codex alimentarius commission

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

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PRINCIPLES AND GUIDELINES FOR THE CONDUCT OF MICROBIOLOGICAL RISK MANAGEMENT
ANNEX II: GUIDANCE ON MICROBIOLOGICAL RISK MANAGEMENT METRICS[1]
AT STEP 4

Prepared by the United States of America with the assistance of Australia, Angola, Belgium, Canada, Denmark, the European Community, Finland, France, Germany, India, Ireland, Italy, Jamaica, Japan, The Netherlands, New Zealand, Nigeria, Switzerland, Thailand, United Kingdom, FAO, WHO, Asociacion Latino Americana de Avicultura, the Industry Council for Development, the International Association of Consumer Food Organizations, the International Dairy Federation, the International Frozen Food

Background

At its 37th Session, the Codex Alimentarius Committee on Food Hygiene (CCFH) advanced the "Draft Proposed Principles and Guidelines for the Conduct of Microbiological Risk Management" including Annex I and Annex II to Step 5. CCFH concluded that Annex III, "Examples of the Use of Food Safety Objectives, Performance Objectives, Microbiological Criteria, Process and Product Criteria," required additional work and de-coupled the annex from the rest of the document so that it could proceed at a separate pace. A working group was formed to address the CCFH's recommendations related to Annex III.

The working group was unclear on the level of detail required by CCFH and developed a single example that it presented in two formats, one with the level of detail required to develop and relate the microbiological risk management metrics for a single pathogen/product pair, and a second that was more abbreviated in terms of technical details.

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[1] *Quantitative expressions that indicate a level of control at a specific step in a food safety risk management system.* (FAO/WHO Report on the Use of Microbiological Risk Assessment Outputs to Develop Practical Risk Management Strategies: Metrics to Improve Food Safety [2006])

The 38th session of CCFH considered that both formats were technically too detailed for the purposes of CCFH and asked the working group to develop an even simpler version of the document. In addition, in order to facilitate the advancement of the "Draft Proposed Principles and Guidelines for the Conduct of Microbiological Risk Management" to Step 8, the Committee put aside the Step 5 sections related to microbiological risk management metrics, directing the working group to include them in Annex III. In addition, CCFH decided to delete Annex I altogether, so Annex III was re-designated Annex II.

The working group has attempted in the current document to meet the needs of the Committee by developing an annex that is focused on general principles and guidelines for the establishment of microbiological risk management metrics. Examples have been restricted to simple identification of potential applications due to the highly technical information that is required to adequately explore an example in any detail. To the greatest extent possible, the working group has attempted to include the Step 5 language that was originally in the parent document with minimal changes. These texts are underlined in the revised annex for the purposes of identification. This underlining will be removed after the text has been reviewed and discussed by CCFH.

The Committee is invited to review the document and to decide on how to proceed on this matter (see Appendix).

Appendix

Draft Principles and Guidelines for the Conduct of Microbiological Risk Management

Annex II: Guidance on Microbiological Risk Management Metrics at Step 4

Introduction

Three general principles are articulated in the "Recommended International Code of Practice General Principles of Food Hygiene," its annex "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application," and the recently adopted "Principles and Guidelines for the Conduct of Microbiological Risk Management:" (i) the stringency of food safety systems should be appropriate for the dual goals of managing risks to public health and ensuring fair practices in the food trade; (ii) the level of control required of a food safety control system should be science-based, risk-based, and transparent; and (iii) the performance of a food safety control system should be verifiable. These goals have traditionally been achieved, in part, through the establishment of microbiological criteria (MC), process criteria (PcC), and/or product criteria (PdC). These metrics have provided both a means of articulating the level of stringency expected of a food safety control system and verifying that this level of control is being achieved. However, these traditional risk management tools have generally not been linked directly to a specific level of public health protection. Instead, these metrics have been based on qualitative consideration of the levels of hazards that are "as low as reasonably achievable," a hazard-based approach that does not directly consider the level of control needed to manage a risk to public health. The recent adoption of the "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius" and the "Working Principles for Risk Analysis for Food Safety for Application by Governments" has emphasized the goal of Codex Alimentarius to develop risk-based approaches that can more directly and transparently relate the stringency of control measures to achievement of a specified level of public health protection.

Recent advances in risk assessment techniques, such as quantitative microbiological risk assessments (QMRA), qualitative risk assessments, and formalized expert elicitations, are increasingly making it possible to more systematically relate the performance of a control measure, a series of control measures or even an entire food safety control system to the level of control needed to manage a food safety risk. This has been particularly true with QMRA techniques which allow the impact of different degrees of stringency to be considered quantitatively in relation to predicted public health outcomes. This increased analytical capability has led to a series of new food safety risk management metrics, such as the Food Safety Objective (FSO), Performance Objective (PO), and Performance Criteria (PC), which are intended to provide a bridge between traditional food safety metrics (i.e. MC, PcC, PdC) and the expected level of public health protection. Such metrics provide a potential means of articulating the level of stringency required of a food safety system at different points in the farm-to-table continuum, thereby providing a means for "operationalizing" the Appropriate Level of Protection (ALOP) concepts envisioned in the WTO SPS Agreement.

As outlined in the "Principles and Guidelines for the Conduct of Microbiological Risk Management," the ability to articulate the expected performance of control measures and food safety control systems in terms of the necessary management of public health risks is a critical component of the evolving Codex Alimentarius risk analysis paradigm. While QMRA is increasingly used to evaluate the ability of control measures and food safety control systems to achieve a desired degree of public health protection, its application to the development of metrics that can be used to communicate this stringency within an international or national food safety risk management framework is still in its infancy. In particular, the risk assessment tools for linking the establishment of traditional metrics and other guidance for the hygienic manufacture, distribution, and consumption of foods to their anticipated public health impact can

be complex and not always intuitive. Furthermore, effective risk assessments generally have to consider the variability and uncertainty associated with risk factors, whereas most risk management decisions which are consistent with the legal frameworks underpinning the authority of most competent authorities must ultimately be simplified to a binary criterion (e.g, "acceptable or not acceptable", "safe or unsafe").

Scope

The purpose of this annex is to provide guidance to Codex and national governments on the concepts and principles for the development and implementation of microbiological risk management metrics, including how risk managers and risk assessors may interact during this process.

The guidance provided by the annex should also prove useful to the food industry and other stakeholders who have the responsibility of devising, validating, and implementing control measures that will ensure that, once established, a microbiological risk management metric will be achieved on a consistent basis.

It is beyond the scope of this document to consider in detail the risk assessment tools, techniques, and mathematical/statistical principles that may be pertinent to the development and implementation of specific metrics for a specific food/hazard.

Use of the Document

This annex provides general guidance on approaches to the establishment of microbiological risk management metrics to more objectively and transparently relate the level of stringency of control measures or entire food safety control systems to the required level of public health protection. The annex also addresses the use of these metrics as a means of communicating and verifying risk management decisions.

This annex should be used in conjunction with the Codex "Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius[2]," "Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30-1999)," "Principles and Guidelines for the Conduct of Microbiological Risk Management[3]," "Working Principles for Risk Analysis for Food Safety for Application by Governments[4]," "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application" (Annex to CAC/RCP 1-1969, Rev. 4 (2003)), and "Proposed Draft Guidelines for the Validation of Food Safety Control Measures" (under development).

Its application is also dependent on having risk assessment and risk management teams that are familiar with the concepts, tools and limitations of both risk management and risk assessment. Accordingly, it is recommended that the members of such teams use this annex in conjunction with standard references such as the technical information developed by FAO/WHO and Codex Alimentarius.

Principles for the establishment and implementation of microbiological risk management metrics

These principles are in addition to those identified in the "Principles and Guidelines for the Conduct of Microbiological Risk Management."

1. The establishment and implementation of microbiological risk management metrics should follow a structured approach, with both the risk assessment phase and the subsequent risk management decisions being fully transparent and documented.
2. Microbiological risk management metrics should be applied only to the extent necessary to protect human life or health and set at a level that is not more trade restrictive than required to achieve an importing member's ALOP.

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[2] Codex Alimentarius Commission, *Procedural Manual*, 16th Ed. Available at http://www.codexalimentarius.net/web/procedural_manual.jsp.
[3] ALINORM 07/30/13, Appendix IV
[4] ALINORM 07/30/33, Appendix VIII

3. Microbiological risk management metrics should be feasible, appropriate for the intended purpose, and applied within a specific food chain context at the appropriate step in that food chain.
4. Microbiological risk management metrics should be developed and appropriately implemented so they are consistent with the requirements of the regulatory/legal system in which they will be used.

Relationship between Various Risk Management Metrics

A key food safety responsibility of competent authorities is to articulate the level of control that it expects industry to achieve. One tool commonly used by competent authorities has been the development and use of food safety metrics. The metrics employed by competent authorities have been evolving over time as management of food safety issues has moved from a hazard-based approach to a risk-based approach.

Traditional Metrics

Traditional metrics for establishing the stringency of one or more steps in a food safety control system include PdC, PcC, and MC.

Product Criterion. A PdC specifies a chemical or physical characteristic of a food (e.g., pH, water activity) that, if met, contributes to food safety. Product criteria are used to articulate conditions that will not support growth of a pathogen of concern or will contribute to inactivation, thereby decreasing the potential for risk to increase during subsequent distribution, marketing and preparation. Underlying a PdC is information related to the frequency and level of the contamination in the food and/or raw ingredients that is likely to occur, the effectiveness of the control measure, the sensitivity of the pathogen to the control measure, the conditions of product use, and related parameters that ensure that a product will not have the pathogen at an unacceptable level when the product is consumed. Ideally, each of these factors that determine the effectiveness of a PdC would be transparently considered when the criterion was being established.

Process Criterion. A PcC specifies the conditions of treatment that a food must undergo at a specific step in its manufacture to achieve a desired level of control of a microbiological hazard. For example, a milk pasteurization requirement of a heat treatment of 72°C for 15 seconds specifies the specific time and temperature needed to reduce the levels of *Coxiella burnetii* in milk by 5 logs. Another example would be specifying the times and temperatures for refrigerated storage which are based on preventing the growth of mesophilic pathogenic bacteria such as *Salmonella enterica* in raw meat. Underlying a PcC should be a transparent articulation of the factors that influence the effectiveness of the treatment. For the milk pasteurization example, this would include factors such as the level of the pathogens of concern in raw milk, the thermal resistance among different strains of the microorganisms, the variation in the ability of the process to deliver the desired heat treatment, and degree of hazard reduction required.

Microbiological Criterion. An MC is based on the examination of foods at a specific point in the food chain to determine if the frequency and/or level of a pathogen in a food exceed a pre-established limit (e.g., the microbiological limit associated with a 2-class sampling plan). Such microbiological testing can either be employed as a direct control measure (i.e., each lot of food is tested and unsatisfactory lots removed) or, in conjunction with a HACCP plan or other food safety control system, as a periodic means of verifying that a food safety control system is functioning as intended. As a technologically-based and statistically-based tool, an MC requires articulation of the number of samples to be examined, the size of those samples, the method of analysis and its sensitivity, the number of "positives" that will result in the lot of food being considered unacceptable or defective (i.e., has a concentration or percentage of contaminated servings exceeding the pre-determined limit), and the probability that the pre-determined limit has not been exceeded. An MC also requires articulation of the actions that are to be taken if the MC is exceeded. The effective use of an MC is dependent on a selection of a sampling plan based on the above parameters to establish the appropriate level of stringency. Since the levels of a pathogen in many

foods can change over the course of their manufacture, distribution, marketing and preparation, an MC is generally established at a specific point in the food chain and that MC may not be pertinent at other points. Underlying an MC should be a transparent articulation of the pre-determined limit and the rationale for the sampling plan chosen.

Emerging Risk Analysis-Based Metrics

The increased emphasis on risk analysis as a means for managing food safety concerns has led to increased interest in the development of risk-based metrics that can be more directly related to public health outcomes through a risk assessment process. Three such risk-based metrics that have been defined by the CAC are the FSO, PO, and PC. The quantitative aspects of these metrics have been specifically defined by the CAC,[5] but application of the metrics that have variations in their quantitative expression may still satisfy the goals and principles presented in this Annex.

Food Safety Objective. The FSO is a metric articulating the maximum frequency and/or concentration of a pathogen at the time of consumption that provides or contributes to the ALOP. An FSO can be an important component of a risk-based system of food safety. By implementing an FSO, competent authorities articulate a risk-based limit that should be achieved operationally within the food chain, while providing flexibility for different production, manufacturing, distribution, marketing, and preparation approaches.

Because of the link between FSO and ALOP, FSOs are established only by national competent authorities. Codex can help in establishing FSOs, for instance, through recommendations based on national or international microbiological risk assessments. Food safety objectives should be given effect by actions at earlier stages in the food chain by the competent authority and/or the individual food business operator (e.g. food manufacturer) setting POs, PCs or MCs, as appropriate.

There are two approaches to establishing an FSO. One is based on an analysis of the public health data and epidemiological surveys. The other is based on analysis of data on the level and/or frequency of a hazard in a food to develop a risk characterisation curve linking hazard levels to disease incidence. If such a curve is available for a given hazard, it can be a helpful basis to relate the FSO to the ALOP.

In countries, FSOs can be used:

- to express the ALOP (whether explicit or implicit) as a more useful parameter for the industry and other interested parties;
- to encourage change in industry food safety control systems, or in the behaviour of consumers, in order to enhance food safety;
- for communication to parties involved in food trade;
- as a performance target for entire food chains to enable industry to design its operational food safety control system (through establishing appropriate POs, PCs and other control measures and interaction between the participants of the food chain in question).

Since the FSO relates to the time of consumption, it is unlikely that a competent authority would use an FSO as a regulatory metric due to the unverifiable nature of this point in the food chain.

FSOs may not be universal among all countries and may need to take into account regional differences.

Performance Objective. The articulation of a PO by a risk manager provides an operational (see below) risk-based limit at a specific point in the food chain, i.e. the maximum frequency and/or concentration of a microbiological hazard at that point in the food chain which should not be exceeded if one is to have confidence that the FSO or ALOP will be maintained. Since a PO is conceptually linked to the FSO and

[5] Codex Alimentarius Commission, *Procedural Manual* 16th Ed.

ALOP, the impact of the steps in the food chain both before and subsequent to the PO should be considered in setting its value. For example, consider a PO for bottled water that specifies that the level of salmonellae after a microbiocidal treatment must be less than -2.0 CFU_{10}/ml. This would require consideration of the level of salmonellae in the incoming untreated water over a period of time, as well as the effectiveness of the microbiocidal treatment to reduce that level of contamination. The establishment of the PO in relation to controlling the overall risk would also have to consider any post-treatment increases in the level of surviving salmonellae or recontamination of the product prior to consumption.

The frequency and/or concentration of a hazard at individual steps throughout the food chain can differ substantially from the FSO. Therefore, the following generic guidelines should apply:

- If the food is likely to support the growth of a microbial hazard between the point of the PO and consumption, then the PO will necessarily have to be more stringent than the FSO. The difference in stringency will depend on the magnitude of the increase in levels expected;
- If it can be demonstrated and validated that the level of the hazard will decrease after the point of the PO (e.g. cooking by the final consumer), the PO may be less stringent than the FSO. By basing a PO on the FSO, the frequency of cross-contamination could also be factored into the control strategy. For example, establishing a PO for frequency of salmonellae contamination of raw poultry earlier in the food chain would contribute to a reduction of illness associated with poultry mediated cross- contamination in the steps to follow;
- If the frequency and/or concentration of the hazard is not likely to increase or decrease between the point of the PO and consumption, then the PO and the FSO would be the same.

A QMRA can assist in determining the relationship between a PO and an FSO. A QMRA can also provide the risk manager with knowledge of hazard levels possibly occurring at specific steps in the chain and of issues regarding the feasibility in practice to comply with a proposed PO/FSO. In designing its food safety control system such that the PO (set by a competent authority or the individual food business) and the FSO (set by a competent authority) are met, the individual food business will have to make provisions reflecting its ability to consistently meet these standards in operational practice, including consideration of a margin of safety.

The individual food business may find it beneficial to establish its own POs. These POs should normally not be universally common and should take into account the position of the business within the food chain, the various conditions at the subsequent steps in the food chain (probability and extent of pathogen growth under specified storage and transport conditions, shelf-life, etc.) and the intended use of the end products (domestic consumer handling, etc.). Although compliance with POs is not always verified by analytical means, verifying that a PO is being consistently met can be achieved by measures such as:

- monitoring and recording of pertinent validated control measures, including establishment of a statistically-based, validated MC for end products;
- surveillance or screening programs on the prevalence of a microbial hazard in a food (especially relevant for POs established by competent authorities).

Performance Criterion. A PC articulates an action that should be achieved by a control measure or a series or a combination of control measures. Generally, a PC is used in conjunction with a microbiocidal (e.g., thermal treatment, antimicrobial rinse) or microbiostatic (e.g., refrigeration, water activity reduction) control measure. A PC for a microbiocidal control measure expresses the desired reduction of the microbial population that occurs during the application of the control measure (e.g., 5-log reduction in the levels of *L. monocytogenes*). A PC for a microbiostatic control measure expresses the maximum increase in the microbial population that is acceptable under the various conditions during which the measure is applied (e.g., less than a 1-log increase in *L. monocytogenes* during refrigerated distribution of a ready-to-eat food). In many instances, the PC describes the outcome that is needed in order to achieve a

PO at a specified point in the food chain. There are a number of factors that would have to be considered in reaching a decision on the value of a PC, such as the variability of pathogen levels in raw ingredients or the variability associated with a processing technology.

PCs are generally set by individual food businesses. A PC may be set by national governments for a specific control measure, where its application by industry is generally uniform and/or as advice to food businesses that are not capable of establishing PCs themselves.

Such PCs are often translated by industry or sometimes by competent authorities into a PcC or a PdC. For example, if a PC indicated that a heat treatment should provide a 5-log reduction of a hazard, then the corresponding process criteria would stipulate the specific time and temperature combination(s) that would be needed to achieve the PC. Similarly, if a PC required that an acidification treatment of a food reduce the rate of growth of a hazard to less than 1-log in two weeks, then the product criterion would be the specific acid concentration and pH that would be needed to achieve the PC. The concepts of process criteria and product criteria have been long recognised and used by industry and competent authorities.

Integration of Microbiological Risk Management Metrics Within a Food Safety Control System

A key concept underlying the "Recommended International Code of Practice General Principles of Food Hygiene" (CAC/RCP 1-1969, Rev. 4-2003) is that key control measures must be integrated into a "farm-to-table" food safety control system in order to consistently produce a food product that achieves the desired level of public health protection (i.e., the ALOP). Since the purpose of implementing microbiological risk management is to articulate and verify, in as an objective and transparent manner as possible, the stringency of control measures needed to achieve a specific level of public health protection, it is likely that metrics may be implemented at multiple points along the food chain. A key to understanding the development of such metrics is an appreciation that the metrics implemented along a food chain should be interconnected. There are two types of interconnections. The first is the relationship among different types of microbiological risk management metrics at a specific step in the food chain. The second is that ideally metrics implemented along the food chain would be integrated such that the establishment of a metric at one point in the food chain can be related to the outcome at another and ultimately to the desired public health outcome.

The PO is likely to be the primary risk-based metric used by competent authorities to articulate the level of control (i.e., frequency and/or concentration) of a hazard at a specified point in the food chain. Once articulated, the PO in conjunction with additional information can be used to derive other microbiological risk management metrics. As a simplified example, consider a PO after a heat treatment of a food is a *Salmonella* concentration of $\leq$ -4.0 $\log_{10}$(CFU/g). If the maximum level of *Salmonella* likely to occur in the food prior to heating is +1.0 $\log_{10}$(CFU/g), then the PC for this step would be a 5-log reduction. The PC value in conjunction with information on the thermal resistance of *Salmonella* could be used to articulate specific time/temperature combinations (i.e., PcC values) that would achieve the 5-log reduction. The same concept underpins the relationship between a PO and an MC. In this instance, the MC is used to verify that a PO is not being exceeded. The PO value in conjunction with information on the likely variance of the pathogen's presence and the level of confidence required by the risk managers is used to develop a sampling plan and decision criteria associated with an MC. In general, the microbiological limit associated with an MC will have to be more stringent that its corresponding PO to take into account the degree of confidence required that the food does not exceed a PO. It is also important for risk managers to appreciate that the implementation of microbiological risk management metrics such as a PC, PcC, PdC, or MC, in combination with the additional information described above, will allow the PO for a control measure to be inferred.

As indicated earlier, the implementation of microbiological risk management metrics at different points along the food chain should take into account the changes in the frequency and/or concentration of a hazard that occur during a specific segment of the food safety control system if the desired level of overall control is to be achieved. Recent advances in QMRA are increasingly allowing microbiological risk

management metrics at different points to be related to each other and to the ultimate level of protection achieved by the overall food safety control system. The ability to relate PO and other metrics implemented at intermediate steps in the food chain to a PO or FSO established by a competent authority would be a useful tool for industry to design and verify that their control measures are achieving the desired level of control.

The integration of microbiological risk management metrics both at a specific point in the food chain and between points in the food chain will require the availability of subject matter experts and appropriate models and data pertinent to the food product and the processes and ingredients used in its manufacture, distribution, and marketing.

Key Risk Assessment Concepts Related to the Development and Use of Microbiological Risk Management Metrics

An integral part of the development of food safety metrics is a consideration of the variability inherent in the food ingredients, the control measures, and ultimately the food that determine the range of results that can be expected when a food safety control system is functioning as intended. Likewise, any uncertainties associated with the parameters affecting the food safety control system must be considered when establishing an integrated set of food safety risk management metrics. Both variability and uncertainty can be evaluated using QMRA techniques in conjunction with an appropriately designed risk assessment, providing a tool for formally evaluating and documenting how these important attributes were considered in the decision-making process.

One of the challenges in establishing and integrating the risk management metrics described above is translating the results of a risk assessment into a set of simple limits that can be communicated and implemented. This reflects that fact that modern QMRA are often based on probabilistic models that typically employ unbounded distributions (e.g., log-normal distributions for microbial populations) that have no maximum value. Thus, there is calculable probability that a metric could be exceeded when the control measure or food safety control system is functioning as intended. For example, if a control measure was designed to ensure that the level of bacteria at an intermediate processing step had a geometric mean of $\log_{10}$(CFU/g) = 3.0 and a standard deviation of 0.3 and was operating as intended, it would be expected that approximately one serving in 200 would have $\log_{10}$(CFU/g) = 4.0 and approximately one serving in 1,000,000 would have $\log_{10}$(CFU/g) = 4.7.

The implication of this concept is a characteristic inherent to the use of microbiological risk management metrics. Using the example above, if it is assumed that an MC was set by the risk manager to have a degree of confidence that a lot having servings that exceeded $\log_{10}$(CFU/g) = 4.5 would be detected and rejected, any occasion when the MC is exceeded will be considered a loss of control, even though there is a small possibility that the system may be working as intended. Microbiological risk management metrics will have to be made "operational" by deciding what portion of a potentially open-ended distribution for an "under control" control measure will be considered as exceeding the limit and the degree of confidence, such that any serving of food exceeding that value is rejected (e.g., 95% confidence that 99% of servings of a ready-to-eat food have less than 1 *Salmonella* per 100 g). While there are techniques that can be used to include some consideration of distributions within risk management decisions and verification criteria (e.g., 3-class attribute sampling plans), a series of operational assumptions will be required for any microbiological risk management metric. A critical component of establishing such a metric is ensuring that the underlying assumptions are understood by the risk managers and interested parties.

An Example of a Process for Establishing and Implementing Microbiological Risk Management Metrics

While the development of microbiological risk management metrics should follow a structured approach, the processes and procedures put into place by competent authorities for the establishment of integrated

microbiological risk management metrics should be highly flexible in relation to what metric is initially used to begin relating the performance of the food safety control system to its public health outcomes. The process can begin with an articulation of a level of disease control that must be achieved (i.e., ALOP), the exposure level that should not be exceeded at consumption (i.e., FSO), a level of control of a hazard that must be achieved at a specific point in the food chain (i.e., PO), a required processing outcome at a specific step (PC), an MC, etc.

When development of a microbiological risk management metric is being considered, there will likely be a need for close communication and mutual understanding between risk assessors and risk managers. The development of specific microbiological risk management metrics will likely require the formation of appropriate risk analysis teams consisting of appropriate subject matter experts. Scientific advice and data for specific hazard/food applications should be acquired from appropriate scientific organizations, competent authorities, process control experts or related sources of scientific expertise.

Where appropriate, risk assessors and risk managers may wish to consider the following protocol, or some variation thereof, as a means of ensuring the principles for microbiological risk management lead to transparent, informed decisions.

a. The risk assessors develop a risk assessment or other suitable scientific analysis that can inform the possible development of microbiological risk management metrics.

b. The risk managers, in consultation with the risk assessors, select one or more sites along the food chain for the product where a risk management metric may be pertinent, useful, and practical for measuring the effective implementation of a control measure, a group of control measures, or a food safety control system.

c. The risk assessors use the risk assessment to evaluate how different values for the microbiological risk management metric being considered are related to the consumers' exposure and the subsequent public health outcomes. Whenever feasible, the risk assessors should provide the risk managers with an array of values for potential microbiological risk management metrics and the corresponding level of protection expected if implemented.

d. The risk assessors use the risk assessment and related tools to ensure that the microbiological risk management metrics being considered by the risk manager are consistent with each other, appropriately taking into account the increases and decreases in hazard levels that may occur during that portion of the food chain.

e. The risk managers evaluate the practical feasibility of achieving the specific level of stringency through implementation of the metric being considered, including consideration of how to verify that the microbiological risk management metric is effectively met.

f. The risk manager selects the microbiological risk management metrics to be implemented, their level of stringency, and the strategy for their implementation.

g. Risk assessors provide advice on the food safety implications of non-compliance with a metric and provide recommendations to risk managers on regulatory responses that are proportional to likely risks.

h. At the request of the risk managers, the risk assessors calculate additional microbiological risk management metrics that may be derived or inferred from the decision in step f.

i. Risk managers review implemented microbiological risk management metrics for the degree of implementation, efficacy, and ongoing relevance. The criteria for review should be decided when the microbiological risk management metrics are initially implemented. For instance, review can be periodic and/or may also be triggered by other factors such as new scientific insights, changes in public health policy, or changes in the food chain context in which the metrics are applied.