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 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 \( a_w \)) 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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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 situations 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

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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):

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

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 \( \text{Salmonella} \) 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 \( \text{Salmonella} \) 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 \( \text{Salmonella} \) 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 criterion 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, aw, 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 aw < 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 \( (G) \) 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.

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. 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 \( 10^5 \). Assuming that the initial level of *Enterobacteriaceae* in raw egg is \( 10^5 \), 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 the stringency of the sampling plan becomes consistent and transparent, which is important in the context of the WTO/SPS agreement.

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References


