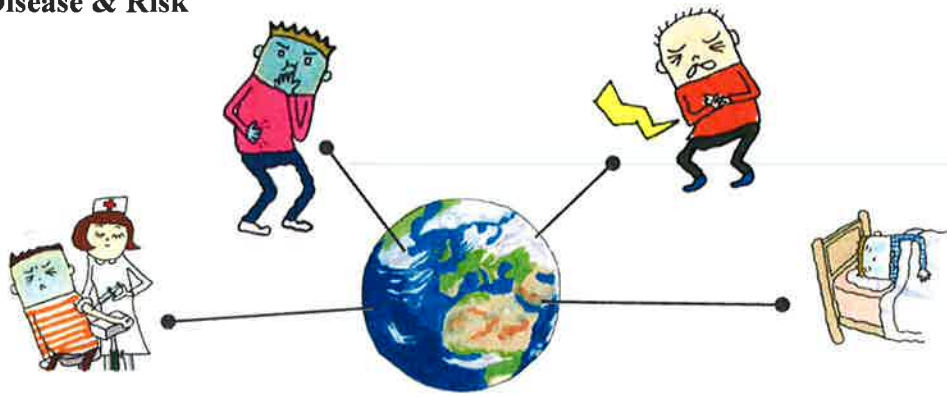
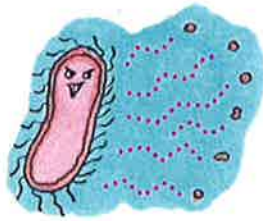


Foodborne Disease & Risk



Diseases caused by foodborne pathogens constitute a worldwide public health problem and preventing them is a major goal of societies.

Microbiological foodborne diseases are typically caused by bacteria or their metabolites, parasites, viruses or toxins.



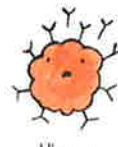
Bacteria Their metabolites



Parasites



Toxins



Viruses

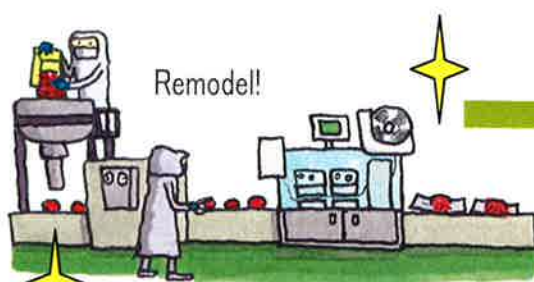
Poor hygienic practices



Poor sanitation

The health impact of different foodborne diseases varies between countries, and depends on foods consumed, food processing, preparation, handling and storage techniques employed, and sensitivity of the population.

While the total elimination of foodborne disease remains an unattainable goal, both government public health managers and industry are committed to reducing the incidence of illness due to contaminated food. However, reducing the number of illnesses will always have a cost to society.



“Cost” not only involves economic impact, but also includes cultural impacts, such as eating habits, etc. For example, banning a particular food commodity, such as unpasteurised milk, may be acceptable to some countries, but not to others.



Unpasteurised milk



All countries aim at reducing foodborne illness; however, most nations do not explicitly state to what degree they would like to reduce the number of foodborne illnesses in their country. Also, individual nations have different opinions about how to balance costs with reductions in foodborne illnesses.

Countries have traditionally attempted to improve food safety by setting microbiological criteria for raw or finished processed products. However, the frequency and extent of sampling used in traditional food testing programs may not provide a high degree of consumer protection. In most cases, a microbiological criterion has been set without estimating its effect on reducing the risk of foodborne disease.

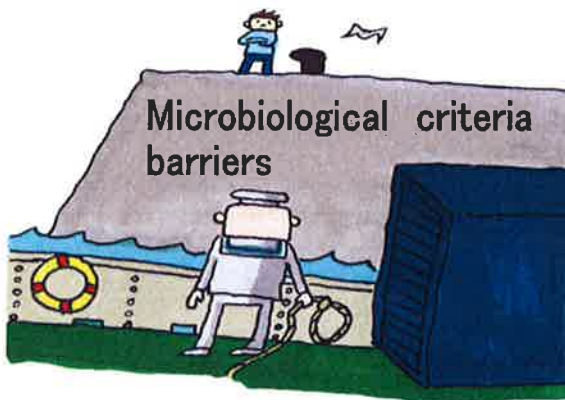


Traditional food testing programs may not provide a high degree of consumers protection.

Countries have been setting microbiological criteria for raw or for finished processed products.

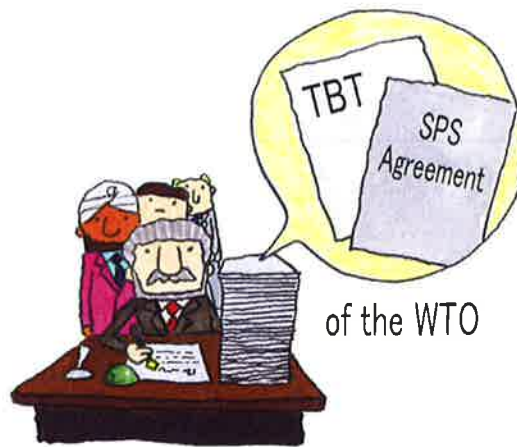


Consumers



Sometimes microbiological criteria established by national governments for different foods have been viewed by other countries as barriers to international trade, especially when a stricter level is imposed than is generally accepted at the international level for foods in trade.

More than 100 countries have signed the Sanitary and Phytosanitary (SPS) Agreement of the World Trade Organization (WTO). This agreement states that “whilst a country has the sovereign right to decide on the degree of protection it wishes for its citizens, it must provide, if required, the scientific evidence on which this level of protection rests.” It follows that if a country sets a microbiological criterion—or any other limit—for a particular health hazard in a particular food product, they must be able to explain, based on scientific data, consideration of risk and societal considerations, the rationale and justification for the criterion. Another WTO agreement, the Technical Barriers to Trade (TBT) Agreement, also requires that a country does not ask for a higher degree of safety for imported goods than it does for goods produced in its own country.



of the WTO

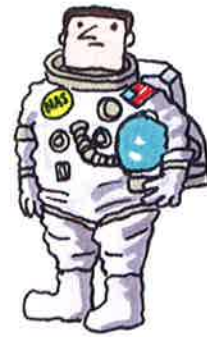


Good Practices and HACCP

Realising the many shortcomings and lack of food safety assurance provided by traditional inspection and sampling/testing of lots, the concept of Hazard Analysis & Critical Control Points (HACCP) was developed in the early 1970s.

The HACCP concept has provided great improvements in the production of safe foods. The goal of HACCP is to focus on the hazards in a particular food commodity that are reasonably likely to affect public health if left uncontrolled, and to design food products, processing, commercialization, preparation and use conditions that control those hazards. To be successful,

HACCP was born because of the U.S. Apollo space mission.



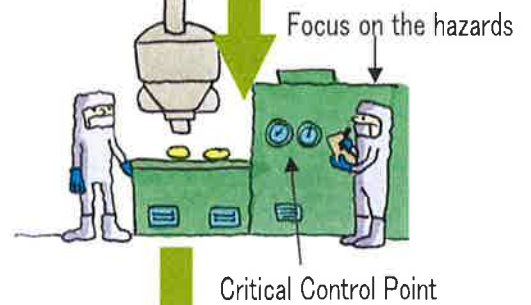
"Can you prove this food is 100% safe?"

Traditional inspection and sampling/testing of lots



Good Agricultural Practices (GAPs) and Good Hygienic Practices (GHPs)

HACCP is built on good production and manufacturing practices, such as good agricultural practices (GAPs) and good hygienic practices (GHPs), which minimize the occurrence of hazards in the product and the production 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.

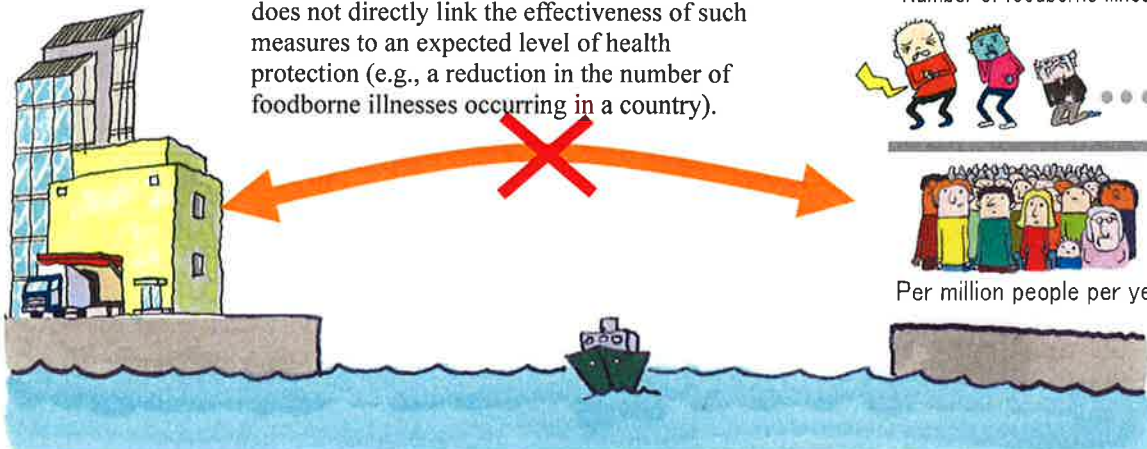


However, HACCP is plant/factory-specific and does not directly link the effectiveness of such measures to an expected level of health protection (e.g., a reduction in the number of foodborne illnesses occurring in a country).

Number of foodborne illnesses

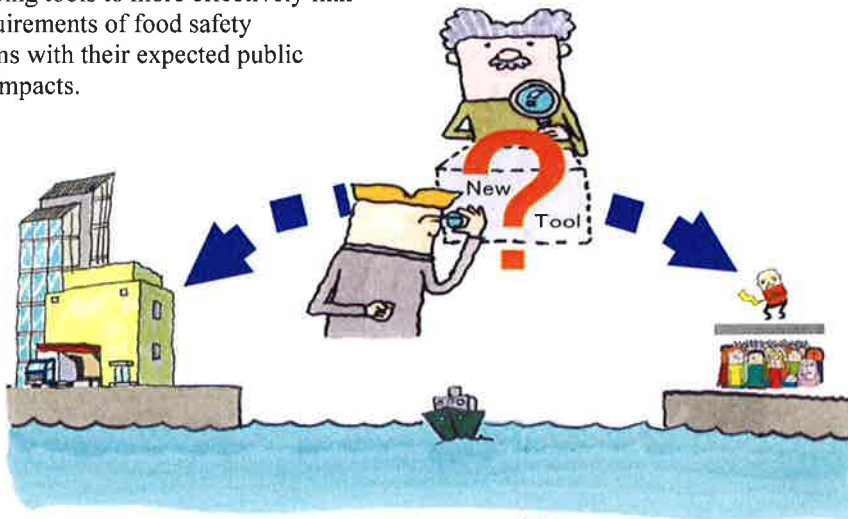


Per million people per year



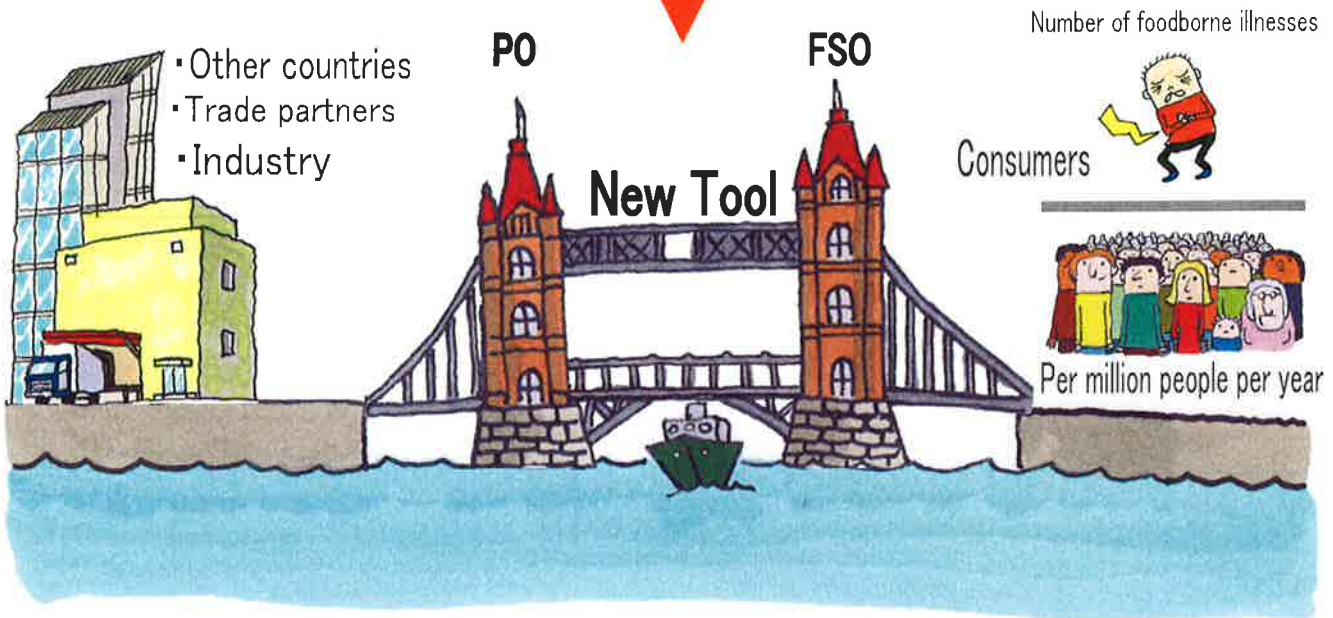
Setting Public Health Goals: The Concept of Appropriate Level of Protection (ALOP)

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 impacts.



This document introduces two such tools: Food Safety Objectives (FSO) and Performance Objectives (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.

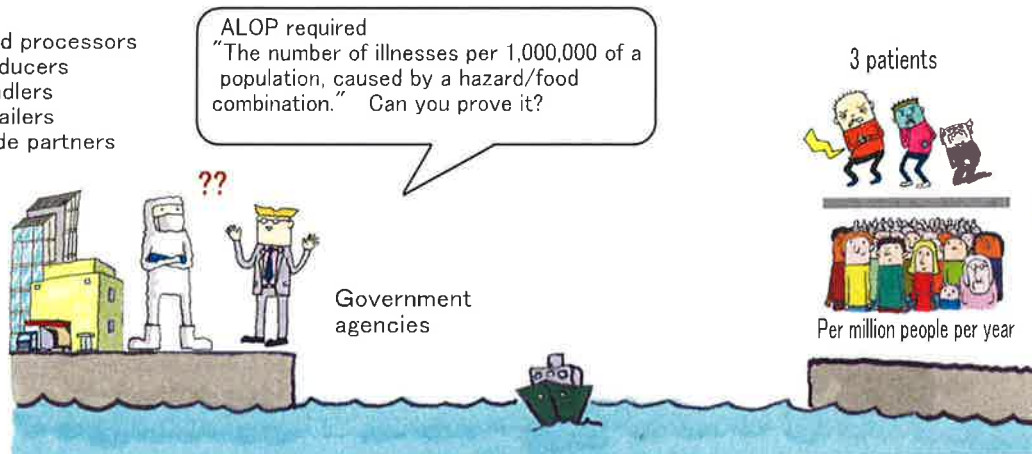
Costs may include industry investment for product reformulation and changes in processing, consumer costs due to increased prices or reduced availability of certain products, and/or regulatory costs in terms of surveillance.



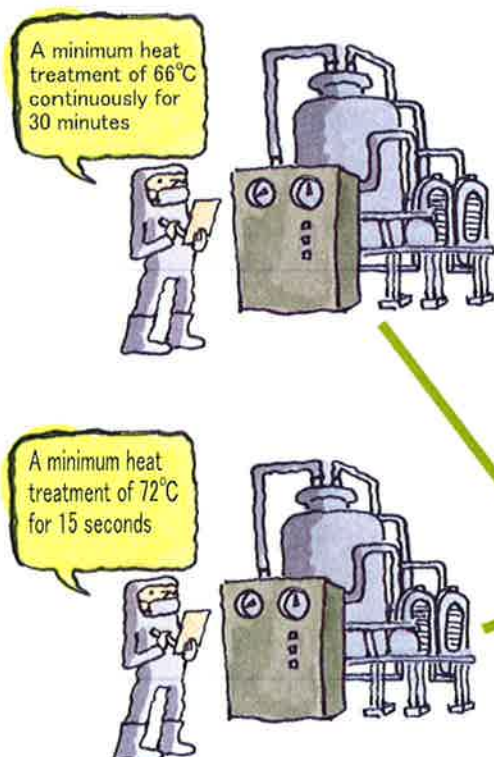
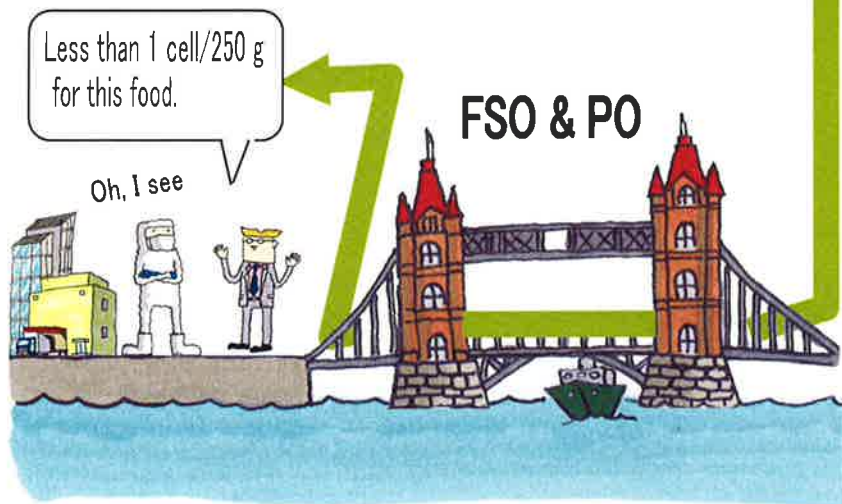
Food Safety Objectives (FSO)

When a government expresses public health goals relative to the incidence of disease, it 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.

- Food processors
- Producers
- Handlers
- Retailers
- Trade partners



To be meaningful, the targets for food safety set by governments need to be translated into parameters that can be assessed by government 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.



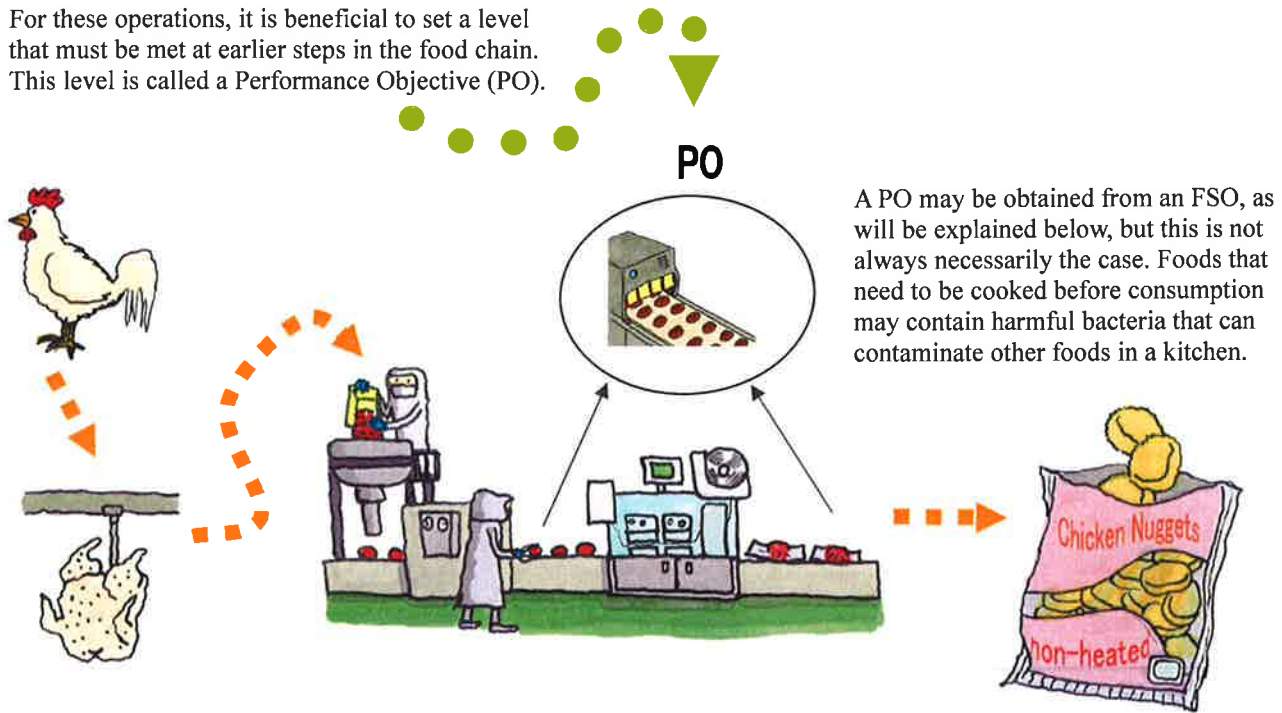
An FSO is “the maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP).” It transforms a public health goal to a concentration and/or frequency (level) of a hazard in a food. The FSO sets a target 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.



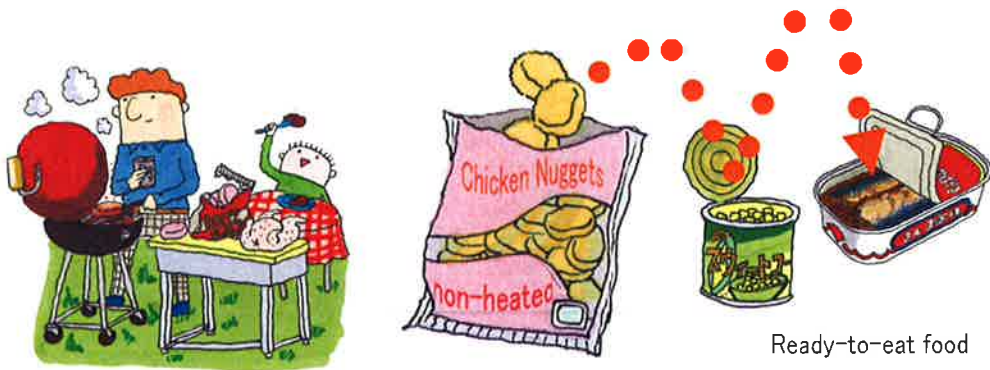
Performance Objectives (PO)

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.

For these operations, it is beneficial to set a level that must be met at earlier steps in the food chain. This level is called a Performance Objective (PO).



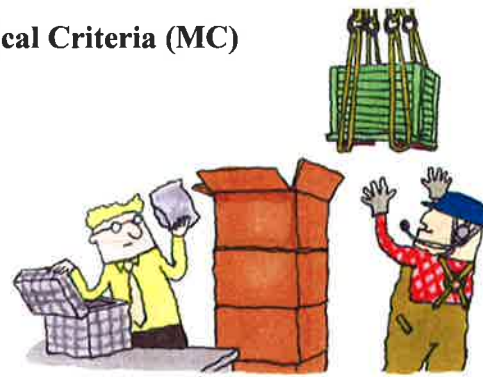
Reducing the likelihood of cross-contamination from these products could be important in achieving a public health goal. The level of contamination that should not be exceeded in such a situation is a PO. For example, raw chicken may be contaminated with *Salmonella*. Although thorough cooking will make the chicken safe (absence of *Salmonella* in a serving), the raw chicken may contaminate other foods during preparation of a meal. A PO stating that “no more than a specified percentage of raw chicken carcasses may contain *Salmonella*” may reduce the likelihood that this pathogen 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.



The raw chicken may contaminate other foods during preparation of a meal.

The Difference Between an FSO, PO and Microbiological Criteria (MC)

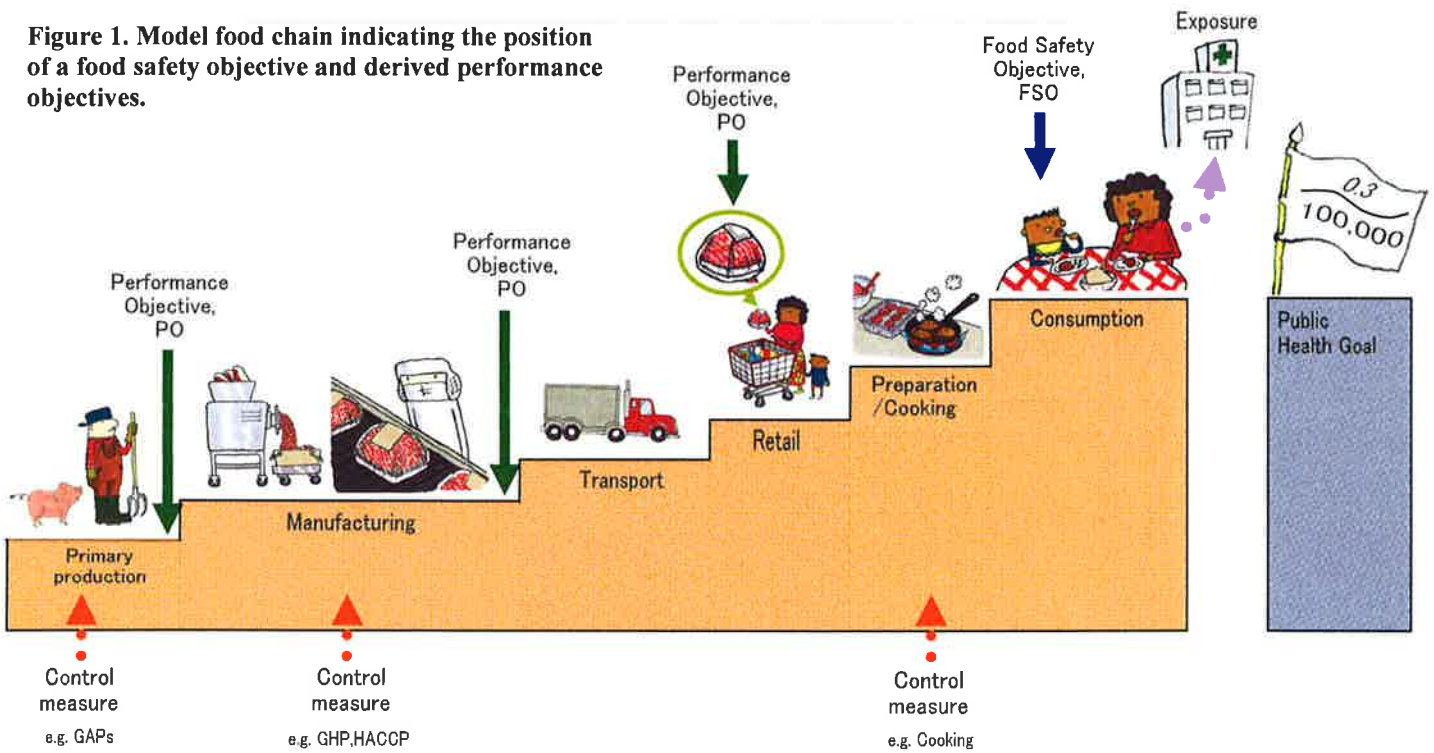
Microbiological criteria (MC) need to be accompanied by specific information, including the type of food product, the sampling plan, methods of examination and the microbiological limits to be met. Traditional MC are designed to be used for testing a shipment or lot of food for acceptance or rejection, especially in situations where no prior knowledge of the processing conditions is available.



A sampling plan is used for testing a shipment or lot of food for acceptance or rejection.

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.



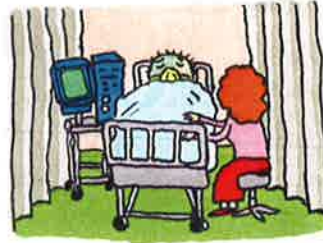
Responsibility for Setting an FSO

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.

FSO: A number and/or frequency of a hazard (e.g., bacteria or toxins) in a food at the time of consumption



Governments typically will 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 WTO SPS Agreement requires that in such instances these values are considered interim measures.



It is not necessary to establish FSOs for all foods. FSOs should only be developed in situations where they will have an impact on public health.

Understanding what 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.



Research helps us to understand:

- ◆ What hazards exist in which foods
- ◆ How to design best practices in food processing and preparation
- ◆ Predict future food safety issues



Food microbiological research is conducted both in academia and in industry.

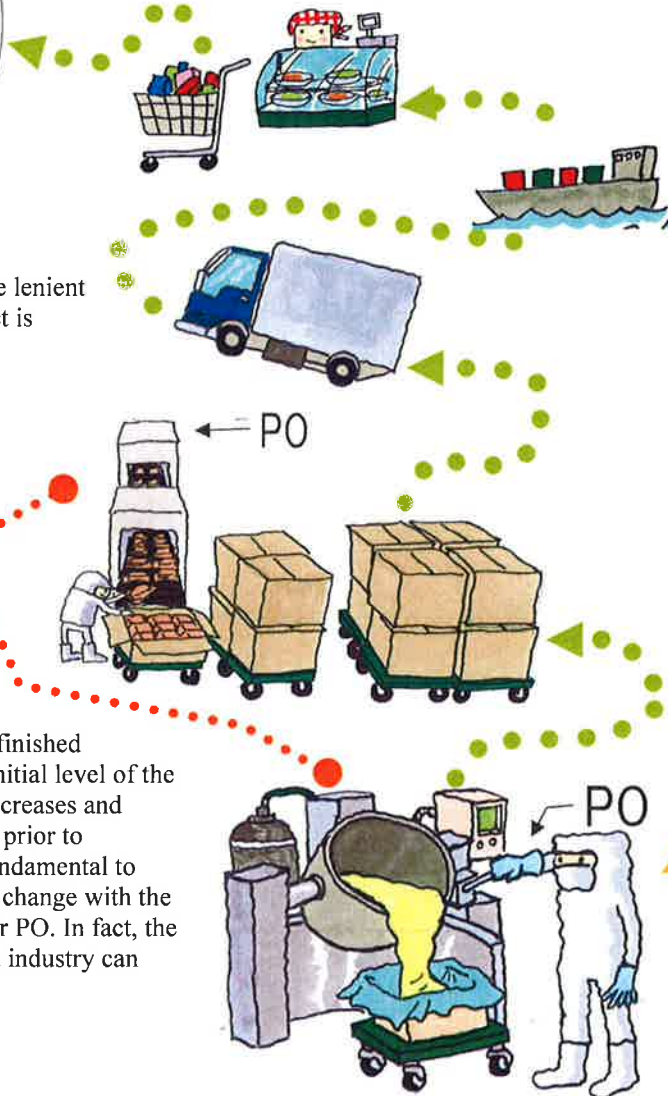
Setting a PO



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.

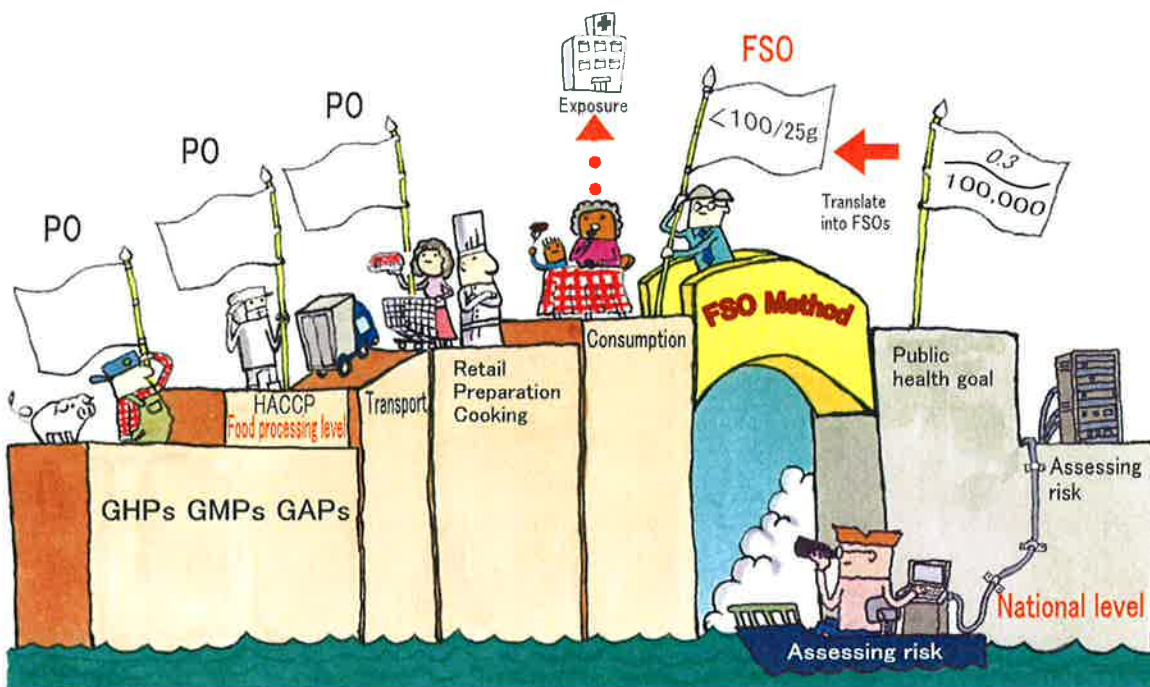
- On the other hand, the POs may be more lenient than the FSO; for instance, if the product is cooked just before consumption.

POs 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.

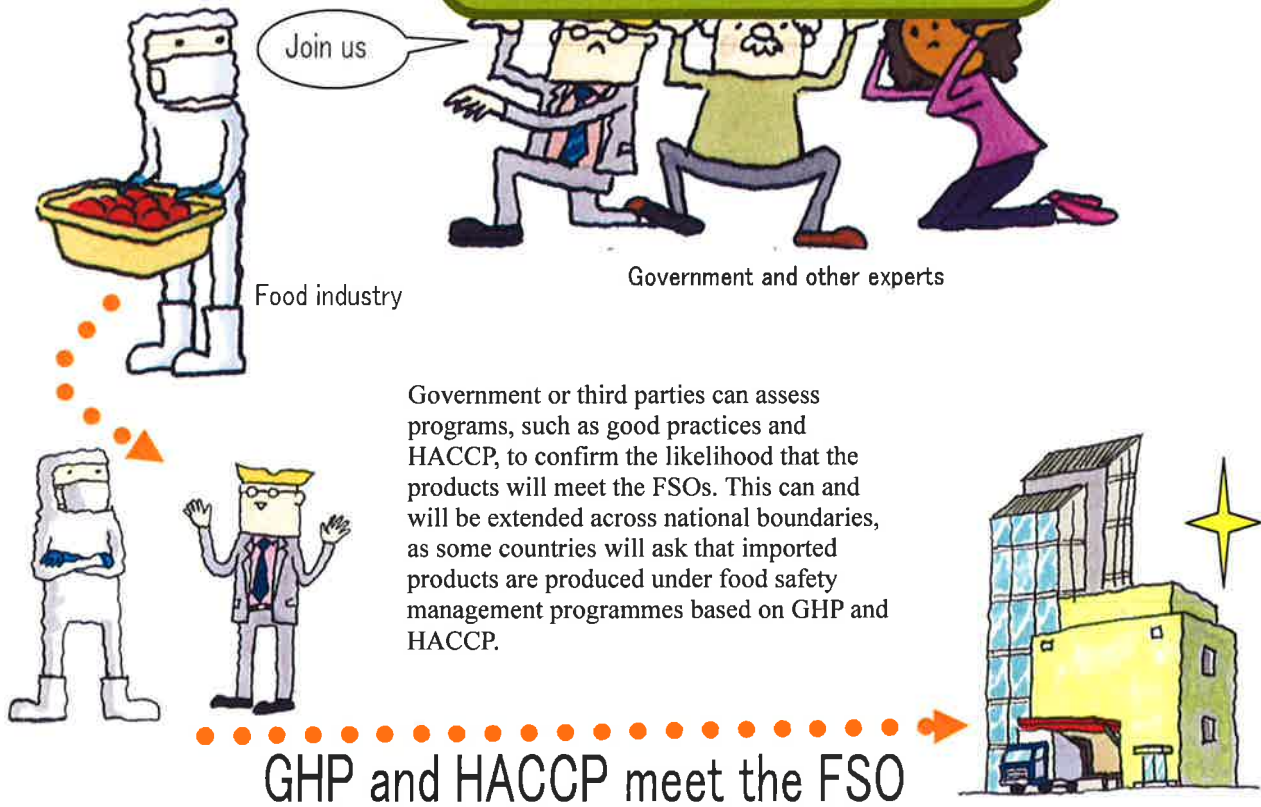
Figure 2. FSOs and POs are means of communicating public health goals to be met by food processors by good manufacturing practices and HACCP. Industry can set POs to ensure that FSOs are met.



Responsibility for FSO Compliance

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.

Responsibility of Public Health and Food Safety

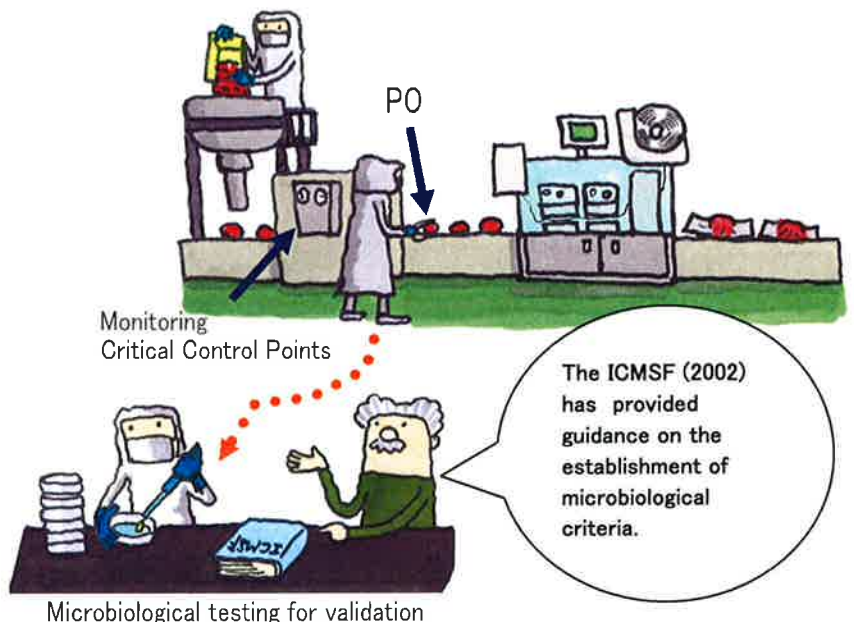


Meeting the FSO



Since the FSO is the maximum level of a hazard at the point of consumption, this level frequently will be very low. As a result, 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.

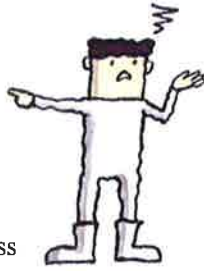


Not All FSOs are Feasible

When establishing FSOs, governments should determine through discussions with relevant experts and stakeholders the feasibility of FSO values under consideration.



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 is to keep the more stringent FSO and 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, such as banning the sale of high-risk beef tissues (spinal cord, root ganglia, tonsils) for human consumption due to the inability to detect and/or eliminate bovine spongiform encephalopathy (BSE).

Enhancing Food Safety Practices

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.