

environment. HACCP involves an assessment of hazards in a particular production sequence and defines steps where control measures that are critical for the safety of a product should be taken. Also, it will state limits, monitoring procedures and corrective actions. However, it is plant/factory specific and does not directly link the effectiveness of such measures to an expected level of health protection, e.g., a reduction in the number of foodborne illnesses occurring in a country.

3. Setting public health goals – the concept of Appropriate Level of Protection (ALOP)

During the past decade, there has been increased interest and effort in developing tools to more effectively link the requirements of food safety programs with their expected public health impact. This document introduces two such tools, the “Food Safety Objective” (FSO) and the “Performance Objective” (PO). These can be used to communicate food safety requirements to industry, trade partners, consumers and other countries. Good practices and HACCP remain essential food safety management systems to achieve FSOs or POs.

Setting goals for public health is the right and responsibility of governments. These goals may specify the maximum number of harmful bacteria that may be present in a food. Where possible, the determination of this number should be based on scientific and societal factors. Costs may include industry costs for reformulation and changes in processing, consumer costs due to increased prices, or reduced availability of certain products, and regulatory costs in terms of surveillance.

In many countries, governments rely on disease and food surveillance data in combination with expert advice on epidemiology, food microbiology and food technology to evaluate which types and numbers of harmful microorganisms in foods will cause disease. The level of risk can be expressed in a qualitative way (e.g., high, medium or low risk), or when possible, as the number of cases of foodborne disease per number of people per year. Particularly in developing countries, disease surveillance data are limited or not available at all. In such instances, estimates of the risk level have to be based on clinical information available (e.g., how many stool samples have been found to contain salmonellae) in combination with results from microbiological surveys of foods, evaluations of the types of foods that are produced, how they are produced and how they are stored, prepared and used. A few countries may use scientific techniques such as Quantitative Microbiological Risk Assessment (QMRA) to estimate the risk of illnesses using detailed

knowledge of the relationship between the number of microorganisms in foods and the occurrence of foodborne diseases.

Whatever method is used to estimate the risk of foodborne illness, the next step is to decide whether this risk can be tolerated or needs to be reduced. The level of risk a society is willing to accept is referred to as the “Appropriate Level Of Protection” (ALOP). Importing countries with more strict requirements for a particular hazard (e.g., harmful bacteria) may be asked to determine a value for the ALOP according to the SPS agreement. When a country is willing to accept the current risk of illnesses, that level is the ALOP. However, most countries will wish to lower the incidence of foodborne disease and may set targets for future ALOPs. For instance, the current level of listeriosis could be 6 per million people per year and a country may wish to reduce this to 3 per million people per year.

4. A Food Safety Objective (FSO)

When a government expresses public health goals relative to the incidence of disease, this does not provide food processors, producers, handlers, retailers or trade partners with information about what they need to do to reach this lower level of illness. To be meaningful, the targets for food safety set by governments need to be translated into parameters that can be assessed by governments agencies and used by food producers to process foods. The concepts of Food Safety Objectives (FSOs) and performance objectives (POs) have been proposed to serve this purpose. The position of these concepts appearing in the food chain can be seen in Figure 1.

An FSO is “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)”. It transforms a public health goal to a concentration and/or frequency (level) of a hazard in a food. The FSO sets a target for the food chain to reach, but does not specify how the target is to be achieved. Hence, the FSO gives flexibility to the food chain to use different operations and processing techniques that best suit their situation, as long as the maximum hazard level specified at consumption is not exceeded. For instance, milk is typically rendered safe by heat processing, however, in the future this may also be achieved by other technologies. This is important in international trade since different techniques may be used in different countries. The “equivalence” of these techniques in reaching a particular level of safety must be evaluated to ensure consumer protection without imposing an unjustified barrier to trade.

5. A Performance Objective (PO)

For some food hazards, the FSO is likely to be very low, sometimes referred to as “absent in a serving of food at the time of consumption”. For a processor that makes ingredients or foods that require cooking prior to consumption, this level may be very difficult to use as a guideline in the factory. Therefore, it is often required to set a level that must be met at earlier steps in the food chain. This level is called a Performance Objective (PO). A PO may be obtained from an FSO, as will be explained below, but this is not necessarily always the case.

Foods that need to be cooked before consumption may contain harmful bacteria that can contaminate other foods in a kitchen. Reducing the likelihood of cross-contamination from these products could be important in achieving a public health goal. The level of contamination that should not be exceeded in such a situation is a PO. For example, raw chicken may be contaminated with *Salmonella*. Although thorough cooking will make the chicken safe (absence of *Salmonella* in a serving), the raw chicken may contaminate other foods during preparation of a meal. A PO of “no more than a specified percentage of raw chicken carcasses may contain *Salmonella*” may reduce the likelihood that *Salmonella* will contaminate other foods. In products, such as ready-to-eat foods, the POs can be calculated from the FSO by subtracting expected bacterial contamination and/or growth between the two points.

6. The difference between an FSO, PO and Microbiological Criteria (MC)

Microbiological criteria need to be accompanied by information such as the food product, the sampling plan, methods of examination and the microbiological limits to be met. Traditional MC are designed to be used for testing a shipment or lot of food for acceptance or rejection, especially in situations where no prior knowledge of the processing conditions is available. In contrast, the FSO or the PO are maximum levels and do not specify the details needed for testing. However, MC can be based on POs in certain instances where testing of foods for a specific microorganism can be an effective means for their verification. There are several approaches to sampling (e.g., lot testing, process control testing) but they all compare the results obtained against a predetermined limit, i.e. a number of microorganisms.

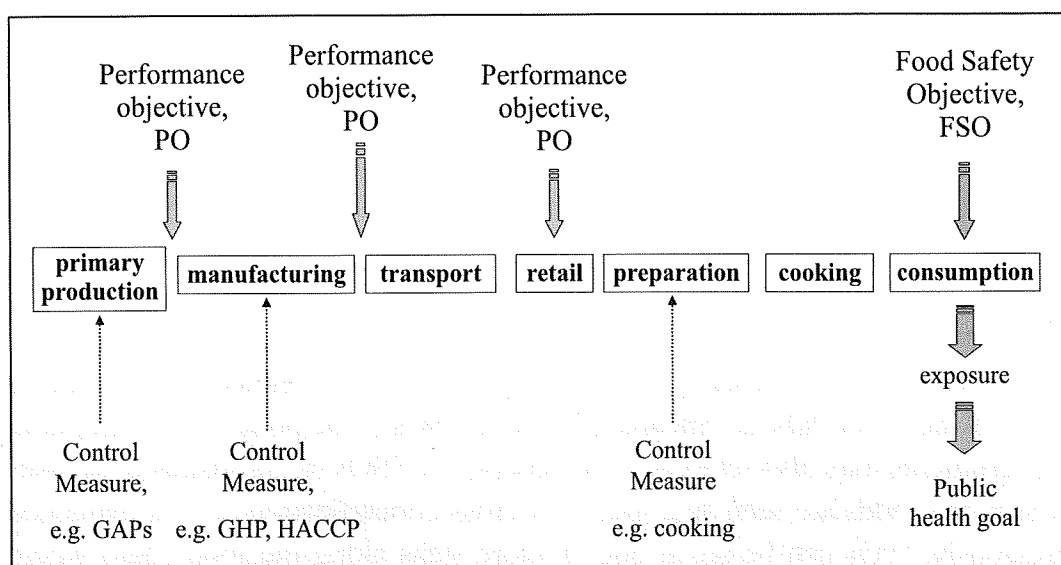


Figure 1. Model food chain indicating the position of a Food Safety Objective and derived Performance Objectives

7. Responsibility for setting an FSO

Deciding if and when to use an FSO is the responsibility of governments. The decision on what is or is not considered acceptable in terms of food safety is the traditional role of government, but the actual expression of a number and/or frequency of a hazard (e.g., bacteria or toxins) in a food at the time of consumption (the FSO) is new. Governments will typically consult with experts in foodborne disease, food microbiology and food processing, as well as other stakeholders to decide what the FSO should be. Sometimes, very quick reaction is required - and expert panels are consulted on short notice and a decision is made. The SPS agreement requires that in such instances, these values are considered interim measures.

FSOs should only be developed in situations where they will have an impact on public health and it is therefore not necessary to establish FSOs for all foods. Understanding which hazards are important in which foods, predicting future food safety concerns and, importantly, designing food processing and preparation procedures that will prevent foodborne diseases from occurring, are major goals of food microbiological research conducted both in academia and in industry. Experts in these areas can assist governments in the development of realistic FSOs.

8. Setting a PO

When an FSO has been set, POs may be set further back in the food chain by taking into account the changes that will occur in the level and/or frequency of the hazard (e.g., the harmful bacteria) between the points where POs are set and consumption. These may be more strict than the FSO to account for contamination or growth of harmful bacteria during distribution, preparation, storage and use of a particular food. On the other hand, the POs may be more lenient than the FSO, for instance, if the product is cooked just before consumption. POs may be set by both government and industry. Considering the diversity of industry, governments may decide to set POs as a means to achieve FSOs at the point of consumption. Governments may also set POs in the absence of FSOs or, for instance, in cases where raw foods are seen as a source of cross-contamination as was explained previously. POs can be set at one or more steps along the food chain where control measures can and should be applied to prevent foodborne diseases, for example, at points where it is important that all products remain below a particular level. POs, like any other microbiological limit for finished products, should take into consideration the initial level of the hazard before any treatment, as well as the decreases and possible increases of that hazard level, if any, prior to consumption. These approaches have been fundamental to safe food processing for decades and will not change with the introduction and implementation of an FSO or PO. In fact, the FSO and PO are additional tools that the food industry can use to build food safety into their products.

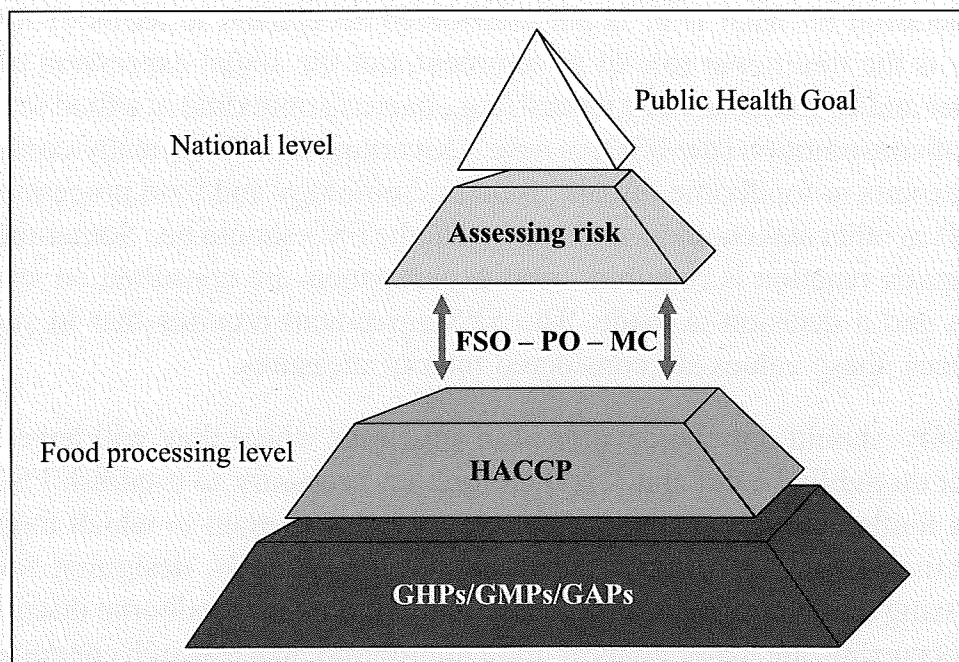


Figure 2. FSOs and POs are means of articulating public health goals to be met by food processors by good practices and HACCP. Also, industry can set POs to ensure that FSOs are met.

9. Responsibility for compliance with the FSO

The marketing of food that is not harmful to consumers when used in the intended way is the responsibility of the various food businesses along the food production chain. This responsibility will not change with the introduction of the FSO and PO concepts. In fact, the use of FSOs and POs will make food professionals involved in the various parts of the food chain more aware of the fact that they share this responsibility. Government or third parties can assess programs, such as the good practices and HACCP, to confirm the likelihood that the products will meet the FSOs. This can and will be extended across national boundaries, as some countries will ask that imported products are produced under food safety management programmes based on GHP and HACCP.

10. Meeting the FSO

Since the FSO is the maximum level of a hazard at the point of consumption, this level will frequently be very low. Because of this, measuring this level is impossible in most cases. Compliance with POs set at earlier steps in the food chain can sometimes be checked by microbiological testing. However, in most cases, validation of control measures, verification of the results of monitoring critical control points, as well as auditing good practices and HACCP systems, will provide the reliable evidence that POs and thus the FSO will be met. Microbiological criteria can be derived from FSOs and POs, if such levels are available. If such levels are not stated, microbiological criteria can be developed, if appropriate. The ICMSF (2002) has provided guidance on the establishment of microbiological criteria.

11. Not all FSOs are feasible

When establishing FSOs, governments should determine through discussions with relevant experts and stakeholders what feasible FSO values should be. In some cases, it may turn out that it is not possible to comply with a set FSO level in practice, and a government may decide to set a less stringent FSO. Such an FSO may be set temporarily until improvements in processing technology make it possible to set a lower (more stringent) FSO. An alternative would be to keep the more stringent FSO and to provide a period during which processing procedures can be changed to meet the FSO. In the first case, it may be appropriate to communicate to consumers the particular risk associated with consuming the product. An alternative approach is the banning of product, e.g., banning of high-risk tissues (spinal

cord, root ganglia, tonsils) of beef to be sold for human consumption due to the inability to detect and/or eliminate bovine spongiform encephalopathy (BSE).

12. Concluding remarks

FSOs and POs are new concepts that have been introduced to further assist government and industry in communicating and complying with public health goals. These tools are additional to the existing programmes of GAPs, GHPs and HACCP which are the means by which the levels of POs and FSOs will be met. Hence FSOs and POs build on, rather than replace, existing food safety practices and concepts.

13. Further reading

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