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Food safety objectives – Concept and current status*

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Introduction

The International Commission on Microbiological Specifications for Foods (ICMSF) has proposed a preventative scheme for managing microbial risks in foods that introduces the important new concept of a food safety objective (FSO). The FSO concept translates public health risk into a definable goal: a specified maximum frequency and/or concentration of a [microbiological] hazard in a food at the time of consumption, which is deemed to provide an appropriate level of health protection (1). The approach enables the food industry to meet a specific FSO by the application of the principles of Good Hygienic Practice (GHP), Hazard Analysis Critical Control Point (HACCP) systems, performance criteria, process/product criteria and/or acceptance criteria. It provides a scientific basis that allows industry to select and implement measures that control the hazard of concern in a specific food or food operation. The concept also enables regulators to better develop and implement inspection procedures to assess the adequacy of control measures implemented by industry, and to quantify the equivalence of inspection procedures in different countries. Thus, the practical value of using the FSO concept is that it offers flexibility of operation: it does not prescribe how an operation achieves compliance, it defines the goal. Establishing a FSO for a specific hazard requires the evaluation of the public health risk associated with the hazard in a food, which may be derived by advice from a few specialists, by larger expert panels, or by conducting a quantitative risk assessment are described.

Appropriate level of protection

The Appropriate Level of Protection (ALOP) as derived from a Microbiological Risk Assessment (MRA) is typically expressed in terms relevant to public health, e.g. as a number of cases per 100000 population. Whilst this serves a purpose when informing the public, especially when communicating a desired reduction in disease, the ALOP is not a useful measure in the further implementation of food safety measures at, e.g., the level of food control/inspection or food production.

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Assume for instance that the current situation with respect to the occurrence of listeriosis in a given population is 0.5 cases per 100000 inhabitants and a government (or international community) wishes to reduce the health risk with a factor of two (which is the ALOP). Industry and food control authorities cannot target, or attempt to control, such terms as 0.25 cases per 100000 population. The FSO simply translates the ALOP to an expression of a measurable concentration or frequency of the hazard in a food.

Recognizing the difficulty of relating control measures directly to an ALOP, the concept of Food Safety Objective (FSO) has been introduced to assist in the development of potential Microbiological Risk Management (MRM) options. Conceptually, the FSO can be viewed as the consumers' maximum level of exposure to a microbiological hazard that still achieves the ALOP. As such, a FSO articulates the overall performance expected of a food chain in order to reach a stated or implied public health goal. The overall performance results from the level of control achieved by the food safety system deployed from "farm to fork". Traditionally, the stringency of a food safety system has been articulated using control measures at various points within the food chain; the actual impact on consumers' exposure to a hazard has, at best, been inferred. However, with the development of techniques in MRA, it is increasingly possible to derive the consumers' exposure and relate that to the risk of adverse public health consequences.

Effective MRA typically requires that additional risk-based milestones be established that articulate how different stages of the overall food safety systems must function to achieve the ultimate food safety outcome required. As a means of addressing this need, two related terms, Performance Objective (PO) and Performance Criterion (PC), have been introduced and defined in this document. The purpose of a PO is to articulate the level of microbial hazard at a particular stage in the food chain that can be tolerated [alternative: that should not be surpassed] in order to still achieve or contribute to achieving the FSO. How the required PO can be achieved is then articulated through PCs, which is defined as "the effect of one or more control measures needed to meet or contribute to meeting a PO."

Food safety objectives

As a temporary compromise, the CCFH Committee decided that the following definition proposed by the ICMSF should be used as the basis for discussion (2): "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)." This definition is based on the fact that the risk characterisation curve of the risk assessment relates the risk (health impact) to the concentration or frequency of the hazard at the point of consumption. It is also recognised that FSOs will need to be used in conjunction with performance criteria or performance objectives to establish the level of control needed at other parts of the food chain.

The term FSO is applicable to situations where either a concentration of a hazard is set (e.g. less than 100 *L. monocytogenes* per gram of ready-to-eat food) or where a frequency is expressed (e.g. less than one per hundred (100 ml) servings of fresh apple cider contains *Salmonella*).

In most cases, the concentration and/or frequency at earlier stages of the food chain than consumption differ from the FSO. For instance, if an FSO for *Salmonella* in fresh apple juice is a frequency of one in 100 servings, a desired outcome earlier in the chain may be specified as less than one in 10000 servings. If a MRA is available, and the risk assessors have been asked to address the effect of specific intervention strategies, the MRA will provide information as to what frequency, e.g. prevalence of *Salmonella* on cider, will result in the desired FSO and thus will meet the ALOP.

Establishment of the FSO

The FSO is the result of using the risk characterisation curve to transform the ALOP to an expression of concentration/frequency of the hazard. As depicted in following figure 1 the ALOP is read on the Y-axis and gives the FSO as the corresponding concentration/frequency of the hazard on the X-axis (3).

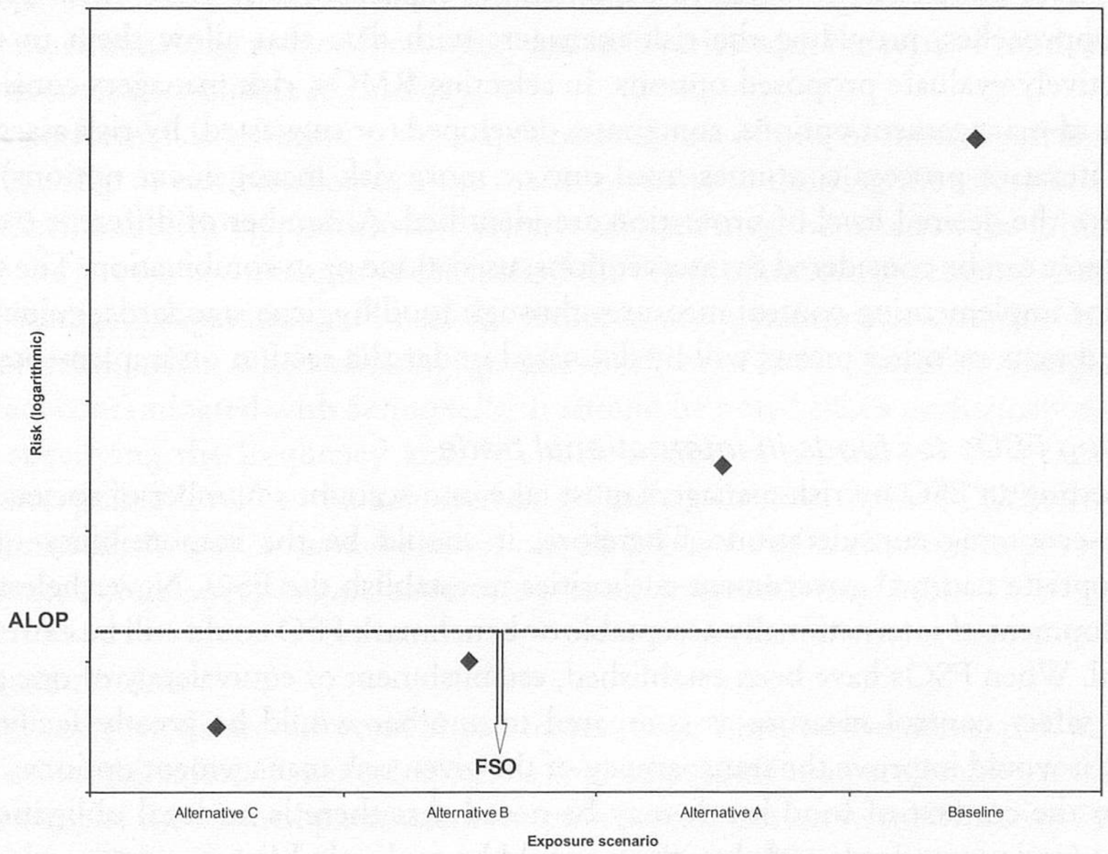

Figure 1 **Risk characterisation curve relating ALOP to FSO**

Variations in the FSO and possible use of MRA

Clearly, the illustration of the relationship between risk and concentration/frequency of the hazard as a single line is oversimplified. The uncertainty associated with the model and the epidemiology, specific confounding factors and the fact that the risk characterisation curve is based on distributions (and thus carries variation) must be taken into account when deriving a FSO. The example above illustrates the "direct" translation of ALOP to FSO will result in the concentration/frequency corresponding to exposure on the X-axis. Because of the considerations of uncertainty and variation inherent to the MRA, the FSO may be set at a lower value to ensure that the desired level of consumer protection is achieved.

Under some circumstances, for example where cross contamination is a major risk factor, it might be more appropriate to control the level of the hazard further up the food chain through the use of a performance criterion or performance standard. This will be discussed further under the section dealing with implementation.

Typically, consideration of risk reduction interventions is based on an evaluation of relative risks, comparing the impact of the management option against the initial baseline risk estimate. This focus on comparative risk reduces the need to focus on establishing an absolute expression [value] of risk associated with each food control strategy.

Assessment of Risk Management Options (RMOs) may be an iterative process. The risk managers know the degree of public health protection that they are aiming to achieve. The risk assessors have examined the impacts of different control options and approaches, providing the risk managers with data that allow them to more objectively evaluate proposed options. In selecting RMOs, risk managers consider a range of management options, sometimes developed (or suggested) by risk assessors. This iterative process continues until one or more risk management options) that achieve the desired level of protection are identified. A number of different control measures can be considered as interventions, used alone or in combination. The strategy for implementing control measures through food hygiene standards, guidelines, related texts or other means will be discussed under the section on implementation.

Setting FSOs for foods in international trade

Setting an FSO by risk managers must take into account a number of societal and socio-economic considerations. Therefore, it should be the responsibility of the appropriate national government authorities to establish the FSO. Nevertheless, the development of internationally acceptable or benchmark FSO could still be extremely useful. When FSOs have been established, establishment of equivalency of one given food safety control measure as compared to another would be greatly facilitated. Also, it would improve the transparency of the given risk management options.

In the context of food law it may be noted that there is no legal obligation to adopt Codex standards and thus there would be no legal obligation on members to accept a FSO into domestic law. However, members would need to have clear justification, based on public health considerations with respect to food safety and sound scientific evidence, if they are to set a FSO that is more stringent than the relevant internationally agreed standard obtained through the Codex process.

The implementation of control measures based on ALOP, FSO and related criteria

From the information provided in an FSO, regulatory authorities and food operators can select appropriate control measures to achieve the intended results safe levels of pathogens. A 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.* One or more control measures may be necessary at each stage along the food chain to assure a food is safe when consumed. In the design of control measures it is necessary to establish what needs to be achieved the **performance criteria** and how it will be achieved through **process and product criteria.**

Performance Criteria

When designing and controlling food operations it is necessary to consider pathogen contamination, destruction, survival, growth, and possible recontamination. Consideration should also be given to subsequent conditions to which the food is likely to be exposed, including further processing and potential abuse (time, temperature, and cross-contamination) during storage, distribution and preparation for use. The ability of those in control of foods at each stage in the food chain to prevent, eliminate or reduce food safety hazards varies with the type of food and the effectiveness of available technology.

A performance criterion is the required outcome of one or more control measures at a step or combination of steps that contribute to assuring the safety of a food (2). When establishing performance criteria account must be taken of the initial levels of the hazard and changes of the hazard during production, processing, distribution, storage, preparation and use. An example of a performance criterion is a 6D kill of salmonellae when cooking ground beef, or <15% of freshly slaughtered broilers contaminated with *Salmonella*. It should be noted that a performance criterion specifying the frequency and/or concentration of a pathogen is identical to 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"* (5).

Process criteria

Process criteria are the control parameters (e.g., time, temperature, pH, a_w) at a step, or combination of steps, that can be applied to achieve a performance criterion. For example, the control parameters for milk pasteurisation in the USA are 71.7 °C for 15 sec. This combination of temperature and time will assure the destruction of *Coxiella burnetii*, as well as other non-sporeforming pathogens that are known to occur in raw milk. Process criteria are identical to critical limits (5) when the control point is a CCP in a HACCP plan.

Product Criteria

Product criteria consist of parameters that are used to prevent unacceptable multiplication of microorganisms in foods. Microbial growth is dependent on the composition and "environment" in the food. Consequently, pH, water activity, temperature, gas atmosphere etc. have an influence on the safety of particular foods where those factors are the main reasons for microbiological safety. For example, it may be necessary for a food to have a certain pH (e.g. pH 4.6 or below) or a_w (e.g. 0.86 or below) to ensure that it will meet an FSO for a pathogen, for which growth in the product must be limited (e.g. *C. botulinum, Staph. aureus* or *L. monocytogenes*).

Examples of performance criteria have been published and include:

- 6D reduction of *Listeria monocytogenes* in ready-to-eat chilled foods
- 5D reduction of *Escherichia coli* O157:H7 for fermented meat products
- On-farm prevalence rates of less than 1 % for salmonellae in livestock and poultry

When establishing performance criteria consideration must be given to the initial level of a hazard and changes occurring during production, distribution, storage, preparation and use of a product. A performance criterion is preferably less but at least equal to the FSO and can be expressed by the following equation:

$$H_o - \Sigma R + \Sigma I \leq FSO$$

Where: FSO = Food Safety Objective
H_o = Initial level of the hazard
ΣR = Total (cumulative) reduction of the hazard
ΣI = Total (cumulative) increase of the hazard

FSO, H_o, R and I are expressed in $\log_{10}$ units.

These criteria are usually not established for control measures designed to avoid certain foods although they may be applied to ensure that the initial level of hazards in ingredients are not excessive. Microbiological testing may thus be used to select ingredients or to obtain information on the initial level of a hazard.

It should be recognized that the parameters that may be used in the above equation are point estimates, whereas in practice, they will have a distribution of values associated with them. If data exist for the variance associated with the different parameters, then the underlying probability distributions may be established using an approach similar to that in risk assessment.

Fresh-cut lettuce example

In the following example *Szabo et al.* (5) worked with a commercial operation to evaluate the effectiveness of two antimicrobial washing agents (sodium hypochlorite, hydrogen peroxide and peroxyacetic acid mixture) against *L. monocytogenes* under simulated fresh pre-cut washing conditions and evaluated the growth potential of this pathogen on the product when packaged in a gas permeable film and stored at either 4 °C or 8 °C for 14 days. The results were used to demonstrate how the commercial operation could meet the FSO for *L. monocytogenes* in fresh pre-cut lettuce by the application of performance, process and microbiological criteria.

As there is no listericidal step included in the production of fresh pre-cut lettuce, the commercial operation that participated in this study will need to use a combination of measures that control *L. monocytogenes* in the product in order to meet a FSO of less than 100 CFU/g of the hazard at the point of consumption including; controlling initial levels present in whole lettuce, preventing contamination during processing, reducing levels with sanitised washing, precluding an unacceptable increase in levels by good temperature control throughout the distribution chain and, if necessary, by using microbiological criteria and validated sampling plans.

For example, if the increase in concentration due to growth of viable cells of *L. monocytogenes* remaining after washing is assumed to be as high as 2.7 log CFU/g (based on our observations) and the initial level of contamination on whole lettuce is taken to be as high as 0.1 log MPN/g then, a performance criterion of at least 0.8 log reduction is required to meet the FSO, as given below:

$$H_o - \Sigma R + \Sigma I \leq FSO$$
$$0.1 - \Sigma R + 2.7 \leq 2$$
$$\Sigma R \leq 0.8 \text{ log CFU/g}$$

The commercial operation that participated in this study could specify a process criterion such as the use of sodium hypochlorite maintained at a concentration of 120 ppm in chilled water with a washing time of 2 min (taking into consideration the mean value of 1.1 log CFU/g ± a standard deviation of 0.3 reduction determined above) in the HACCP plan, which would achieve the necessary log reduction of *L. monocytogenes* to meet the FSO. Alternatively, the processor could specify use of 120 ppm of the hydrogen peroxide and peroxyacetic acid mixture in chilled water for 2 min (taking into consideration the mean value of 1.4 log CFU/g ± a standard deviation of 0.5 reduction determined above). There may exist a scope for the commercial operation to reduce the concentration of these antimicrobial agents and the contact time and still meet the FSO. This would require further evaluation including in-house validation of the system as influenced by washing system design, water quality, treatment time, produce throughput, and process control.

Summary

This contribution describes the mechanism of establishing a Food Safety Objective (FSO) from an Appropriate Level of Protection (ALOP) derived from a Microbiological Risk Analysis (MRA). It discusses further performance and process criteria applied by food processors to match the FSO – this illustrated by an example.

Zusammenfassung

Dieser Beitrag beschreibt die Bestimmung eines «Food Safety Objectives (FSO)», abgeleitet von einem «Appropriate Level of Protection (ALOP)», welches auf Grund einer mikrobiologischen Risikoanalyse (MRA) definiert wurde. Es werden auch die Kriterien, «process und performance criteria», diskutiert, die vom Hersteller angewendet werden sollten, um die festgelegte FSO zu erreichen – dies wird anhand eines Beispieles illustriert.

Résumé

Cette contribution décrit la détermination d'un « Food Safety Objectives (FSO) », dérivé d'un niveau approprié de protection (ALOP) établi sur la base d'une évaluation des risques microbiologiques (MRA). Sont également discutés, les critères de processus et de performance nécessaire au producteur pour atteindre le FSO établi – ceci est illustré par un exemple.

Key words

Food safety objectives, appropriate level of protection, performance criteria, process criteria

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