

FOOD SAFETY OBJECTIVES – ROLE IN MICROBIOLOGICAL FOOD SAFETY MANAGEMENT



Summary report of a Workshop held in April 2003

Organised by the ILSI Europe Risk Analysis
in Microbiology Task Force in collaboration
with the International Commission on Micro-
biological Specifications for Foods (ICMSF)



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ROLE IN MICROBIOLOGICAL
FOOD SAFETY MANAGEMENT***

BY MIKE STRINGER

**SUMMARY REPORT OF A WORKSHOP HELD IN APRIL 2003 IN MARSEILLE, FRANCE
ORGANISED BY THE ILSI EUROPE RISK ANALYSIS IN MICROBIOLOGY TASK FORCE
IN COLLABORATION WITH THE INTERNATIONAL COMMISSION ON
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FOREWORD

With the increasing international trade in food and the fact that manufacturing sites in one country may provide raw materials to other manufacturers or finished goods (products) for large numbers of consumers living in importing countries, it is critically important that there be a harmonisation of food safety control procedures. The World Trade Organization (WTO) has been a central force in stimulating the concept of *equivalence*, introduced in the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures (WTO, 1995). In this agreement, and in case of differences, each WTO member must accept the sanitary measures of other members as equivalent to their own measures, provided they offer the same level of protection. In 2003, the Codex Alimentarius Commission adopted the Guidelines for the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems (CAC, 2003a). In 2002, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) held a joint consultation meeting in Kiel to explore the principles and to establish guidelines for incorporating microbiological risk assessment in the development of food safety standards, guidelines and related texts. In this consultation, concepts such as *appropriate level of protection* and *food safety objectives* were discussed in detail. Codex Alimentarius, under the auspices of FAO and WHO, is drafting guidelines for microbiological risk management, in which it is expected that these concepts will be laid down.

In recent years, considerable advances have been made in establishing procedures for enhancing the management of microbiological food safety, and ILSI and the International Commission on Microbiological Specifications for Foods (ICMSF) have played a significant role in this process. The ICMSF recently published a volume in which it discussed the introduction of FSOs in food safety management as a means to translate “risk” into definable goals for operational food safety management systems and provided a number of working examples for illustration (ICMSF, 2002).

In 1998, ILSI Europe published its report on food safety management tools, which sought to describe how the tools available at the time interacted with each other. This included the use of hazard analysis and critical control point (HACCP), as described in ILSI Europe’s concise monograph on the subject (1997; currently under revision). The validation and verification of HACCP was the subject of another report published by ILSI Europe in 1999. In 1993, ILSI Europe convened a workshop on the “Minimum Infective Dose”, an attempt to capture current views on the subject with respect to its use in developing risk control procedures (ILSI Europe, 1995). In 1999, ILSI Europe organised a workshop entitled “Microbiological Risk Assessment,” which was held at Food Micro ‘99 in the Netherlands; the proceedings were published in 2000 as a special issue of the *International Journal of Food Microbiology*.

This report summarises the results of a joint ILSI Europe/ICMSF workshop, “Impact of Food Safety Objectives on Microbiological Food Safety Management”, held in Marseille, 9–11 April 2003, to consider the potential impact of the new concept of food safety objectives on existing microbiological food safety management procedures.

EXECUTIVE SUMMARY

The management of the microbiological safety of food has become increasingly important for a number of reasons, including the following:

- The increasing globalisation of the food supply chain
- A consumer population that is far more knowledgeable and discerning on issues associated with the food production chain and particularly those related to food safety
- Highly sophisticated innovations in product development, which have come to rely increasingly on adherence to strict product and process controls.

Indeed, in many areas of the food chain, microbiological safety is the major risk concern, which has led to a much greater focus on public health and methods for establishing clear health targets. Given the difficulty of using public health goals such as an appropriate level of protection (ALOP) to establish control measures, the concept of food safety objectives (FSOs) was introduced to provide meaningful guidance to food safety management in practice. It is evident that specific targets need to be selected in the food chain that can be linked directly to improvements in public health, such that public health goals begin to drive the performance requirements of the food safety management chain. Currently, such links do not exist, and guidance is provided by “compliance levels” or “acceptance criteria” in the form of standards, guidelines or specifications. It is important to demonstrate the relationship between food safety management practices and national public health goals and that this relationship is transparent throughout the international trading chain.

While scientists involved in the International Commission on Microbiological Specifications for Foods (ICMSF), the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO) and Codex have been able to participate in or follow the evolving debate on the development and application of ALOPs and FSOs, the wider scientific community has had little exposure to these concepts. This workshop provided the first opportunity for a cross-section of food safety management professionals to consider the issues in depth.

Workshop participants agreed unanimously that the linkage between food safety management practice and defined public health goals provided by the ALOP/FSO concept was both laudable and desirable. However, in considering the impact of the integration of the concept with current food safety management tools, considerable confusion was apparent in the use of terminology, particularly for performance criteria, performance standards and targets. In addition, while it was recognised that an FSO should exist at or close to the point of consumption, a case was made for also considering an FSO at the point of purchase for foods requiring a degree of consumer handling and preparation.

It is important that an authoritative international body such as Codex provides unambiguous guidance on the recommendation for use of the ALOP/FSO concept in practice. Indeed, the Codex Committee on Food Hygiene is currently discussing principles and guidelines for the conduct of microbiological risk management.

It is also timely for renewed thought on international collaboration in the collection of microbiological data. Guidelines should be developed on the type and format of data, such that data provided for microbiological risk assessment and the subsequent development of ALOPs and FSOs lead to sound and objective policy decisions. It is critical that FSOs be achievable by current good industrial* and consumer practices, and as we inevitably seek to improve standards of public health protection, industry must be able to meet such standards in commercial practice. This process will present a fresh challenge to the way science, government and industry interact in the future.

**In this document, industrial refers to practices throughout the food chain, that is, primary production, manufacture, distribution and retail.*

OBJECTIVES

The goals of the workshop were:

- To consider the emerging concept of the food safety objective and to summarise the status of current understanding
- To evaluate the scientific basis and rationale for the introduction of food safety objectives
- To assess the potential role of food safety objectives in current food safety management programmes throughout the food chain
- To identify key issues that need to be addressed to progress the food safety objective concept in practice.

HISTORY AND INTRODUCTION

With the increasingly international nature of the agri-food chain, it is more important than ever that systems for the control of hazards and management of food safety be established with operating principles that are unambiguous and acceptable worldwide.

Up to one-third of the populations of developed countries are affected by foodborne illnesses each year. Food and waterborne diarrhoeal diseases, for example, are leading causes of illness and death in less-developed countries, killing an estimated 2.2 million people annually (WHO, 2002). The increase in human infections with *Salmonella enteritidis* in Europe and North America in the past 20 years has been dramatic, as has the increase in *Campylobacter* infections in many countries throughout the world. In developed countries, much of this disease is considered to be preventable. Although the emphasis in preventive public health measures has been on established pathogens, consideration should also be given to viruses, parasites and emerging pathogens.

Additionally there is growing concern that increased international trade in both raw materials and finished goods may lead to the introduction of disease to areas currently free from a given hazard, or may increase the likelihood that some new or emerging microbiological hazard will be spread.

DEFINITION

Appropriate level of protection – “the level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.”

WTO (1995)

For these reasons, the Codex Alimentarius Committee on Food Hygiene has taken a prominent role in defining new approaches to enhancing the safety of food production¹. It is most important that any such developments meet the requirements of the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (WTO/SPS Agreement) (WTO, 1995), which states that foods can be freely imported if they would not endanger the country’s appropriate level of consumer protection (ALOP).

In the same agreement, risk assessment was identified as an important tool for assisting in the elaboration of food safety measures. It is recognised that the primary focus of food safety measures and associated regulatory activities is the protection of public health. It follows that the degree of “regulatory control” placed on a particular pathogen and food combination should be a function of, or proportional to, the risk to public health.

Although defining an acceptable level of risk is exceedingly difficult, it is important to communicate that a level of zero risk cannot be attained or expected. In the context of food safety, an ALOP is a statement of the degree of public health protection that is to be achieved by the food safety systems implemented in a country. Typically an ALOP would be articulated as a statement related to the disease burden associated with a particular hazard–food combination and its consumption in a country. It is often framed in a context of continual improvement in relation to disease reduction (FAO/WHO, 2002).

1. Please note the information given in Annex 1 to this report.

ALOPs can be expressed as a public health goal in terms of numbers of cases per given number of population over a specific time period, for example, 1 in 100,000 per annum. In the United States, the document “Healthy People 2010” (U.S. Department of Health and Human Services, 2002) addresses some of these food safety goals and describes health objectives for the decade. Using the numbers of illnesses in 1997 for infections associated with *Campylobacter*, *Listeria monocytogenes*, *Escherichia coli* O157:H7 and *Salmonella* spp. as a starting point, Healthy People 2010 seeks a 50% reduction in the numbers of cases per 100,000 population by the year 2010. It is acknowledged that the target rate of reduction is not really science-based and reflects rather a willingness to accept a significant reduction in the illness burden. It is extremely difficult for any government body or international agency to quantify the level of risk that a society is willing to tolerate or accept, or even to specify who has the ultimate responsibility to make such a decision. A quantification of the risk can be viewed as the “cost” society is willing to bear to achieve a specific degree of control over a hazard, whether human, economic, ethical, medical or legal.

Thus the ALOP will be influenced by a perception of the degree of risk, that is, the severity of the hazard, the anticipated ability of the consumer to control it, and the degree of concern associated with a particular hazard. At present, proposed ALOPs describe the risk for “whole populations”, which comprises a mix of normal, healthy individuals, young children and infants, aged people and those compromised by illness or disease. Assumptions are also made on the population’s average annual consumption patterns for certain foods.

The major challenge in formulating ALOPs is that such public health goals are set for populations rather than directly related to specific population sub-groups and food types. It is therefore important to establish a meaningful link between continually improving public health goals and the factors or targets that can be addressed by parties associated with the production, manufacture, distribution and preparation of foods.

For microbiological issues, the International Commission on Microbiological Specifications for Foods (ICMSF) and the international food safety community have been exploring the concept of food safety objectives as a “bridge” between an ALOP and the various performance or process criteria routinely used in production and manufacture. The intention is that an ALOP will be translated into an FSO that specifies the product and hazard combination concerned. Since the FSO is not always controllable and measurable in terms of maximum hazard concentration and/or frequency (nor is it intended to be), it must be converted into something that can be controlled and measured in the food supply chain, such as performance criteria and specific control measures. In this way, the public health goal (the ALOP) can be translated into a description of the amount of hazard at the point of consumption (the FSO) and can be used to set targets (criteria) at relevant points in the food chain.

Therefore, the FSO provides a link between public health goals and performance and process criteria used in the industry. It represents a clear goal relevant to food control measures, and it provides a more objective and practical (or quantifiable) approach to establishing the stringency of food control systems.

DEFINITION

Food safety objective – “the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of health protection.”

ICMSF (2002)

The FSO concept is not yet in operation, although some countries are beginning to explore the potential contribution it will make to enhancing food safety control and how it will relate to existing control measures. There is no international agreement on the application of FSOs. Within the EU there is also no agreement on how the concept will be applied or how it will be integrated into existing food safety management systems, nor is there any reference to it in existing or forthcoming food legislation. Because the incidence of foodborne disease, patterns of consumption of different foods, and perceptions of acceptable risk vary from country to country, attempting to introduce common FSOs will be a significant challenge. One of the major areas of uncertainty is the true incidence of illness attributable to each foodborne pathogen. A major study of infectious intestinal disease in the UK has shown, for example, that for every reported case of *Campylobacter* infection there are likely to be seven more that are not reported (Food Standards Agency, 2000). The so-called multipliers will vary between countries. It has been estimated that in the United States foodborne diseases cause around 76 million illnesses and 5000 deaths each year in a population of 268 million (Mead *et al.*, 1999). However, only a fraction of outbreaks are reported.

The lack of clearly articulated targets for disease reduction has been a major limitation of most existing food safety systems, although some countries are now initiating major risk-reduction-based, target-driven efforts to improve food safety. FSOs set by governments can function as such targets to help in guiding disease reduction efforts.

MANAGEMENT OF MICROBIOLOGICAL SAFETY

Government and the food industry each has an important role to play in identifying, assessing and managing risks associated with the consumption of food and drink. In the process of establishing ALOPs, authorities may want to take into account the need for consumer protection and other societal factors, as appropriate for the nation or population they represent. In many cases, the aim of articulating ALOPs will be to “cap” the level of risk in the population at the actual level delivered by the current food safety management system. Starting at the current degree of control in this way can provide a baseline against which to set future targets, as appropriate.

Considerable advances have been made in the area of quantitative risk assessment as a means of obtaining a more accurate evaluation of risk potential. It should be recognised that quantitative risk assessment brings together a suite of sophisticated (mathematical) data handling and modelling techniques that will not always be necessary or applicable. The main principles of risk assessment (i.e. structure, openness and objectivity) can also be adhered to in descriptive (qualitative) or deterministic risk assessment approaches.

Food management systems must be designed to apply to many different types of food chains, varying in structure, complexity, logistics and operational features. The interactions within any food management system are likely to be dynamic, depending on changes in the food supply chain. There should be a clear understanding of the level of success of the management operation. Ultimately, food safety management activities should result in the improved health status of the consumer population to which they relate.

In recent years, many groups and individuals in public and private organisations have contributed to a more objective and systematic approach to the understanding and management of microbial risks associated with food. The ICMSE, for example, has outlined a stepwise procedure describing the sequence of events involved in the management of pathogens in foods that embraces the potential contribution to be made by the use of FSOs. The steps, from the microbiological risk assessment to the development of an FSO, are briefly described in the following sections. It must be emphasised, however, that there is still considerable debate concerning the level of detail involved at each stage.

Using the FSO at the point of consumption as a target for the food chain leaves flexibility for those involved in individual food chains to determine how the target will be achieved. Thus it recognises that while food chains are highly variable, they must comply with common end-point targets. The FSO is a target that different food chains relevant to a specific products–pathogen combination can be expected to achieve.

Conduct a microbiological risk assessment (MRA)

An evaluation of risk can be undertaken at many different levels, ranging from the use of one or more experts through an extensive risk profile to the use of formal qualitative or quantitative risk assessment. As outlined earlier, the stringency of the control system must be proportional to the severity or likelihood of illness. It may also be influenced by the degree of urgency in the need for such a microbiological evaluation. Although there is agreement in principle that risk assessment should be used, there is no general agreement as to when to use it or what level of quantitative rigour the assessment process should have.

Risk assessment comprises four key stages: hazard identification, exposure assessment, hazard characterisation and risk characterisation. The final stage results in a risk estimate, for example, a measure of the level of risk in a given population size associated with a particular food or food category. If a risk assessment process is going to influence the establishment of an FSO, it is important that those making the assessment have an intimate understanding of where there is sound data on which to make decisions or judgements. It is even more important to acknowledge where data is limited or non-existent and hence decisions and judgements must be made on the basis of limited knowledge. These needs have led to much emphasis in the process of MRA of quantifying data variability and uncertainty.

DEFINITION

Hazard identification – “the identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.”
CAC (1999)

Hazard identification is the first stage in a risk assessment. It involves gathering information on a specific pathogen–food combination in relation to a given set of adverse health effects. This stage depends on the availability of good quality microbiological and epidemiological data.

DEFINITION

Exposure assessment – “the qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food as well as exposures from other sources if relevant.”
CAC (1999)

Exposure assessment (EA) is an overall estimation of the level of pathogens or toxin in food as ingested. It may involve knowledge of the presence of microbial hazards in raw materials and the subsequent opportunity for survival and growth during the manufacture, storage, distribution and retail of foods. Food consumption patterns in different populations will provide important additional information.

DEFINITION

Hazard characterisation – “the qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with the hazard. For the purpose of microbiological risk assessment the concerns relate to microorganisms and/or their toxins.”
CAC (1999)

Hazard characterisation addresses the severity and nature of adverse health effects resulting from the ingestion of microorganisms or toxins. In hazard characterisation, often a dose-response assessment is undertaken. A dose-response assessment is a statement of the probability that an adverse health effect will occur in a given category of consumers after exposure to a variable level of pathogen or toxin.

DEFINITION

Risk characterisation – “the process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment.”

CAC (1999)

Risk characterisation combines the information from the hazard identification, exposure assessment and hazard characterisation to produce a statement on risk which is an estimate of the probability and severity of illness associated with a given exposure, for example, number of cases of illness per 100,000 population in a year. It is important to understand the impact of variability in factors on the risk characterisation, and it is critical that the risk estimate be made with knowledge of the uncertainty.

Generating an effective MRA requires a good understanding of the dose-response model and the inherent variability associated with different strains of pathogens, different sectors of the population and interactions with the food matrix.

There are different views on how important it is to conduct a full quantitative microbiological risk assessment in order to determine a view of illness potential. Some believe that a qualitative MRA, an extensive risk profile or a risk evaluation by an expert panel can provide equally reliable estimates of the probability of illness. For example, the ICMSF (2002) holds the view that a full risk assessment according to the Codex procedures may not be necessary in all cases to determine an FSO.

Consider risk management issues

Whereas it is widely proposed that ALOPs be established on the basis of scientific and technical information complemented by socio-economic considerations, some believe that the establishment of an FSO focuses on scientific and technical information. Such information will give insight into the variability and uncertainty in the risk estimate and, generally, into the robustness of the risk assessment, which is important when considering whether to include a margin of safety in setting the FSO. Also important in setting the FSO is the variability in the technical capabilities of the various supply chains affected and in the expected compliance and control levels achieved in practice. Stakeholders in this discussion are mainly risk managers and risk assessors, who in turn involve, as they see fit, representatives from the affected private-sector industry. While several countries have considered the setting of ALOPs and FSOs on a case-by-case basis, involving those stakeholders appropriate for the specific hazard–food issue in question, delegates to the workshop from The Netherlands explained that their country’s approach is to establish an independent body in which representatives of the wider stakeholder group decide on ALOPs and FSOs for all risks.

Develop an FSO

From the risk assessment process, it can be readily appreciated that there is a relationship between the probability of disease and the number of pathogens ingested; therefore, the exposure in terms of numbers of microorganisms in a given amount of food is related to the number of cases per given population. Although the ideal public health goal may be zero cases of illness from a pathogen in a given food, it is not a realistic one. Nevertheless, there will be a tendency to evolve towards increasingly stringent target FSOs in the continual search for improvement in food safety and reduction in foodborne illness.

It is important that targets reflect the dynamic nature of foodborne illness risk. With almost all foods, the best opportunities for risk reduction are not presented by measures taken at the end of the food chain, at the point or time of consumption, where the FSO is defined. Rather, risk reduction probably needs to target earlier points in the food chain, where proper reduction or control of hazard level leads to risk reduction because it reduces the actual exposure of consumers at the end of the chain. This certainly holds for risks related to hazards that enter food supply chains early on. A marked exception may be cross-contamination in the premises where final preparation takes place (e.g. a food professional's or consumer's kitchen). Cross-contamination is a well-appreciated issue that can be controlled by use of appropriate measures, such as physical separation of raw and processed foods or ingredients, awareness and training on proper cleaning and handling practices, etc.

The majority of delegates at the workshop agreed that the most desirable point of application of an FSO is at the point of consumption of a product. It was agreed that this is clearly sensible for ready-to-eat (RTE) products but would not be a realistic proposition for raw products that must be prepared by the consumer prior to consumption, such as raw chicken. For such products, the concept of an FSO at the start of preparation or at the point of purchase was introduced. Delegates felt that the application of an FSO at different stages of the food manufacture and distribution chain could be acceptable as long as an FSO was clearly labelled as such – for example, point of consumption or point of purchase. In either case, the principle discussed was that an FSO was to be applied at, or as close as reasonably possible to, the point of consumption. The stakeholders in the food chain would then have the freedom to achieve the FSO as best as technically achievable and would have a series of targets along the chain to enable it to achieve the desired end point.

Some hypothetical examples of FSOs could include:

- An amount of staphylococcal enterotoxin in cheese not exceeding 1 µg/100 µg
- A frequency of *Salmonella enteritidis* in eggs not exceeding 1 egg per 100,000
- A concentration of total aflatoxins in raw peanuts not exceeding 15 µg/kg
- A concentration of salmonellae in powdered milk below 1 cfu/100 g.

When developing an FSO on the basis of a risk assessment, the dilemma is whether to base predictions on currently achievable best practice or on a worst-case scenario. In some sectors of the food industry, best practices have developed over the years and are well established. In these cases, it is possible to use best practices and effective control measures currently in place as the basis for setting an FSO. However, with a pathogen such as *E. coli* O157:H7 in, for example, ground/minced beef, effective control measures throughout the chain are not as well established, and a worst-case scenario might be an appropriate basis for setting an FSO.

Several questions arise. Will FSOs be set for all pathogens? If so, should they all have the same stringency? If not, how will priorities be established as to which pathogens to address? Since setting FSOs is the responsibility of governments, prioritisation is in their hands as well. It is conceivable that they will decide not to set FSOs for pathogens that are considered a low-risk public health issue or for pathogens for which mandating specific control is preferred. Resource limitations may prompt decision makers to set FSOs first for the higher-risk pathogens. An FSO may need to be established for a sub-population exhibiting a particular level of concern or need for protection. In such cases, either a more stringent FSO is set that must be valid for the entire population, or alternatively, a more lenient FSO is set for the entire population with additional measures to protect the specific sub-population.

Decide on the FSO level

In deciding on the appropriate FSO, those responsible will consider the specified ALOP (and the important factors underlying its value) as well as issues such as the following:

- Insight into the question of risk, specifically the uncertainty and variability in exposure assessment and hazard characterisation
- The expected efficiency of microbiological risk management options (implemented via control measures) to deliver the FSO
- The technical capabilities of the affected supply chains and compliance measures
- Enforcement and monitoring aspects
- Short-term and long-term risk reduction policy.

The translation from ALOP to FSO will be a most important step and will involve a close working relationship between food safety or risk management professionals in the food industry and government health protection agencies. Implementation of the control measures in the chain that ultimately are expected to deliver the FSO is through appropriate inclusion of such measures in the food safety management system(s) used in the particular chains (mostly good manufacturing practice [GMP], good hygienic practice [GHP] and HACCP). When particular food supply chains do not meet FSOs, they should either improve control measures and upgrade their technical capability in order to comply with the FSO or remove the product from the market.

Confirm whether an FSO is technically feasible

Achieving the given FSO depends to a large extent on the efficiency of the control measures along the food chain. A number of elements can be used to assess whether the FSO is technically achievable. This important step will again involve a close working relationship between food safety or risk management professionals in the food industry and government health protection agencies. It will be necessary to establish whether GMP/GHP and HACCP systems can provide the level of technical control needed to achieve the FSO. If not, the product/process manufacturing procedures should be re-evaluated and adapted until the FSO is achieved. If an FSO has been issued by a government as justified and technically achievable, then best practices and control measures need to be implemented such that the FSO is complied with.

The ICMSF has proposed a relationship expressed in the form of a simple conceptual equation that describes the impact of the different elements on the overall microbiological load (ICMSF, 2002):

$$H_0 - \Sigma R + \Sigma I \leq \text{FSO}$$

where H_0 = initial level of the hazard,
 ΣR = the sum of the hazard reductions,
 ΣI = the sum of any increase (growth or recontamination), and
 FSO, H_0 , ΣR and ΣI are expressed in \log_{10} units.

It is important to note that increases and reductions (I and R) can be interconnected. For example, a mild inactivation treatment may influence the growth of sub-lethally damaged cells after recovery. In deriving and validating an FSO, it is important to consider both the prevalence and the concentration of the relevant pathogen in a food at points in a food chain – that is, from “farm to fork”. Microbiological information is often collected in the form of presence or absence data.

Increasingly, the benefits of collecting data on concentration and frequency are being recognised, and ideally both should be available. Caution should be exercised in the way they are used, particularly if mean values are used (often the arithmetic mean is the best default assumption). Furthermore, the potential value of global data sets and the need for a common framework for data collection are gaining recognition. This approach would allow the identification of areas that are data rich and, more significantly, those that are data poor.

In evaluating an FSO, it is important to distinguish between concentration (organisms per gram) and dose (organisms per consumption). It is also important to keep in mind that microorganisms will not be evenly distributed in a food. Thus, when setting an FSO, ideally both the prevalence and the concentration/distribution of a pathogen in a food must be considered. In cases in which no growth is possible and the probability of having more than one organism per serving is very low, only prevalence might be important. If prevalence is around 100%, only the concentration might be relevant, but many intermediate cases exist. If both are relevant, an equivalence curve between prevalence and mean concentration can be determined, giving the boundary between “accept hazard level” and “reject hazard level”. A boundary line will be based on a best-estimate dose-response relation, a default consumption level (and sometimes default consumer handling). An example is shown in Figure 1.

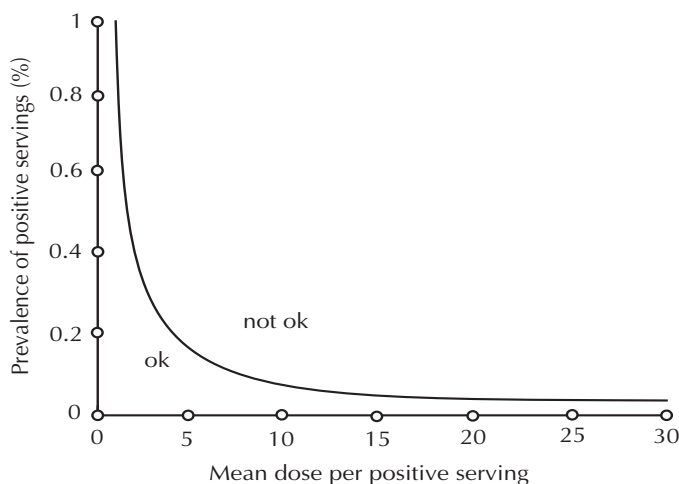


Figure 1: Prevalence-dose equivalence curve: boundary between acceptance and rejection for various mean doses and prevalence, determined by the line of equivalent risk (from Havelaar et al., 2004)

An exposure assessment (EA) is a reflection of the fate of the pathogen in the food chain. Due consideration is given to all opportunities for survival, growth and recontamination and the impact of processing steps designed to inactivate or eliminate the microorganisms in question. Although in theory an EA could be based on sampling at or close to the point of consumption, this would not allow for the selection of risk management interventions, which would have to occur farther back in the chain. Typically, target levels (FSOs) will not be directly measurable microbiologically at the point of consumption – which in turn means that, typically, whether foods meet the FSO cannot be verified by microbiological testing. This certainly holds true for food prepared by consumers. When “point of consumption” includes receipt, handling and storage of foods or food ingredients before final preparation by food professionals (e.g. catering/ food service), some form of control and verification can possibly be applied before the stage of final preparation. However, as noted earlier, for efficient risk reduction one might want to focus on opportunities earlier in the chain. For most microbial hazards, an analysis of the pathogen in a product throughout the whole food chain is preferable in order to derive an accurate exposure assessment.

Since verification of compliance with an FSO will not be possible through testing at the point of consumption, the proper design and implementation of the food safety system(s) throughout the course of the food supply chain becomes a major issue. Validation of the proper functioning of the design of the food safety management systems must be undertaken. A detailed analysis of the pathogen in a given food pathway can be used to determine equivalent risks between, for example, different types of processes, such as heat inactivation compared with a filtration approach. Caution must be exercised in interpretation because of the uncertainties involved. The two processes may be equivalent with one organism but not others, owing to factors such as metabolism, physiology, differences in response to various stresses and expression of pathogenicity.

Role of performance standards and performance criteria in the FSO concept

An ALOP is a statement of the degree of public health protection that is deemed necessary and that has to be achieved by the food safety systems in a country. To translate an ALOP into an FSO, the known consumption pattern in that country must be taken into account. If a country has a given incidence of salmonellosis attributable to poultry and wishes to implement a programme to reduce it, it can choose between two approaches. The first is to state a specific health goal, such as a reduction in the incidence of illness. An underlying assumption here is that there are practical measures that can be taken to achieve such a reduction. The other approach is to evaluate the performance of all available risk management options and then select the ALOP on the basis of the lowest risk level. This is often referred to as the “as low as reasonably achievable” (ALARA) approach (FAO/WHO, 2002). An FSO for *Salmonella* in poultry may be absence of the organism in a serving. Currently, in many countries throughout the world, *Salmonella* is present in raw poultry at varying percentages. A government health agency may wish to set a performance standard (PS) by which, say, not more than 15% of poultry is contaminated at the point of retail.

DEFINITION

Performance standard – “the level of a hazard to be achieved at a specific point in the food chain.”

Note: The use of the word “standard” does not imply that the specified level of the hazard would be a regulatory mandatory requirement.

Based on van Schothorst (2002)

Products such as poultry meat require further handling and thermal treatment before consumption. Good working and hygienic practices during preparation can contribute to achieving the FSO, as can the introduction of a PS aimed at limiting the entry of the pathogen into the food chain. However, there is no direct relationship between a PS for broilers and the FSO at consumption of the cooked meat.

With certain RTE products, such as chilled meals, that do not support the growth of *Listeria monocytogenes*, the FSO at consumption and a PS ex-factory may have the same value. However, manufacturers may wish to build in a safety margin to allow for handling and consumer practices. If growth of *L. monocytogenes* is likely to occur in an RTE product after it leaves a manufacturing site, a PS may be set that is sufficiently stringent to account for the possible increase in the pathogen. Setting a PS or introducing a safety margin are food safety management decisions, and they will be based on information from a number of sources.

DEFINITION

Performance criterion – “the outcome of a process step or a combination of steps (change in the level of a microorganism or microbial toxin).”

Based on van Schothorst (2002)

FSOs may be valuable in providing evidence that a product meets the ALOP set by an importing country, and they can be used to help establish PC or PS. The existence of such PC and PS ensures that the food safety system is transparent and thus provides evidence of equivalence in accord with the WTO/SPS agreement. The outcomes of all control measures are defined as performance criteria (PC).

It is important that the PC be validated (see ILSI Europe, 1999).

Examples of well-established performance criteria include:

- 12D reduction of proteolytic *Clostridium botulinum* in low-acid canned foods (Stumbo, 1973)
- 6D reduction of *L. monocytogenes* in RTE chilled foods (Lund *et al.*, 1989 and ECFE, 1996)
- 6D reduction of psychotrophic *C. botulinum* in pre-packed chill-stored foods with extended shelf life (ACMSF, 1992 and ECFE, 1996).

Where needed, establish microbiological criteria

DEFINITION

Microbiological criterion – “the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot.”

CAC (1997a)

Codex describes how microbiological criteria (MC) should be established; they should include the following:

1. A statement of the microorganisms of concern and/or their toxins or metabolites and the reason for that concern
2. The analytical methods for their detection and/or quantification
3. A plan defining the number of field samples to be taken and the size of the analytical unit
4. Microbiological limits considered appropriate to the food at the specified point(s) in the food chain
5. The number of analytical units that should conform to these limits.

Although MC differ in both function and content from FSOs, there are some similarities in the way they are established. According to Codex, in order to establish MC, consideration should be given to the following:

- Evidence of actual or potential hazards to health (can be epidemiological evidence or the outcome of an MRA)
- The microbiology of raw materials
- The effect of processing
- The likelihood and consequences of contamination and growth during handling, storage and use
- The category of consumers at risk
- The cost/benefit ratio of the application
- The intended use of the food.

It is therefore important to appreciate the distinction between an FSO and a microbiological criterion. This distinction has been succinctly summarised by van Schothorst (2002) and is shown in Table 1.

Table 1: Characteristics of FSOs and microbiological criteria

Food safety objective	Microbiological criterion
<p>A goal on which food chains can be designed so that the resulting food will be expected to be safe</p> <p>Aimed at consumer protection</p> <p>Applies to food at the moment of consumption</p> <p>Components:</p> <ul style="list-style-type: none"> • Maximum frequency and/or concentration of a microbiological hazard • Product to which it applies <p>Used only for food safety</p>	<p>A statement that defines the acceptability of a food product or lot of food</p> <p>Confirmation that effective GHP and HACCP plans are applied</p> <p>Applies to individual lots or consignments of food</p> <p>Components:</p> <ul style="list-style-type: none"> • Microorganisms of concern and/or their toxins/metabolites • Sampling plan • Analytical unit • Analytical method • Microbiological limits • Number of analytical units that must conform to the limits <p>Used for food safety or quality characteristics</p>

Source: Based on van Schothorst (2002).

Sampling plans are associated with microbiological criteria but not with FSOs. The FSO is (indirectly) an expression of the stringency required in food safety management in view of the level of public health concern. As such, it provides a link to the control measures applied by food manufacturers. There will be a relationship between an MC and an FSO, but it may not be a direct one.

Assume that an FSO of <100 cfu/g has been set for *L. monocytogenes* in a stable RTE food at the point of consumption. This concentration can be measured by conventional microbiological techniques, but conducting measurements at the point of consumption will not be practical. Since the hazard level will not change in a stable food, in this case an MC of the manufactured product can be directly related to the FSO. However, if the RTE food was not stable and an MC was considered for the product leaving the factory, then due account needs to be given to the fate of the pathogen in the product between the factory and consumption. If, for example, a 100-fold increase is anticipated in the concentration of the pathogen, a PS for the product ex-factory specifying “absence of *L. monocytogenes* in 1 gram” (or <1 cfu/g) would allow compliance with the FSO. An MC at the point of the PS could be used to test, by conventional microbiological methods, whether the PS was met and thus whether the FSO was achieved.

In many cases, MC cannot be directly linked to an FSO or a PS because of the low level of the pathogen to be achieved and the absence of relevant indicators. For example, for the sterilisation of a low-acid canned product, a “botulinum cook” is usually applied: the product receives a thermal treatment that will reduce the concentration of spores of *C. botulinum* by a factor of 10¹². Even if a larger indicator group, such as “total viable anaerobic spores”, could be used to check whether a heat treatment was performed, it would not be possible to determine the presence of spores in a sufficiently large quantity of food to verify whether the PS has been achieved.

Summary

A number of different and sometimes new terms and concepts were introduced in the foregoing to describe how an FSO at the point of consumption relates to food safety management principles in the food supply chain. It may be helpful to give an example of how these relate to each other:

- The **hazard** is *C. botulinum*.
- The **performance criterion** is the change in numbers, i.e. 12D reductions.
- The **process criterion** is the critical limit of 2.45 min/121°C.
- The **performance standard** is <1 spore/10¹² g after processing (assuming an initial concentration (H₀) of <1 cfu/g).
- The **food safety objective** is <1 spore/10¹² g (when the product is ready for consumption).

It is critically important that those responsible have a clear understanding of the essential requirements for food safety control in international trade. Ideally, importers and exporters in different countries would be trading in food and drinks within a framework of inspection and certification controls that are equivalent insofar as they meet common objectives. Criteria for accepting lots or consignments of food are generally referred to as acceptance criteria. Acceptance criteria allow the regulatory management systems in various countries to differ, provided they produce the same level of public health protection (articulated in an ALOP, for example). The WTO concept of equivalence may well address issues other than microbiological safety, including chemical, physical and biological hazards.

All of these food management controls are designed to enhance the safety of food supplied to the consumer, and therefore it is important that factual information be communicated clearly to the consumer. Consumers are reluctant to accept a given level of risk unless they have control over the decision of whether to accept that particular risk, such as deciding to travel in an aeroplane or a car. With foods, consumers expect zero risk and often do not appreciate that in practice this is not achievable. However, consumers will understand and accept a continued stepwise effort toward improvements that will reduce risk. Thus, presentation of the facts is critically important.

EXAMPLE OF USING AN FSO WITH *LISTERIA MONOCYTOGENES* IN COLD-SMOKED SALMON

The potential use of an FSO was presented to the workshop in the form of an example case study on *Listeria monocytogenes*. The example was based in part on a risk assessment conducted in the United States regarding foodborne *L. monocytogenes* in a range of RTE foods that was available at that time as a draft (U.S. Food and Drug Administration/USDA Food Safety and Inspection Agency [FDA/FSIS], 2001) and was later refined and amended (FDA/FSIS, 2003). It was also based in part on a risk assessment of *L. monocytogenes* in RTE foods conducted by FAO/WHO that was available in a draft version at that time and is expected to be updated shortly (FAO/WHO, 2004).

Please note that in presenting this example here, we chose not to use the numbers and figures of the example as it was presented to the workshop, but to include data from the particular studies, as reported after the workshop had concluded, when the risk assessments on which the example was based had progressed further. Thus, the example will be more consistent with the advanced status of the risk assessments. A second rationale for this change is that the example was given at the workshop only to illustrate the principles of the use of the FSO. The example was not intended to convey specific and validated data. The illustrative purpose can be achieved by either data set. Readers interested in the specific numbers from the example are referred to the original documents.

Many food products have been linked to listeriosis, including cold-smoked fish. Depending on the processing plant, between 3% and 100% of cold-smoked salmon samples can be positive for the pathogen in 25 g samples (Jørgensen and Huss, 1998). U.S. data indicate an incidence rate of 4%–5% for *L. monocytogenes* in smoked fish (Gombas *et al.*, 2003). Buchanan *et al.* (1997) developed a dose-response curve for the organism. In the example presented here, RTE fish products are used as the basis of a worst-case scenario.

As projected by an expert consultation on risk assessment of *L. monocytogenes* in RTE foods (FAO/WHO, 2004), elimination of food servings containing high mean dose levels (i.e. $>10^{4.5}$ cfu/serving) at the time of consumption would have a large impact on the number of predicted cases. The consultation calculated that a reduction of approximately 99% could be potentially achieved even when the most conservative assumption for the *maximum** numbers of *L. monocytogenes* consumed in a serving ($10^{7.5}$ maximum cfu/serving) was used.

Because of the widespread occurrence of *L. monocytogenes*, it is extremely difficult (and expensive) to produce RTE foods without sporadic occurrences of the organism at low levels. As indicated above, the dose-response relationships (and resulting risk estimate) indicate that such low levels constitute a very low risk. Consequently, compliance to an FSO of 100 *L. monocytogenes* per gram would represent a major improvement of public health.

* It is assumed that the estimate of the dose-response *r*-value – and therefore the range of concentrations that are most relevant – is determined by the maximum level of organisms in a food product. For instance, when the maximum level is $5 \cdot 10^5$ cfu/g, and when the serving size is 60 g, the maximum dose is $60 \cdot 5 \cdot 10^5 = 10^{7.5}$. In that case, 99% of the cases of listeriosis are caused by doses $>10^{4.5}$ cfu/serving. When a higher asymptote is assumed (e.g. 10^8 cfu/g), even higher ranges are the only relevant ranges determining the risk of listeriosis per serving.

Exposure assessment

The risk assessments of both FDA/FSIS (2001) and FAO/WHO (2004) address a broad range of RTE products. In this illustration, only one product group is used to develop some example risk assessment outcomes. A total of 80,000 tons per year of cold-smoked salmon are consumed by the nations in which this product is assumed to have an importance. The combined population of these countries is some 880 million people. If we assume that the average serving size is 60 g, we can calculate that in one year the population consumes a total of 1,330 million servings (about 1.5 servings per person per year). If we further assume that the total number of cases of listeriosis per year from all foods is 0.5 per 100,000 population, then there would be a total of 4,400 cases per year in the population of 880 million people. It is not known how many of these cases are indeed caused by cold-smoked salmon and how many have other causes.

The FAO/WHO risk assessment on *L. monocytogenes* in RTE foods (2004) estimates the risk of listeriosis per serving of smoked fish to be high (2.1×10^{-8} cases per serving) as compared with some other types of RTE foods (for milk, for example, the risk per serving was estimated at 5.0×10^{-9} cases per serving). Globally, however, consumption is moderately frequent (0.15 to 18 servings per year), and therefore the total number of cases of listeriosis resulting from exposure would be rated as moderate (0.0046 cases per 100,000 people per year). In countries where the consumption is much greater, such as in northern Europe, the risk per serving is similar, but a greater number of cases per 100,000 people per year would be expected because of the higher number of servings. Likewise, in populations for which the consumption of cold-smoked salmon is less relevant, a different level of risk may be projected.

Risk management options

L. monocytogenes can be controlled but probably not eliminated from cold-smoked salmon production. As outlined above, it is also known that low levels of *L. monocytogenes* are consumed daily in a variety of RTE cold-smoked fish, including cold-smoked salmon, without major adverse effects, as there are few documented incidents of listeriosis linked to these products.

Contamination rates of raw fish vary with geographical region, but initial levels (H_0) are typically low, and <1 cfu/g is used in the example.

During processing, contamination or recontamination may occur, and 1 cfu/g can be assumed as the contamination level (initial contamination plus recontamination = 1 cfu/g). Growth during subsequent storage may vary. Some investigators report only marginal growth during storage (Jørgensen and Huss, 1998), whereas others report sporadic high levels (Gombas *et al.*, 2003). Therefore, for some products a value of 1–2 log units may be valid, whereas for others 5–6 log units may apply. Typically ΣI due to contamination or recontamination is an absolute figure, such as 1 or 10 cfu/g, whereas ΣI due to growth is an increase. Assuming the consumer eats the fish “raw”, i.e. without further antimicrobial treatment such as cooking, there will be no reduction. Thus, $\Sigma R = 0$.

These data and assumptions can be combined in the conceptual equation presented earlier. In this equation, bacterial numbers are expressed in log-units: $H_0 - \Sigma R + \Sigma I \leq \text{FSO}$.

When the FSO for the pathogen–product combination is 2 (FSO level = 100 cfu *L. monocytogenes* per gram [*Lm/g*]);

with an initial contamination (H_0) level that typically is very low in the raw product or that is at the assumed low level of 1 cfu/g due to recontamination, $H_0 \approx 0$ (level ≤ 1 cfu/g);

with $\Sigma R = 0$ and $\Sigma I \leq 2$ (growth is restricted and does not increase by more than 2 log until consumption);

the equation reads: $0 - 0 + 2 \leq 2$.

Under these conditions, the FSO is met.

When growth is strong, ΣI may reach the high levels quoted above; and

the equation changes to: $0 - 0 + 6 > 2$.

Now the FSO level would be exceeded.

- In order to meet the FSO, control measures need to be taken. Reducing H_0 will not ensure that the FSO is met, as long as the recontamination remains at the assumed 1 cfu/g level.
- Rather, control measures are needed that ensure a significant reduction of ΣI , that is, measures that prevent or limit contamination and recontamination and subsequent growth to 2 log units.
- Such measures can relate to shortening the specified shelf life or considering intrinsic or extrinsic factors that can sufficiently restrict the growth of *L. monocytogenes*.
- These measures need to be implemented as part of GHP and HACCP.

Performance standard

If growth of *L. monocytogenes* is possible or likely during storage and distribution, the FSO must be translated into a performance standard (PS) to compensate for the amount of growth expected between the end of production and consumption.

For example, it has been demonstrated that in naturally contaminated cold-smoked salmon stored at 5°C, about a 1 log increase occurs during a three-week storage period (Jørgensen and Huss, 1998).

Therefore, if a shelf life limit of less than three weeks (at 5°C) is specified, the PS of 10 cfu *Lm/g* at the end of the processing line will allow the FSO to be met. Most processors will set a PS of <10 cfu/g to build in a safety margin, although at present there is no consensus on what this safety margin should be.

If more pronounced growth is expected, for example, as a result of storage at higher temperatures or a longer specified shelf life, then the absence of the pathogen in a defined quantity (1 g, 10 g, or 25 g) must be required. And, in contrast, if no growth will occur, the PS can be equivalent to the FSO of 100 cfu/g.

Product and process criteria

DEFINITION

Product criterion – “a parameter of a food that is essential to ensure that a performance standard or food safety objective is met.”

Based on van Schothorst (2002)

The safety of cold-smoked salmon depends on the use of appropriate raw materials, limitation of recontamination, and combinations of salt and low temperature after processing to limit the growth of low levels of *L. monocytogenes*.

Currently, no processing operation in the preparation of cold-smoked salmon provides a listericidal step. It is difficult to set product criteria for *L. monocytogenes* in the absence of control measures to control growth.

DEFINITION

Process criterion – “a control parameter (e.g. time, temperature, pH, a_w [water activity]) at a step that can be applied to achieve a performance criterion.”

Based on van Schothorst (2002)

It should be noted that ongoing work on control measures such as the use of lactate-diacetate, lactic acid bacteria, and specific smoke–NaCl combinations may result in the development of product criteria that may control the growth of the organism.

Microbiological criteria

The use of microbiological criteria, which include sampling and testing plans, may in some specific cases serve as a control measure. When the establishment of microbiological criteria is chosen as a risk management option, such criteria should be based on an FSO of <100 cfu/g or a PS derived from this level. They may be used as acceptance criteria in situations in which the history of the product is not known, at points such as at port-of-entry. It should be considered for each product–hazard combination if other acceptance criteria will provide a higher level of confidence. It is fairly evident that, in practice, for cold-smoked salmon, one way for an MC of ≤ 100 cfu/g for a product with a three-week shelf life can be achieved is to prevent or limit growth of the organism to 1 or 2 logs, reduce the initial level, and prevent recontamination.

In the determination or enumeration of *L. monocytogenes*, there is a degree of uncertainty in the analytical technique itself. It is important to understand its impact on the use of testing as a control measure. In the specific *L. monocytogenes* example presented here, other parameters – such as the variation in the composition of the salmon (matrix effect), the variation in the level of pathogen injury and thus the viability of different strains, and the composition and level of the competitive flora – will have an impact on the analytical performance and thus the degree of uncertainty.

HOW DOES THE HAZARD ANALYSIS CRITICAL CONTROL POINT (HACCP) CONCEPT RELATE TO FSOs?

The hazard analysis and critical control point (HACCP) was originally developed by the Pillsbury Company, working with NASA and the U.S. Army Laboratories at Natick, to assure that food supplied to the manned space programme was microbiologically safe (Anon, 1973; Bauman, 1974). Over the years it has been adopted by Codex, EU and other national and international regulatory bodies as the foundation of microbiological food safety management, allowing food manufacturers, retailers, distributors and caterers the ability to identify hazards and determine critical control points and effective control measures. The FSO concept provides a functional link between risk assessment (including MRA) and risk management, of which HACCP is a key component in the food industry.

DEFINITION

Critical control point – “step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.”
CAC (1997b)

The interpretation of what is meant by “acceptable level” is left to the HACCP team in the context of the regulatory environment in which it operates. The FSO concept will enable a more objective and universal understanding of what that acceptable level is in a given product/process situation. Thus it would give manufacturers a quantitative target at which to aim. Such a defined target would enable individual food processors and manufacturers the opportunity to define and implement the necessary control measures to achieve the required level of safety. This flexibility could be exercised in different ways by individual manufacturers. This approach would be valuable not only for existing products but also in the new product development process. Another major benefit to manufacturers with the establishment of a quantitative target level (FSO) is that food control authorities would be able to judge all manufacturers against a common target. This would be beneficial not only at the national level but also, increasingly so, at the international level in the effort to establish equivalence.

An FSO is established for a specific combination of pathogen and food (e.g. *L. monocytogenes* and RTE foods), whereas in the course of an HACCP study, this hazard and all other relevant microbial, chemical and physical hazards associated with different products in this broad category still need to be taken into account. The message concerning the role and aim of an FSO should therefore be clearly communicated – an FSO is established to address a specific hazard in a specific product category that is significant from a public health perspective. In order to meet the FSO for a specific hazard in a specific food, the food safety management systems used in the supply chain (e.g. HACCP, GMP, GHP) need to be amended to consider the required control of the hazard next to all other hazards that the systems need to control and for which no FSO may be articulated. In this respect, it is evident that the scope of HACCP is much wider than microbial hazards of public health concern and that setting an FSO should be seen as a separate, higher-level activity that is not specific to the particular food chain or food operation.

Based on their experience and history in manufacturing foods, industry has a wealth of data and information that would be of use during the process of undertaking an MRA or similar exercise. The extensive consideration of hazards, which is an integral part of the HACCP process, can contribute significantly to the MRA process, and exposure assessment in particular. The type of data available at the manufacturing level is probably different from that used by food control authorities and can therefore be considered a valuable complement. There will be some variability in the data from the manufacturing sector because of the different approaches to defining and implementing control measures, which may vary with the type of product manufactured and the monitoring system adopted by the manufacturer. In any case, manufacturing sector data certainly contain realistic and historical information on the incidence and prevalence of certain pathogens in raw materials, intermediate products and processing environments, the effect of processing steps on their viability, the effect of hurdle systems on their ability to grow and so on. Of particular value is the information they can provide about the presence and behaviour of these pathogens as well as of indicator organisms in processing environments, which are of importance in recontamination and thus in the pathogens' presence in finished products. It is evident, therefore, that food manufacturers have an important role to play in providing data to the MRA, which will support the establishment of FSOs.

Although a great deal of data have been and are being generated, the format in which they are currently available may be a limiting factor in their transmission to teams performing microbiological risk assessments. Data are usually generated and compiled in a format that is suitable for an individual manufacturer and that allows it to manage its particular process. This format may differ considerably from one manufacturer to another and may not be suitable for risk assessors. If data are shared, it may lead to differences in interpretation between manufacturers and/or authorities and manufacturers. For this reason it would be necessary to develop appropriate formats and channels through which such data could be made available to risk assessors. This could be achieved through neutral channels, such as professional organisations compiling data provided by "member" companies or by an organisation mandated by both authorities and manufacturers. For a number of products and product categories, data from manufacturers and handlers would also contribute to the establishment of an FSO without necessarily having to perform a full microbiological risk assessment. This is the case where hazards are fully controlled by the manufacturers and therefore products have little or no impact on public health. For this reason it is important that food manufacturers be involved as stakeholders in the evaluation of the data.

There is one significant key difference between the HACCP approach and the FSO concept. As proposed by Codex and ICMSF, an FSO relates to a single pathogen–food combination, such as *Salmonella* and eggs, *L. monocytogenes* and RTE foods, or *Vibrio parahaemolyticus* and seafood. The risk assessments that would lead to the definition and establishment of an FSO for each of these combinations are performed taking into consideration all products manufactured and consumed in the same region or country, that is, taking into account all types of products and their manufacturers and handlers. These range from home-made products to artisanal products manufactured by small businesses to products manufactured industrially by large processors as well as imported products handled and sold by retailers. During such a risk assessment no consideration is made of individual manufacturers, which may use different methods to produce essentially the same product.

In contrast, HACCP takes into consideration all pathogens related to a particular product and considers their occurrence and fate along the whole chain from the raw materials to the consumer. While generic HACCP plans have been developed and are available – and are helpful particularly for small and medium-sized manufacturers – they have to be adapted to the specific conditions of the location where they will be applied. Usually, HACCP plans are specific to a single factory and take into account its particular situation, source of raw materials, layout of the lines, processing techniques and equipment. Thus, HACCP plans cannot be transferred between factories. In fact, depending on the situation, the critical control points identified may be considerably different from one location to another. Therefore, the control measures implemented to achieve the FSO (heat treatments, the design of the hurdle system in a food and the like) can differ from one location to another.

These differences in achieving the target raise the question of how is it possible to demonstrate that different control measures produce the same outcome. This question can be addressed only through validation of individual measures to demonstrate that they are appropriate and deliver the expected level of control. Validation is an essential step, since it is the only way to demonstrate that the control measures chosen to achieve the required level of safety are performing. This is essential to allow for the flexibility in manufacturing methods, design of the process and final product characterisation.

In the context of HACCP, validation and verification have been defined and their role and purpose described in some detail (ILSI Europe, 1999). Validation is concerned with obtaining evidence that the elements of the HACCP plan are based on sound scientific and technical knowledge and result in the establishment of an effective HACCP plan. Once an HACCP plan has been established and validated, verification is the process of ensuring that compliance is achieved in practice. In relation to FSOs, the use of validation is in its infancy, and there is still considerable debate on exact requirements. During manufacture, numerous processing steps are applied for quality purposes, for example, to achieve a distinct colour, flavour, or taste. It is clear that some but not all of these processes also contribute to the products' safety. However, in most cases, there is no knowledge about the precise (quantitative) contribution that these processing steps make, and therefore the margin of safety is not known. If care is not taken in situations of changing process conditions, the lack of knowledge about safety margins may lead to the production of unsafe products. Issues related to processed foods are frequently related to post-process contamination, and therefore preventive measures are implemented to eliminate or minimise such risks. The validation of measures to ensure minimisation of the risk of post-process contamination or recontamination is relatively difficult to accomplish.

In more than one way, designing and implementing risk-reduction measures at the population level (through setting ALOPs and FSOs) can be compared to the principal activities that form the basis for HACCP. In both, the design needs to be validated to work in practice, while the output is not necessarily effectively verified (and monitored) by microbiological testing. Therefore, assurance that the food safety management systems deliver the required output must be derived from monitoring the proper functioning of key elements of performance control (e.g. key or "critical" control measures) in the food chain.

CURRENT STATUS OF THE FSO CONCEPT

The role of the FSO

The ICMSF originally developed the term FSO, building on the use of the term by Jouve (1992) in describing quality objectives. The ICMSF recently published “Microorganisms in Food 7: Microbiological Testing in Food Safety Management” (2002), which gives a comprehensive account of the FSO/ALOP concept in relation to other microbiological food safety tools. Codex Alimentarius has given consideration to the use of the FSO concept within the Codex Committee on Food Hygiene. At the 35th session of the Codex Committee on Food Hygiene, held in Florida (CAC, 2003b), comments were received on the “Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management”. The following comment was attributed to the European Community: “The European Community feels that the concept of FSO is not yet fully developed and accepted, and there is still need for a profound discussion by the Committee on this important issue. Therefore, the Community recommends that the concept of FSO and its application should be discussed thoroughly at the forthcoming CCFH meeting. Especially the option of setting FSOs versus performance standards to stages of the food chain other than the time of consumption should be reflected in this discussion”.

In the same document and in relation to performance criteria, the International Dairy Federation (IDF) commented: “It is important that there is clear distinction between an FSO, a performance criterion and a microbiological criterion as these are different risk management options. An FSO is an expression of the required (absolute) outcome of *all control measures* applied *throughout the food chain*. A microbiological criterion is an analytical expression of the (absolute) outcome in terms of hazard levels at a specified point in the food chain. These specified points could be after applying a process step or combinations of process steps and as outcome expressions at various stages along the food chain (e.g. raw materials). The draft definition of ‘performance criteria’ also relates to (absolute) outcome and therefore expresses the same as FSOs and microbiological criteria, depending on at which stage within the food chain it applies. Therefore, if this risk management option is to be of any value, a performance criterion must not relate to (absolute) outcome (result of control measure(s) in terms of hazard levels) but to the relative effect of control measure(s), such as minimum reduction rates”.

Specifically on the role of FSOs, the IDF also commented:

“In general we have great faith in the future role of the FSO-concept as a key instrument to ensure food safety and effective risk communication in supplementing more traditional instruments such as microbiological criteria, GHP codes, HACCP-guidelines, etc.”. Finally, the IDF “considers that it is possible to establish international FSOs for some hazards (e.g. for *Listeria monocytogenes* in ready-to-eat foods), while recognising that local conditions may provide the rationale for applying other FSOs according to specific ALOPs”.

The position of the FSO in the farm-to-fork food chain

In light of the discussions so far, the most appropriate point at which to set the FSO is at “the point of consumption”, meaning at actual consumption or close to consumption. As for the latter, mainly this refers to where the food is prepared for consumption, although some delegates proposed that FSOs could be meaningful as early in the chain as “point of purchase” or “at end of manufacture”. In all cases, for the benefit of operational food safety management, the control of key steps along the food chain (e.g. at the farm, after processing, during distribution) should be governed by performance standards that are, or could be related to the FSO.

Furthermore, defining an FSO at the moment of consumption allows for a much better relation and link to established public health goals defined by authorities. It implies as well that the protection of the consumer can be fully achieved only with appropriate information. For numerous products, the way they are prepared and consumed plays an essential role in ensuring their safety. The term “food prepared according to its intended use” as defined by Codex Alimentarius would then attain its full meaning and importance.

The points of enforcement along the chain could nevertheless vary and be defined according to the type of product. This would be the case for raw foods or ready-to-eat foods, and in such cases other targets, such as performance standards, could be established and used along the food chain.

Until recently, both national and international organisations gave considerable effort to the establishment and application of microbiological risk assessment. The same organisations are now beginning to consider the FSO concept and how it can contribute to food safety management. To date, emphasis has been on the technical issues and the way FSOs can be used by risk managers to enhance food safety. The Dutch Ministry of Agriculture, Nature Management and Fisheries recently requested that the National Reference Centre for Agriculture, Nature and Fisheries, the RIKILT Food Safety Institute, and the Agricultural Economics Research Institute develop a case study on FSO-based policy for a microbiological hazard (*Campylobacter*) and a chemical hazard (dioxin). The report was published in 2002 (Swarte *et al.*, 2002). The authors commented with respect to *Campylobacter* that the food safety policy is not very transparent and that scientific, socio-economic and technical considerations are all part of the risk management process. However, it is not clear on what grounds decisions are made and what weight is given to the different arguments. Policy objectives are not explicit, and therefore goals and the means to achieve them remain a matter of debate. The workshop received a comprehensive overview of the Dutch study and the potential role of ALOPs and FSOs in establishing a clear policy. The authors of the Dutch study concluded by stating that FSOs can be a powerful tool for risk management and that they can translate public health goals directly to appropriate food safety measures and convey these goals throughout the entire food chain. ALOP/FSO-based policy requires an integrated approach of risk assessment, risk management and process management.

It is of interest to note that Szabo *et al.*, (2003) have published a paper on the assessment of control measures to achieve a food safety objective of less than 100 cfu of *L. monocytogenes* per gram at the point of consumption for fresh pre-cut iceberg lettuce. The paper represents the first industrial consideration of the application of an FSO. Recognising that the FSO is a relatively new concept, the authors comment that the FSO aims to link information from risk assessment and risk management processes with practical measures that allow industry to exercise control over a given hazardous agent.

CONCLUSIONS AND FUTURE REQUIREMENTS

The participants in the workshop were all food safety professionals drawn from the fields of government health protection agencies and food and drink research centres, including universities and food manufacturing companies. Some of those attending have been closely involved in the deliberations of Codex, ICMSF and FAO/WHO on the FSO concept and therefore had a more informed view of its potential value and impact. However, it was evident in the discussions that a number of unanswered questions remain about the role and application of FSOs along with, perhaps understandably, a degree of confusion over terminology. The following are some of the key areas that will need to be addressed in the future:

1. During the course of the workshop it was clear that delegates were using terms such as FSO, performance criteria, and target to mean different things. It should be noted that debate on the ALOP and FSO concepts is ongoing in the Codex Committee on Food Hygiene in relation to the discussion on the draft document on the Principles and Guidelines for the Conduct of Microbiological Risk Management (CAC, 2003b)¹.
2. At present there is no European or wider international agreement on the use and application of FSOs. Codex is actively discussing the concept, ICMSF has recently published (2002) on the subject, and FAO/WHO have held an expert consultation (2002). Questions with an important international dimension include the following:
 - Will there be an attempt to embrace the FSO in some sort of legal framework?
 - How will governments objectively measure the impact of an FSO on disease reduction?
 - Whose responsibility will it be to set an FSO?
 - Will the FSO have any legal authority over imports and exports and in agreements between suppliers and buyers in the commercial world?
3. It is likely that ALOPs and FSOs will apply to a population in general; the question arises as to how we can effectively protect sub-populations within the community that have a higher sensitivity to disease potential.

A number of key scientific challenges need to be further addressed to allow the robust application of the FSO concept. A greater understanding of the behaviour of both established and emerging foodborne pathogens and new knowledge about host response mechanisms will allow more accurate assessments of risk to be conducted.

4. There appear to be differences of opinion about the necessity or value of undertaking a full quantitative MRA as a precursor to the establishment of an FSO. The question arises – can a qualitative MRA, risk profile, or expert opinion provide the necessary input to evaluate risk? The ICMSF appears to hold the view that a quantitative MRA may not be obligatory. It was certainly the view of the workshop delegates that for a target such as an FSO, one should consider whether it is realistic and achievable by best industrial practice and that an FSO should be set in close collaboration with industry and other stakeholders.

1. Please note the information given in Annex 1 to this report.

5. To maximise the potential contribution FSOs can make at the international level, it will be important to:
 - Focus food safety research funding more towards MRA and FSO data gathering requirements. Clearly, if government food safety policy worldwide is going to be more target-driven, then the best available information must be gathered and used to make informed decisions. It will be of considerable interest to see how the FSO copes with national differences in data, such as prevalence rates of pathogens in foods and consumption data for different foods. An important output from the meeting was the recognition that industry collects a vast amount of data, which could provide valuable input to the risk assessment process, and therefore that mechanisms should be explored to harness this information. It will be complementary to the data usually compiled by government health protection agencies, since it will relate directly to the process control variables and guide the understanding of what is best achievable industrial practice.
 - Explore the contribution of new molecular typing systems on surveillance and the ability to attribute particular foods to a pattern of illness.
6. Throughout the workshop discussions, issues of uncertainty and variability of data were highlighted. It is of paramount importance that any statement on risk, in whatever form, be qualified by reference to the level of confidence in the data used to make the statement.

Discussions within Codex, ICMSF and at the FAO/WHO expert consultation have clearly progressed on the assumption that an FSO would be applied at the point of consumption. There was much debate at the workshop as to whether this was the only approach and whether FSOs could apply elsewhere in the food chain. There was general agreement that the FSO should be at or close to the point of consumption, but in the case of some foods, where consumer practices may have a significant influence on microorganism growth potential or recontamination, a case was made for an FSO at the point of purchase. In this way the various elements in the supply chain would have the freedom to set performance and process criteria in order to achieve the desired end point. For the FSO concept to be utilised effectively, a clear strategy must exist for all stakeholder involvement and communication.

In summary, the workshop, through a series of introductory papers and focused discussion groups, provided a forum for detailed consideration of the FSO concept. The ALOP and FSO approaches are evolving concepts, and this workshop identified a number of issues that need further debate at the international level. It is hoped that the workshop was successful in bringing together a wide range of stakeholders in food safety management and provided a stimulus to further developments of the FSO concept by encouraging an active exchange of views.

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ANNEX 1

Readers will be interested to note that the definitions for food safety objective (FSO), performance objective (PO) and performance criterion (PC) as proposed by the Codex Committee on Food Hygiene were recently endorsed (May 2004) by the Codex Committee on General Principles. The definitions are 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.

(CAC, 2004)

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