Food safety objective: An integral part of food chain management

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Abstract

The concept of food safety objective has been proposed to provide a target for operational food safety management, leaving flexibility in the way equivalent food safety levels are achieved by different food chains. The concept helps to better relate operational food safety management to public health goals, i.e. to an appropriate level of protection. The FSO articulates the joint target of a food chain, including all relevant links in that chain, and is common to all other food chains relevant to a pathogen/commodity combination. Performance objectives and performance criteria are two new concepts proposed recently to complement that of food safety objectives with respect to food safety control and control measures and process criteria regarding operational food safety management. All concepts together help government to give guidance to food chains about the expected safety of food products and at the same time help food chains to design their food production and food safety management systems such that there is compliance with this expectation.

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1. Food safety management

In the course of human history, the scope and complexity of food safety management on the operational level has increased dramatically. In ancient times when food safety was the sole responsibility of the hunter/gatherer, the chain of responsibility was a very short one. Gradually, the scope increased further over small communities, regions and countries to now reach international scales. Concomitantly, the chain of responsibility has become longer and more complex as have the food supply chains to deliver the products to the consumers.

Today, with important changes in lifestyles and demographic compositions and with global food markets becoming increasingly more common place, we see the food supply growing ever rapidly in size and diversity. To keep pace with all the scaling up in the food supply chain and the diversification of food on the market, it has been necessary to adapt and improve the food safety management systems on a continuous basis as well. In recent years the control over the safety and quality of food produced has become tighter and tighter. Food safety management systems such as Hazard Analysis Critical Control Points (HACCP) and the pre-requisite systems Good Manufacturing Practice (GMP) and Good Hygiene Practice (GHP) have provided the professional players in the food supply chain with excellent tools (van Schothorst, 2004). Excellent provided they are used for design and implementation of a specific food manufacturing process in a proper and diligent way. Globally, both with governments and food professionals there is a good buy-in for HACCP and food safety management systems that are based on comparable principles. Notably, HACCP and its prerequisite systems are very specific to the food...
production facility that they have been developed for (Fig. 1).

Many different food professionals are involved in the chain of food production, e.g. from primary production, distribution, processing and manufacture, packaging, retail, to food service and preparation in the home by consumers. All those different professionals provide particular contributions depending on the specific structure and logistics of individual chains. The understanding of their role and responsibility in the overall management of the safety of the food product that is leaving a food chain needs clear co-ordination (Gorris, 2002). Specific concepts have been developed in food safety management, i.e. microbiological criteria, control measures, and process criteria, which support this co-ordination. In addition, stakeholders in food safety management such as governments, trade or sector organisations have developed guidelines, best practice advice, regulations and food safety standards.

Considering that many different food chains exist, with an enormous variety in structures, logistics and chain participants, and that they will undoubtedly change rapidly, scale-up and diversify continuously, food safety management at any scale (regional, national, local, factory) is a challenge. Ideally, each food production chain is managed integrally, across all links in the chain. Ideally as well, there is explicit knowledge about the success of this management, whether the underlying measures work to the extent projected. Ideally, again, the success of food safety management should be reflected in the health status of the population concerned.

2. Food safety control

Analyses of public health problems and their association to the food supply, have brought about the opinion in many a government that our current food supply is probably safer than ever before. Considering the enormous volume of food that, on a global scale, is produced and consumed safely, this apparent confidence is warranted. Nevertheless, the statistics indicate that even in industrialised countries one out of every three people has a food-borne microbial illness event every year (WHO, 2002). We recognise that food safety is not an absolute. It is a continuum of more or less safety.

At a governmental level, food safety control for public health protection by necessity covers the range of different food chains relevant to a certain food product or product group, including all relevant producers, manufacturing sites and food service establishments within the country as well as those importing into the country. FAO and WHO have called upon countries to apply modern international food safety and quality standards to protect consumer health. Appreciating the complexity of the current food safety supply within and across countries, both organisations advocated using Risk Analysis as the single framework for building food safety control programs. Partly through the activities of Codex Alimentarius and ad hoc expert consultations, FAO and WHO have developed a series of guidelines and reports that detail out the various steps in Risk Analysis, namely Risk Management, Risk Assessment and Risk Communication.
With respect to food-borne pathogens possibly associated to particular foods, Risk Analysis is about to be generally accepted by governments as the framework to (1) estimate the impact of a particular hazard on public health, (2) define an appropriate level of public health protection against that hazard and (3) establish guidelines to ensure the supply of safe foods (Gorris, 2002). Public health protection is paramount, but the facilitation of fair trade is a second important area of application of Risk Analysis as it is advocated to use the framework in the development of Codex Alimentarius Standards, Codes and Guidelines.

The current health status of a population is evaluated conducting a Microbiological Risk Assessment (MRA) for a product or product group to which a pathogen is associated (Buchanan, Smith, & Long, 2000; Lammerding & Fazil, 2000). An MRA can give an absolute or a relative indication of the health status, i.e. provide an absolute numerical expression of the risk at population level respectively a relative or benchmarked expressing (e.g. a ranking). Importantly, MRA studies can be developed on many levels of detail, amongst many others depending on the complexity of the issue, the urgency for obtaining the risk estimate and the data available (van Gerwen & Gorris, 2004). What all MRA studies should have in common is that they involve all relevant food products in a country or imported into a country (Fig. 1). They should keep to the important basic principles of being structured, systematic, transparent, and open studies. They also should give detailed account of all information that is important to understand the process by which the risk estimate has been arrived at as well as the content of the study. Thus, for instance, data considered, data rejected and rationale for that, models used, assumptions made and opinions all should be specified. With the risk estimate, an account of variability and uncertainty should be given.

The risk estimate, whether an absolute or relative expression, within the framework of Risk Analysis can be used by risk managers (in countries, likely the competent authority) to decide on an appropriate course of action. In some cases, the risk to the population does not necessitate action, in others specific measures are needed to reduce the burden of disease. In the latter case, risk managers may choose to set health protection goals and use these to formulate targets for all the relevant supply chains to meet. As a matter of principle, policy should be in place that helps governmental risk managers to decide on what in the WTO–SPS Agreement (WTO, 1995) is called an Appropriate level of protection (ALOP). A definition of ALOP is given in Table 1. Articulating an ALOP or any other form of public health goal is a way to express, on a population level, what level of risk a society is prepared to tolerate or is considering to be achievable. Agreeing on such levels and possibly striving for continuous improvement in the levels over time, is a key element in the Risk Analysis process.

3. Food safety objective as a food safety control concept

An ALOP, expressed for instance as a numbers of illnesses in a population per annum, is not a measure that is meaningful for food safety management in practice. The food safety professionals responsible for controlling the specific hazards possibly associated to food ingredients they use or the food products they market need more specific guidance from food safety control authorities. To that end, and within the current Risk Analysis framework, it is proposed that, when deemed appropriate, competent authorities can formulate a so-called Food Safety Objective (FSO). An FSO specifies the level of a hazard (in terms of concentration and/or frequency)

### Table 1

<table>
<thead>
<tr>
<th>Definitions for the key concepts in risk analysis based food control</th>
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<tbody>
<tr>
<td><strong>Appropriate Level of Protection (ALOP)</strong></td>
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<tr>
<td>Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory (WTO, 1995)</td>
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<tr>
<td><strong>Food Safety Objective (FSO)</strong></td>
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<td>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). (CAC, 2004)</td>
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<tr>
<td><strong>Performance Objective (PO)</strong></td>
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<tr>
<td>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. (CAC, 2004)</td>
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<tr>
<td><strong>Performance Criterion (PC)</strong></td>
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<tr>
<td>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 (CAC, 2004)</td>
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<tr>
<td><strong>Control Measure (CM)</strong></td>
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<tr>
<td>Any action and activity that can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level (it can be microbiological specifications, guidelines on pathogen control, hygiene codes, microbiological criteria, specific information (e.g. labelling), training, education, and others) (ICMSF, 2002)</td>
</tr>
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that can be tolerated in the final product when it is consumed. Setting an FSO at the moment of consumption is supported by the International Commission on Microbiological Specifications for Foods (ICMSF), as this is the moment when no change in the hazard level can occur anymore and essentially the consumption event is required to have a possible impact on public health (ICMSF, 2002). Table 1 gives the definition of FSO as it is now endorsed by the Codex Alimentarius Commission (CAC, 2004). Some hypothetical examples of FSO values are given in Table 2.

Knowledge from the MRA study, characteristics and capabilities of the supply chains affected, and ambitions for public health protection are all considered when an FSO is derived from an ALOP. In this way, the FSO reflects the stringency that governmental food safety control deems necessary for operational food safety management to implement. In this respect, the FSO value is an important communication tool for the overall management of the chain as it articulates the expected level of control on hazard levels in food chains to deliver a product considered safe. It is a concept that bridges from a population’s generic requirements to specific operational measures, and as such should be accepted as an integral part of food chain management (Fig. 2). To use the FSO as an overall target at the end of a food chain leaves flexibility to individual food chains in the way this target is achieved. It acknowledges that food chains can be very different, but nevertheless should comply with a common target.

An FSO can be set on the basis of a public health goal directed towards protecting a sub-population of concern. In this case, there are two options to follow. Either the FSO that protects the sub-population of concern is implemented to be valid for the population as a whole or an FSO that protects the general population is implemented in concert with additional measures that protect the specific sub-population of concern. Although the concept of FSO has been proposed to be a specific derivative of an ALOP established considering results of an MRA study, an ALOP can be decided on without having an MRA available. In practice, countries may already have articulated public health goals without referring to them as ALOPs or using Risk Analysis to establish them. Also, FSOs can be set without formal public health goals for instance as the hazard level at consumption that would follow from complying to public health goals for instance as the hazard level at consumption that would follow from complying to existing microbiological criteria earlier on in the chain.

Governmental risk managers may choose to implement specific risk management measures (standards, microbiological criteria, hygiene code, labelling, education, etc.) in addition to an FSO. Such measures may be relevant to all or the majority of supply chains so they should be included in all cases. Alternatively, such measures may be essential additions to the target without

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**Table 2**

Hypothetical examples of concepts used in food safety control

**Example: Food Safety Objectives**
- *Listeria monocytogenes* in a ready-to-eat food product shall not exceed 3.5 log_{10} CFU/serving size of food when eaten
- The concentration of aflatoxin in shelled, roasted peanuts shall not exceed 15 µg/kg when consumed

**Example: Performance Objectives**
- *Salmonella* and pathogenic *E. coli* shall not exceed 1 CFU/10 L when fruit juice is packaged for distribution
- *Clostridium perfringens* shall not exceed 100/g in cooked meat or poultry products when ready for distribution

**Example: Performance Criteria**
- Assure a 12 log reduction of *Clostridium botulinum* in low acid canned foods
- Heat process juice to achieve a 5 log reduction of enteric pathogens
- Avoid more than 3 log 10 CFU increase in *S. aureus* during the manufacture of cheese and fermented meats

**Example: Control Measures**
- Selection of certified infectious pathogen-free ingredients
- A product requirement, e.g. pH below 4.6 (product criterion)
- Education catering staff about proper hygiene

**Example: Process Criteria**
- Three minutes at 121 °C for 12-D inactivation of spores of proteolytic *C. botulinum*
- Ten minutes at 90 °C for 6-D inactivation of spores of non-proteolytic *C. botulinum*
- Fifteen seconds at 71 °C commercial pasteurisation of fluid milk
which the ALOP may not be met. Importantly, the FSO is just one of the options to give guidance to food safety management the expected management of risks. As there are often many links in a food supply chain it may be necessary to establish or define several operational targets along the chain that help ensure that the chain as a whole operates to meet the FSO at consumption. It is evident thus, that close collaboration of all stakeholders in the chain is required to achieve that common goal. All stakeholders should share due responsibility related to their “span-of-control” in the chain. They all need to understand how to relate their food safety management activities to that of the whole chain, i.e. how to come to an integrated management of the food supply chain.

4. Other food safety management targets

In addition to the use of existing generic concepts (i.e. GHP, GMP, HACCP) and specific concepts (i.e. microbiological criteria, control measures, process criteria) in the management at individual steps, for the benefit of adequate control over a hazard in a chain it may be relevant to specify one or more targets earlier in the food chain that need to be complied with in order to comply to the FSO. In recent discussions (ILSI, 2004) the rationale for having such targets was clearly established. It has been proposed to call these targets Performance Objective (PO), which are equivalent to FSO, specifying hazard levels that are tolerable, but which are set at one or more specific steps earlier in the food chain (CAC, 2004). The definition for PO is given in Table 1. POs are determined they have to be articulated with a common goal. All stakeholders should share due responsibility related to their “span-of-control” in the chain. They all need to understand how to relate their food safety management activities to that of the whole chain, i.e. how to come to an integrated management of the food supply chain.

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In several cases, having a target early on in the food supply chain may be much more relevant in terms of guidance to hazard control than having one at the end of the chain. For example, with the production of poultry, minimising the level of hazards such as Salmonella or Campylobacter on raw poultry in primary production can be an efficient strategy in order to limit spread of the pathogen as well as cross-contamination with processed foods at the point of preparation. Stipulating POs that relate to the prevalence of such pathogens at the primary production step can give appropriate guidance for hazard control at that step. In this case, the FSO at the end of the chain, when the poultry product has been adequately cooked and there is no reason or benefit of intervention in the hazard level would merely dictate the expected stringency in hazard control at that final stage. Some hypothetical examples of PO values are given in Table 2.

To comply with a PO or an FSO, at the operational level, control measures need to be established. A definition of control measures is shown in Table 1. Examples of control measures are given in Table 2. At a particular stage in the chain, one or more control measures can be implemented as part of the product and process design to control a hazard. A new term has been proposed (CAC, 2004) to describe the overall effect of the control measures on the hazard level at a step, namely the Performance Criterion (PC). The definition of PC can be found in Table 1. A PC indicates the change in hazard level required at a specific step in order to reduce the hazard level at the start of the step to a level at the end of the step that complies with the PO or the FSO. Obviously, the hazard level at the beginning of a step (also referred to as H0 in ICMSF, 2002) matters in establishing the PC required in a step. The higher the starting hazard level, i.e. the more bacteria enter the step, the larger the PC needs to be to achieve a particular level at the end of the step (the PO). The PC thus always has to be considered in conjunction with a starting hazard level. PCs are the specific operational, supply chain measures at (a) specific step(s) that result in meeting the objective for that step, the PO. When a PC is effective at time of consumption (e.g. a required minimum effect of a heat treatment during preparation in order to cause a specific reduction in the hazard level) it actually is the FSO that is met. Such a PC can be part of the product design, but can be relied upon only under specific conditions. PCs may concern a required reduction of the hazard, avoiding increase (limit to 0) or assuring a minimal increase. PCs in general will be decided on by food safety managers as key points in the design of the production of a food in a supply chain. PCs can be achieved by one or more control measures and as such are a reflection of the concrete management measures that assure that a product is safe and produced to meet the proper specifications. Some hypothetical examples of PC values are given in Table 2.

With respect to guidance milestones, there are thus now two discrete elements proposed: a single FSO at the time of consumption and one or more POs, as required, at earlier points in the food chain. These milestones are not intended to be enforced but should provide guidance to what level of a hazard should not be surpassed at that point helping food safety managers
to design the correct operational control measures at the step in the chain. Complying with the hazard level tolerated at the moment of consumption, the FSO, is a shared responsibility for all parties together. This requires an appropriate design of the complete chain, which is helped by specifying POs and PCs as food control guidance targets or food safety management measures at relevant points in the production chain. Although PO and PC like the FSO are not intended to be enforced, these concepts on occasion could lend themselves to be verified by specific testing or could be linked to specific microbiological criteria.

Fig. 3 gives an overview of how various guidance milestones and operational measures relate to each other in an imaginary food supply chain. Operational measures may include single control measures or sets of control measures working in concert (within the design of the food safety performance at the step) to achieve a certain effect, termed the Performance Criterion, on the hazard level in the food product when leaving the step. There are many different types of control measures, instigated by regulation or chosen by the industry, the proper functioning of which needs to be monitored and verified by the industry. The stringency in the control of the food safety system(s) operating in the food chain should be such that any exposure of the public at time of consumption does not unduly add to the burden of disease of the population by complying to the ALOP or any other form of public health goal articulated.

5. Unique role of FSO

There is intentional similarity in the concepts of FSO and PO since both are guidance values for the hazard level at points in a food chain. Whereas FSOs by concept are only set by competent bodies/governments, POs can be set by industry or by such bodies/governments. The latter, for instance, could propose PO values when they want to define default milestones in a typical food production chain in a generic “guidance” fashion. Industry can choose to define PO values in the very specific case of a food production chain, for instance, to improve the integration of the overall supply chain management. The question arises why two different terms (FSO and PO) are proposed for the same kind of guidance. It would have been simpler to have just one of them. The rationale is that the end of the chain hazard level needs to be considered as quite a unique guidance point. Here are a number of reasons for this (not an exhaustive list):

1. The FSO set at the far end of the chain is the only guidance point that is directly related to the actual public health impact. Without consumption of the product there is no exposure of the consumer to the

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Fig. 3. Schematic representation of how governmental or country level guidance along an imaginary food chain links in with operational level measures at relevant points. The guidance is given in the form of FSO or PO values stipulated by the appropriate food control function. The operational level measures are embedded in the food safety management systems operated in the chain, such as GHP, GMP, HACCP.
hazard and no health implication. From the point earlier in the chain where a PO may be set, the possibility remains that a food is not consumed or the events following the PO are different in practice than assumed when establishing the PO level. In other words, it is thus not assured that PO equals the FSO level.

2. An FSO set at the point of consumption relates to the level of the pathogen that can be consumed without an unacceptable impact on public health at the population level; it relates to the actual exposure and the response at population level; on a population level, exposure is composed of several, quite variable factors, most importantly the concentration and frequency of the hazard occurring in the product at the moment of ingestion and the amount of product ingested. Also, the ALOP relates to exposure and response at population level, thus to consumption patterns affecting actual ingestion next to the level and frequency of the hazard occurring in food. However, while ALOP relates to this on a higher level and encompasses all factors, an FSO needs to be meaningful to the supply chain and effective in delivering the intention of risk management in terms of food safety. For this reason, an FSO can refer to either a concentration or a frequency or to both.

3. The FSO is valid for all different types of supply chains producing a particular product. Food chains can be very different in their infrastructure, partnerships, logistics and level of hazard control exercised at specific points. Nevertheless, the FSO now defines the hazard level that should not be surpassed at consumption and as such assures a form of equivalence in the level of safety provided in the final food product at consumption thus potentially, at maximum, has an equal tolerable impact on public health.

4. The FSO is the value that should lead the development of PO values earlier in the chain, when appropriate. POs and other target or control measures can be developed, in principle, both in a “downstream” and in an “upstream” although this will actually depend on the mathematical rigor that applies. Working in a downstream direction, essentially one is testing the hypothesis whether the food safety management system of a particular food chain as currently designed would comply with the FSO. In the upstream direction, POs and other targets or control measures are arrived at by reversed engineering starting from the FSO value. In both directions, modelling and mathematical calculations are important tools to relate measures and targets. Additionally, specific information available from an MRA study will be helpful in the exercise.

5. Whereas the FSO gives guidance to the stringency required overall, it is more or less left open how compliance to the FSO is achieved. In other words, it is left flexible how a food chain structures and organises itself to produce the food such that it is in compliance and equivalent safety is provided through different chains. This avoids undue external constraints on the food chains and allows them to produce within their internal constraints (e.g. with respect to technologies, materials, processes, chain organisation, and intended market) as long as compliance is evidenced. It also fosters innovation, as not only conventional technologies and processes can be applied. This flexibility cannot be given in a generic way considering POs earlier in the chain.

6. The FSO is the anchor-point between operational management of food supply chains and public health protection; the former relates to a very high level of specificity (in terms of management and consumer population affected)—the latter relates to a low level of specificity—thus, the relationship between ALOP and FSO is not a direct relationship, but a conversion in which operational characteristics and population characteristics are considered. In the conversion, confidence in the technical capabilities of operational management to deliver the stringency required can be accounted for by introducing a sense of conservatism (safety factor) in deciding on the appropriate FSO value. Such a conversion can meaningfully be done at the end of the chain as this is the point of equivalence in terms of final hazard level. Points earlier in the food chain may relate to POs, but these points may differ between food chains and hazard levels thus may differ as well.

7. The concept of FSO is meaningful both to exposure assessment professionals and to epidemiologists; it bridges the domains necessary to relate operational level management to country level monitoring and surveillance; only when this link exists, systems at national level will be able to assess whether food safety management measures deliver what is expected in public health protection.

Where deemed necessary, governments can choose to mandate specific POs, PCs or control measures as appropriate defaults in the food chain at earlier steps than consumption, as is currently done for certain control measures. One example where such specific measures could prove to be important is in the prevention of cross-contamination at the point where food is prepared for final consumption. In this case, the occurrence of cross-contamination is a generic issue affecting the safety of all ready-to-eat products. For instance, pathogens present on raw food products such as red meats or poultry products could transfer to processed, ready-to-eat foods through manual handling, cooking utensils or surfaces. In this case, both the meat and poultry as well as the ready-to-eat product may have FSOs associated. However, as they are generic appropriate
preventative or control measures relating to cross-contamination should better not be linked to a specific food (i.e. as a PO, PC or control measure at that step) but should be part of general hygiene measures to be kept to in all cases during preparation.

6. Some considerations for future developments

Food operations do not need to completely change the way they manage food safety now a number of new concepts have been introduced in food safety control. At an operational level, many of the concepts, standards and guidelines that are used to date will be needed in the future. However, what is a new aspect is that food safety management will need to be able to design their operations in such a way that the food at the moment it is eaten complies with the FSO. The established food safety management systems (i.e. HACCP, GHP, GMP) and supply chain targets (e.g. microbiological specifications or process criteria) will continue to be used in order to meet the FSO. They will not become obsolete but remain a necessary, integral part of the future food safety management.

The concept of FSO is important for governmental bodies working on food safety control and legislation since they are responsible for coherent and appropriate public health protection but also for the integrity of food safety management as it relates to the overall food chain. Many aspects and issues are yet to be discussed in detail for all stakeholders to recognise the function and full value of the FSO concept. Important elements yet to gain experience with are the establishment of an FSO on the basis of ALOP or other public health goals, as well as the possible enforcement of POs (or FSOs) or related PCs, standards and control measures.

An FSO need not only be derived from an articulated public health goal, such as the ALOP, and on the basis of an MRA. Provided sufficient insight is available in the food supply chain and the dynamics of a relevant pathogen, existing measures can implicitly indicate a level of the pathogen that is achieved at the end of the chain. Although this empirically derived value can be termed an FSO, after all it is expressed in the same terms and positionned at the chain-end, it does not comply necessarily with the basic concept that the FSO links the public health goals to the management of the supply chain. This, because the direct relationship between the FSO and the ALOP or of the FSO and the hazard characteristics (exposure dose–response) is needed to make this link.

Another question is about the true meaning of the word “objective”. FSO is a target that different food chains relevant to a certain product/pathogen combination realistically can meet. It, however, is not a “minimum requirement” but rather a “maximum tolerable level”. However, is it or can it be a “bright line in the sand” that must not be crossed? One proposition is, that it is not. A target is not an absolute maximum. There however, should be sufficient stringency build in the FSO that there should be some tolerance in achieving it with certain reliability (Havelaar, Nauta, & Jansen, 2004). The alternative proposal is that the FSO indeed is a bright line. Given that the FSO holds at a point where control and enforcement commonly are impossible, governmental confidence in compliance will have to relate to targets (i.e. POs) and control measures earlier in the chain, in combination with the use of modelling to relate hazard levels at these points to the level of the hazard at the end of the chain.

Despite the fact that many details underlying the setting and compliance to the FSO as yet need further maturation, the consideration of FSOs and related concepts such as PO and PC as integral parts of food safety control has gained solid support both within the context of public health protection and international trade.

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