Food safety objectives as a tool in development of food hygiene standards, guidelines and related texts.

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This paper represents the situation as of the beginning of 2002 and does not reflect changes that may have occurred since then. In 2004 The Codex Alimentarius Commission adopted definitions for Food Safety Objective, Performance Objective and Performance Criterion. These can be found in the report of the Commission and the 13th edition of the Codex Procedural Manual.

1 Scope

This document describes how Food Safety Objectives (FSOs), Performance Standards (PSs) and related parameters can be derived from an ALOP/TLR. Particularly the role and establishment of microbiological criteria is presented. A practical example of the use of the various parameters to assure food safety is given. Detailed information concerning a number of topics is given in the Appendix.

The views expressed herein are those of the author and do not necessarily represent those of the World Health Organization nor of the Food and Agriculture Organization of the United Nations nor of their affiliated organization(s).

The 27th Session of the Codex Alimentarius Commission adopted the following definitions.

**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.

These supercede those that are described in this paper.
2 Objectives of Governmental Food Control Agencies and their risk managers

The roles of governments are according to the Codex General Principles of Food Hygiene (CAC, 1997a):

- to protect consumers adequately from illness or injury caused by food
- to maintain confidence in internationally traded food.

The WTO/SPS agreement (WHO, 1997) describes the rules for the international trade in safe food and has introduced the term "appropriate level of protection" (ALOP) to express what is mentioned in the first bullet point above. This ALOP has also been called "acceptable level of risk". This term is similar to the expression "tolerable level of risk" (TLR) preferred by the ICMSF, because it recognises that risks related to the consumption of food are seldom accepted, but at best tolerated. Also implied is that for a number of food safety hazards, “zero risk” does not exists and/or too costly (financial, societal) to achieve.

One of the tasks of governmental Risk Managers is thus to decide upon what is adequate, appropriate or tolerable in terms of food safety or health risk. How they have to do this is not described in detail by the WTO or the Codex. However, The determination of ALOP/TLR should be science based, should include economic and societal factors and should minimise negative trade effects.

Integral to the agreement is that imported food should not compromise the ALOP. An exporting country can contest an importing country's judgement that a food is not meeting the ALOP, by using scientific methods such as risk assessment. Codex standards, codes and guidelines are mentioned as reference documents. A country cannot demand that imported foods are "safer" than similar domestically produced foods. Figure 1 illustrates how Microbiological Risk Assessment (MRA) could be used in acceptance procedures of internationally traded food products.

Under the heading of transparency it is mentioned that member states shall ensure that "reasonable questions can be answered concerning SPS measures and that relevant documents can be provided such as: risk assessment procedures, factors taken into consideration, as well as the determination of the ALOP". Changes in regulations should be notified. Although it is not specified how an ALOP should be expressed, it is commonly seen as the number of illnesses per annum that should not be exceeded.

Use of MRA in International Trade

Risk Manager in exporting country
Risk Manager in importing country

Risk Assessor in exporting country

Determines Risk Estimate (RE)

RE > TLR : food rejected

RE < TLR : food accepted

Risk Manager in exporting country may contest TLR

Defines the Tolerable Level of Risk (TLR =ALOP)

WTO
Figure 1. The use of MRA in judging the acceptance of foods in international trade based on the ALOP/TLR concept.

At a national level, one of the concerns of a government in protecting consumers from food safety hazards is that imported food would not provide the appropriate level of protection (ALOP). Another concern is that the level of protection that has been previously achieved is no longer sufficient due to changes in the food chain, changes in consumption habits, or because new hazards have emerged. This situation may be reflected in increased incidence of foodborne illness or epidemiological data linking a certain food to a particular hazard. Governments also have general programmes, or initiate specific ones, to improve food safety. Since resources are limited, priorities have to be set; risk assessment may be a tool in achieving this. A general flow of events in Food Safety Management systems is presented in Figure 2 (ICMSF 2002). Some important terms and documents are discussed in Annex 1.

Since MRA is according to the WTO/SPS agreement and Codex documents an important food safety management tool it merits further analysis.
Figure 2. A Food safety management scheme based on Codex documents mentioned in the text and the list of references.
3 MRA inputs and outputs

The last element of MRA is risk characterization (CAC, 1999a), often leading to the determination of a risk estimate (with attendant uncertainties). Such an estimate can be: the number of cases of a specific illness per 100,000 persons in (a certain category of) the population per year, as caused by a specific pathogen/product combination. In order to arrive at such a figure, the level of exposure (frequency and concentration) of a hazard at the moment of consumption has to be determined. Currently a product/pathogen/pathway (PPP) analysis is used for this purpose. The fate of the pathogen from “farm to fork” is described and quantified, often using predictive modelling and Monte Carlo techniques. Risk Managers can decide whether the risk is tolerable (less than the TLR), or that control measures have to be considered (risk estimate higher that the TLR).

A PPP analysis can also be used to calculate the effect of various potential control measures (scenario simulations) on the risk estimate. Such data may be of great value for Risk Managers in their decision making. For example introducing a cooling step directly after laying the eggs in the PPP for _S. Enteritidis_ in shell eggs, the risk of illness could be reduced with 12% according to an USA study (FSIS 1998).

An important outcome of a MRA is the establishment of a relationship between the exposure (the level of a hazard in a food) and the incidence of the disease it causes in a given population. This may be represented by a hazard characterization curve. The slope of this curve is specific to the hazard, the food, the nature of the illness and the category of consumers for which the curve has been determined. If such a curve is available for the incidence of disease for a specific pathogen-food combination, it can be used to establish a Food Safety Objective (FSO) (see 7.1.3 and Fig. 2).

Another output of MRA is the recognition that certain data are scarce or even completely missing. Some data may be crucial for making a scientifically justified decision and a worst-case scenario or precautionary approach may be taken. It is therefore in the interest of all parties to provide relevant data to risk assessors in order to diminish the uncertainties that accompany the risk estimate.

4 Food Safety Objectives

Recognizing the difficulty of using public health goals such as an ALOP or TLR to establish control measures, the concept of Food Safety Objectives (FSOs) has been introduced. A FSO converts the ALOP/TLR into parameters that can be controlled by food producers and monitored by government agencies. The ALOP/TLR is an expression of a public health risk, while a FSO expresses the level of a hazard in relation to this risk. It is the level of a hazard during eating that determines the probability of a harmful effect. Therefore a FSO was defined at the last CCFH meeting (CAC, 2001b) as: _"the maximum frequency and/or concentration of a microbial hazard in a food at the moment of consumption that provides the appropriate level of health protection"_.

The establishment of a FSO for Codex purposes is a Risk Management activity. The primary purpose of an FSO is to translate a public health goal (i.e., a desired level of consumer protection) to measurable attributes which allows industry^2^ to set control measures for processes. The FSO also allows comparison between foods produced in different countries. For a further discussion of the FSO concept see Annex 2.

One of the outputs of a MRA as mentioned above is a relationship between the level of a hazard in a food and the incidence of the disease it causes in a given population i.e. the hazard characterization curve. If such a curve is available, the FSO can be determined by positioning the

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^2^ The term "industry" means: an organisation, company or group of individuals (cooks) working professionally in the food chain from primary agricultural production to the sale to, or preparation of food for, the consumer. The particular meaning in this document depends on the context in which it is used.
ALOP (the probability of illness) on the y-axis and reading the corresponding level of the hazard (FSO) on the x-axis (see Fig. 2).

Even when no ALOP is determined and the risk assessment does not provide the necessary information, FSOs can still be established. Investigations of foodborne illnesses and epidemiological surveillance programmes provide information about which foods have caused adverse health effects and which pathogens were implicated. Industry records are another important source of information. Many foods processed for safety have a good history of providing an appropriate level of health protection. When such foods were implicated in food-borne illness this was mostly caused by deviations from Good Manufacturing/Hygienic Practices or accidents that were not detected in time. A good example is the safety record of industrially produced shelf-stable canned products. By analysing the production of such a food, an estimate can be made of the level of a potential hazard that may remain in the food. This level may than be used to establish a FSO or a Performance Standard (see 7.1.5) without having to perform an often expensive and time-consuming MRA.

5 Performance Standards

For the purpose of this document the term Performance Standard (PS) will mean: the frequency and/or concentration of a hazard in a food at any point in the food chain [other than at the moment of consumption] required to achieve a FSO. N.B.: the use of the word "Standard" does not imply that the specified level of the hazard would be a regulatory mandatory requirement. The term Performance Standard (PS) is chosen because in trade these criteria play an important role. The FSO sets the level of a hazard at the moment of consumption, a point in the food chain where foods are no longer traded. The term is already used for this purpose in certain countries.

A FSO for Salmonella in poultry meat may be "absence in a serving". Currently broilers in most countries contain this pathogen, and a government may want to limit the contamination by setting a PS of "not more than 15% of broilers may contaminated". Proper cooking and application of Good Hygienic Practices during preparation should assure that the FSO is achieved, while the market is not disrupted by a PS equal to the FSO, which in many countries is not achieved.

When a stable Ready-To-Eat (RTE) food is dealt with, the FSO and the PS 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 takes into account that some abuse may occur during further handling and that this should not lead 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 in a HACCP study or an exposure assessment of a MRA.

When microbial growth will occur after a product leaves the factory, the PS is more stringent than the FSO. This would apply, for example, to certain RTE products with extended shelf-life in which L. monocytogenes can multiply. Obviously, the PS can be less stringent than the FSO when a product needs to be cooked before consumption and when the Performance Criterion of this preparation step, in combination with the H_{in}, would assure that the FSO would be met. The case of Salmonella in broilers is a good example of this.

It should be mentioned here that a PS can be set at any point in the food chain and that it is at least at the same level as the "acceptable level" to be achieved at a Critical Control Point (CCP). A CCP is defined as: a 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).

6 FSO and Product/pathogen/Pathway Analysis
The ICMSF has introduced a simple equation that summarises the fate of a hazard along the food chain as follows:

\[ H_0 - \Sigma R + \Sigma I \leq FSO \]

where:
- \( FSO \) = Food Safety Objective
- \( H_0 \) = Initial level of the hazard
- \( \Sigma R \) = the cumulative (total) decrease in level
- \( \Sigma I \) = the cumulative (total) increase in level
- \( \leq \) = preferably less than, but at least equal to

\( FSO, H_0, R, \) and \( I \) are expressed in \( \log_{10} \) units

\( I \) (increase) is determined by growth (\( G \)) as well as by recontamination (\( RC \)). Since the FSO is the level of a hazard at the moment of consumption, another term is needed to describe the level at another point in the food chain. The term Performance Criterion has been proposed by the ICMSF, but this term is also used to describe the outcome of a processing step (for example a 6 decimal reduction of a pathogen). For this reason the term Performance Standard is used in this document to reflect the level of a hazard (see 7.1.4) and Performance Criterion to describe the impact of a process on the level of a hazard (see 7.1.6)

As a consequence of this, the following equation is proposed:

\[ H_0 - \Sigma R + \Sigma I_{RC} + \Sigma I_G = PS \]

\[ H_0 - \Sigma R + \Sigma I_{RC} + \Sigma I_G = PS \]

\[ H_0 - \Sigma R + \Sigma I_{RC} + \Sigma I_G \leq FSO \]

where:
- \( FSO \) = Food Safety Objective
- \( PS \) = Performance Standard
- \( H_0 \) = Initial level of the hazard
- \( \Sigma R \) = the cumulative (total) decrease of the hazard
- \( \Sigma I_{RC} \) = the cumulative (total) recontamination with the hazard
- \( \Sigma I_G \) = the cumulative (total) growth of the hazard
- \( \leq \) = preferably less than, but at least equal to

Note that the PS of one point of the food chain may be the \( H_0 \) of the following one.

This equation is helpful to determine the effect of control measures necessary to meet a FSO. It is important to recognise that data used in PPP analyses, that can be used to determine the various values of \( H_0, R, I_{RC}, I_G \), and PS, may differ according to their source and use.

\[ \text{Only two stages in the food chain are mentioned here for simplicity reasons. In reality more stages have to be distinguished.} \]

3
A PPP analysis carried out by governmental risk assessors uses all available data. Many raw materials, processing conditions, warehousing and distribution conditions, retail, preparation and use practices have to be taken into account. The more the variety of data will reflect the reality, the better the risk estimate will be. Various scenarios can simulate potential control options deemed necessary to improve the safety of a product, i.e. leading to different FSOs. These data can be useful in the establishment of generic HACCP plans.

A PPP analysis carried out by HACCP teams during product development or during the study of an existing production line is very specific. It takes into account the microbiological condition of the raw materials used, what the actual processing conditions are, as well as what is happening with the product after it leaves the production site. If the level of the hazard at the moment of consumption is estimated to be higher than the FSO, control measures have to be changed or introduced in order to remedy this situation.

7 Performance Criteria and their validation.

The term Performance Criterion (PC) is used to express the outcome [impact] of a process step or a combination of steps (decrease, increase or change in the level of a micro-organism or microbial toxin). An example of a PC is a 6D kill of salmonellae when cooking ground beef.

A PC does not only refer to a reduction in numbers, it may also be used to limit recontamination and growth. For example, if the FSO for *L. monocytogenes* in a non-stable RTE food is <100/g and the PS after a cooking step during production is absence in 10g, then the PC for recontamination (RC) could be < 1/g and the PC for growth (G) <10^2.

Setting PCs based on Performance Standards is an excellent means of assuring that the system becomes transparent and it will serve to obtain evidence of the equivalence mentioned in the WTO/SPS agreement. It helps to shift from the old system of compliance with processes and Process Criteria to compliance with objectives. The consequence of this is, of course, that evidence needs to be provided that the required PS is achieved with the PC applied i.e. the PC needs to be validated.

Validation is an increasingly important aspect of Food Safety Management (ILSI, 1999). Validation of a defined set of control measures requires that their effectiveness be measured against an expected outcome in controlling a hazard, normally expressed in terms of a performance criterion. Thus, control measures should be validated to prove that they meet established performance criteria for controlling a specific hazard(s) in a food (s) in order to meet a given FSO.

Validation can include the use of laboratory data in the form of predictive microbial models and challenge tests, the use of data collected during normal processing in the food operation, comparison with similar processes/products as well as the use of other expert knowledge. These principles of validation are elaborated further in the "Discussion paper on proposed draft guidelines for the validation of food hygiene control measures" (CX/FH 01/13).

8 Process Criteria

Process criteria are the control parameters (e.g., time, temperature, pH, aw) at a step, or combination of steps, that can be applied to achieve a Performance Criterion (PC). For example, the control parameters to achieve at least a 6 decimal reduction of *L. monocytogenes* in milk are 71.7°C for 15 sec (ICMSF, 1996). Process criteria are identical to critical limits (CAC, 1997b) when the control point is a CCP in a HACCP plan.

Correctly applied process criteria for the preparation of food prior to consumption on the label is very important. Cooks have no means to check whether a FSO is achieved. They can, and should,
monitor parameters such as time and temperature. Providing other information concerning the importance of Good Kitchen Practices is part of Risk Communication (FAO/WHO, 1998).

The Codex document on General Principles of Food Hygiene (CAC, 1997a) refers also to this: "governments should provide health education programmes which effectively communicate the principles of food hygiene to industry and consumers". Moreover, this document also mentions that: "Industry should ensure that consumers have clear and easily-understood information, by way of labelling and other appropriate means, to enable them to protect their food from contamination and growth/survival of foodborne pathogens by storing, handling and preparing it correctly". And finally, it is stated that consumers should recognize their role by following relevant instructions and applying appropriate food hygiene measures, i.e. apply the correct process criteria.

9 Product Criteria

Safety of foods is achieved by, among other factors, applying extrinsic and intrinsic parameters that govern inactivation and growth of micro-organisms. Extrinsic parameters determine the effectiveness of heat treatments etc. that are discussed in 7.1.7 as Performance Criteria. Parameters intrinsic to the foods that are used to prevent unacceptable growth of microorganisms are called product criteria.

Multiplication and/or toxin formation are dependent on the formulation, composition and “environment” in the food. Parameters such as pH, \( a_w \), temperature, structure, additives, competitive flora, gas atmosphere etc. are used to control growth. For example, to prevent \( L\) monocytogenes reaching levels above 100/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 \( A_w < 0.92 \).

In summary, Process Criteria deal with treatments used to render foods safe, product criteria are used to keep them safe. Both may be the result of PPP analyses and epidemiological data, or based on a FSO or PS.

10 Microbiological Acceptance Criteria

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 is called a Microbiological Criterion (MC) according to Codex (CAC, 1997c).

A Microbiological Criterion consists of:
- a statement of the microorganisms 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
- 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.

In order to decide whether or not an 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 MRA),
- the microbiology of raw materials (\( H_0 \)),
- effect of processing (R),
- likelihood and consequences of contamination (\( I_{RC} \)) and growth (\( I_G \)) 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.

These considerations are of a very general nature and apply to all foods. When dealing with specific foods, decisions must be made where criteria are to be applied in the food chain and what would be achieved by applying them.

Microbiological Criteria differ in function and content from FSOs (see Table 7.1). However, occasionally the limit in a criterion is the same as a FSO or a PS as, for instance, in the case of the FSO for \textit{L. monocytogenes} in a stable RTE product. A FSO will normally not prescribe a sampling plan. For MCs it is essential that such a plan is developed, because that will assist in achieving the transparency and equivalence mentioned in the WTO/SPS agreement.

The Codex document specifies that, in developing sampling plans, the severity of the hazard and assessment of the likelihood of its occurrence must be considered, but for more guidance the document refers to ICMSF Book 2 (ICMSF, 1986). The first part of this book that deals with the scientific rationale for the development of sampling plans has been revised and published as ICMSF Book 7: Microbiological testing in food safety management (ICMSF, 2002).

The FSO states the level of a hazard at the moment of consumption, this is normally not the point in the food chain where samples are taken and tested for the frequency and/or the concentration of a pathogen. Therefore, Microbiological Criteria (MC) have to be related to other points in the food chain, i.e. to Performance Standards (PCs). The character of this relationship will depend on whether the level or concentration of a certain micro-organism or a group of certain microorganisms (indicators) are measurable or not.

A proposed FSO for \textit{L. monocytogenes} in a stable ready to eat (RTE) food is $< 100/g$ at the moment of consumption. This concentration can be determined with classical microbiological procedures such as plate count or MPN techniques. A MC could be directly related to this concentration, because in a stable RTE food, the level of \textit{L. monocytogenes} would not change. The number of samples to be taken would reflect the safety factor that a government or a company applies.

### Table 7.1. Characteristics of FSOs and Microbiological Criteria

<table>
<thead>
<tr>
<th>Food Safety Objective</th>
<th>Microbiological Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>A goal upon which food processes can be designed so the resulting food will be safe</td>
<td>A statement that defines acceptability of a food product or lot of food</td>
</tr>
<tr>
<td>Aimed at consumer protection</td>
<td>Confirmation that effective GHP and HACCP plans are applied</td>
</tr>
<tr>
<td>Applied to food at the moment of consumption</td>
<td>Applied to individual lots or consignments of food</td>
</tr>
<tr>
<td>Components: - Maximum frequency and/or concentration of a microbiological hazard.</td>
<td>Components: - Micro-organism of concern and/or their toxins/metabolites - Sampling plan - Analytical unit</td>
</tr>
</tbody>
</table>
- Analytical method
- Microbiological limits
- Number of analytical units that must conform to the limits

If the RTE food is not stable, then it will depend on when the sampling is done, 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 increase were envisaged, then the criterion at the moment of sampling would be absence of \textit{L. monocytogenes} in one gram of a certain number of samples of the product. This would still be measurable. However, if a 10'000 fold increase is foreseen, the criterion should be absence in at least 100 gram, which would become much more difficult to determine.

If the FSO for \textit{Salmonella} in dried egg is set at \(< 1/10 \text{ kg}\), testing for compliance would become impossible. In such case, a criterion could be based on the concentration of an indicator group of microorganisms such as \textit{Enterobacteriaceae}. When the initial number of \textit{Salmonella} (H\textsubscript{0}) in raw egg would be 1/g, a \(10^5\) reduction should be obtained (PC) in order to achieve the FSO (assuming a 10 fold increase in numbers due to the evaporation of water during drying). The group of \textit{Enterobacteriaceae} has more or less the same heat resistance as \textit{Salmonella} (Cox et al., 1988). This means that in order to achieve the FSO, the number of these indicators should also be reduced with a factor \(10^5\). Assuming that the initial level of \textit{Enterobacteriaceae} in raw egg is \(10^5\) this would mean that the criterion would be absence of these indicators in a number of samples of 1 gram. This criterion is again measurable.

Indicators that have a relationship with measures to control a pathogen are not always available. For example, for the sterilisation of a low acid canned product a so-called "bot cook" is applied. This means that the product receives a thermal treatment that reduces the concentration of spores of \textit{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, it would not be able to determine the presence of spores in a sufficient large quantity of food to check whether the PC was met.

In many cases, microbiological criteria cannot be directly based on a FSO or a PS, because of the low level of the pathogen to be achieved and the absence of relevant indicators. In these cases, the ICMSF approach to use a kind of primitive risk assessment as basis for the selection of "Cases" and the suggested sampling plans is still recommended. By using the appropriate criteria for the selection of the Cases, the best use of available resources is achieved. Moreover, the reason for choosing the stringency of the sampling plan becomes consistent and transparent, which is important in the context of the WTO/SPS agreement.

Annex 3 describes the ICMSF approach to select sampling plans based on so-called cases.

\textbf{11 Example: \textit{Listeria monocytogenes} in cold-smoked salmon}

\textbf{11.1 Risk assessment and risk estimate leading to a FSO}

Both FAO/WHO (2001) and US FDA (2001) are currently in the process of carrying out quantitative risk assessments on \textit{L. monocytogenes} in ready-to-eat foods. The following paragraphs are to a large extend exerts from these documents. \textit{L. monocytogenes} is a ubiquitous bacterium typical of decaying plant material and it is also associated with several animals. \textit{L. monocytogenes} can cause
L. monocytogenes can easily be isolated from RTE food products in low concentrations. Thus between 3 and 80% of samples of cold-smoked fish are positive for the organism. It typically occurs in levels of < 10 /gram but is sporadically isolated at higher levels. Inoculated trials have shown that rapid growth may occur in the vacuum-packed chill-stored product. Based on German data on prevalence and levels of \( L. \) monocytogenes, Buchanan et al. (1997) developed a dose-response curve for the organism. The study used cold-smoked salmon as the food case. This study, as well as the very thorough studies by FAO/WHO and US FDA conclude that although one cannot define a threshold concentration, i.e. a minimal infectious dose, low levels of the organism (< 100 cfu/g) are very unlikely to cause disease. The FAO/WHO team concluded as part of an expert consultation in May 2001 that if levels of \( L. \) monocytogenes were kept below 1000 cfu/g at point of consumption, then 99% of all listeriosis cases would be eliminated.

Due to the widespread occurrence of \( L. \) monocytogenes it will be extremely difficult (and expensive) to produce all RTE foods without sporadic occurrence of the organism in low levels. The dose-response relationships (and resulting Risk Estimates) indicate that such low levels constitute a very low risk. In the terminology introduced above, an ALOP/TLR could be <100 cfu/g (assuming serving sizes of ≤100 gram). Following this line of thought, a FSO is derived directly from the ALOP and could be <100 \( L. \) monocytogenes per gram at point of consumption.

### 11.2 Risk Management Options

In principle, two interlinked systems exist for the management of microbial risks: the implementation of GHP and of HACCP. A hazard analysis of \( L. \) monocytogenes in cold-smoked salmon production, distribution and use reveals that with current processing and storage practices, no CCPs exists. Thus the organism survives the processing steps (no listericidal step) and the typical storage conditions (vacuum-packed, chill-stored (5°C), NaCl at 3-6% (water phase salt) and pH of approx. 6.2) does not guarantee against growth to hazardous levels. It must be emphasised that control measures that prevent growth after production can be introduced, e.g. by frozen storage or by limiting shelf life. \( L. \) monocytogenes is capable of colonising food processing environments, and product contamination typically is caused by contamination during processing rather than by survivors from the raw material. \( L. \) monocytogenes may hide in brines, colonise slicers and have its harbouring niches in drains and on floors. Therefore the GHP programme of a food processing plant with \( L. \) monocytogenes as an identified hazard, must focus specific actions on eliminating and surveying this bacterium.

### 11.3 Performance Standards

In several RTE products, \( L. \) monocytogenes will not grow during storage and the PS for instance at the end of processing can then equal the FSO. However, if growth of the organism is possible/likely during storage and distribution, the FSO must be translated to a PS depending on the amount of growth expected between sampling and consumption. Thus, it has been demonstrated that in naturally contaminated cold-smoked salmon stored at 5°C, approx. 1 log increase occurs during a 3 week storage period (Jørgensen and Huss 1998). Thus using a shelf life limit of 3 weeks or shorter at chill temperatures, a PS of 10 \( Listeria \) per gram at the end of the processing line will allow the FSO to be met. Most processors will set a PS of <10 \( Listeria \) per gram to built in safety margins.
11.4 Process and Product Criteria

The preservation and safety of cold-smoked salmon depends on use of appropriate raw materials and combinations of salt and low temperature after processing. Since no listericidal step is included in the processing and neither of the food preservation parameters will control growth of *L. monocytogenes*, effective process or product criteria cannot be identified.

11.5 Microbiological Criteria

When the establishment of microbiological criteria is chosen as a risk management option, such criteria should be based on the FSO of <100/g or a PS derived from this level. They may be used as acceptance criteria in situations where the history of the product is not known, at points such as at port-of-entry or at certain retail outlets. It should be considered in each product/hazard combination if other acceptance criteria will provide a larger degree of safety assurance. Also, the product should be epidemiologically linked to the hazard – or a hazard analysis should indicate reason for concern (van Schothorst 1996). This is the case with cold-smoked salmon since listeriosis has been linked to cold-smoked trout (Swedish outbreak with 9 infected people and 2 fatalities), and several inoculated food trials have demonstrated growth in the product.

As with other microbiological criteria, careful consideration must be given to the choice of sampling plans and the degree of assurance it provides. Currently spreadsheet systems are available that allows one to determine the performance of a particular sampling plan (www.icmsf/samplingplans.htm). For instance, if a sampling plan with 20 samples are used and c= 0 and m=100, then there is a 95% (or higher) probability of rejecting lots if the mean concentration of *Listeria* in the lot is ≥ 15 cfu/g. It therefore follows that even with 20 samples, the probability of accepting a lot which actually contains *L. monocytogenes* increases rapidly if the mean concentrations drops below 15 cfu/g.

Similarly, a sampling plan with 10 samples and c=0 and m=100 has a 95% (or higher) probability of rejecting the lot if the mean concentration is ≥ 30 cfu/g. If a sampling plan uses only 5 samples and c=0 and m=100, then there is a 95% probability of rejecting the lot if the mean concentration is ≥ 80 cfu/g. These figures emphasise the well-known fact, that low levels of pathogens are difficult to control using sampling and testing.

If products are inspected just before consumption or the product does not support growth, the MC can equal the FSO. Depending on the assurance required from the sampling, i.e. the probability of only accepting acceptable lots, the number of samples is decided upon.

Questions evaluating the use and selection of MC for *Listeria monocytogenes* in cold-smoked salmon

<table>
<thead>
<tr>
<th>Questions</th>
<th>Answers</th>
<th>Proceed to</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Has the food received a listericidal treatment</td>
<td>No, the cold-smoking process, although sometimes reducing numbers of <em>L. monocytogenes</em>, cannot guarantee that the organism is removed.</td>
<td>If yes, proceed to 2)</td>
</tr>
<tr>
<td>2) Is recontamination likely ?</td>
<td>Yes. Several studies have documented that the main source of <em>Listeria</em> contamination is the process environment (slicers, brine) itself.</td>
<td>If yes, proceed to 4)</td>
</tr>
<tr>
<td>3) Is the presence of <em>Listeria</em></td>
<td>Yes. Although plant contamination</td>
<td>If yes, proceed to 4)</td>
</tr>
<tr>
<td>Question</td>
<td>Response</td>
<td>Notes</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Is L. monocytogenes likely?</td>
<td>can be minimised, its presence in the product is not unexpected.</td>
<td>If no: <strong>Do not test</strong></td>
</tr>
<tr>
<td>4) Will the food receive a listericidal treatment prior to consumption?</td>
<td>Cold-smoked salmon is typically eaten without heating</td>
<td>If yes: <strong>Do not test</strong>  If no, proceed to 5)</td>
</tr>
<tr>
<td>5) Is it likely that multiplication to levels of &gt; 100/g or ml at the moment of consumption will take place during the intended conditions of storage, distribution and use?</td>
<td>Yes. Examine 20 samples</td>
<td>c=0 and m=100</td>
</tr>
<tr>
<td></td>
<td>No. Examine 10 samples</td>
<td>c=0 and m= N – where N is a product specific level that is set (a PS) so that the level does not increase above the FSO of 100/g at point of consumption</td>
</tr>
<tr>
<td></td>
<td></td>
<td>absence in 25 g samples if no data on the product are available.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reject if any sample contains &gt; 100 <em>L. m.</em> per gram</td>
</tr>
</tbody>
</table>

(based on CAC 2001b)

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**Figure. 3.** Hazard Characterization curve of *L. monocytogenes*, based on Joint FAO/WHO Expert Consultation 2001 (Food and Nutrition paper 72).
12 References


CAC (2001a), "Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management", *CX/FH 01/7, 34th Session of the Codex Committee on Food Hygiene*, FAO, Rome.


CX/FH 01/13 (2001), Discussion paper on proposed draft guidelines for the validation of food hygiene control measures.


ICMSF (2002) "Microbiological testing in food safety management", Wolters-Kluwers, USA (to be published).


### Glossary

**Acceptance criteria for lot acceptance**
These are statements of conditions that differentiate acceptable from unacceptable lots (batches) of food. (Microbiological Criteria as defined by Codex is such a criterion).

**ALOP (Appropriate level of protection)(WTO).**
the level of protection deemed appropriate by the Member [State] establishing a SPS measure to protect human life or health within its territory.

**Control (verb)**
To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

**Control (noun)**
The state wherein correct procedures are being followed and criteria are being met.

**Control measure**
Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

**Corrective Action**
Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

**Critical Control Point (CCP)**
A 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.

**Critical Limit**
A criterion which separates acceptability from unacceptability.

**Deviation**
Failure to meet a critical limit.

**Dose-Response Assessment**
The determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response).

**Expert Panel**
A group of individuals who collectively have knowledge or experience with a hazard or food and the conditions that can lead to foodborne illness and have the ability to provide advice based on available scientific information.

**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.

**Food Safety Objective (FSO)**
The maximum frequency and/or concentration of a microbiological hazard in a food at the moment of consumption that provides the appropriate level of health protection [ALOP].

**Hazard**
A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

**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 their toxins.

**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.

**Hazard analysis (in HACCP)**
The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

**HACCP**
A system that identifies, evaluates, and controls hazards which are significant for food safety.

**HACCP plan**
A document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.

**Monitor**
The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

**Performance Criterion (ICMSF 1998, 2002)**
The required outcome [impact] of a step or combination of steps that contribute to assuring a food safety objective [FSO] is met.

**Performance Standard (proposal)**
The required outcome [level of a hazard] of a step or combination of steps that contribute to assuring that a food safety objective [FSO] is met. [The level of a hazard at any point in the food chain other than at the moment of consumption]
The control parameters of a step, or combination of steps, that can be applied to achieve the performance criterion.

**Product Criteria** (proposal)
Control parameters in a food used to prevent unacceptable growth of microorganisms.

**Risk**
A function of the probability of an adverse health effect, and the severity of that effect, consequential to a hazard(s) in food.

**Risk Analysis**
A process consisting of three components: risk assessment, risk management and risk communication.

**Risk Assessment**
A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.

**Risk Assessment** (WTO).
The evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs.

**Risk Characterization**
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 characterization and exposure assessment.

**Risk Communication**
The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

**Risk Estimate**
Output of Risk Assessment

**Risk Management**
The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options.

**Safe Food*** (the Codex document gives this as the definition for food safety – not safe food)
Food that does not cause harm to the consumer when it is prepared and/or eaten according to its intended use

**Sensitivity analysis**
A method used to examine the behaviour of a model by measuring the variation in its outputs resulting from changes in its inputs.

**Step**
A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

**TLR (Tolerable Level of Risk)** (ICMSF 2002).
The level of risk adopted following consideration of public health impact, technological feasibility, economic implications, and that which society regards as reasonable in the context of and in comparison with other risks in everyday life.

**Transparent**
Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review.

**Quantitative Risk Assessment**
A Risk Assessment that provides numerical expressions of risk and indication of the attendant uncertainties.

**Qualitative Risk Assessment**
A Risk Assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk.

**Validation**
Obtaining evidence that the elements of the HACCP plan are effective.

**Validation (CX/FH 01/13)**
"The process of ensuring that a defined set of control measures is capable of achieving control over a specific hazard(s) in a specific food(s).

**Verification**
The application of methods, procedures, and tests, in addition to those used in monitoring to determine compliance with the HACCP plan, and/or whether the HACCP plan needs modification.

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**ANNEX 1: TERMINOLOGY AND RELEVANT CODEX DOCUMENTS**

It is in the interest of consumer protection and international trade in food that a common language is used. Many conflicts, misconceptions and misinterpretations can be prevented when a common language is agreed upon. For this purpose definitions should be as clear as possible, and the use of a certain jargon is often unavoidable. The WTO/SPS agreement and Codex have given a number of definitions relevant to this paper, which have been assembled in the glossary.
The ICMSF (1998) has added a few definitions concerning the levels of hazards in foods along the food chain, and control measures that may be necessary to reach them or maintain them. Since their publication several concepts have been further developed and are published in ICMSF Book 7 (2002). However for the purpose of Codex some of the ICMSF terms and their definitions may need to be modified, as will be explained in this document.

The first term that needs clarification is the word "standard". In the Codex system every output of the Commission that has to do with the identity of a certain product, what it should contain or not contain, how it should be produced, processed, handle, prepared and used is a standard. Originally all Codex Standards were recommendations that had to be put into local laws in order to make them mandatory. Codes and particularly Guidelines were not always meant to become mandatory, but this does not relate to their use in the WTO/SPS context. The SPS agreement does not make a distinction between the various documents; they all serve as a reference for the trade in safe food.

Taking this into consideration, the following Codex documents have to be dealt with.

- **Principles and guidelines for the conduct of microbiological risk assessment**, CAC/GL 30-1999. [Document 1 in Fig. 2]
  Most definitions concerning MRA and mentioned in the glossary are taken from this document. It is worth mentioning that the WTO/SPS agreement also gives a definition of risk assessment i.e.: "...the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs".

- **Proposed draft Principles and Guidelines for the Conduct of Microbiological Risk Management**, CX/FH 01/7, 2001a. [Document 2 in Fig. 2]
  In this document the subjects of ALOP and Food Safety Objective (FSO) are dealt with. The outcome of this Expert Consultation will most probably have an influence on the current text. The definition of FSO was changed during the last discussion of this document during the Food Hygiene Committee meeting in 2001 into the one that is in the glossary.

- **Recommended international code of practice, general principles of food hygiene**, CAC/RCP 1-1969,Rev. 3 (1997), [Document 3 in Fig. 2]
  This document describes the basics of producing safe food. Section 5.2.3 deals with microbiological and other specifications. It is mentioned that: "where microbiological, chemical or physical specifications are used in any food control system, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and action limits. No reference is made to the following document.

- **Principles for the establishment and application of microbiological criteria for foods**, CAC/GL 21-1997, [Document 4 in Fig. 1]
  In the introduction it is mentioned that "Microbiological criteria (MC) should be established according to these principles and be based on scientific analysis and advice, and, where sufficient data are available, a risk analysis appropriate to the foodstuff and its use". MC are specifically used for testing of food when no other, more efficient, means for determining its acceptance is available. A MC can be the same as a specification mentioned above, when they are applied at the end of a production line.

- **Hazard analysis and critical control point (HACCP) system and guidelines for its application**, Annex to CAC/RCP 1-1969,Rev. 3 (1997), [Document 3 in Fig. 2]
  At Critical Control Points contamination with hazards is prevented, hazards are eliminated or reduced to acceptable levels. How such levels are to be established is not specified. A critical limit separates acceptable from unacceptable, it may be a level of a hazard, but it may also be a process parameter such as time, temperature, pH, aw etc. The definition of validation is taken from this document.
ANNEX 2: NEED FOR AND USE OF FOOD SAFETY OBJECTIVES

Recognizing the difficulty of using public health goals such as an ALOP or TLR to establish control measures, the concept of Food Safety Objectives (FSOs) has been introduced. An FSO converts the ALOP/TLR into parameters that can be controlled by food producers and monitored by government agencies. The ALOP/TLR is an expression of a public health risk, while an FSO expresses the level of a hazard in relation to this risk. Therefore an FSO can be defined as: "the maximum frequency and/or concentration of a microbial hazard in a food at the moment of consumption that provides the appropriate level of health protection". The establishment of an FSO for Codex purposes is a Risk Management activity. The primary purpose of an FSO is to translate a public health goal (i.e., a desired level of consumer protection) to measurable attributes which allows industry to set control measures for processes. The FSO also allows comparison between foods produced in different countries.

Examples of possible FSOs are:

- the amount of staphylococcal enterotoxin in cheese must not exceed 1µg/100g.
- the concentration of aflatoxin in peanuts must not exceed 15 µg/kg.
- the level of L. monocytogenes in ready-to-eat foods must not exceed 100 cfu/g at the time they are consumed.
- the concentration of salmonellae should be less than 1cfu/100kg of milk powder.

While the FSOs at first glance seem similar to microbiological criteria as defined by Codex (CAC/GL 21–1997), they differ in several ways. In many cases FSOs will not be measurable by microbiological testing (e.g., <1 cfu salmonellae/100kg of milk powder). FSOs are not developed for microbiological testing of the product, are not applied to individual lots or consignments and they do not specify sampling plans, number of analytical units, etc. (see Table 1). An FSO defines the level of a hazard at the moment of consumption, and can be used to define the level of control that is expected for a food operation (i.e. the Performance Standard to be met). FSOs should be met through the implementation of GHP and HACCP systems as well as correct food preparation and use practices. This is in line with the Codex definition of food safety: "assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use" (CAC/RCP 1-1969, Rev. 3 (1997))

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4 The term "industry" means: an organisation, company or group of individuals (cooks) working professionally in the food chain from primary agricultural production to the sale to, or preparation of food for, the consumer. The particular meaning in this document depends on the context in which it is used.
Whenever possible, FSOs should be quantitative and verifiable. However, this does not mean that they must be verifiable by microbiological testing. For example, an FSO for low acid canned foods might be established in terms of the probability of a viable spore of *C. botulinum* being present as being less than 0.000000000001 per can. It would be impossible to verify this by end-product testing, but it would be verifiable by measurement of time/temperature protocols that are based on a performance criterion.

The FSO allows control authorities to communicate clearly to industry what is expected of foods produced in properly managed operations. The FSO establishes the stringency under which food control systems must operate by specifying the frequency or concentration of a microbiological hazard that should not be exceeded. It thereby forms the basis by which control authorities can establish standards and assess whether an operator is in compliance and producing safe foods. Thus, the FSO has very practical value and can be commonly understood and applied by industry and regulators alike.

FSOs also can be used to force change in an industry and enhance the safety of certain products. Many examples could be cited where epidemiological data indicated that particular foods were linked to foodborne illness. In response to this information governments used various mechanisms at their disposal to bring about the changes necessary to reduce or eliminate the risk of disease. In some cases, modifications in commercial practices were necessary, including the adoption of new or more reliable technologies. The establishment of an FSO could be used by risk managers in government to communicate to industry the level of control expected and, thereby, force change. The FSO may require some operators to modify their operation, implement more effective technologies, change the formulation of the product, adopt tighter control systems, or even cease operation.

Since an FSO does not specify how an operator manages compliance, the concept offers considerable flexibility of operation. This can enable one operator to use formulations (product criteria), equipment and procedures (process criteria) that differ from other operators. This flexibility does not imply less food safety assurance. On the contrary, assessment of the operations can provide a high level of confidence in the safety of food being produced by operations that have been designed and validated to meet the relevant Performance Standards and FSOs. The foods from such operations seldom need to be tested for the relevant pathogen(s) to verify compliance. Instead, verification can be achieved through record review and observation of GHP and HACCP.

It is not necessary to establish an FSO for all foods or known hazard-food combinations. In some cases the potential microbiological hazards associated with a food represent so little risk that an FSO is not needed (e.g., granulated sugar, sweetened condensed milk, most breads, pineapple, carbonated beverages). In other cases the association of a pathogen with a food is so variable, or the food comprises many components, that identifying the foods for which FSOs should be set is not possible.

**In summary**, the concept of an FSO offers many advantages for both control authorities and industry because they can be used to:

- translate a public health goal to a measurable level of control upon which food processes can be designed so the resulting food will be microbiologically safe
- validate food processing operations to ensure that they will meet the expected level of control
- assess the acceptability of a food operation by control authorities or other auditors
- highlight food safety concerns, separate from quality and other concerns
- force change in a food commodity and improve its safety
- serve as the basis for establishing microbiological criteria for individual lots or consignments of food when its source or conditions of manufacture are uncertain.

Establishing an FSO is a risk management activity in which governments and stakeholders (such as consumers and industry) come to an agreement on the level of a food safety hazard in a food
that is technically achievable and tolerable for consumer protection. Ideally, an FSO would be based on the frequency or concentration of a pathogen in a food that would not cause disease. This would be equivalent to finding a no-effect dose, the value that is used for setting tolerable levels of daily exposure for acutely toxic chemicals. It is clear that certain foodborne pathogens have clearly definable threshold levels below which they pose no risk to the consumer. This is for instance the case for certain toxigenic foodborne pathogens (i.e., microorganisms that cause disease through the production of a toxin) that there is a threshold concentration of cells below which the micro-organism does not produce sufficient toxin to cause an adverse effect. For example, it is generally accepted that low levels (i.e., < $10^4$ cfu/g) of *S. aureus* in a food do not represent a direct risk to humans, whereas higher levels (> $10^5$ cfu/g) do so through the production of enterotoxin to levels that could cause staphylo-enterotoxicosis (> 1 µg/100g set as FSO in the example mentioned before).

For infectious pathogens, most current models are based on the assumption that there is a chance, however remote, that one single cell may cause disease. For *L. monocytogenes* current dose-response data indicate that the chance of illness from a single cell varies from 1x10^{-5} (in butter causing listeriosis in a vulnerable population) to 8x10^{-15} (US FDA model for listeriosis in the elderly population) (FAO/WHO 2000). Risk assessments can help to identify how the frequency and/or concentration of a microbiological hazard in a food or group of foods can influence the probability of incidence of a disease. There is a relationship between the level of a hazard in a food and the incidence of the disease it causes in a given population. This relationship may be represented by a hazard characterization curve. The slope of this curve is specific to the hazard, the food, the illness and the category of consumers for which the curve has been determined. If such a curve is available for the incidence of disease for a specific pathogen-food combination, the selected ALOP can be positioned on the y-axis and the corresponding level of the hazard (FSO) can be obtained on the x-axis.

Even when an ALOP is not explicitly determined, and the risk assessment does not provide the necessary information, FSOs can still be established. The relationship between the microbiological hazard, the food and the disease may be elucidated from historical data on foodborne illness, through a combination of passive and active epidemiological programs, case-control studies, and other pertinent public health studies. Investigations of foodborne illness should also provide information about whether a certain sub-population is at higher risk and the severity of the disease. This knowledge should be supplemented with data derived from laboratory research and from steps in the food chain that may be important relevant to the disease. Records of foods processed for safety may provide useful data concerning the level of consumer protection normally achieved. This knowledge can form a solid basis for a managerial risk evaluation and determination of an FSO.

During the development of an FSO, risk managers in industry and government must confirm that the FSO is technically achievable through implementation of GHP and HACCP. If the proposed FSO is technically achievable then appropriate process/product criteria can be established for the affected food operations and individual food operators can implement the necessary control measures. If, however, it is determined that the proposed FSO is not technically achievable; then, the product, process, and/or the FSO should be modified. If this is not possible, or if the public does not accept the proposed FSO, it may be appropriate to ban the affected products, processes, or foods. It should be noted that an exporting country may encounter the same problem, i.e. that meeting the FSO is technically not achievable, and as a consequence the product cannot be exported. FSOs play an important role in providing the transparency specified in the SPS agreement.
ANNEX 3: ESTABLISHMENT OF SAMPLING PLANS FOR MICROBIOLOGICAL ACCEPTANCE CRITERIA

1. Introduction

For certain foods Codex Alimentarius has developed microbiological criteria, but for many other foods such criteria do not exist. However the “Principles for the Establishment and Application of Microbiological Criteria for Foods”, (CAC/GL 21-1997) prescribe how such Criteria should be developed. The text clearly describes the principles, but it lacks details concerning sampling plans and their interpretation.

2. Establishment of microbiological criteria

According to the “Principles for the Establishment and Application of Microbiological Criteria for Foods”, consideration should be given to:

- evidence of actual or potential hazards to health,
- the microbiology of raw materials,
- effect of processing,
- 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 and
- the intended use of the food.

These considerations are of a very general nature and apply to all foods. When dealing with specific foods, decisions must be made where criteria are to be applied in the food chain and what would be achieved by applying them.

3. Sampling plans

In CAC/GL 21-1997, in developing sampling plans, the severity of the hazard and assessment of the likelihood of its occurrence must be considered. A scientific rationale for the development of sampling plans has been developed and published by the ICMSF (2002).

The ICMSF approach distinguishes three categories of hazards based upon the relative degree of severity of their effects:

- severe hazards, life threatening,
- serious hazards, incapacitating but not life threatening,
- moderate hazards, severe discomfort of short duration.

This categorisation and the examples presented in Table 1 were based on the best epidemiological data available at the time of publication, but may need to be reviewed when new data become available.

The other factor to be considered is the likelihood of occurrence of an adverse effect, taking account of the anticipated conditions of use. Here the ICMSF again recognises three categories:

- conditions that would reduce the risk,
• conditions that would increase the risk and
• conditions that would not cause a change in risk.

Combining the three levels of severity of a health effect with the categories of likelihood of occurrence leads to different levels of concern called “cases” by the ICMSF, case 7 being of lowest concern to food safety and case 15 of the highest.

Taking into account the likelihood of a health effect, cases 9, 12 and 15 represent the highest levels of concern because they refer to situations where pathogens can multiply in the food under expected conditions of handling, storage, preparation and use. Cases 7, 10 and 13 represent the lowest levels of concern, because they refer to intermediate situations of concern where the level of the hazard is likely to be reduced before consumption, for instance during preparation. Cases 8, 11 and 14 refer to situations where the level of the hazard would remain the same between the time of sampling and the time

Based on these nine cases, the ICMSF developed 2-class sampling plans in which “n” indicates the number of sample units to be tested and “c” the number of defective sample units that can be accepted. These sampling plans are summarised in Table 2. The plans direct more of the available resources for analysis towards those situations with a high level of concern.

Often 25 g or ml of the samples taken from a lot is analysed, but a smaller or larger weight or volume can be used to decrease or increase the stringency of the sampling plan. Using 25 g analytical units means that in Case 10 Salmonella would be "absent" (not detected) in 125 g, and in Case 15 in 1.5 kg. When pathogens are homogeneously distributed throughout a lot, or when samples are taken at random, statistical methods can be used to express the likelihood of contamination of the lot. Finding no Salmonella when applying Case 10 would mean that 90% of the lots containing 2% defectives would be accepted (with a probability of 95%). For Case 15 it would mean that 30% of such lots would be accepted. However, in many cases the distribution of contaminants is not homogeneous and random sampling is most of the time not possible. This clearly illustrates that examination of batches, lots or consignments of products for the presence of pathogens has as a control measure only limited value.
### Annex 3 Table 1.

**Categories of hazards with some examples**

| 1. Moderate, severe discomfort, short duration | S. aureus  
V. parahaemolyticus  
B. cereus  
C. perfringens |
| 2. Serious, incapacitating, not life threatening | Salmonella (non typhi)  
Yersinia enterocolitica  
Shigella (non dysenteriae I)  
Listeria moncytogenes |
| 3A. Severe, life-threatening for general population | C. botulinum  
V. cholera 01  
S. typhi  
Enterohaemoragic E.coli |
| 3B. Severe for restricted populations | Campylobacter jejuni  
Enteropathogenic E.coli  
Listeria monocytogenes |
Annex 3   Table 2.

Plan stringency (Case) in relation to degree of health concern and conditions of use

<table>
<thead>
<tr>
<th>Degree of concern relative to</th>
<th>Conditions in which food is to be expected health effect handled and consumed after the usual course of events</th>
<th>Conditions reduce degree of concern</th>
<th>Conditions cause no change in concern</th>
<th>Conditions may increase concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate, severe discomfort, short duration</td>
<td>Case 7</td>
<td>Case 8</td>
<td>Case 9</td>
<td></td>
</tr>
<tr>
<td>n = 5, c = 2</td>
<td>n = 5, c = 1</td>
<td>n = 10, c = 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serious, incapacitating, not life threatening</td>
<td>Case 10</td>
<td>Case 11</td>
<td>Case 12</td>
<td></td>
</tr>
<tr>
<td>n = 5, c = 0</td>
<td>n = 10, c = 0</td>
<td>n = 20, c = 0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Severe, life-threatening for general population and Severe for restricted populations</td>
<td>Case 13</td>
<td>Case 14</td>
<td>Case 15</td>
<td></td>
</tr>
<tr>
<td>n = 15, c = 0</td>
<td>n = 30, c = 0</td>
<td>n = 60, c = 0</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

n = the number of sample units tested
c = the number of defective sample units which can be accepted