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Impact of Food Safety Objectives on Microbiological Food Safety Management

Proceedings of a Workshop held on 9–11 April 2003 in Marseille, France

ILSI



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



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FOOD CONTROL

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Summary report [☆] Food safety objectives—role in microbiological food safety management

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Abstract

The Workshop, organised by ILSI-Europe, provided for the first time an opportunity for government, industry and academia to consider the implications of the evolving concept of the Food Safety Objective (FSO) in microbiological food safety management. The historic development of the concept and its relationship to other established food safety tools was discussed at length. An example application of an FSO was described for *Listeria monocytogenes* in cold-smoked salmon. The Workshop identified a number of conclusions and requirements for future consideration.

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1. 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

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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

^{*} 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 Microbiological Specifications for Foods (ICMSF).

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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; 2004). 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.

2. 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 ¹ 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 prac-

¹ In this document, industrial refers to practices throughout the food chain, that is, primary production, manufacture, distribution and retail.

tice. This process will present a fresh challenge to the way science, government and industry interact in the future.

3. 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.

4. History and introduction

With the increasingly international nature of the agrifood 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 production. ² 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).

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" (US Department of Health & 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.

² Please note the information given in Annex 1 to this report.

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, Slutsker, & Dietz, 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.

5. 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 ICMSF, 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.

5.1. 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.

5.2. 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 caseby-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.

5.3. 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 wellappreciated 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 g.
- 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.

5.4. 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.

5.5. 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):

$$H_0 - \sum R + \sum I \leqslant FSO$$

where H_0 = initial level of the hazard, $\sum R$ = the sum of the hazard reductions, $\sum I$ = the sum of any increase (growth or recontamination), and FSO, H_0 , R and I 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

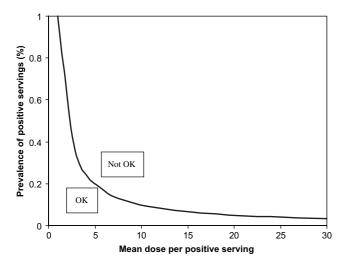


Fig. 1. Prevalence–dose equivalence curve: boundary between acceptance and rejection for various mean doses and prevalence, determined by the line of equivalent risk (from Havelaar et al., 2004).

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 Fig. 1.

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. Typ-

ically, 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.

5.6. 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 perfor-

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)

mance standard (PS) by which, say, not more than 15% of poultry is contaminated at the point of retail.

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 *L. 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, Knox, & Cole, 1989 and ECFF, 1996).
- 6D reduction of psychotrophic *C. botulinum* in prepacked chill-stored foods with extended shelf life (ACMSF, 1992 and ECFF, 1996).

5.7. 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:

- 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.

Sampling plans are associated with microbiological criteria but not with FSOs. The FSO is (indirectly) an

Table 1 Characteristics of FSOs and microbiological criteria

Food safety objective	Microbiological criterion
A goal on which food chains can be designed so that the resulting food will be expected to be safe	A statement that defines the acceptability of a food product or lot of food
Aimed at consumer protection	Confirmation that effective GHP and HACCP plans are applied
Applies to food at the moment of consumption	Applies to individual lots or consignments of food
Components:	Components:
Maximum frequency and/or concentration of a	 Microorganisms of concern and/or their toxins/metabolites
microbiological hazard	Sampling plan
Product to which it applies	Analytical unit
	Analytical method
	Microbiological limits
	 Number of analytical units that must conform to the limits
Used only for food safety	Used for food safety or quality characteristics

Source: Based on van Schothorst (2002).

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.

5.8. 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 $<1 \text{ spore}/10^{12} \text{ g}$ after processing (assuming an initial concentration (H_0) 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.

6. 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 *L. 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 (US Food & Drug Administration/USDA Food Safety & 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 has since been published (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 & Huss, 1998). US data indicate an incidence rate of 4–5% for *L. monocytogenes* in smoked fish (Gombas, Chen, Clavero, & Scott, 2003). Buchanan, Damert, Whiting, and van Schothorst (1997) developed a doseresponse 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* ³ 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.

6.1. 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 1330 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 4400 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 $(2.1 \times 10^{-8} \text{ cases per serving})$ 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 (0.15–18 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

³ *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 5×10^5 cfu/g, and when the serving size is 60 g, the maximum dose is $60 * 5 \times 10^5 = 10^{7.5}$. 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.

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.

6.2. 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 & 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 $\sum I$ due to contamination or recontamination is an absolute figure, such as 1 or 10 cfu/g, whereas $\sum I$ 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, $\sum R = 0$.

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

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, $H_0 \le 0$ (level ≤ 1 cfu/g);

with $\sum R = 0$ and $\sum I \le 2$ (growth is restricted and does not increase by more than 2 log until consumption); the equation reads: $0 - 0 + 2 \le 2$.

Under these conditions, the FSO is met.

When growth is strong, $\sum I$ 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 ∑I, 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.

6.3. 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 & 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.

6.4. 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, $a_{\rm w}$ [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.

6.5. 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 threeweek 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.

7. 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 US Army Laboratories at Natick, to assure that food supplied to the manned space programme was microbiologically safe (Food Safety Through the Hazard Analysis & Critical Control Point System, 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 manufac-

turers. 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.

8. Current status of the FSO concept

8.1. 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 *L. monocytogenes* in ready-to-eat foods), while recognising that local conditions may provide the rationale for applying other FSOs according to specific ALOPs".

8.2. 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.

9. 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). 4
- 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/

⁴ Please note the information given in Annex 1 to this report.

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 fur-

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.
- 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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Industry members of this Task Force are Barilla, Beverages Partners Worldwide, Groupe Danone, Masterfoods, McDonald's, Nestlé, SQTS - Swiss Quality Testing Services and Unilever. For further information about ILSI Europe, call +32 2 771.00.14 or email info@ilsieurope.be. The opinions expressed herein are those of the authors and do not necessarily represent the views of ILSI and ILSI Europe.

Appendix A. 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 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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Use of food safety objectives as a tool for reducing foodborne listeriosis

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Abstract

Listeria monocytogenes is a foodborne pathogen that can cause listeriosis, a rare but severe disease whose invasive form has an estimated fatality rate of 20–30% of those who become ill. Typically, listeriosis occurs in individuals who have one or more underlying conditions that depress immune function, which makes them susceptible to the illness. Risk management strategies are required throughout the food chain to reduce the incidence of foodborne listeriosis. Public health objectives can be established to ensure continuous improvement in the health of the population with respect to a particular hazard and ideally should be based on an assessment of the risk to the population by the hazard. Food safety systems can be based on meeting a specific public health objective, to reduce the burden of foodborne disease. The International Commission on Microbiological Specifications for Foods has proposed the establishment of Food Safety Objectives (FSO) to provide a link between a public health objective and performance objectives and performance criteria that are established to control a foodborne hazard. An FSO can be used as a risk management tool for L. monocytogenes in ready-to-eat foods as the FSO establishes the stringency of the measures being used to control the hazard by specifying the frequency and/or cell number of L. monocytogenes in the food that should not be exceeded at the time of consumption. To establish an FSO based on a public health objective, the level of exposure that meets the public health objective must be determined. This requires an understanding of the risk characterization curve and the dose-response relationship for both the normal and the susceptible populations. This may be difficult, as there is considerable variation in the degree of susceptibility of individuals to L. monocytogenes, depending on their age, whether or not they are pregnant, and the severity of any underlying illness. It is likely that when establishing an FSO for L. monocytogenes both the normal and susceptible subpopulations will have to be considered. If the FSO is being met, there should be a concomitant reduction in illness as long as the main factors influencing the risk at the population level remain within the boundaries of the risk assessment. A reduction in illness can be measured through disease surveillance. Once a public health goal is achieved, new, technologically feasible goals should be considered to foster continuous improvement in reductions of listeriosis. Implementing effective food safety control measures, which ensure that the FSO is being met consistently, is key to reducing foodborne listeriosis.

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1. Introduction

Listeria monocytogenes is a foodborne pathogen that can cause listeriosis. In adults, listeriosis occurs in an invasive or a noninvasive form. After initial flu-like symptoms (fever, fatigue, malaise, nausea, cramps, vom-

iting, and diarrhea), invasive listeriosis in adults is characterized by the onset of septicemia and meningitis. In a pregnant woman, invasive listeriosis can lead to spontaneous abortion (CDC, 1998; Linnan et al., 1988). Invasive listeriosis typically occurs in susceptible individuals who have one or more underlying conditions that depress immune function, which pre-dispose them to this disease. Susceptible individuals include patients with

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cancer or undergoing treatment with steroids or cytotoxic drugs; pregnant women or neonates; renal transpatients recipients: with plant immunodeficiency syndrome (AIDS); and the elderly (Gellin & Broome, 1989; Goulet & Marchetti, 1996; Jensen, Frederiksen, & Gerner-Smidt, 1994; Slutsker & Schuchat, 1999). Invasive listeriosis has an estimated fatality rate of 20-30% of those who become ill (Mead et al., 1999). A noninvasive form of listeriosis resulting in febrile gastroenteritis has been documented in several outbreaks (Dalton et al., 1997; Salamina et al., 1996). The frequency of febrile gastroenteritis as a result of L. monocytogenes infection is undetermined, as are host characteristics associated with this syndrome.

Reducing the incidence of foodborne listeriosis requires controls throughout the food chain to minimize the likelihood that food becomes contaminated with L. monocytogenes and to prevent growth of L. monocytogenes to high numbers in ready-to-eat foods that support growth of this pathogen. This is achieved by implementing Good Hygiene Practices (GHP), Good Management Practices (GMP) and Hazard Analysis Critical Control Point (HACCP) systems. Food safety expectations are often based on how well an industry is capable of performing, i.e., the concept of ALARA (As Low As Reasonably Achievable) rather than a stated degree of stringency. The current standard for L. monocytogenes in the USA for regulatory purposes is no L. monocytogenes cells detected in the sample size tested. For a sample size of 25 g, this standard equates to <0.04 cfu/g. If this were achieved for all foods, the predicted number of cases of listeriosis would be <1 per year, based on estimates from the FDA risk assessment (HHS/USDA, 2003) and the draft FAO/WHO risk assessment (FAO/WHO, 2003). As there are an estimated 2500 cases of listeriosis in the USA per year (Mead et al., 1999) this standard is clearly not being achieved for all foods.

2. Public health goals

A public health goal is a statement of a country's appropriate level of protection (ALOP). Public health goals are established to ensure continuous improvement in the health of the population and ideally should be based on an assessment of the risk to the population by a particular hazard. Food safety standards should be set to meet public health goals. The ALOP concept was introduced in the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), which promotes the use of risk assessment based on objective and accurate scientific data when setting food safety standards. The ALOP is defined as the level of protection deemed appropriate by the member-country establishing a sanitary or phyto-

sanitary measure to protect human, animal or plant life or health within a territory. The ALOP is viewed as the degree of risk that a society is willing to tolerate, or accept, and measures what is achievable before "costs" to society become too great. Costs may be human, economic, ethical, medical, legal, etc. The ALOP will be influenced by the perception of risk, which is a function of the ability of a consumer to control the hazard, the severity of the hazard, and the degree of outrage associated with a hazard. The ALOP may include safety margins deemed appropriate for minimizing illnesses and to account for uncertainty. The safety margins employed should be proportional to the uncertainty as measured by the underlying risk assessment. As uncertainty is reduced through acquiring more information, the ALOP can be readjusted.

In the USA, a public health objective of 0.25 cases of listeriosis per 100,000 population per year has been proposed (Healthy People 2010 (www.healthypeople.gov)); a public health goal that has been interpreted as being a statement of the country's ALOP. Unlike chemical agents where there may be a distinct threshold below which a compound is not toxic, an ALOP for an infectious agent should not be viewed as an absolute end point, i.e., once it is achieved, there should be continued efforts to reduce the impact of the disease on public health. However, an underlying assumption is that it is not possible to have zero risk for most microbial food safety hazards.

3. Food safety objectives

Food safety management systems can be based on meeting a specific public health objective if the degree of stringency of the system is related to the public health objective rather than based on ALARA. However, a major hurdle to implementing the ALOP concept is that metrics used to articulate public health goals are typically not in a form that can be employed by the food industry or food control agencies to establish the required stringency for food safety systems. The International Commission on Microbiological Specifications for Foods (ICMSF, 2002) has proposed the establishment of Food Safety Objectives (FSO) at the time of consumption to provide a link between public health objectives and target points earlier on in the supply chain, referred to as performance criteria (PC). The FSO is defined as "the maximum frequency and/or concentration of a microbial hazard in a food considered tolerable for consumer protection at the time of consumption". Setting the FSO at the time of consumption requires consideration of the likelihood and impact of contamination at all points further back in the food chain. In the ICMSF concept, PC could refer to both a change in a hazard level as well as to

a hazard level. To clarify this, two new terms have been proposed, Performance Objectives (PO) and Performance Criteria (PC). A PO is the maximum level (frequency and/or concentration) of a hazard in a food at a specified point in the food chain that should not be exceeded in order to achieve an FSO. A PC is the outcome of one or more steps in the food safety management system that must be met in order achieve an FSO. For example, the outcome could be a particular minimum reduction in the hazard level required, or a maximum increase in the hazard level tolerable. Processors or legislative authorities may need to set POs or PCs at lower levels than the FSO to ensure that the FSO is met. The intention of FSO is that they be established by government regulatory agencies and serve as a means of communicating public health goals to industry and other stakeholders in a form that they can measure and influence.

When establishing PC for *L. monocytogenes*, consideration must be given to the initial levels of the organism and to any changes that may occur during production, distribution, storage, preparation, and use of a product. The PC can be expressed conceptually by the following equation introduced by the ICMSF (2002):

$$H_0 - \sum R + \sum I \leqslant FSO$$

where H_0 = initial level of the hazard; $\sum R$ = total (cumulative) reduction of the hazard; $\sum I$ = total (cumulative) increase of the hazard; FSO = food safety objective.

FSO, H_0 , R and I are expressed in \log_{10} units and, by definition, R is negative (reduction) and I positive (i.e., an increase).

4. Establishing a food safety objective—scientific considerations

Setting an FSO can involve:

- (1) Identification of a public health concern and the need for management actions.
- (2) Evaluation of the level of risk (e.g., by conducting a risk assessment).
- (3) Articulation of the public heath goal.
- (4) Determination of the maximum level of exposure that would achieve the public health goal (including consideration of the need to build in an extra margin of safety to account for variability in food safety management performance and uncertainty in our knowledge on the level of risk)—this is the FSO.
- (5) Evaluation of the feasibility of complying with the FSO
- (6) Implementation of the FSO by the industry.

Clearly, L. monocytogenes poses a public health concern and risk management actions are required to reduce the levels of listeriosis that currently exist. The prevailing level of risk can be determined by conducting a risk assessment. A risk assessment is a systematic means for assessing the severity of hazards, their level and the likelihood of occurrence. When assessing risks, the nature of the hazard, the likelihood that an individual or population will be exposed to the hazard, and the likelihood that exposure will result in an adverse health effect are considered. Details of how to undertake microbial risk assessments are described elsewhere (Buchanan et al., 1998, Buchanan, Smith, & Long, 2000; CAC, 1999; ILSI RSI, 1996, 2000; Lammerding & Fazil, 2000; Miller, Whiting, & Smith, 1997). The information developed during the risk assessment process can be used to help make risk management decisions, i.e., determine the most appropriate way to prevent or minimize harm from the hazard.

An FSO can be used as a risk management tool for L. monocytogenes in ready-to-eat foods, i.e., the FSO establishes the stringency that the measures used to control L. monocytogenes must achieve by articulating the frequency or cell number of L. monocytogenes in the food that should not be exceeded at the time of consumption. The establishment of an FSO based on a public health goal requires an understanding of risk characterization curves which relate, via an established dose-response curve, the relationship between exposure and public health outcome for susceptible populations. A dose-response analysis is undertaken as part of a risk assessment, to characterize the relationship between dose, infectivity and the likelihood and severity of the spectrum of adverse health effects associated with the hazard in an exposed population. Doseresponse relationships may be determined by human volunteer feeding trials, but for L. monocytogenes, such trials are not ethical as listeriosis is a life-threatening disease and may not be meaningful if conducted in healthy adults, because healthy adults are not the atrisk population and rarely contract listeriosis. Mice have been used to develop dose-response models for L. monocytogenes, but their utility is limited due to the uncertain correlation with the human response to the pathogen. In addition, there is considerable variation among strains of L. monocytogenes in their ability to cause disease, and this should be considered when developing dose-response curves. Despite these uncertainties, dose-response relationships have been estimated based on studies in animal models and human illness data for both the normal healthy population and for many at risk populations (Buchanan, Damart, Whiting, & van Schothorst, 1997; Farber, Ross, & Harwig, 1996; HHS/USDA, 2003; Lindqvist & Westoo, 2000).

Once an assessment of risks has been made, a public health goal can, in principle, be articulated. Following this, an FSO can be established with consideration to the dose-response relationship, and other factors (e.g., economic, societal) that the authority establishing the FSO determines appropriate. When establishing an FSO, the susceptible populations who are most likely to become ill should be considered. One challenge lies in adequately defining this population, which is not monolithic and may contain a wide range of degrees of susceptibility. At the extreme, there may be individuals (e.g., transplant patients immediately after surgery) who are so susceptible to L. monocytogenes and opportunistic pathogens that the only protective FSO would be the total exclusion of foodborne exposure to the pathogen until the patients once again have a reasonable level of immune function (Lyytikäinen et al., 2000). In these populations, strict avoidance of foods that pose an increased risk of listeriosis may be necessary, and the only practical safety strategy may be the consumption of only commercially-sterile foods.

When establishing the FSO, an evaluation should be made to determine whether the FSO is achievable, i.e., whether food safety management systems can be implemented that will ensure that the FSO is met. For certain products it may be that current technologies in the industry do not allow the FSO to be met. In such instances, the food control agency and the industry have effectively three choices, revise the FSO, identify a surrogate product (e.g., consumption of pasteurized milk instead of raw milk), or remove the product from commerce. If an FSO has been deemed technically feasibly, food industries will use GHP/GMP and HACCP approaches to control the hazard at the appropriate level and manage the risk. A broad range of food control measures are available which can either prevent contamination of foods by L. monocytogenes or prevent growth of L. monocytogenes in ready-to-eat foods such as (a) reformulation of foods so they do not support the growth of L. monocytogenes, (b) post-packaging listericidal treatments, (c) reduction of shelf life, or (d) use of competitive flora to minimize growth of L. monocytogenes.

FSOs will generally have to be implemented via the establishment of POs and PCs because an FSO is at the time of consumption so that it can be related directly to the public health goal. In the case of a ready-to-eat product that does not support growth of *L. monocytogenes*, the PC or PO at the manufacture may be the same as the FSO (e.g., the frequency and level of *L. monocytogenes* in a hard cheese). Alternatively, the PO or PC for a product may be substantially different at specific steps in the food chain in order to achieve the stated FSO. For example, if a ready-to eat product supports the growth of *L. monocytogenes* during normal refrigerated storage (e.g., cooked turkey roll, hummus) the PO at the point

of manufacture will likely be more stringent than the FSO to account for the potential growth of the microorganism during distribution and home-use. Conversely, if a product is reliably and consistently cooked just prior to consumption (e.g., reheated frankfurters), a PO set at the time of manufacture could be less stringent than the FSO. However, care must be taken in such instance to ensure that L. monocytogenes infections are not caused by the product cross-contaminating other foods before it is reheated. By defining food safety goals in terms of FSO and their corresponding PO and PC, the focus is on defining what needs to be accomplished and allows the manufacturers to decide what strategy will be effective for their products and technological capabilities. This flexibility is one of the advantages of the FSO concept.

If the FSO is being met, the public health goal upon which it is based should be met. Assuming that the public health goal relates to a risk reduction, a reduction in the extent of illness in the population related to the particular hazard should become apparent through disease surveillance. However, the relationship between compliance and concomitant reduction in illness should not be blindly assumed. A reduction might not be apparent if the main factors influencing the risk as identified in the risk assessment have changed (significantly) outside the boundaries captured in the assessment. In this case the new burden of disease is not comparable anymore to the one prevailing when the risk assessment was performed. Verification through the acquisition of disease and food surveillance data is needed to estimate the burden of disease and relate it to the level of compliance to the FSO. Verification should be a critical component of the post-implementation activities of national food safety management systems. However, this requires that the disease and food surveillance systems be integrated in such a manner that they are capable of differentiating the efficacy of the FSO from a failure to achieve the necessary degree of compliance. If such enhanced surveillance capability could be integrated with enhanced risk assessment capabilities, we should be much closer to the goal of being able to establish and implement transparent, public health-based, risk-based, verifiable food safety systems at both national and international levels.

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Food safety objective: An integral part of food chain management

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Abstract

The concept of food safety objective has been proposed to provide a target for operational food safety management, leaving flexibility in the way equivalent food safety levels are achieved by different food chains. The concept helps to better relate operational food safety management to public health goals, i.e. to an appropriate level of protection. The FSO articulates the joint target of a food chain, including all relevant links in that chain, and is common to all other food chains relevant to a pathogen/commodity combination. Performance objectives and performance criteria are two new concepts proposed recently to complement that of food safety objectives with respect to food safety control and control measures and process criteria regarding operational food safety management. All concepts together help government to give guidance to food chains about the expected safety of food products and at the same time help food chains to design their food production and food safety management systems such that there is compliance with this expectation.

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1. Food safety management

In the course of human history, the scope and complexity of food safety management on the operational level has increased dramatically. In ancient times when food safety was the sole responsibility of the hunter/ gatherer, the chain of responsibility was a very short one. Gradually, the scope increased further over small communities, regions and countries to now reach international scales. Concomitantly, the chain of responsibility has become longer and more complex as have the food supply chains to deliver the products to the consumers.

Today, with important changes in lifestyles and demographic compositions and with global food mar-

kets becoming increasingly more common place, we

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see the food supply growing ever rapidly in size and diversity. To keep pace with all the scaling up in the food supply chain and the diversification of food on the market, it has been necessary to adapt and improve the food safety management systems on a continuous basis as well. In recent years the control over the safety and quality of food produced has become tighter and tighter. Food safety management systems such as Hazard Analysis Critical Control Points (HACCP) and the pre-requisite systems Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP) have provided the professional players in the food supply chain with excellent tools (van Schothorst, 2004). Excellent provided they are used for design and implementation of a specific food manufacturing process in a proper and diligent way. Globally, both with governments and food professionals there is a good buy-in for HACCP and food safety management systems that are based on comparable principles. Notably, HACCP and its prerequisite systems are very specific to the food





Fig. 1. Panel A depicts all production facilities involved in the manufacture and marketing of a certain food product within a country. Food Safety Management, i.e. the details of GMP, GHP and HACCP provisions, are specific to the facility, the processing line and the exact product composition and processing. Panel B illustrates that, for a specific food product, microbiological risk assessment considers all foods consumed in a country, whether produced in that country or imported; it involves all different production facilities, a multitude of production-lines and product compositions and processing. MRA takes a generic, population level view on the overall production and marketing of a food product.

production facility that they have been developed for (Fig. 1).

Many different food professionals are involved in the chain of food production, e.g. from primary production, distribution, processing and manufacture, packaging, retail, to food service and preparation in the home by consumers. All those different professionals provide particular contributions depending on the specific structure and logistics of individual chains. The understanding of their role and responsibility in the overall management of the safety of the food product that is leaving a food chain needs clear co-ordination (Gorris, 2002). Specific concepts have been developed in food safety management, i.e. microbiological criteria, control measures, and process criteria, which support this co-ordination. In addition, stakeholders in food safety management such as governments, trade or sector organisations have developed guidelines, best practice advice, regulations and food safety standards.

Considering that many different food chains exist, with an enormous variety in structures, logistics and chain participants, and that they will undoubtedly change rapidly, scale-up and diversify continuously, food safety management at any scale (regional, national, local, factory) is a challenge. Ideally, each food production chain is managed integrally, across all links in the chain. Ideally as well, there is explicit knowledge about the success of this management, whether the underlying measures work to the extent projected. Ideally, again, the success of food safety management should be reflected in the health status of the population concerned.

2. Food safety control

Analyses of public health problems and their association to the food supply, have brought about the opinion in many a government that our current food supply is probably safer than ever before. Considering the enormous volume of food that, on a global scale, is produced and consumed safely, this apparent confidence is warranted. Nevertheless, the statistics indicate that even in industrialised countries one out of every three people has a food-borne microbial illness event every year (WHO, 2002). We recognise that food safety is not an absolute. It is a continuum of more or less safety.

At a governmental level, food safety control for public health protection by necessity covers the range of different food chains relevant to a certain food product or product group, including all relevant producers, manufacturing sites and food service establishments within the country as well as those importing into the country. FAO and WHO have called upon countries to apply modern international food safety and quality standards to protect consumer health. Appreciating the complexity of the current food safety supply within and across countries, both organisations advocated using Risk Analysis as the single framework for building food safety control programs. Partly through the activities of Codex Alimentarius and ad hoc expert consultations, FAO and WHO have developed a series of guidelines and reports that detail out the various steps in Risk Analysis, namely Risk Management, Risk Assessment and Risk Communication.

With respect to food-borne pathogens possibly associated to particular foods, Risk Analysis is about to be generally accepted by governments as the framework to (1) estimate the impact of a particular hazard on public health, (2) define an appropriate level of public health protection against that hazard and (3) establish guidelines to ensure the supply of safe foods (Gorris, 2002). Public health protection is paramount, but the facilitation of fair trade is a second important area of application of Risk Analysis as it is advocated to use the framework in the development of Codex Alimentarius Standards, Codes and Guidelines.

The current health status of a population is evaluated conducting a Microbiological Risk Assessment (MRA) for a product or product group to which a pathogen is associated (Buchanan, Smith, & Long, 2000; Lammerding & Fazil, 2000). An MRA can give an absolute or a relative indication of the health status, i.e. provide an absolute numerical expression of the risk at population level respectively a relative or benchmarked expressing (e.g. a ranking). Importantly, MRA studies can be developed on many levels of detail, amongst many others depending on the complexity of the issue, the urgency for obtaining the risk estimate and the data available (van Gerwen & Gorris, 2004). What all MRA studies should have in common is that they involve all relevant food products in a country or imported into a country (Fig. 1). They should keep to the important basic principles of being structured, systematic, transparent, and open studies. They also should give detailed account of all information that is important to understand the process by which the risk estimate has been arrived at as well as the content of the study. Thus, for instance, data considered, data rejected and rationale for that, models used, assumptions made and opinions all should be specified. With the risk estimate, an account of variability and uncertainty should be given.

The risk estimate, whether an absolute or relative expression, within the framework of Risk Analysis can be used by risk managers (in countries, likely the competent authority) to decide on an appropriate course of action. In some cases, the risk to the population does not necessitate action, in others specific measures are needed to reduce the burden of disease. In the latter case, risk managers may choose to set health protection goals and use these to formulate targets for all the relevant supply chains to meet. As a matter of principle, policy should be in place that helps governmental risk managers to decide on what in the WTO-SPS Agreement (WTO, 1995) is called an Appropriate level of protection (ALOP). A definition of ALOP is given in Table 1. Articulating an ALOP or any other form of public health goal is a way to express, on a population level, what level of risk a society is prepared to tolerate or is considering to be achievable. Agreeing on such levels and possibly striving for continuous improvement in the levels over time, is a key element in the Risk Analysis process.

3. Food safety objective as a food safety control concept

An ALOP, expressed for instance as a numbers of illnesses in a population per annum, is not a measure that is meaningful for food safety management in practice. The food safety professionals responsible for controlling the specific hazards possibly associated to food ingredients they use or the food products they market need more specific guidance from food safety control authorities. To that end, and within the current Risk Analysis framework, it is proposed that, when deemed appropriate, competent authorities can formulate a so-called *Food Safety Objective* (FSO). An FSO specifies the level of a hazard (in terms of concentration and/or frequency)

Table 1
Definitions for the key concepts in risk analysis based food control

Appropriate Level of Protection (ALOP)

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)

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). (CAC, 2004)

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. (CAC, 2004)

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)

Control Measure (CM)

Any action and activity that can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level (it can be microbiological specifications, guidelines on pathogen control, hygiene codes, microbiological criteria, specific information (e.g. labelling), training, education, and others) (ICMSF, 2002)

that can be tolerated in the final product when it is consumed. Setting an FSO at the moment of consumption is supported by the International Commission on Microbiological Specifications for Foods (ICMSF), as this is the moment when no change in the hazard level can occur anymore and essentially the consumption event is required to have a possible impact on public health (ICMSF, 2002). Table 1 gives the definition of FSO as it is now endorsed by the Codex Alimentarius Commission (CAC, 2004). Some hypothetical examples of FSO values are given in Table 2.

Knowledge from the MRA study, characteristics and capabilities of the supply chains affected, and ambitions for public health protection are all considered when an FSO is derived from an ALOP. In this way, the FSO reflects the stringency that governmental food safety control deems necessary for operational food safety management to implement. In this respect, the FSO value is an important communication tool for the overall management of the chain as it articulates the expected level of control on hazard levels in food chains to deliver a product considered safe. It is a concept that bridges from a population's generic requirements to specific operational measures, and as such should be accepted as an integral part of food chain management (Fig. 2). To use the FSO as an overall target at the end of a food chain leaves flexibility to individual food chains in the way this target is achieved. It acknowledges that food chains can be very different, but nevertheless should comply with a common target.

An FSO can be set on the basis of a public health goal directed towards protecting a sub-population of concern. In this case, there are two options to follow. Either the FSO that protects the sub-population of concern is implemented to be valid for the population as a whole or an FSO that protects the general population is implemented in concert with additional measures that protect

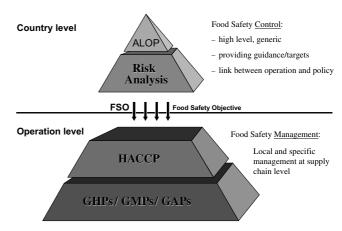


Fig. 2. Illustration of how Food safety control at a country level can link into Food Safety Management at the operational level through a Food Safety Objective set by a governmental competent authority on the basis of a public health goal (ALOP) established following the Risk Analysis framework.

the specific sub-population of concern. Although the concept of FSO has been proposed to be a specific derivative of an ALOP established considering results of an MRA study, an ALOP can be decided on without having an MRA available. In practice, countries may already have articulated public health goals without referring to them as ALOPs or using Risk Analysis to establish them. Also, FSOs can be set without formal public health goals for instance as the hazard level at consumption that would follow from complying to existing microbiological criteria earlier on in the chain.

Governmental risk managers may choose to implement specific risk management measures (standards, microbiological criteria, hygiene code, labelling, education, etc.) in addition to an FSO. Such measures may be relevant to all or the majority of supply chains so they should be included in all cases. Alternatively, such measures may be essential additions to the target without

Table 2 Hypothetical examples of concepts used in food safety control

Example: Food Safety Objectives

- Listeria monocytogenes in a ready-to-eat food product shall not exceed 3.5 log₁₀ CFU/serving size of food when eaten
- \bullet The concentration of aflatoxin in shelled, roasted peanuts shall not exceed 15 $\mu g/kg$ when consumed

Example: Performance Objectives

- Salmonellae and pathogenic E. coli shall not exceed 1 CFU/10 L when fruit juice is packaged for distribution
- Clostridium perfringens shall not exceed 100/g in cooked meat or poultry products when ready for distribution Example: Performance Criteria
- Assure a 12 log reduction of *Clostridium botulinum* in low acid canned foods
- Heat process juice to achieve a 5 log reduction of enteric pathogens
- Avoid more than 3 log 10 CFU increase in S. aureus during the manufacture of cheese and fermented meats
- Example: Control Measures
 Selection of certified infectious pathogen-free ingredients
- A product requirement, e.g. pH below 4.6 (product criterion)
- education catering staff about proper hygiene

Example: Process Criteria

- Three minutes at 121 °C for 12-D inactivation of spores of proteolytic C. botulinum
- Ten minutes at 90 °C for 6-D inactivation of spores of non-proteolytic C. botulinum
- Fifteen seconds at 71 °C commercial pasteurisation of fluid milk

which the ALOP may not be met. Importantly, the FSO is just one of the options to give guidance to food safety management the expected management of risks. As there are often many links in a food supply chain it may be necessary to establish or define several operational targets along the chain that help ensure that the chain as a whole operates to meet the FSO at consumption. It is evident thus, that close collaboration of all stakeholders in the chain is required to achieve that common goal. All stakeholders should share due responsibility related to their "span-of-control" in the chain. They all need to understand how to relate their food safety management activities to that of the whole chain, i.e. how to come to an integrated management of the food supply chain.

4. Other food safety management targets

In addition to the use of existing generic concepts (i.e. GHP, GMP, HACCP) and specific concepts (i.e. microbiological criteria, control measures, process criteria) in the management at individual steps, for the benefit of adequate control over a hazard in a chain it may be relevant to specify one or more targets earlier in the food chain that need to be complied with in order to comply to the FSO. In recent discussions (ILSI, 2004) the rationale for having such targets was clearly established. It has been proposed to call these targets Performance Objective (PO), which are equivalent to FSO, specifying hazard levels that are tolerable, but which are set at one or more specific steps earlier in the food chain (CAC, 2004). The definition for PO is given in Table 1. POs are linked to the FSO and, when proposed by governments, can be viewed as a kind of milestones that governments provide as guidance in order to help meet the FSO. However, POs can also be decided on by operational food safety managers as an integral part of the design of the production of a food in a supply chain. Establishing POs can be a matter of reverse engineering into the food chain starting from the FSO, but could also mean forward engineering from what is current practice in terms of, for instance, standards or microbiological criteria at a certain step. In any event, when POs are determined they have to be articulated with a good understanding of the events before and after the point that the PO is valid for and that have an influence on the hazard level.

In several cases, having a target early on in the food supply chain may be much more relevant in terms of guidance to hazard control than having one at the end of the chain. For example, with the production of poultry, minimising the level of hazards such as *Salmonella* or *Campylobacter* on raw poultry in primary production can be an efficient strategy in order to limit spread of the pathogen as well as cross-contamination with processed

foods at the point of preparation. Stipulating POs that relate to the prevalence of such pathogens at the primary production step can give appropriate guidance for hazard control at that step. In this case, the FSO at the end of the chain, when the poultry product has been adequately cooked and there is no reason or benefit of intervention in the hazard level would merely dictate the expected stringency in hazard control at that final stage. Some hypothetical examples of PO values are given in Table 2.

To comply with a PO or an FSO, at the operational level, control measures need to be established. A definition of control measures is shown in Table 1. Examples of control measures are given in Table 2. At a particular step in the chain, one or more control measures can be implemented as part of the product and process design to control a hazard. A new term has been proposed (CAC, 2004) to describe the overall effect of the control measures on the hazard level at a step, namely the Performance Criterion (PC). The definition of PC can be found in Table 1. A PC indicates the change in hazard level required at a specific step in order to reduce the hazard level at the start of the step to a level at the end of the step that complies with the PO or the FSO. Obviously, the hazard level at the beginning of a step (also referred to as H₀ in ICMSF, 2002) matters in establishing the PC required in a step. The higher the starting hazard level, i.e. the more bacteria enter the step, the larger the PC needs to be to achieve a particular level at the end of the step (the PO). The PC thus always has to be considered in conjunction with a starting hazard level. PCs are the specific operational, supply chain measures at (a) specific step(s) that result in meeting the objective for that step, the PO. When a PC is effective at time of consumption (e.g. a required minimum effect of a heat treatment during preparation in order to cause a specific reduction in the hazard level) it actually is the FSO that is met. Such a PC can be part of the product design, but can be relied upon only under specific conditions. PCs may concern a required reduction of the hazard, avoiding increase (limit to 0) or assuring a minimal increase. PCs in general will be decided on by food safety managers as key points in the design of the production of a food in a supply chain. PCs can be achieved by one or more control measures and as such are a reflection of the concrete management measures that assure that a product is safe and produced to meet the proper specifications. Some hypothetical examples of PC values are given in Table 2.

With respect to guidance milestones, there are thus now two discrete elements proposed: a single FSO at the time of consumption and one or more POs, as required, at earlier points in the food chain. These milestones are not intended to be enforced but should provide guidance to what level of a hazard should not be surpassed at that point helping food safety managers

to design the correct operational control measures at the step in the chain. Complying with the hazard level tolerated at the moment of consumption, the FSO, is a shared responsibility for all parties together. This requires an appropriate design of the complete chain, which is helped by specifying POs and PCs as food control guidance targets or food safety management measures at relevant points in the production chain. Although PO and PC like the FSO are not intended to be enforced, these concepts on occasion could lend themselves to be verified by specific testing or could be linked to specific microbiological criteria.

Fig. 3 gives an overview of how various guidance milestones and operational measures relate to each other in an imaginary food supply chain. Operational measures may include single control measures or sets of control measures working in concert (within the design of the food safety performance at the step) to achieve a certain effect, termed the Performance Criterion, on the hazard level in the food product when leaving the step. There are many different types of control measures, instigated by regulation or chosen by the industry, the proper functioning of which needs to be monitored and verified by the industry. The stringency in the control of the food safety system(s) operating in the food chain should be such that any exposure of the public at time of consumption does not unduly add to the burden of disease of the population by complying to the

ALOP or any other form of public health goal articulated.

5. Unique role of FSO

There is intentional similarity in the concepts of FSO and PO since both are guidance values for the hazard level at points in a food chain. Whereas FSOs by concept are only set by competent bodies/governments, POs can be set by industry or by such bodies/governments. The latter, for instance, could propose PO values when they want to define default milestones in a typical food production chain in a generic "guidance" fashion. Industry can choose to define PO values in the very specific case of a food production chain, for instance, to improve the integration of the overall supply chain management. The question arises why two different terms (FSO and PO) are proposed for the same kind of guidance. It would have been simpler to have just one of them. The rationale is that the end of the chain hazard level needs to be considered as quite a unique guidance point. Here are a number of reasons for this (not an exhaustive list):

1. The FSO set at the far end of the chain is the only guidance point that is directly related to the actual public health impact. Without consumption of the product there is no exposure of the consumer to the

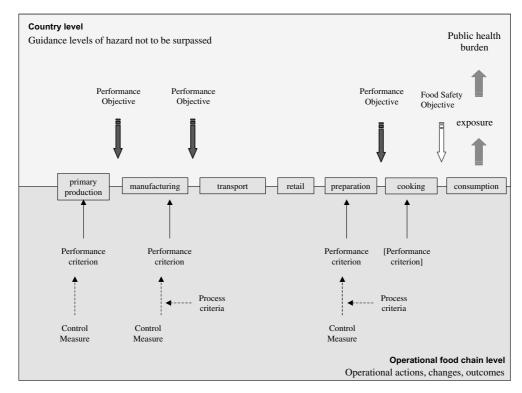


Fig. 3. Schematic representation of how governmental or country level guidance along an imaginary food chain links in with operational level measures at relevant points. The guidance is given in the form of FSO or PO values stipulated by the appropriate food control function. The operational level measures are embedded in the food safety management systems operated in the chain, such as GHP, GMP, HACCP.

hazard and no health implication. From the point earlier in the chain where a PO may be set, the possibility remains that a food is not consumed or the events following the PO are different in practice than assumed when establishing the PO level. In other words, it is thus not assured that PO equals the FSO level.

- 2. An FSO set at the point of consumption relates to the level of the pathogen that can be consumed without an unacceptable impact on public health at the population level; it relates to the actual exposure and the response at population level; on a population level, exposure is composed of several, quite variable factors, most importantly the concentration and frequency of the hazard occurring in the product at the moment of ingestion and the amount of product ingested. Also, the ALOP relates to exposure and response at population level, thus to consumption patterns affecting actual ingestion next to the level and frequency of the hazard occurring in food. However, while ALOP relates to this on a higher level and encompasses all factors, an FSO needs to be meaningful to the supply chain and effective in delivering the intention of risk management in terms of food safety. For this reason, an FSO can refer to either a concentration or a frequency or to both.
- 3. The FSO is valid for all different types of supply chains producing a particular product. Food chains can be very different in their infrastructure, partnerships, logistics and level of hazard control exercised at specific points. Nevertheless, the FSO now defines the hazard level that should not be surpassed at consumption and as such assures a form of equivalence in the level of safety provided in the final food product at consumption thus potentially, at maximum, has an equal tolerable impact on public health.
- 4. The FSO is the value that should lead the development of PO values earlier in the chain, when appropriate. POs and other target or control measures can be developed, in principle, both in a "downstream" and in an "upstream" although this will actually depend on the mathematical rigor that applies. Working in a downstream direction, essentially one is testing the hypothesis whether the food safety management system of a particular food chain as currently designed would comply with the FSO. In the upstream direction, POs and other targets or control measures are arrived at by reversed engineering starting from the FSO value. In both directions, modelling and mathematical calculations are important tools to relate measures and targets. Additionally, specific information available from an MRA study will be helpful in the exercise
- 5. Whereas the FSO gives guidance to the stringency required overall, it is more or less left open how compliance to the FSO is achieved. In other words, it is

- left flexible how a food chain structures and organises itself to produce the food such that it is in compliance and equivalent safety is provided through different chains. This avoids undue external constraints on the food chains and allows them to produce within their internal constraints (e.g. with respect to technologies, materials, processes, chain organisation, and intended market) as long as compliance is evidenced. It also fosters innovation, as not only conventional technologies and processes can be applied. This flexibility cannot be given in a generic way considering POs earlier in the chain.
- 6. The FSO is the anchor-point between operational management of food supply chains and public health protection; the former relates to a very high level of specificity (in terms of management and consumer population affected)—the latter relates to a low level of specificity—thus, the relationship between ALOP and FSO is not a direct relationship, but a conversion in which operational characteristics and population characteristics are considered. In the conversion, confidence in the technical capabilities of operational management to deliver the stringency required can be accounted for by introducing a sense of conservatism (safety factor) in deciding on the appropriate FSO value. Such a conversion can meaningfully be done at the end of the chain as this is the point of equivalence in terms of final hazard level. Points earlier in the food chain may relate to POs, but these points may differ between food chains and hazard levels thus may differ as well.
- 7. The concept of FSO is meaningful both to exposure assessment professionals and to epidemiologists; it bridges the domains necessary to relate operational level management to country level monitoring and surveillance; only when this link exists, systems at national level will be able to assess whether food safety management measures deliver what is expected in public health protection.

Where deemed necessary, governments can choose to mandate specific POs, PCs or control measures as appropriate defaults in the food chain at earlier steps than consumption, as is currently done for certain control measures. One example where such specific measures could prove to be important is in the prevention of cross-contamination at the point where food is prepared for final consumption. In this case, the occurrence of cross-contamination is a generic issue affecting the safety of all ready-to-eat products. For instance, pathogens present on raw food products such as red meats or poultry products could transfer to processed, readyto-eat foods through manual handling, cooking utensils or surfaces. In this case, both the meat and poultry as well as the ready-to-eat product may have FSOs associated. However, as they are generic appropriate preventative or control measures relating to cross-contamination should better not be linked to a specific food (i.e. as a PO, PC or control measure at that step) but should be part of general hygiene measures to be kept to in all cases during preparation.

6. Some considerations for future developments

Food operations do not need to completely change the way they manage food safety now a number of new concepts have been introduced in food safety control. At an operational level, many of the concepts, standards and guidelines that are used to date will be needed in the future. However, what is a new aspect is that food safety management will need to be able to design their operations in such a way that the food at the moment it is eaten complies with the FSO. The established food safety management systems (i.e. HACCP, GHP, GMP) and supply chain targets (e.g. microbiological specifications or process criteria) will continue to be used in order to meet the FSO. They will not become obsolete but remain a necessary, integral part of the future food safety management.

The concept of FSO is important for governmental bodies working on food safety control and legislation since they are responsible for coherent and appropriate public health protection but also for the integrity of food safety management as it relates to the overall food chain. Many aspects and issues are yet to be discussed in detail for all stakeholders to recognise the function and full value of the FSO concept. Important elements yet to gain experience with are the establishment of an FSO on the basis of ALOP or other public health goals, as well as the possible enforcement of POs (or FSOs) or related PCs, standards and control measures.

An FSO need not only be derived from an articulated public health goal, such as the ALOP, and on the basis of an MRA. Provided sufficient insight is available in the food supply chain and the dynamics of a relevant pathogen, existing measures can implicitly indicate a level of the pathogen that is achieved at the end of the chain. Although this empirically derived value can be termed an FSO, after all it is expressed in the same terms and positioned at the chain-end, it does not comply necessarily with the basic concept that the FSO links the public health goals to the management of the supply chain. This, because the direct relationship between the FSO and the ALOP or of the FSO and the hazard characteristics (exposure dose–response) is needed to make this link

Another question is about the true meaning of the word "objective". FSO is a target that different food chains relevant to a certain product/pathogen combination realistically can meet. It, however, is not a "minimum requirement" but rather a "maximum tolerable

level". However, is it or can it be a "bright line in the sand" that must not be crossed? One proposition is, that it is not. A target is not an absolute maximum. There however, should be sufficient stringency build in the FSO that there should be some tolerance in achieving it with certain reliability (Havelaar, Nauta, & Jansen, 2004). The alternative proposal is that the FSO indeed is a bright line. Given that the FSO holds at a point where control and enforcement commonly are impossible, governmental confidence in compliance will have to relate to targets (i.e. POs) and control measures earlier in the chain, in combination with the use of modelling to relate hazard levels at these points to the level of the hazard at the end of the chain.

Despite the fact that many details underlying the setting and compliance to the FSO as yet need further maturation, the consideration of FSOs and related concepts such as PO and PC as integral parts of food safety control has gained solid support both within the context of public health protection and international trade.

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A proposed framework for the use of FSOs

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Abstract

This article is based on a background paper prepared for the ILSI Europe workshop on "The impact of Food Safety Objectives on Microbiological Food Safety Management". It describes the how the concept of "Food Safety Objectives" (FSOs) can be used to target HACCP plans. FSOs describe the level of a hazard at the moment of consumption, they are considered to be "acceptable levels" of pathogens. Control measures applied from farm to fork must assure that such levels are not exceeded. In order to achieve such levels, Performance Criteria (PCs) are set to assure that a certain killing effect of a process or treatment is achieved or that a potential increase in numbers does not result in unacceptable levels of pathogens in a product. For reasons explained in this article, the term Performance Objective (PO) is introduced to designate levels of pathogens at stages in the food chain before the moment of consumption. In order to meet PCs, POs or FSOs, process criteria (such as time and temperature) and product criteria (such as pH and $a_{\rm w}$) need to be specified in the HACCP plans or in other documents. FSOs and POs are food safety targets and differ as such from Microbiological Criteria which are designed to accept or reject foods based on test results. Examples are given to illustrate that, although some of the terms may be new to certain sectors in the food chain, the concepts have been applied for many years in food processing.

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Keywords: Food safety management; Food safety objectives; Performance objectives; Performance criteria

1. Making safe food

Experience has shown that when good practices, i.e. good agricultural practices, good manufacturing practices and good hygienic practices, are applied from farm-to-fork, i.e. at the agricultural level, during manufacturing, commercialisation, preparation and use, a safe food product is almost always obtained. In cases of microbiological foodborne infections or intoxications, investigations have revealed that in most cases deviations from such practices had occurred and/or that they were not detected in time. A more systematic approach, the Hazard Analysis Critical Control Point Analysis (HACCP), was developed to prevent such situ-

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ations and its application is widely advocated. In HACCP, potential hazards or hazardous conditions are identified and analysed and, where necessary, control measures and monitoring systems put in place. Monitoring should allow detecting deviations in time, and prevent that potentially unsafe products reach the consumer. Specific control measures should prevent or eliminate hazards or reduce them to acceptable levels. The HACCP approach can in principle be applied by food industry in the widest sense, i.e. by all food professionals involved in a farm-to-fork food chain, e.g. primary production, manufacture, retail, catering and food service.

The acceptable level of a microbiological hazard is currently not often expressed in terms of its frequency and/or concentration, but just as the level which is as low as reasonably achievable (ALARA). The latest developments in food control advocate a move away from ALARA food safety management to a more risk-based and targeted approach. By using the concept of the Food Safety Objectives (ICMSF, 1998) national competent authorities aim to give more concrete guidance to food industries on the level of a hazard deemed tolerable in a product at consumption. In order to meet the FSO, food chains need to employ a set of treatments in the various steps involved that best suit their particular circumstances.

The treatments used during production, manufacturing and preparation are often clearly defined by particular food industries. In some instances, guidance on default treatments is given to industries by governments where such guidance is deemed necessary. For example, in the production of low acid canned shelf stable products the application of a sterilising treatment is advised (or required) that assures a 12 decimal reduction (12 D) of C. botulinum (the so-called "bot-cook"). Many cooking practices applied by industries have been designed to ensure that at least a 6 decimal reduction of Salmonella is achieved. However, it should be pointed out that the level of a hazard in a finished product is not only determined by the magnitude of the effect of a control measure, such as a heat treatment providing for a 6 D or 12 D reduction, but depends also on the initial level before the treatment. Default treatments as well as treatments designed by food industries can only be based on knowledge of initial hazard levels as they typically occur, and it would be appropriate to assess that such typical levels apply.

The Codex Alimentarius definition of Control Measure is: "any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level" (CAC, 1997b). The International Commission for the Microbiological Specifications of Foods (ICMSF) suggested term for this acceptable level is "performance criterion" with the following definition: "the required outcome of a step, or combination of steps, that contribute to assuring that a Food Safety Objective is met" (ICMSF, 2002). A performance criterion can, according to this definition, be expressed as a frequency of contamination and/or the concentration of the hazard per unit of mass, volume or surface area. However, it can also represent a change in numbers of the hazard present in a product, for example as a magnitude of reduction expressed as a D value. Recently the Codex Alimentarius Commission (CAC, 2004c) agreed to use the term performance criterion (PC) for the latter and performance objective (PO) for the former expression (see section on terminology). In the remainder of this paper, these agreed terms have been adopted unless stated otherwise.

In the context of this paper it is relevant to recall the definition of safe food, i.e.: "food that does not cause harm to the consumer when it is prepared and/or eaten according to its intended use" (CAC, 1997a). Ensuring

food safety in practice then means that there is knowledge about the initial level of a hazard, that a treatment is applied that would reduce the hazard to a certain level or with a specified magnitude, that subsequent recontamination and growth are controlled and that the preparation and use of the food are carried out as intended. Making safe food implies thus that criteria are set for the initial level, the effect of the treatment(s) and for the extent of growth. However, recontamination can also occur and is much more difficult to deal with. Recontamination is unintentional, and often its occurrence and magnitude are constantly changing. When a treatment is effectively applied, growth is not an important factor, because in most servings the hazard will be virtually absent. In the example of the Bot-cook mentioned above, C. botulinum will be absent in 1010 servings of 100 g when assuming an initial level of 1 cfu/g in the raw materials. In this case, growth from cells of the pathogen surviving the treatment is not of importance. However, if recontamination occurs after treatment leading to a level of 1 cfu/g at a frequency of, for example, one in 1000 servings, growth will thus have an important impact. It should be realised that the level of the hazard resulting from recontamination is often more important than the initial level before treatment and/or the reduction obtained by the treatment. Many heat treatments achieve a hazard level of <1 cfu/10⁶ g (6D) because the initial level is mostly <1 cfu/g, and thus a recontamination rate of 1 cfu/10⁴ g would determine the level in the finished product even when no growth occurs.

For this reason it is important to point to the "conceptual equation" introduced by the ICMSF (2002), which expresses the relationship between the "initial level", "reduction", "increase" and the Food Safety Objective (FSO):

$$H_0 - \sum R + \sum I \leqslant FSO$$

FSO is Food Safety Objective, H_0 is the initial level of the hazard, $\sum R$ is the cumulative (total) decrease in level, $\sum I$ is the cumulative (total) increase in level (due to recontamination and/or growth), \leq is preferably less than, but at maximum equal to; all values are expressed in \log_{10} units

In this equation, "increase" includes both recontamination and growth. The equation expresses the thought process that every food professional has to apply in designing a safe food product. It also mirrors a "Product-Pathogen-Pathway" (PPP) analysis, a methodology that is commonly used in Microbiological Risk Assessment (MRA). In both cases, the necessary treatments at individual steps in a food chain are considered in the light of what happens before the step as well as what happens after the step up to consumption. In every step, the same thought process applies and therefore the

"equation" can be used at all steps of the food chain, from farm-to-fork. This means that it can be used to derive the level of the hazard at the end of the food chain (the FSO) as well as a level earlier on in the chain (a PO). For instance, the initial level (H_0) of a hazard in a raw material entering a factory is the PO of the producer of the raw material. In the same manner the PO of a manufacturer's end product is the H_0 for the retailer, caterer or homemakers.

Also in the context of HACCP it is important to set a target level at the moment of consumption. HACCP deals with the safety of the product "from farm to fork", and not from "raw material to finished product". A manufacturer needs to consider what may happen with the product in the distribution chain and after purchase. Proper preparation instructions should ascertain that, when correctly applied, the FSO at the moment of consumption is achieved. According to the Codex General Principles of Food Hygiene, it is the responsibility of the producer to clearly describe how the food should be prepared, and the responsibility of the consumer (or whoever prepares the meal) to follow these instructions (CAC, 1997a).

2. Terminology

An FSO was defined by the ICMSF as: "A statement of the maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection" (ICMSF, 2002). This was based on the fact that it is the food as consumed that determines whether someone may get ill, not the food that still needs further preparation. A potentially unsafe food such as a raw hamburger or raw poultry meat can be rendered safe by proper heating. The FSO for Salmonella in these two products may be "absence in a serving". While cooked hamburgers and poultry meat are thus safe at consumption, they may be contaminated at a certain low level before cooking and may contaminate other foods when good kitchen practices are not adhered to. When the contaminated foods are ready-to-eat, there can be a safety issue. Evidently the FSO for foods prepared in conjunction with the raw hamburger or chicken should be different from the level of Salmonella on these products and due account needs to be given of the possibility of cross-contamination. For this reason it has been suggested that food safety targets or objectives should also be set for the level of the hazard at other moments then at consumption. The ICMSF fully recognised this and proposed the term Performance Criterion for levels at earlier points in the food chain. Others stated a preference to use the term FSO also to provide targets at earlier steps in the food chain, i.e. at the moment of purchase (ILSI, 2004).

A working group assigned to improve the Codex Committee for Food Hygiene draft guidelines on Microbiological Risk Management (CAC, 2004a) preferred to keep the term FSO for the hazard level at the moment of consumption only. This group suggested to use the term performance objective (PO) for hazard levels at other points in the food chain that can be used to manage food safety. In their opinion, the expression "performance criterion" (PC) should be kept to describe the outcome of control measures in terms of changes in hazard levels. It is not the purpose of this paper to discuss the pro's and con's of these various terms, the intention is to clarify how an FSO at the moment of consumption can be used by industry to assure the safety of food.

3. The use of FSOs in the production of safe food

The situation described in the first part of this manuscript reflects what the case is currently, since in most situations no FSO has been set. The HACCP study starts with identifying all significant hazards in raw materials and the effects of the control measures during production, distribution, preparation and use in order to evaluate the safety of a product at the moment of consumption. In principle, this is a farm-to-fork management process. However, once FSOs have been established, HACCP will become much more targeted, turning the management process into a fork-to-farm approach. The control measures and the good practices employed during agriculture, manufacturing, preparation and use are derived from the level of the hazard that has been set as the FSO or its related PO.

4. Setting performance objectives

It is assumed here that the FSO for Salmonella in poultry meat is "absence in a serving". Currently, broilers in most countries contain this pathogen, and a government may want to limit the contamination by setting a PO at the moment that broilers leave the farm. A PO equal to the FSO, which in many countries is not achieved, would evidently seriously disrupt the market. A PO of, for instance, "not more than 15% of broilers may be contaminated" might be more feasible. Proper cooking and application of Good Hygienic Practices during preparation should assure that the FSO is achieved. In this case there is clearly not a direct "mathematical" relation between the FSO and PO. In other situations this could be the case.

For example, when a stable ready-to-eat (RTE) food is dealt with, the FSO and the PO may be the same, but frequently a producer may want to built-in a "safety factor", in order to be "on the safe side". This would be done to take into account possible abuse during further

handling and to avoid that this leads to illness. The magnitude of this "safety factor" may be the result of an analysis of distribution, sales, preparation and use practices carried out during the Hazard Analysis step in a HACCP study or it may be derived from risk assessment and management carried out by a governmental body. When microbial growth can occur in a RTE product after it leaves the factory, the PO needs to be more stringent than the FSO. This would apply, for example, to certain RTE products with extended shelf-life in which *L. monocytogenes* can multiply. The extent of the growth during further distribution can be estimated, and the PO for the product leaving the factory set accordingly.

5. Setting performance criteria

If the initial level of a pathogen in a raw material were 10 cfu/g and the PO would specify "absence in 1 kg", then a treatment would be required that achieves a 4 decimal reduction. The performance criterion (PC) in this case would be a 4 decimal reduction. If the initial level would be higher or lower, this criterion would change accordingly in order to meet the PO.

A PC does not only specify a reduction in numbers or prevalence, it may also be used to express the maximum acceptable increase in the level of a pathogen as a result of recontamination and/or growth. For example, assume for instance that the FSO for *L. monocytogenes* in a non-stable RTE food is <100 cfu/g and the hazard level after a factory cooking step during production is "absence in 10 g". In this case, the PC ex-factory could specify that the hazard level should be "<1 cfu/g due to recontamination" and "less than <10² cfu/g due to growth".

6. Setting control parameters (process criteria)

In order to assure a required change, e.g. a reduction, in numbers is achieved, control parameters such as criteria for time, temperature, flow rate, etc. have to be clearly specified. For example, the process criteria to achieve at least a 6 decimal reduction of *L. monocytogenes* in milk are 71.7 °C for 15 sec (ICMSF, 1996). Such process criteria are the critical limits in a HACCP plan when the control occurs at a Critical Control Point.

Correct application of instructions for the preparation of food prior to consumption is also very important. Cooks have no means to check whether an FSO is achieved. They can, and should, therefore monitor parameters such as time and temperature. Providing accurate and easy to understand preparation/cooking instructions on the label is thus essential in assuring that FSOs are met.

7. Setting intrinsic product parameters (product criteria)

Safety of foods is achieved by, among other factors, applying extrinsic and intrinsic parameters that govern inactivation and growth of microorganisms. Selection of appropriate intrinsic parameters is of great importance to prevent unacceptable growth of microorganisms.

Multiplication and/or toxin formation are dependent on the formulation, composition and "environment" in the food. Parameters such as pH, $a_{\rm w}$, temperature, structure, additives, competitive flora, gas atmosphere etc. are used to control growth. For example, to prevent L. monocytogenes reaching levels above 100 cfu/g in a RTE food during distribution, sale and storing at home, it may be necessary that a food has a pH < 4.6 or an $a_{\rm w}$ < 0.92.

Such parameters, used to keep food safe can be based on an FSO or PO.

8. The use of FSOs in international trade

Much information concerning this aspect of FSOs can be found in the report of a recent FAO/WHO consultation (FAO/WHO, 2002). Here, just a few points are mentioned and particular attention will be given to the establishment of Microbiological Criteria.

FSOs can be used as a basis for elaborating Performance Objectives, as discussed above. Setting these maximum hazard levels tolerated is an excellent means of assuring that the system becomes transparent. It will serve to obtain evidence of the equivalence in the safety of food products and of meeting the Appropriate Level of Protection (ALOP) of importing countries, both mentioned in the WTO/SPS agreement (WTO, 1955). Setting Performance Objectives helps to shift from the old system of compliance with specific processes and process parameters to compliance with objectives. The consequence of this is, of course, that evidence needs to be provided that the required FSO or PO is indeed achieved. In other words, FSOs, Performance Objectives and Performance Criteria need to be duly validated (ILSI Europe, 1999).

Validation can include the use of laboratory data in the form of frequency or concentration of hazards in foods and results of challenge tests. Predictive modelling may be used to simulate the fate of hazards along the food chain or in specific steps in the chain. Data collected during normal processing in the food operation, comparisons with similar processes/products as well as the use of expert knowledge are other important resources for validation. These principles of validation are elaborated further in the draft Codex document: "Proposed draft guidelines for the validation of food hygiene control measures" (CAC, 2004b).

9. Setting microbiological acceptance criteria

Microbiological examination of food is still widely used when no more reliable means of assuring or judging the acceptability of food is available.

A Microbiological Criterion (MC) used in international trade should consist of:

- a statement of the micro-organisms of concern and/or their toxins/metabolites and the reason for that concern,
- the analytical methods for their detection and /or quantification,
- a plan defining the number of field samples to be taken and the size of the analytical unit,
- the microbiological limits considered appropriate to the food at the specified point(s) of the food chain,
- the number of analytical units that should conform to these limits.

Although Microbiological Criteria differ clearly in function and content from FSOs and POs, there are similarities in their establishment. In order to decide whether or not a MC should be established, and what the content should be, consideration should be given to:

- evidence of actual or potential hazards to health (epidemiological evidence or the outcome of a Microbiological Risk Assessment),
- the microbiological status of raw materials (H_0) ,
- the effect of processing (R),
- the likelihood and consequences of contamination (*I*) and growth (*I*) during handling, storage and use,
- the category of consumers at risk,
- the cost/benefit ratio of the application and
- the intended use of the food.

In developing sampling plans for MCs, the severity of the hazard and assessment of the likelihood of its occurrence, i.e. the level of public health concern of a product must be considered. ICMSF (2002) has provided guidance on this topic. It is noteworthy that a spreadsheet can be downloaded from www.icmsf.com that can be used to understand the mathematical interpretations of several sampling plans.

An FSO is a level of a hazard that, as a target for food safety management, should not be exceeded and it should also be an expression of this concern. Unlike the situation with MCs, there will normally be no sampling plans associated with FSOs. One reason for this is that an FSO states the level of a hazard at the moment of consumption, which is normally not the point in the food chain where samples are or can be taken and tested for the frequency and/or the concentration of a pathogen. However, POs set earlier in the food chain may specify hazard levels at points where microbiological

methods can be applied to measure hazard levels. Ultimately, there should thus be a relationship between an FSO and a MC. This relationship is often not a direct, mathematical one. This will depend on whether the hazard level expressed by an FSO or PO is measurable with microbiological methods or not. Also the character of this relationship will depend on whether the frequency or concentration of a certain microorganism, or a group of microorganisms (indicators), are measurable or not.

As an example, assume that the FSO set for L. monocytogenes in a stable RTE food is <100 cfu/g. This concentration can be determined with classical microbiological procedures, such as plate count or MPN techniques but it will not be feasible to do this at the moment of consumption. However, a MC for the product at the factory stage can be directly related to the concentration at consumption because the level of L. monocytogenes in a stable RTE food will not change between production and consumption. The number of samples to be taken and the specified limit (level) can reflect the safety factor possibly built into the FSO or the related factory-stage PO.

If the RTE food is not shelf-stable, then it will depend on when the sampling is done (e.g. at the factory stage), how much time is envisaged between sampling and consumption and what the conditions for growth are expected to be during this time. If a 100-fold or more increase were envisaged, then the PO at the moment of sampling would be "absence of *L. monocytogenes* in at least one gram". Most probably the limit would be set at a lower level which would become more and more difficult to measure in practice.

Assume that the FSO for Salmonella in dried egg is set at <1 cfu/10 kg, product. The same level could be taken as the PO at the factory stage. However, testing for compliance would become impossible because of the very low level of the hazard. In such a case, a criterion could be based on the concentration of an indicator group of microorganisms such as Enterobacteriaceae. When the initial number of Salmonella (H_0) in raw egg would be 1 cfu/g, a 5 decimal reduction should be obtained in order to achieve the FSO and PO, assuming a 10 fold increase in numbers due to the evaporation of water during drying. The group of Enterobacteriaceae has more or less the same heat resistance as Salmonella (Cox, Keller, & van Schothorst, 1988). This means that in order to achieve the PO, the number of these indicators should also be reduced with a factor 10⁵. Assuming that the initial level of Enterobacteriaceae in raw egg is 10⁵, this would mean that the MC would be "absence of the indicators in a number of samples of one gram". This criterion is again measurable.

However, indicators that have a meaningful relationship with measures to control a pathogen are not always available. For example, as already mentioned, for the sterilisation of a low acid canned product a "bot cook" is applied. This thermal treatment reduces the concentration of spores of *Clostridium botulinum* by a factor 10^{12} . Even if an indicator group such as "total viable spores" could be used to check whether a heat treatment was performed, one would not be able to determine the presence of spores in a sufficient large quantity of food to check whether the PO is indeed met.

In cases that MCs cannot be directly based on an FSO or a PO because of the low level of the target microorganism (pathogen or indicator) or the absence of relevant indicators, ICMSF proposes to use a kind of semi-quantitative risk assessment for the selection of "Cases" and the accompanying sampling plans (ICMSF, 2002). By using the appropriate criteria for the selection of the Cases, the best use of available resources is achieved. Moreover, the rationale behind he stringency of the sampling plan becomes consistent and transparent, which is important in the context of the WTO/SPS agreement.

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Practical considerations on food safety objectives

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Abstract

The concept of food safety objectives (FSO) is very strong in that it may make food safety transparent and quantifiable. This brings a major advantage in that one can ensure food safety at the process where it is the most effective in meeting the overall integrated objective. A practical overview is given how to derive FSOs from population health goals, through product group health objectives. Then these FSOs can be used to assign the responsibilities over the various parts of the food chain, and within one part of the chain over the various process stages, linking finally the limits of the CCPs in HACCP to the overall public health objective. Determination of characteristic numbers (log change in numbers) can help to supply the quantification of the various parts. Finally, the impact of the statistical distribution of the concentration of pathogens in foods is taken into account, and how it impacts compliance to an FSO.

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Keywords: Food safety objectives; Appropriate level of protection; Characteristic numbers; HACCP; Critical limits

1. Introduction FSO: food safety objective

The principle of food safety objectives as proposed by the ICMSF (2002) and CCFH (Codex Alimentarius Commission (2004)) is very simple, and that is its power. By integrating the changes in a hazard from the initial level (H_0) minus the sum of the reductions (R) plus the sum of growth (G) and (re)contamination (C) one arrives at a concentration/prevalence that at consumption must be lower than a food safety objective (FSO) (Fig. 1).

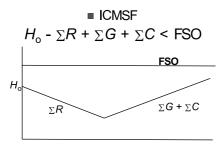
This FSO is a concentration and/or a prevalence based on the so-called appropriate level of protection (ALOP). The ALOP clearly shows the philosophy that greater public health good is achieved by setting a public health goal and then determining the frequency and/or level of a hazard in food that is compatible with that goal rather than trying to eliminate all hazards from

the food supply. One can better set an "appropriate" level and assure that it is not exceeded, than to mislead people believing that zero risk exists. The word appropriate can also be considered as dynamic and that in the future one might set another level.

Definitions and the correct representation of units is of importance:

- First of all the equations are based on log values. (For clarity FSO is only used on log basis and 10^{FSO} is used if not on log basis).
- To avoid misunderstanding one should always clearly distinguish between concentration and dose and it is important to report units: concentration (organisms per gram) or dose (organisms per serving, for example 100 g, differs by a factor 100).
- One should clearly define the end-point and the corresponding/appropriate units of risk: whether it is infection, illness, or death (endpoint), and the population that is considered. Whether risk is measured as health outcome per consuming occasion, year, or

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FSO: Food Safety Objective (cfu/g or prevalence)

Fig. 1. Schematic representation of the FSO-concept.

lifetime exposure is of very large importance. This seems obvious, but in many publications the unit cannot be figured out, therefore much more emphasis on the correct reporting is necessary. Reporting of a number without defining the "case" and the population on which it is based and the time frame, is of no use.

2. Setting of the FSO: distribution of ALOP over product groups and translation of health burden to concentration

In order to think of the way to translate an ALOP into an FSO, one should first consider about the flow of information in a structured way. If one accepts this procedure, one can include in this process additional factors like stochastic behaviour or safety factors, but first one should look at the basic steps.

If one has set for example an ALOP for *Listeria monocytogenes* mortality of 5 deaths/million/year for the total population, one may first attribute this ALOP over the various sources (food, water, person–person etc.) or product groups, since an FSO can be based on different specific product groups (for example ready-to-eatfoods, raw meats, etc.).

$$ALOP = \sum ALOP_p \tag{1}$$

In words, the total number of cases (ALOP), equals the sum of the cases per source or product group $(ALOP_p)$, the number of cases per million per year in this example. It should be realised that if the FSO is defined for a specific group of food products or even a very global group of food products, there always may be additional product groups and other sources determining the health objective.

If, for example, one tolerates 1 death/million/year for smoked fish, 3 deaths/million/year for ready to eat meats and 1 deaths/million/year for raw milk cheeses (note: assuming that these three products are the sole responsible for listeriosis; 1 + 3 + 1 = 5), one can translate this level (1 death/million/year) to an FSO for raw milk cheese. To determine this FSO, one needs the total consumption per year and the infectivity of the cell:

ALOP = deaths per million per year

- = servings per million per year
- · probability of mortality per serving
- = servings per million per year
- · probability of mortality for one cell

$$\cdot \operatorname{dose} = S \cdot 1E6 \cdot r \cdot D \tag{2}$$

with S being the number of servings per person per year, r the probability of mortality following exposure to 1 organism, and D the dose consumed. This holds if the dose is in the range where the probability is proportional to the dose. With the dose equal to the product of the mass per serving (M) and the concentration, which is $10^{\rm FSO}$ (since FSO is the log of the concentration) one gets:

$$10^{\text{FSO}} \cdot M \cdot S \cdot 1\text{E6} \cdot r = \text{ALOP} \tag{3}$$

If for instance the per person consumption of raw milk cheese is 50 servings of 30 g/year and the probability of mortality after consumption of 1 *L. monocytogenes* is 7.2E-12 (assuming 20% risk group * 1.2E-10 probability of illness (Buchanan, Damert, Whiting, & van Schothorst, 1997) * 30% mortality) and using the equation:

$$\begin{aligned} &10^{\text{FSO}} \cdot \frac{30 \text{ g}}{S} \cdot \frac{50 \text{ S}}{p \cdot \text{year}} \cdot \frac{1 \text{E6}p}{\text{million}} \cdot 7.2 \text{E} - 12 \frac{\text{death}}{\text{List}} \\ &= 0.0108 \frac{\text{death}}{\text{year} \cdot \text{million}} \cdot \frac{\text{g}}{\text{List}} \cdot 10^{\text{FSO}} = 1 \frac{\text{death}}{\text{year} \cdot \text{million}} \end{aligned}$$

with S meaning serving and p persons.

So this results in an FSO of 2 ($10^{FSO} = 100$ Listerial g). Graphically this is represented in Fig. 2. It should be noted that the curvature in Fig. 2 depends on both the infectivity of the organism (r) and the total consumption per year ($1E6 \cdot M \cdot S$).

This is the basic calculation scheme. But there are important attention points:

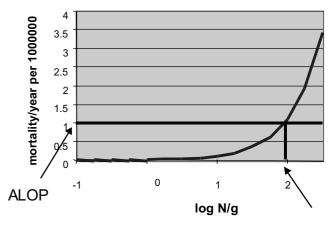


Fig. 2. Relation between ALOP and FSO.

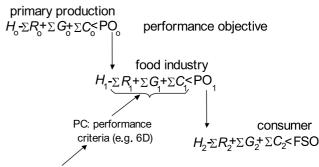
- (1) The dose response relation is not linear for high doses (what a high dose is depends on the infectivity of the organism. As long as $D \cdot r < 0.1$ the error of assuming that the probability is proportional to the dose is below 5% for the exponential model).
- (2) All variables are stochastic and this needs to be taken into account.
- (3) The concentration in food in the distribution chain is often assumed to be log normally distributed. Therefore, it are often the high doses with low probability that are determinant for the response. So one should not set an FSO on a level only, but on an average value (or a probability lower than *x* that it is higher than a certain level).
- (4) If prevalence is lower than 100% this factor needs also been taken into account. The FSO is then not a log concentration, but can be set as the concentration multiplied with the prevalence. So if the concentration is 500 cfu/g in 20% of the cases (and 0 in the remaining 80%), this is considered equal as 100 cfu/g, so FSO = 2 (this holds if one is still in the linear part of the dose–response curve, i.e. 20% probability of a five times higher illness probability, results in an equal risk).

3. Distribution over the chain

In order to meet the FSO at the end of the chain, one can set performance objectives (PO) along the chain. The PO is a term equivalent to the FSO but indicates the targets at earlier stages; targets that will allow the FSO to be met. In this manner responsibilities and specifications of all partners in the chain may be quantified, agreed, and transparent. This has a great advantage in that one can do the main interventions at the stage where it is the most effective. Within a single segment of the chain one can subdivide again the PO over the various steps in the process with performance criteria (PC), for example for a specifically required reduction (e.g. 10⁶ reduction). This goes along with the establishment of process criteria (for example 71.5 °C, 15 s) or product criteria (for example pH < 4.5). In this manner process and product criteria in for example HACCP are all together interconnected to the FSO and thus to the overall ALOP (Fig. 3).

4. Quantitative methods

To estimate the values in the FSO equation one can use microbiological methods or use quantitative microbiology. Characteristic numbers (Zwietering, 2002) showing the change in log numbers, can supply the necessary numbers for the equation in a direct way for every



process/product criteria (e.g. 71.5 °C,15s)

Fig. 3. Link of process/product limits with FSO.

stage in the chain, with the first characteristic number the Step Characteristic (SC):

$$SC = \frac{kt}{\ln(10)}$$
 for growth (G) or inactivation (R) (4)

In which k is the specific growth rate or inactivation rate and t is the time.

Secondly a Contamination Characteristic (CC) can be defined:

$$CC = \log \left(\frac{N_{\text{in}} + R_{\text{c}}}{N_{\text{in}}} \right)$$
 for (re)contamination (C) (5)

in which $N_{\rm in}$ is the numbers entering the stage and $R_{\rm c}$ is the (re)contamination rate.

It should be noted that SC is only "condition" dependent, i.e. the effect of a heat treatment remains the same whether the initial level of microorganisms is 10³ organisms/g or 1 organism/g, e.g. a 6D reduction. Therefore growth and inactivation are "additive" on a logarithmic scale. CC on the contrary is also state dependant, depending on the number of entering microorganisms. Contamination is "additive" on a linear scale and not on a logarithmic scale. An example of the quantification of characteristic numbers is given in Fig. 4.

5. Difference between growth/inactivation and (re)contamination

As noted above, SC (or $\sum G, \sum R$) is only condition dependant and the order of the increases or decreases is not of relevance. If growth and inactivation processes are considered to follow first order kinetics, it is possible to express a process without recontamination as

$$N = N_0 \cdot \exp(k_1 t) \cdot \exp(k_2 t) \cdot \exp(k_3 t) \cdot \exp(k_4 t) \dots$$
 (6)

with k the specific growth or inactivation rate, depending on the actual conditions in the stage.

On a log scale these kinetics become additive:

$$\log(N) = \log(N_0) + \frac{k_1 t}{\ln(10)} + \frac{k_2 t}{\ln(10)} + \frac{k_3 t}{\ln(10)} + \frac{k_4 t}{\ln(10)}$$
$$= H_0 + \text{SC}_1 + \text{SC}_2 + \text{SC}_3 + \text{SC}_4$$
(7)

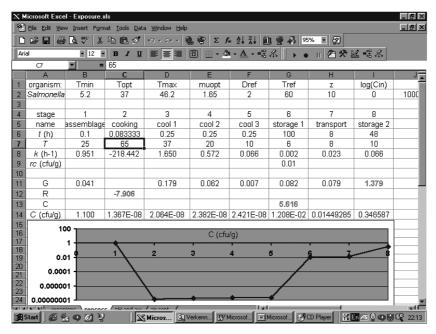


Fig. 4. Quantification of $\sum G$, $\sum R$, and $\sum C$ in an example process line.

If for example SC_2 is an inactivation, and the other 3 growth, $\sum G = SC_1 + SC_3 + SC_4$ and $\sum R = SC_2$. In principle the outcome will be equal if process steps are interchanged. It does not matter if first a 4 log growth and then a 6 log reduction takes place, or first a 6 log reduction and then 4 log growth, the result will in any case be an overall 2 log reduction. This can also be seen from the fact that in Eq. (4) the effect is only dependant on k and not on the actual level.

There are three exceptions:

- (1) If within growth the stationary phase is reached, but this is generally not the case for pathogens (and should not be).
- (2) If the number of organisms in a product unit becomes smaller than 1. Even in that case for large numbers of product units and proportional dose response relations without threshold, this does not have an overall effect on the outcome of the risk estimate.
- (3) History effects may make a dependence between stages.

On the other hand, contamination is additive on a linear scale but not on a logarithmic scale. This results in the fact that CC (or $\sum C$) is state dependant. For a case where in all stages of the process both growth or inactivation and contamination can take place one gets:

$$N = ((((N_0 + R_{c1}) \cdot \exp(k_1 t) + R_{c2}) \cdot \exp(k_2 t) + R_{c3})$$

$$\cdot \exp(k_3 t) + R_{c4}) \cdot \exp(k_4 t) \dots$$
(8)

In this case the final effect can be totally different in case contamination occurs at stage 1, 2, 3 or 4 (for example before or after pasteurisation). This can also be seen from Eq. (5) where the characteristic number depends on the recontamination level (R_c) and on the actual state ($N_{\rm in}$). A recontamination with 10 cells per gram is much more important if the actual concentration is 1 cfu/g than if it is already 100 cfu/g.

6. Overall picture

Finally the characteristic numbers (SC, CC or $\sum G$, $\sum R$, $\sum C$) of all process steps of all parts of the chain are combined (Fig. 5) with the initial number ($N_0 = 10^{Ho}$) to determine the concentration at consumption (N_t). This allows defining the exposure (dose = concentration * serving size), which is translated, with the dose–response relation, into a probability of illness or death based on one serving, the risk per serving (RpS). This probability is multiplied with the total number of servings per year per million people, resulting in the probability of one case or the number of cases per year per

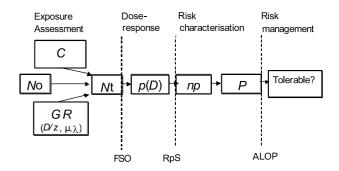


Fig. 5. Overall analysis of the connection between exposure assessment, dose–response, risk characterisation and management.

million people. It is then up to risk managers to evaluate this value and to decide whether it is tolerable/ appropriate.

In this, Eq. (3) is used: $10^{\text{FSO}} \cdot M \cdot S \cdot 1\text{E6} \cdot r = A\text{LOP}$, but with $D = 10^{\text{FSO}} \cdot M$, the dose; $n = S \cdot 1\text{E6}$, the total numbers of servings per year per million people, p(D) = rD, the probability given dose D, this can also be written as

$$D \cdot n \cdot r = ALOP \tag{9}$$

If the prevalence is lower than 100% this means that there is a probability that the concentration or dose is present in the product unit, but there are also units without any pathogen. In such a case the equation to be used is

$$D \cdot P \cdot n \cdot r = M \cdot C \cdot P \cdot n \cdot r = M \cdot 10^{\text{FSO}} \cdot n \cdot r = \text{ALOP}$$
(10)

with $10^{\text{FSO}} = C \cdot P$, so $\text{FSO} = \log(C \cdot P) = \log(C) + \log(P)$.

7. Distributions of exposures

In many cases prevalences of various levels are known. In these cases the highest concentrations are usually the ones determining the main number of cases of illness. In these cases the contribution of the various concentration ranges can be added:

$$M \cdot \sum_{i} (C_{i} \cdot P_{i}) \cdot n \cdot r = ALOP$$
 (11)

If we have, for instance:

- (1) 57% no L. monocytogenes,
- (2) 30% around 10/g L. monocytogenes,
- (3) 10% around 100/g L. monocytogenes,
- (4) 3% around 1000/g L. monocytogenes.

The number of people getting ill from eating this product per 1 million product units of 100 g (assuming that 20% of the people is in risk groups, and that for these risk groups the r of the exponential dose response relation equals 1.2E-10) results in:

- (1) 0 cases,
- (2) $M \cdot C \cdot P \cdot n \cdot r = 100 \cdot 10 \cdot 0.3 \cdot 1E6 \cdot 0.2 \cdot 1.2E 10$ = 0.0072,
- (3) $M \cdot C \cdot P \cdot n \cdot r = 100 \cdot 100 \cdot 0.1 \cdot 1E6 \cdot 0.2 \cdot 1.2E 10 = 0.024$,
- (4) $M \cdot C \cdot P \cdot n \cdot r = 100 \cdot 1000 \cdot 0.03 \cdot 1E6 \cdot 0.2 \cdot 1.2E 10 = 0.072.$

The total is therefore 0.103 cases per million servings. The highest concentration range gives the largest contribution (70%), albeit the low prevalence. If the contamination of this 3% could be prevented, the health burden

would be reduced by a *factor* 3.3 in this hypothetical example. Note that in this example the endpoint of the case is illness (mortality is not taken into account) and that it is expressed in per million servings, and not per million people per year.

With, for instance, 50 servings per year per person, this would result in 5.2 cases of illness per year, and assuming 30% mortality, 1.5 deaths per million per year. The number 0.103 (illnesses per 1E6 servings) seems to be lower than in the earlier example (1 death per million per year), but it is not.

Maybe in reality there are also products at concentrations of 10,000/g, but that go undetected. And if these are present in more than 0.3% of the cases they are the most relevant (and the probability of detecting this 0.3% if present, would even with 60 samples only be 16%).

8. Combination of prevalence, and the statistical distribution of the concentration into an FSO

If an FSO is set at 2 (100 cfu/g) or -2 (1 cfu/100 g), one can achieve this goal by controlling the average level, the spread of the distribution and the prevalence. If one has the simple case of a log normal distribution of organisms in a product, which is often a good approximation, one can determine the mean concentration by

$$\log(\overline{C}) = \overline{\log(C)} + 0.5\sigma_{\log}^2 \cdot \ln(10) \tag{12}$$

Note that the log of the mean concentration $(\log(\overline{C}))$ is larger than the mean log concentration $(\log(C))$.

Together with the prevalence P (presence/absence) one gets:

$$(\overline{\log(C)} + 0.5\sigma_{\log}^2 \cdot \ln(10)) + \log(P) = FSO$$
 (13)

So if the FSO is set at 2 (100/g) equal results can be obtained (Table 1) for example with an exact concentration of 100/g, with prevalence 100%, or by a mean $\log(C)$ of 0.85 with a standard deviation of 1 (so $\log C = \text{normal}(0.85, 1)$) and a prevalence 100%. This again results in the same as a mean log concentration of 2, standard deviation of 1 and a prevalence of 7%. These calculations only hold if the range of doses are in the linear part of the dose–response relation, that is for doses where for the exponential model $1 - \exp(-D \cdot r) \approx D \cdot r$ (as long as $D \cdot r < 0.1$, the error is below 5%).

The equation also holds for lower, and even unmeasurable FSOs. For example if absence in 100 g is set as level, FSO = -2 (Table 2). The same equations can be used resulting in the same phenomena as Table 1.

9. Definitions

Another point is the harmonisation of definitions. In the food safety literature various definitions do exist.

Table 1 Various mean log concentrations, standard deviations and prevalences, resulting in the achievement of the same FSO

-				
Mean log(C)	σ	P	FSO	
2	0	1	2	
1.93	0.25	1	2	
1.71	0.5	1	2	
0.85	1	1	2	
2	0.25	0.847	2	
2	0.5	0.515	2	
2	1	0.071	2	
3	0	0.1	2	
3	0.25	0.085	2	
3	0.5	0.052	2	
3	1	0.0071	2	

For example, ALOP (Appropriate Level of Protection), TLR (Tolerable Level of Risk), ALR (Acceptable Level of Risk) are all used to express the same public health goal. It is important to select only one term to avoid confusion. Level of protection has a more positive aspect since it uses protection and not risk, but on the other hand tolerable shows a more dynamic behaviour than the word acceptable. Recently, CODEX (Codex Alimentarius Commission, 2004) selected the term ALOP. Secondly the FSO is defined at the point of consumption. This is important because when the FSO is moved away from the point of consumption, it becomes less related to the public health objective and interventions after the point at which the limit is set can have an impact on public health. Also for performance objectives and performance criteria, their exact definition have been decided on (Codex Alimentarius Commission, 2004):

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 con-

Table 2 Various mean log concentrations, standard deviations and prevalences, resulting in the achievement of the same FSO

Mean log(C)	σ	P	FSO	
-2	0	1	-2	
-2.07	0.25	1	-2	
-2.29	0.5	1	-2	
-3.15	1	1	-2	
-2	0.25	0.847	-2	
-2 -2	0.5	0.515	-2	
-2	1	0.071	-2	
-1	0	0.100	-2	
-1	0.25	0.085	-2	
-1	0.5	0.052	-2	
-1	1	0.0071	-2	

sumption 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 (Codex Alimentarius Commission, 2004).

10. Conclusions

- The FSO concept is very strong in that it makes food safety transparent and quantifiable.
- This brings a major advantage in that one can control safety in that part where it is the most efficient but keep to an integrated objective.
- Correct use and reporting of units is of great importance.
- Characteristic numbers can supply the necessary quantification of the various parts of the equation.

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Towards an FSO/ALOP based food safety policy

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Abstract

To gain more insight in the possible process of setting a food safety objective (FSO), a concept developed by Codex Alimentarius for microbial hazards, in national food safety policy, a study was executed in the Netherlands. This Dutch study consisted of a case study regarding the process of setting a FSO for a chemical and for a microbiological hazard as well as of a theoretical study concerning the possible development of new decision-making tools. The study resulted in a model for a decision-making process that integrates life sciences, socio-economical studies and technology assessment. It also features close interaction between policymakers and researchers. As a result of the study, it is advised to install an independent advisory committee that helps government in deciding on appropriate levels of protection of the population and setting FSOs.

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Keywords: Food safety objectives; Public policy; Consumer protection

1. Introduction

At national as well as international level, efforts are made to define the concept of food safety objective (FSO). FSOs are proposed to be a metric that gives guidance to food production and preparation professionals concerning the expected compliance of foods to consumer protection policy with regard to a possibly associated hazard. FSOs should be arrived at in an objective and transparent way. Within the Codex Alimentarius Food Hygiene Committee (CCFH), the following working definition of a food safety objective is currently discussed: "The maximum frequency and/or concentration of a microbiological hazard in a food at the time of consumption that provides the appropriate level of protection" (ALOP) (CAC, 2003). While Codex considers FSOs only for microbial hazards, in principle, the concept could apply to other types of hazards as well.

* Corresponding author. Fax: +31 318 822550. E-mail address: r.a.donker@minlnv.nl (R.A. Donker). The concept of ALOP was introduced in the WTO Agreement on the application of sanitary and phytosanitary measures (the SPS Agreement) in 1995 (WTO, 1995). An ALOP is defined in the SPS agreement as: "The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory". The purpose of the SPS-agreement was to increase the transparency of SPS-measures. It is the prerogative of individual Member states to determine what constitutes an ALOP that is appropriate for its population. Discussion is actively ongoing whether in addition to scientific insights, other factors can be considered in the decision on an ALOP. Such other factors could be for instance technological and economical (Table 1)

An ALOP can be expressed in a range of terms, for instance from broad public health goals to a quantitative expression of the probability of an adverse public health consequence or an incidence of disease.

By formulating an FSO, governments communicate to interested private and public parties a more practical

Table 1

- Scientific and production factors All available scientific evidence;
- Relevant processes and production methods;
- Relevant inspection, sampling and testing methods;
- Prevalence of specific diseases or pests;
- Existence of pest—or disease—free areas;
- Relevant ecological and environmental conditions;
- Quarantine or other treatment.

Economical factors

- The potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease;
- The costs of control or eradication in the territory of the importing member;
- The relative cost-effectiveness of alternative approaches to limiting risks.

form of food safety guidance than the rather abstract ALOP. In particular guidance is given to food industry (e.g. primary producers, food processors, catering, distribution and retailers) involved in the production of the particular food as to the required level of control over the hazard in the food such that consumers are duly protected. FSOs can then be translated into a set of quantitatively stated requirements that enable appropriate design of product, process and control measures (Jouve, 1999). In this context, the agro-food industry would use FSOs as a means to co-ordinate risk management in the production process throughout the farm-tofork production chain.

Up to now, the international discussion has focused on the scientific development of FSOs and its use by governmental risk managers and the food industry. The implications and chances of implementing FSOs in the policy-making process have hitherto received not much attention. Since the scientific development of FSOs by organisations as the Codex Alimentarius, the International Commission on Microbiological Specifications for Food (ICMSF) and the International Life Sciences Institute (ILSI) progresses it is time to consider the first steps towards the implementation of FSOs in public policy.

2. Goal

The Netherlands Ministry of Agriculture, Nature Management and Fisheries wanted to gain more experience and insight in the process of establishing food safety objectives. To this end, the National Reference Centre for Agriculture, Nature Management and Fisheries, the RIKILT Food Safety Institute and the Agricultural **Economics** Research Institute commissioned to execute a case study on FSOs based policy for a microbiological hazard (Campylobacter) and a chemical hazard (dioxins) as well as a theoretical study on the implementation of FSOs in policy processes.

The purpose of this research was to investigate whether the Codex Alimentarius concept of FSO could be of added value for policymakers in comparison to current food safety policy.

Important questions that needed to be answered for the implementation of FSO policy were:

- What information is needed to establish quantitative FSOs in an objective and transparent way?
- What procedures are to be followed?
- Who should be involved in the process of deciding on an FSO, when and to what extent, in order to arrive ant a broadly supported FSO?

3. Microbiological hazards: the *Campylobacter* case

In policy processes, four separate phases can in general be distinguished: (1) the phase of recognition of the existence of a problem, (2) formulation and demarcation of the policy problem, (3) development of possible solutions and (4) implementation and maintenance of management.

The recognition phase for Campylobacter in the Netherlands was between 1992 and 1997 when incidents caused by Campylobacter, together with Salmonella incidents, became more and more a political issue. Since 1997 several plans have been launched to tackle the Campylobacter problem. However, the policy process seemed to go back and forth between the policy formulation and solution phases without making any significant progress. Up to this date possible solutions did not led to a decrease in *Campylobacter* incidence or to a clear management of the problem. The microbiological case also showed that the present food safety policy for Campylobacter was not very transparent. Although scientific, socio-economical and technical considerations were indeed part of the risk management process, it was not clear on which grounds decisions were made and what weight was given to the different arguments. Responsibilities and targets for the stakeholders involved were not clearly defined. Notably, policy objectives were not made explicit, due to which goals and means to achieve remained a matter of debate and opinion. It was expected that the introduction of an ALOP based on the life-sciences, socio-economical data and current technical possibilities would set a clearer political goal in reducing food-borne Campylobacter infections. FSOs derived from the ALOP could then set explicit target levels at the time of consumption. Chain-reversal would effectively set guidelines for the entire food chain to achieve the FSO. Individual companies could thus be held accountable for their efforts to achieve the FSO.

4. Chemical hazards: the dioxins case

The application of risk analysis to chemical hazards has a longstanding tradition. Risks are interpreted on generally the basis of experimental studies and acceptable daily intakes (ADIs) are set for individual chemicals that represent principally safe levels of intake. Public management of chemical hazards is clearly based on either physiological, scientific evidence or on ALARA principles. Although dispute about specified ADIs and the scientific means of calculating them is probably inevitable, there is no debate on the principles of the ADI concept.

However, for chemical hazards it is more difficult to set a meaningful ALOP as compared to ALOPs for microbiological hazards. With chemical hazard, often there is no proof of causality between a chemical hazard and an individual case of a food-borne disease because impacts of chemical hazards may be more chronic in nature. A second complication regarding ALOPs for chemicals is that most chemical hazards can be found in a variety of products, both food and non-food, and in our direct living environment. On the other hand the ADI concept is based on scientific considerations, which certainly can be taken into account in the ALOP/FSO approach.

5. Discussion

One of the advantages of an ALOP/FSO based policy is that information from life sciences, socio-economical studies and agro-technology/agro-logistics can explicitly be taken into consideration when deciding on an ALOP and on subsequent FSOs. These different scientific fields should closely interact with each other. Policy makers, food industry, consumers and other stakeholders should likewise interact closely to achieve effective development of FSOs and ALOPs. Since food safety on an operational level is primarily the responsibility of the food industry, the food industry is responsible for meeting ALOPs and FSOs. The national authorities however are responsible for controlling the process of setting, achieving and evaluating ALOPs and FSOs. The implementation of an FSO policy could result in less governmental involvement in detailed measures concerning food safety, leaving the food industry more freedom and flexibility to organise their quality management tools (HACCP, GMP, etc.).

The development of ALOPs and FSOs is an iterative process, periodically starting a new cycle. This means that the FSO/ALOP-system should in principle be flexible, allowing for policy adaptations due to new scientific insights and shifts in societal and political priorities. A system of checks and balances ensures the effectiveness of measures and that public health goals remain up to date (see Fig. 1).

Overall, the FSO/ALOP-system could be divided in four major phases:

- 1. Risk assessment,
- 2. Setting ALOPs and FSOs,
- Translating risk management to process management,
- 4. Feedback on risk assessment and risk management, starting a new cycle or consolidation.

Based on a risk profile, the initial inventory of a food safety problem that is compiled by the governmental risk managers within the framework of risk analysis, a hazard can be examined from different viewpoints, as discussed in CCFH (CAC, 2003). Risk assessors are then briefed regarding the risk management question they are asked to address in the risk assessment phase. Current risk assessment is usually an assessment of the characteristics of a microbiological or biochemical hazard, taking into account an estimate of the occurrence of such a hazard in foods and the actual exposure of consumers. In order to implement effective risk management, other factors such as socio-economical factors and technological possibilities should be taken into account as well. Before an ALOP can be set, different outcomes of risk management options should be evaluated by developing different scenarios for intervention strategies as well as the resulting public health impact, socioeconomic consequences and technological development. A decision then has to be made on an appropriate ALOP and FSO, considering the outcomes of the different scenarios and the risk management options available. The FSO can be implemented, using food safety management metrics such as performance criteria. Obviously, it is important to establish methods to assess whether the FSO is met. Also, a periodical evaluation of the FSO is needed to ensure that it still meets the food safety policy. When a new ALOP has been decided on, there may be a need to adapt the FSO.

This management model can be made operational within the current public machinery of most countries. Because ALOPs are set at population level and FSOs—where possible—at consumer level, less governmental involvement and concomitant greater responsibility for the food industry can be effectuated without compromising public consumer protection.

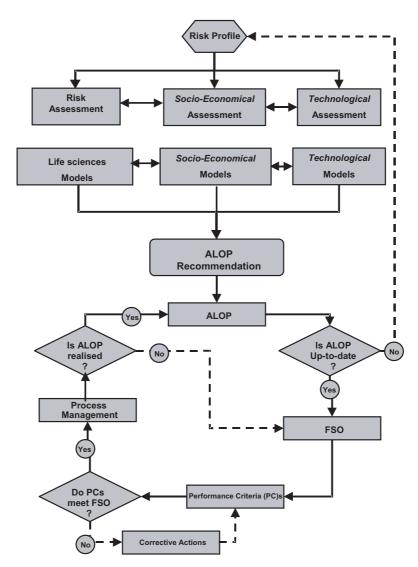


Fig. 1. Management model for the development of an ALOP and FSO. Data from different assessments is used in an integrated recommendation for an ALOP. At the consumer level, an FSO is derived from an ALOP, the FSO is communicated through the food chain by setting performance criteria in accordance with the FSO. Individual businesses must arrange the process management so performance criteria are met. A system of checks and balances ensures that food safety policies keep up with scientific, technological and social developments and ensures that policy targets are met.

In support of setting new FSOs and ALOPs, the Dutch government commissions research institutes to perform risk assessments, socio-economical impact studies and technological analysis. It is crucial that research institutes of all fields involved will closely co-operate and take into account available knowledge of the food industry. The research institutes should develop different scenarios based on life sciences, socio-economic research and technical analysis. However, it is proposed (de Swarte et al., 2002) that it should not be these research institutes who ultimately recommend ALOPs or FSOs to the government. Instead, an independent ALOP/ FSO advisory committee should be installed to review the different scientific scenarios, weigh the arguments of stakeholders and thus in the end come to an independent advice for ALOPs and FSOs. Independent representatives of the scientific community, the agro-food industry and consumer organisations could participate in such an advisory committee. It is of course the government who is finally responsible for setting ALOPs and FSOs and for enforcing measures that warrant that food industry complies to the ALOPs and FSOs.

Most governments have advisory scientific bodies on food safety and these could be capable of evaluating scenario's and advising risk managers responsible for setting ALOPs and FSOs. A specific and independent ALOP/FSO advisory committee will be a novelty for most. However, it is felt that such a committee in best placed to assess the consequences of different risk management options and, based on the information accumulated in considering different scenarios, to give advise to the government on appropriate ALOPs and FSOs. Evi-

dently, the proposed integration of scientific/technical expertise with socio-economical and consumer level thinking should be within the scope of such a committee. Committee members also need to have a good appreciation of the risk analysis framework and its different elements in order to adequately fulfil their role.

Choosing an appropriate ALOP is very much a political decision. Setting an FSO is less political, and will be based more on scientific, technical and socio-economical factors. Setting an FSO will divide and prioritise the ALOP among different food groups and needs to take into account the prevailing technical capabilities in and the current food safety performance of the relevant food chains. However, FSOs could be set and adapted without changing the political goals of an ALOP. Once an FSO is set, the food industry is responsible for setting up management systems that deliver a level of food safety in compliance to the FSO. Performance criteria and other metrics on the operational level can be derived by food industry from FSOs by chain-reversal, in effect articulating appropriate food safety standards for individual links in the chain. Such standards as well as particular control measures that government may choose to mandate should be enforced and inspected by (private and public) certification and inspection systems.

Some improvements of the existing approaches to risk assessment, management and risk communication are needed in order to make the integrated ALOP/FSO model work more smoothly.

Improvements relating to risk assessment

- Current risk assessment focuses mainly on life sciences. ALOP/FSO methodology must also take into account socio-economic and technological consequences of risk management. Consequently, in the future, life sciences, social sciences and engineering need to co-operate more closely to develop integrated scenario's for assessing risk management options.
- In order to set meaningful ALOPs and consequent FSOs a better knowledge of the impact of a food safety hazard is needed. Epidemiological data can help gain more insight on the impact and to develop models on major sources of infection and public health impact of food-borne illnesses. Epidemiological data for food-borne illnesses can be quite scarce, depending on the pathogen and the country or region considered. Often, epidemiological data are not accumulated in a way that it is directly usable in risk assessment. There is clear room for improvement in that respect.

Improvements relating to risk management

 If FSOs are indeed set at the time of consumption, as proposed in the working definition of CCFH, a better knowledge of consumer behaviour and insight in key

- aspects of the capabilities and food safety performance of the agro-food business is necessary in order to set appropriate FSOs. In part, such insight is brought to bare by a close involvement of the private sector as a particular stakeholder in the risk management process. Also other parties can contribute significantly here, including academia specialised in consumer behaviour as well as consumers themselves or their representatives.
- Performance criteria and other food safety management measures are governed by private law; they should be an agreement between two or more links in the chain of a food supply chain. These private performance criteria must lead to the achievement of FSOs, which are subject to public law. It is not clear yet what legal implications this may have. One of the advantages of the ALOP/FSO methodology is that food safety measures are directly linked to public health goals. In order to evaluate the effectiveness of ALOP/FSO-food safety policy, more knowledge is needed on public health figures of food-borne illnesses and patterns of food consumption.

Improvements relating to risk communication

 By explicitly stating a level of safety by setting an ALOP, implicitly one sets a level of unsafety. Society, consumers and politicians will have difficulty accepting a certain level of unsafety. In order to successfully implement an ALOP/FSO based policy it is important new risk communication tools are developed to overcome this problem.

6. Conclusion

FSOs can be powerful tools in risk management. FSOs assist governments in conveying health goals throughout the food chain. FSOs actually help translate health goals into appropriate food safety measures. An ALOP/FSO based policy requires more than a better understanding of risk assessment or better process management at individual businesses. It requires an integrated approach of risk assessment, risk management, process management and above all, risk communication. This means a new challenge in the way scientists, politicians, policymakers and food operators interact.

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