be able to illustrate the relationship between control measures and the ALOP and/or public health goals. The establishment or definition of public health goals can be facilitated using epidemiology based tools which can provide the means to assess the current burden of illness and conduct source attribution studies.

The Codex Alimentarius Commission has defined risk-based microbiological targets, namely Food Safety Objectives (FSO), Performance Objectives (PO) and Performance Criteria (PC) (see text box for definitions). These targets are suggested as intermediate targets to communicate in an explicit way to the affected food industry the limits required at specific points in food supply chains to achieve a specified public health goal or level of protection.

While an FSO may be used as a metric for translating control measures into public health outcomes, PO and PC are more likely to be the metrics used for establishing the stringency of a food safety system. An important reason for this is that PO and PC can be utilized at points in the food supply chain where control measures can be implemented and verified, through the implementation of appropriate microbiological criteria, processing criteria and product criteria.

Three new “intermediate” targets are defined by Codex (Procedural manual, 16th ed.)⁷, as follows:

- Food Safety Objective (FSO): The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).
- Performance Objective (PO): The maximum frequency and/or concentration of a hazard in a food at a specified step in the food-chain before the time of consumption that provides or contributes to an FSO or ALOP, as applicable.
- Performance Criterion (PC): The effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO.

As well as linking food safety performance to explicit public health goals this approach contributes to better compliance in food safety control, enabling proper verification through applying metrics.

Impact of the Choice of Risk Assessment type

MRA can provide valuable information about the complex dynamics of pathogen behaviour and transmission along the food-chain. A well designed risk assessment provides the means to evaluate and compare the effects of different control measures on public health risk to consumers (i.e., risk per servings) or risk to a country (i.e., risk per annum) on an industry wide basis. This *direct* application of MRA has been demonstrated by a number of risk assessments at both the national and international level and is widely recognized as one of the strengths of MRA.

In the establishment of quantitative targets the type of MRA that is used to quantify the relationship between exposure through consumption of contaminated food and its health impact (illness) is an important choice. MRAs may be qualitative or quantitative in nature, so it is necessary to consider how the type of MRA will impact the way it is used in risk management. Different types of quantitative microbiological risk assessment (QMRA) can be applied: deterministic or probabilistic. *Deterministic risk assessment*, based on single value inputs and outputs, provides a relatively straightforward means of using MRA to develop metrics. However this comes at a cost in providing less accurate information, e.g. limited insights into uncertainty and a tendency to focus on extreme situations such as worst-case scenarios. *Probabilistic risk assessment* provides the means to overcome these disadvantages and in principle offers the best opportunity for operationalizing intermediate targets. The inputs and outputs of the probabilistic approach are a distribution of values, and this poses a challenge of how to express the outcome as a metric to be achieved by appropriate control measures. Work is ongoing to better elucidate how each of the above risk assessment approaches may be used to establish quantitative targets.

Stringency of Food Safety Systems and Role of Compliance

Risk management does not end with the selection of appropriate control measures. It must be followed-up with monitoring activities to determine the level of compliance. The effectiveness of a particular control measure can be highly influenced by the level of compliance with that measure. Too high a level of stringency may reduce the level of compliance, whereas a very high degree of compliance may be achieved with something slightly less stringent. For example, some countries have experienced that demanding total absence of a pathogen in certain foods, where low levels of such pathogens do not cause disease, can give a lower level of industry compliance than selecting a specific (low) limit of accepted concentration (e.g. 10/g). In this way, in special cases, the final public health outcome could be better with a less stringent - but still safe - limit. MRA allows

consideration and comparison of such scenarios to facilitate the selection of the most appropriate risk management option.

Future Work: the way forward

- Microbiological risk assessment, as well as other tools, including those based on epidemiology and economic analysis, have a valuable role to play in food safety risk management. Such tools are considered highly desirable as a means of establishing a quantitative relationship between exposure through consumption of contaminated food intake and its health impact. Making tools more widely available with user friendly interfaces, such as the web-based risk assessment tool on *Enterobacter sakazakii*^{8,9} in powdered infant formula currently under development by FAO and WHO, is an important part of the efforts to facilitate the use of MRA by risk managers.
- MRA already provides the means to directly evaluate the efficacy of control measures and their impact on public health and can already be used by risk managers in the management of certain food safety issues.
- The use of intermediate targets, which link actual control measures to the level of public health protection, is considered an important development in the evolution of food safety risk management systems. Therefore, FAO and WHO are continuing work to address the technical aspects of using MRA to establish these intermediate targets and ultimately provide practical guidance in this area.

References

- 1 Codex Alimentarius Commission. Principles and Guidelines for the Conduct of Microbiological Risk Assessment. CAC/GL-30 (1999)
http://www.codexalimentarius.net/download/standards/357/CXG_030e.pdf
- 2 FAO and WHO Microbiological Risk Assessments are available at:
http://www.fao.org/ag/aqn/agns/jemra_riskassessment_en.asp and
<http://www.who.int/foodsafety/micro/jemra/assessment/en>
3. FAO, WHO. The interaction between assessors and managers of microbiological hazards in food. Report of a WHO expert consultation, (2000).
<http://www.who.int/foodsafety/publications/micro/march2000/en>
4. FAO, WHO. Principles and guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts, Report of a Joint FAO/WHO Consultation, (2002).
<http://www.who.int/foodsafety/publications/micro/march2002/en>
5. FAO, WHO. Development of practical risk management strategies based on microbiological risk assessment outputs. Report of a Joint FAO/WHO Consultation, (2006).
<http://www.who.int/foodsafety/micro/jemra/meetings/2005/en>
6. FAO, WHO. Risk Assessment of *Salmonella* in eggs and broiler chickens. Microbiological Risk Assessment Series, No. 2. (2002)
<http://www.who.int/foodsafety/publications/micro/salmonella/en>
7. Codex Alimentarius Commission. Procedural Manual. 16th edition,
ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_16e.pdf
8. FAO, WHO. *Enterobacter sakazakii* and other microorganisms in powdered infant formula. Meeting Report. Microbiological Risk Assessment Series, No. 6, (2004)
<http://www.who.int/foodsafety/publications/micro/mra6/en>
9. FAO, WHO. *Enterobacter sakazakii* and *Salmonella* in powdered infant formula: Meeting report, Microbiological Risk Assessment Series No.10 (2006).
<http://www.who.int/foodsafety/publications/micro/mra10/en>

Additional Resources

10. FAO, WHO. Food safety risk analysis - A guide for national food safety authorities (2006)
<http://www.who.int/foodsafety/publications/micro/riskanalysis06/en>

11. Codex Alimentarius Commission. Draft Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM) (2006)
http://www.codexalimentarius.net/download/report/671/al30_13e.pdf (Appendix 4).

INFOSAN serves as a vehicle for food safety authorities and other relevant agencies to exchange food safety information and to improve collaboration among food safety authorities at both the national and international level.

INFOSAN Emergency, embedded in INFOSAN, links official national contact points to address outbreaks and emergencies of international importance and allows for the rapid exchange of information. INFOSAN Emergency is intended to complement and support the existing WHO Global Outbreak Alert and Response Network (GOARN).

INFOSAN is operated/managed by WHO, Geneva. It currently includes 161 Member States.

More information is available at: www.who.int/foodsafety