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# Operationalising a performance objective with a microbiological criterion using a risk-based approach

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ABSTRACT

In this concept paper, we have developed three case scenarios to illustrate how one can derive a Microbiological Criterion (MC) from a Performance Objective (PO) or from a Food Safety Objective (FSO). In the first scenario, we show how one can derive an MC from a PO that is set as a numerical limit to the concentration of a pathogen. In the second scenario, it is shown how one can derive an MC from a PO that is set as the limit to the prevalence or proportion of a microorganism. In the final scenario, we show how to derive an MC from an FSO for a product supporting growth of the target pathogen between the PO and FSO. These case scenarios present guidance on how to derive an MC from risk-based metrics and very explicitly detail all the steps to be taken and assumptions/decisions that need to be made. In all three cases, MCs could successfully be established, but to do so required specific data, assumptions and decisions, as appropriate.



## 1. Introduction

Microbiological criteria have been used for many years and have contributed to improving food hygiene and food safety. Advances in the use of quantitative microbiological risk assessments have helped to develop increasingly more quantifiable estimations of public health risk and a determination of the impacts of interventions used. This has led to a series of additional risk management metrics being introduced for managing food safety: Food Safety Objective (FSO), Performance Criterion (PC), Performance Objective (PO), and Process/Product Criteria. Ideally, these metrics should be established on the basis of an articulated public health target, such as the Appropriate Level of Protection (ALOP) (van Schothorst, Zwietering, Ross, Buchanan, & Cole, 2009). A PO, which can be established at any point in a food supply chain other than at the point of consumption, is a risk-based metric allowing government risk managers and food business operators to stipulate the required stringency of a food safety management system at a particular point in a food supply chain. A PO has been defined as 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 (at the point of consumption) or ALOP (the public health outcome), as applicable. This target should be achieved by the responsible food business operator at that particular point, taking into consideration the control measures used in the food safety management system.

Establishing a microbiological criterion (MC) is one way to verify if a PO has been met, i.e., it is one way to "operationalise" the PO. In this concept paper, we have developed three case scenarios to illustrate how one can derive an MC from a PO or from an FSO.

## 2. Establishment and application of a PO and MC using a risk-based approach

A PO can be derived from a health target (e.g., ALOP) or an FSO developed by a competent authority, or it can be established on the basis of a quantitative risk assessment developed for the relevant pathogen in a particular food for/by a competent authority. Additionally, food business operators can choose to use any of the methods that a competent authority uses. Food business operators can establish a PO on the basis of either an FSO set by a competent authority, or an evaluation (usually quantitative) of the fate of the

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hazard in the specific food supply chain, ultimately resulting in an estimate of the risk.

When a competent authority establishes a PO at a particular point in the food supply chain for the purpose of providing regulatory guidance to the relevant food industry, the authority may choose to establish an MC at the same point to verify if the PO has been met. As a regulatory standard, the MC can be used to assess whether the food business operator is meeting the required performance for their food safety control program. Likewise, if a PO is established by a competent authority or by a food business operator or by multiple operators as part of their management of a hazard in a specific food commodity supply chain, an MC can be established by the food business operator(s) to verify that the PO is being met consistently.

In both cases, it is the industry or food business operator that takes action to achieve the PO, i.e., designs a food safety management system that will consistently meet the PO. Table 1 provides an overview of the various metrics and notes responsibilities and conditions for setting individual metrics, including the MC.

A PO can be established at any point in a food supply chain (other than at the point of consumption), such as for raw materials, ingredients, intermediate and final products within primary production, manufacture, distribution, products on the market and in foodservice operations, and an MC established based on a specific PO is applied to the corresponding point in the food supply chain.

### 2.1. Assumptions/decisions to be made for the establishment of an MC in relation to an FSO/PO

i. First, an assumption must be made regarding the distribution of the pathogen in the lot of food. Knowing the actual distribution within a lot can be very beneficial in establishing a suitable MC and should be used when available. In the absence of such data, a log-normal distribution is often assumed (i.e., the assumption that the logarithms of the microbial concentrations are normally distributed), and a default value for the standard deviation applied. Generally in such cases, variability in concentration levels within a lot can be described as having a standard deviation of 0.2 $\log_{10}$ cfu/g for foods with a "homogenous" distribution of microbes (e.g., liquids with a degree of mixing), 0.4 $\log_{10}$ cfu/g for foods with "intermediate homogeneity" (e.g., ground semi-solids) and 0.8 $\log_{10}$ cfu/g for foods that are not homogenous (e.g., solid foods). It could be that in certain cases even greater non-homogeneity could occur, e.g., if clumping occurs or if the contamination is restricted to only the surface of a food. If new information becomes available, the standard deviation could be updated to more accurately reflect the actual or changed variability. In addition, if more information is available concerning between-lot variability, this also could be included in the analysis of the relation between the MC and the FSO/PO.

ii. The second requirement is to define the "maximum frequency and/or concentration" of the hazard that will be used to specify the FSO/PO, including what proportion (e.g., 95%, 99%, 99.9%, etc.) of the distribution of possible concentrations must satisfy the limit, so that the FSO/PO is met. Alternatively, the assumption may be made what part of the frequency distribution can exceed the limit, e.g., for example, it is acceptable that 1 or 5% of all the units in the lot exceed the limit.

In establishing an MC for regulatory purposes, it is up to the competent authorities to decide the proportion of the distribution that should either meet or that can be accepted to exceed the limit (FSO/PO), based on the public health outcome to be achieved. This would then define if a lot is actually either conforming or not conforming to the FSO/PO, based on the actual concentration distribution within the lot.

iii. The third decision is to specify the level of assurance needed to ensure that a non-conforming lot is detected and rejected (e.g., with 95% or 99% confidence) by the specific number and size of samples taken. Alternatively, the probability of rejecting a conforming lot may be considered.

**Table 1**
Responsibilities for developing metrics.

| Metric | Developed by | Comments | Example(s) |
|---|---|---|---|
| Appropriate level of protection (ALOP) | Governments/ member countries | An ALOP is level of public health impact based on what is currently achievable in a country (as opposed to a *public health goal* which looks forward to what one wants to achieve in the future) | Less than *x* cases/year of foodborne disease *y* in the country |
| Food Safety Objective (FSO) "The maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the ALOP" (Codex definition) | Governments/ member countries | - FSO is a number, a frequency or a combination of both of a hazard in a food at the time of consumption<br>- Not necessary to establish for all foods<br>- Should only be developed where it assists in making a public health impact<br>- From an FSO, one can derive an MC | *x*% of product has less than 100 cfu/g of *Listeria monocytogenes* in a smoked salmon product at the time of consumption |
| Performance Objective (PO) | Industry<br>Governments/ member countries | - Can be established at any point in the food chain<br>- A PO can be derived from an ALOP, FSO or another PO<br>- From a PO, one can derive an MC<br>- PO's may be stricter or more lenient than FSOs to account for any increases or decreases in the levels of a pathogen in the production/supply chain.<br>- Industry can set POs to ensure that FSOs are met | No more than 10% of raw chicken carcasses after cooling can contain *Salmonella* spp. |
| Microbiological criterion (MC) | Governments/ member countries<br>Industry | - An MC should only be established when there is a definite need and where its application is practical<br>- For governments, the need is public health protection related, while for industry the need is meeting government or industry targets with regards to controlling hazards in foods<br>- Can be established from an FSO, PO or an ALOP<br>- Includes information such as the food product, the sampling plan, the method and the microbiological limit(s) to be met | *Cronobacter* spp. in powdered infant formula;<br>$n = 30$; $c = 0$; $m = 0/10$ g; 2-class plan; ISO method |