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Principles of food safety Risk management

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Abstract

The FAO/WHO preliminary Risk management framework and principles are described and discussed. The importance of emerging problems with food-borne pathogenic microorganisms is stressed, as is the importance of development of international co-operation based upon agreed principles in this area. It is argued that Risk management information should move as freely over the borders as food itself. The concept of "target risk levels" is introduced, reflecting the dynamic nature of food-borne microbial disease risk. Target risk levels should be set primarily in relation to the incidence of human disease; however, in a number of cases Risk management initiatives will only indirectly relate to human disease and the primary initiatives will centre around the definition of tolerable hazard levels in the food. The food safety objectives defined as part of the Risk management process should be used to govern HACCP as an outcome definition, and additionally some of the information generated as part of the Risk management process can be used in the HACCP systems, notably in the hazard analysis step of HACCP.

1. Introduction

Risk analysis comprises Risk assessment, Risk management and Risk communication (FAO/WHO, 1995). Risk can be defined as "a function of the probability of an adverse effect and the magnitude of that effect, consequential to a hazard(s) in food" (FAO/WHO, 1995). The word management stems from the Italian verb *maneggiare*, meaning to ride a horse with skill, and in contrast to the confusion of the use and meaning of some of the other words of the Risk analysis realm, the perception of this concept is generally straight forward. In Codex alimentarius terminology Risk management is the process of weighing policy alternatives in the light of the results of Risk assessment and, if required, selecting and implementing appropriate control options, including regulatory measures (FAO/WHO, 1996).

In the last decade different regulatory areas have acknowledged the need to assess and manage microbiological risks on the basis of scientific approaches. Internationally, the Risk assessment framework in the area of genetically modified microorganisms was primarily initiated through OECD work in the mid-eighties (OECD, 1986). These principles were later elaborated and formalised in EC Directives 90/219/EEC and 90/220/EEC. Likewise the regulation of microbial pesticides in the EC is governed by a Directive 91/414/EEC, where microbial Risk assessment plays a major role.

Over the last 10–15 years the diseases and the disease prevalences related to food-borne pathogens have changed considerably. In the post-war era general hygienic principles in food production were developed and for a long period the level of hygiene was thought to match and control the food-borne pathogens. However, in the 1980s and 1990s emerging pathogens have caused new and increasing problems all over the world (WHO, 1995; Tauxe, 1997). Examples of these pathogens are *Salmonella*, *Campylobacter*, *Yersinia*, Enterohemorrhagic *E. coli* (EHEC) and *Listeria* monocytogenes.

The causes behind the new problems have not been elucidated so as to be able to pin-point solutions to the control. New production systems in the primary production as well as in the manufacturing sector are likely to have had an influence. Other changes in the food production chain from farm to table, including changes in kitchen habits at the consumer level have also been mentioned in this context. Generally, it should be kept in mind that the significant increase in international food (and production animal) trade will probably increase these problems in the future. The spread of antibiotic resistant *Salmonella* strains and the (global) increase in *Salmonella enteritidis* in poultry and eggs are probable examples.

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The new international trade agreements: World Trade Organisation (WTO) puts emphasis on scientifical Risk analysis and the WTO SPS agreement (Article 2, paragraph 2) establishes that sanitary measures should be based on scientific principles and should not be maintained without sufficient scientific evidence.

Risk analysis should be used to enhance protection of human health and minimise the incidence of food-borne disease through establishing realistic and achievable levels of control of food-borne hazards, and basing food safety policies on the practical application of the results of Risk assessment and Risk management.

2. Risk management

According to the outcome of the FAO/WHO Expert Consultation on the Application of Risk Management to Food Safety Matters, Risk management should be governed by the following principles (FAO/WHO, 1997):

- Risk management should follow a structured approach
- the protection of human health should be the primary consideration
- decisions and practices should be transparent
- Risk assessment policy determination should be a specific component
- the functional separation of Risk management and Risk assessment should be maintained in order to ensure the scientific integrity of the Risk assessment process
- decisions should take into account the uncertainty in the output of the Risk assessment
- Risk management should include clear, interactive communication with consumers and other interested parties in all aspects of the process
- Risk management should be a continuing process taking into account all newly generated data in the evaluation and review of management decisions

Risk management comprises four steps (FAO/WHO, 1997):

1. Risk evaluation,
2. Risk management option assessment,
3. implementation of management decision, and
4. monitoring and review.

Risk evaluation comprises:

- identification of a food safety problem,
- establishment of a risk profile, i.e. a description of the situation, product or commodity involved, the values expected to be placed at risk such as human health or economic concerns, the potential consequences, the consumer perception of the risks, and the distribution of risks and benefits,
- ranking of the hazard for Risk assessment and Risk management priority,
- establishment of Risk assessment policy for conduct of Risk assessment, setting guidelines for value judgements and policy choices which may need to be applied at specific decision points in the Risk assessment process,
- commissioning of Risk assessment,
- consideration of the result of Risk assessment.

Risk management option assessment includes:

- identification of available management options,
- selection of preferred management option, including consideration of an appropriate safety standard , such as "zero-risk" standards (usually implicit in ADI levels), "balancing" standards (cost-benefit or As Low As Reasonably Achievable) or "threshold" standards (acceptable level of risk established),
- final management decision.

Implementation of management decision is a self-explanatory stage.

Monitoring and review comprises:

- assessment of effectiveness of the measures taken,
- the review of Risk management and/or Risk assessment as necessary.

The outcome of the risk evaluation process combined with an evaluation of management options should result in a decision on the management of the risk. In arriving at this decision, human health protection should be the primary consideration, with other factors (costs, feasibility, risk perception, etc.) being considered as appropriate. The implementation of the management decision should be followed by monitoring the effectiveness of the control measure relative to its impact on risk to the exposed consumer population.

All interested parties (stakeholders), likely to be affected by the risk or the outcome of the Risk management process, should have an opportunity for input into the Risk management process. Such groups may include (but should not be limited to): regulatory bodies (normally initiators of the process), consumer organisations, representatives of the agricultural and food industry, and representatives of education and research institutions. Input from interested parties can be introduced and considered at every stage of the Risk management policy formulation process, including evaluation and review.

3. The use of risk estimates and reduction in risk levels

The initial part of the Risk management process sets the stage for a Risk assessment, which should result in a *risk estimate*. Risk estimates should be related to time,

i.e. the estimates will change over time as a consequence of changes in level of the hazard in the food, consumer habits etc. In arriving at risk estimates it should be remembered that food-borne disease data are often outbreak data. Nevertheless for many food-borne hazards the majority of disease cases are single (sporadic) cases. It could be argued that for *Salmonella*, *Campylobacter*, *Yersinia*, and probably EHEC the number of sporadic cases reflects the base-line prevalence of the hazard in the primary food chain more accurately than outbreak data. Outbreaks, on the other hand, in general tend to be a consequence of hygienic breakdown at some point of the chain. It is not prudent to base Risk management decisions upon outbreak data alone, and certainly risk estimates should always include both the sporadic and the outbreak fraction of human cases.

The information from the Risk assessment combined with the general food safety objectives for the society at risk will form part of the basis for Risk management decisions, the other part relating to the practical situation, i.e. the management options.

The risk estimate represents the actual risk level, which can be higher or lower than the acceptable risk level. If the actual level is higher than the acceptable risk level, Risk management decisions are necessary to define initiatives to reach the *target risk level.* The use of the word "target risk level" reflects the dynamic nature of food-borne microbial disease risk. Target risk levels should be set primarily in relation to the incidence of human disease, since the risk concept inherently relates to human disease. However, in a number of cases Risk management initiatives will only indirectly relate to data on human disease and the primary initiatives will centre around the definition of tolerable hazard levels in the food.

The determination of acceptable levels of risk depends not only upon the hazard and risk situation, but also upon a number of socio-economic and technological factors. According to these factors the best management option could be:

- control at the source,
- action plans in the production level,
- introduction of general hygiene measures,
- introduction of specific production control measures (HACCP?),
- mandatory criteria in the final product,
- consumer education or a combination of these.

4. Risk management at the national and international level

Whereas Risk management activities at international level (Codex alimentarius) are not likely to include implementation, monitoring and review, Risk management at national level will normally include all elements.

The outcome of the Risk management process for a specific hazard will differ in various societies, due to natural or cultural differences. These differences could be due to societal values, but they could also represent different exposure situations in different countries and as such could be scientifically justified.

By internationally adopting general principles of Risk management and Risk assessment, the basic data to govern food safety policies will be comparable between countries and a potential process of policy harmonisation will have a sound foundation. This will hopefully lead to a situation in the near future where food-borne hazards can be efficiently controlled also at the international level.

Therefore *Risk management information should move as freely over the borders as food itself*, and Risk management experience from one country should ideally be applicable in another. A network ensuring the open distribution of Risk assessment and Risk management data relating to microbiological food safety to all parts of the world should be initiated, preferably as a FAO/WHO initiative.

Differences in the prevalence of various food-borne pathogens in the food chain do exist between regions. Region to region variation in food-borne disease patterns emphasises this. These differences may be "natural" or may be a result of active and extensive control programmes. Examples of the latter include cysticercosis/taeniasis in cattle, trichinosis in swine, brucellosis in ruminants, salmonellosis in various species, and campylobacteriosis in poultry, which have been eradicated or the prevalence of which has been significantly reduced in some countries. For the protection of human health, it is important that these low prevalences of zoonotic pathogens in the food chain can be maintained.

Because significant differences in the prevalence of food-borne pathogens can be found between different regions, food safety objectives in general and more specifically sampling plans, criteria etc. should not always be considered universally common, but should reflect relevant and significant regional differences. Additionally regional differences in socio-economic and technological factors, including cost-benefit considerations, will underline the necessity to accept the concept of "regionality" in Risk management strategies. The concept of regionality is discussed by Kruse (1999).

5. Risk management and HACCP

Trends in national food safety initiatives show a paradigm shift, moving away from "vertical" detailed legislation, placing more emphasis on Risk analysis and "horizontal" general rulings. The importance of co-operation between different public health and food safety authorities is now emphasised in many countries, and

the concept of a total overview of the problems "from farm to table" is taking over. The legalised introduction of HACCP in many countries should be seen in this light.

In general, Risk management decisions can influence all other hygiene initiatives. Information generated as part of the Risk management process can be used in the design of HACCP systems, notably some of the Risk assessment information can be used as part of the input into the hazard analysis step of HACCP, as can the establishment of food safety objectives.

The concept of general hygiene rules combined with specific control of critical points along the total chain of food production from farm to table will constitute important parts of most Risk management initiatives in the future.

References

FAO/WHO (1995). Application of risk analysis to food standards issues. Report of the joint FAO/WHO expert consultation. Geneva, Switzerland, 13–17 March 1995. WHO: Geneva.

FAO/WHO (1996). Report of the 12th session of the Codex Committee on general principles. Paris, France 25–28 November 1996, Codex Alimentarius Commission. Rome: FAO.

FAO/WHO (1997). Application of risk management to food safety matters. Report of the joint FAO/WHO expert consultation. Rome, Italy, 27–31 January 1997. Rome: FAO.

Kruse, H. (1999). Special regional requirements: future concerns. *Food Control* 10 (4–5) 315–320.

OECD (1986). Recombinant DNA safety considerations. Paris: OECD.

Tauxe, R. V. (1997). Emerging food-borne diseases: An evolving public health challenge. *Emerging Infectious Diseases* 3 (4) 425–434.

WHO (1995). Report of the WHO consultation on emerging food-borne diseases, Berlin, 20–24 March 1995. Geneva: WHO.