Public Consultation on:

Draft opinion of the Scientific Panel on Biological Hazards on microbiological testing, criteria and other objectives

Self-tasking issue

(EFSA-Q-2005-296)

SUMMARY

In the communication between risk assessors and risk managers and in the provision of scientific advice in relation to the establishment of microbiological criteria, it is of utmost importance to have a common understanding of the concept of criteria, e.g. microbiological criteria and the new objectives established recently by Codex (Codex, 2004). The present opinion aims i) to clarify the links between and possible uses of the concepts Appropriate Level of Protection (ALOP), Food Safety Objective (FSO), Performance Objective (PO), Performance Criteria (PC) and microbiological criteria in relation to opinions on biological hazards and ii) to identify circumstances where the use of microbiological criteria as a tool for defining the acceptance of an end product might be appropriate and likely to improve consumer protection.

ALOP is a statement of the public health goals that is achieved by the food safety measures applied in a country, i.e. a quantification of the disease burden within a country linked to the implementation of food safety measures. The setting of an ALOP is a risk management decision under governmental responsibility taking into account both scientific knowledge and other aspects such as socio-economical factors in a country. Although the assessment of whether ALOP is met may be difficult, it is an important element of the overall food safety policy. The implicit ALOPs should be replaced by explicit ALOPs in order to be able to better link the FSOs, POs etc to the ALOP.

FSOs and POs are risk management targets that can be used to ensure that the established ALOP is achieved. While the FSO is a target at the point of consumption, the PO is a target at a specified step in the food chain before the point of consumption.

When FSOs and POs are established it is important to decide how they should be verified i.e. by which means, at which level, and at which point in time. FSOs and POs are targets and define the acceptable limits in the frequency/number of the hazards in foods. They are, however, not necessarily going to be verified by testing.

FSOs/POs are tools to communicate to the industry what the expected food safety outcome of the process is at a specified point in the food chain. The FSOs and POs only represent targets while a microbiological criterion consists of more specific elements such as the analytical method, the sampling plan, microbiological limit(s), the specified point of the food chain where the limit(s) apply, the number of analytical units that should confirm to the limit(s) and the actions to be taken when the criterion is not met. It is recommended that FSOs and/or POs should be established for the most important pathogens/food combinations and be followed by establishment of microbiological criteria, performance criteria, process and product criteria as appropriate.

Food safety is ensured through the implementation of HACCP principles in the food industry, together with GHP / GMP, and microbiological testing is used only as one of many tools to verify that the HACCP or GHP/GMP is well implemented and that the possible hazards are eliminated or controlled. MC should still be used in assessing compliance of tested lots or consignments of food where there is no adequate information available about conditions under which the food was produced. MC should also find utility to verify the continuing effectiveness of all parts of a food safety control system.

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BACKGROUND

In the communication between risk assessors and risk managers and in the provision of scientific advice in relation to the establishment of microbiological criteria, it is of utmost importance to have a common understanding of the concept of criteria, e.g. microbiological criteria and the new objectives established recently by Codex (Codex, 2004). The purpose of this opinion is to:

- Clarify the links between and possible uses of the concepts Appropriate Level of Protection (ALOP), Food Safety Objective (FSO), Performance Objective (PO), Performance Criteria (PC) and microbiological criteria in relation to opinions on biological hazards,
- Identify circumstances where the use of microbiological criteria as a tool for defining the acceptance of an end product might be appropriate and likely to improve consumer protection.

DEFINITIONS

The Codex Alimentarius has developed new concepts for food safety. The associated definitions, adopted by Codex Alimentarius Commission (CAC) in 2004 and in the case of ALOP by WTO (1995) through the SPS agreement, are:

Appropriate Level of Protection (ALOP): The level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal and plant life or health within its territory[1].

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 appropriate level of protection (ALOP)[2].

Performance Objective (PO): 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 appropriate[2].

Performance Criterion (PC): 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[2].

Process Criterion (PrC): The parameters of a control measure that if properly applied have been established as meeting, either alone or in combination with other control measures, a performance criterion[2]

Product criterion: The physical or chemical attribute of a product that if properly applied as a control measure has been established as meeting, either alone or in combination with other control measures, a performance criterion.

Microbiological Criterion (MC): A criterion defining the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms

[1] WTO, 1995
[2] CAC, 2004

including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot[3].

In the new European Regulation[4] on microbiological criteria the following definitions exist:

Microbiological criterion: A criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of microorganisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

Food safety criterion: A criterion defining the acceptability of a product or a batch of foodstuff applicable to products placed on the market.

Process hygiene criterion: A criterion indicating the acceptable functioning of the production process. Such a criterion is not applicable to products placed on the market. It sets an indicative contamination value above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law[2].

For the purpose of this opinion, the terms of 'risk analysis' and 'precautionary principle' are defined as following:

Risk analysis: A process consisting of three interconnected components: risk assessment, risk management and risk communication[5]

Precautionary principle: Article 7 of the Regulation 178/2002[3] formally establishes the Precautionary Principle as an option open to risk managers when decisions have to be made to protect health but scientific information concerning the risk is inconclusive or incomplete in some way.

[3] CAC/GL 21,1997
[4] Regulation 2073/2005, OJ L338, 22/12/2005, p1
[5] According to the regulation 178/2002, OJ L31 01.02.2002 p1

1. INTRODUCTION

For many years authorities have set limits or criteria for microbiological contaminations in foods without strictly following the framework laid down by the ICMSF (1986) and the Codex Alimentarius (Codex, 1997), that specify requirements regarding sampling plans, methodologies and evaluation of results. Criteria have often been set based upon experience of food production and processing, research and expert opinions of what was considered achievable in relation to the application of good hygienic practices on the one hand, and what was necessary to ensure food safety on the other. In many cases, the criteria have been used as an objective without specifying sampling plans and methods. In 1999, the Scientific Committee on Veterinary Measures Relating to Public Health (SCVPH) evaluated the microbiological criteria for food products of animal origin for human consumption used within the EU-legislation (SCVPH, 1999). It was concluded that existing microbiological criteria had not been established on the basis of a risk assessment and that most of these criteria were not based on Codex Alimentarius principles.

The risk analysis framework, laid down by the Codex Alimentarius during the past ten years, has made it increasingly possible to link food safety activities to public health via risk assessment. Based on 'the formal risk analysis approach' concepts that have evolved include Appropriate Level of Protection (ALOP), Food Safety Objective (FSO) and Performance Objective (PO). Furthermore, this new framework emphasizes that Performance Criteria (PC), Process Criteria (PrC) and Microbiological Criteria (MC) should be scientifically based. However, it is still unclear how these new concepts will be used in the future in Risk Analysis. Neither the well-established criteria nor these new concepts have been used consistently. Moreover, unlike microbiological criteria, FSO and PO are targets. However, it has not been elaborated how, or whether, they should be verified, and the actions that should be taken if they are not met.

The European Commission (EC) has adopted new regulation on microbiological criteria for foodstuffs, which came into force on 1st January 2006[6]. This legislation does not include the establishment of FSOs and POs. The regulation introduces two different types of criteria; Food Safety Criteria and Process Hygiene Criteria.

EFSA's BIOHAZ Panel has, on several occasions, been asked by the EC to provide opinions on the possible and appropriate use of microbiological criteria. The BIOHAZ Panel identified the difficulties in providing scientific advice on the use of microbiological criteria while new concepts in this area are being elaborated and when the scope is not completely defined. Importantly, with the new concepts, microbiological criteria must be discussed in a broader perspective than previously. As a consequence, the BIOHAZ Panel has undertaken this self-tasking issue aiming to clarify the links between, and possible use of, the new concepts of ALOP, FSO, PO, PC and microbiological criteria in relation to opinions on biological hazards.

[6] Regulation 2073/2005, OJ L338, 22/12/2005, p1

2. APPROPRIATE LEVEL OF PROTECTION

With the World Trade Organization (WTO) agreement in 1995, the international trade of goods, including food, became more regulated and standardized. For international trade in food, two of the most important agreements are "The Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures" and the "Technical Barriers to Trade (TBT) Agreement", known as the SPS and TBT agreements respectively (WTO, 1995). The SPS agreement is the primary WTO agreement covering international trade in food and agricultural commodities, including live animals and plants, with the aim of improving human health, animal health and the phytosanitary situation, establishing multilateral framework for development, adoption, and enforcement of SPS measures to minimize trade impact, and harmonizing SPS measures between countries via the Codex Alimentarius Commission in the case of foods.

The SPS agreement introduces the concept of Appropriate Level of Protection (ALOP). In the SPS agreement, it is noted that many Members otherwise refer to this concept as the "acceptable level of risk". The SPS agreement states that "no Member should be prevented from adopting or enforcing measures necessary to protect human, animal or plant life or health, subject to the requirement that these measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members where the same conditions prevail or a disguised restriction on international trade".

In order to achieve harmonization, importing countries should base SPS measures on international standards and exporting countries should, at the minimum, meet international standards. However, countries can require higher levels of SPS protection than the international standard if scientifically justified and based on risk assessment *("Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence", "Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations"*). Hence, the SPS agreement identifies risk assessment as an important tool for assisting the elaboration of food safety measures.

The primary focus of food safety measures and associated regulatory activities is the protection of public health. Although determining the appropriate level of protection is difficult, it is important to acknowledge that zero risk cannot be attained. ALOP is a statement of the public health goals that should be achieved by the food safety measures applied in a country, i.e. a quantification of the disease burden within a country linked to the implementation of food safety measures. The setting of an ALOP is a risk management decision under governmental responsibility taking into account both scientific knowledge and other aspects such as socio-economical factors in a country. An ALOP can be set for the population as a whole, or can be specific for sub-populations at particular risk. ALOPs can be expressed as numbers of cases per given number of population over a specific time period, e.g. number of cases in

100,000 inhabitants per annum, the number of cases per 100,000 consumer years, or the likelihood of suffering a food-related illness from one serving.

An ALOP may be explicit (articulated as a public health goal in terms of numbers of cases) or implicit (not articulated). So far, worldwide, very few ALOPs have been explicitly articulated. The ICMSF (2005) gives as a theoretical example of a public health goal, the reduction of the number of listeriosis cases attributable to the consumption of frankfurters by some value, e.g. 50% reduction. However, in USA for example, "Healthy People 2010" seeks a 50% reduction in the total numbers of cases by the year 2010 attributable to thermophilic *Campylobacter*, *Listeria monocytogenes*, *Escherichia coli* O157:H7 and *Salmonella* spp. In Finland, Sweden and Norway, it could be said that there is an ALOP for salmonellosis. In 1995, when the EU accepted that in these countries *Salmonella* was virtually absent from the domestic food producing animals and products thereof, the ALOP for domestically acquired salmonellosis in these countries was considered to be high. Consequently these countries were allowed to require additional guarantees for *Salmonella* when importing such animal products.

In many countries, when the incidence of e.g. listeriosis increased, it was deemed intolerable, and measures to decrease those incidences were established in food chain. Although those targets were not usually called ALOPs, and furthermore, do not qualify as specific ALOPs according to the current principles, they have been useful as an overall aim for the management of food safety.

Sometimes it might be simpler to target a reduction in the number of all human cases rather than specifying for particular hazard/foodstuff combinations the specific ALOP or the number of human cases judged to be acceptable annually and attributed to a specific type of food. Stringer (2005) emphasises that the major challenge in formulating ALOPs is that those public health goals are usually set for populations rather than directly related to specific population sub-groups and food types.

Examples of different types of ALOPs are shown below:

1. ALOP as an incidence of human cases of a particular disease annually reported (e.g. 1 case of *L. monocytogenes* per 100,000 inhabitants),
2. ALOP as a hazard-foodstuff combination (e.g. an incidence of human listeriosis cases caused by consumption of frankfurter),
3. ALOP as a hazard-group of foodstuffs combination (e.g. an incidence of human listeriosis cases caused by consumption of ready-to-eat foods where growth is possible),
4. ALOP as the reduction in the incidence of human cases of a particular disease annually reported (e.g. a 50% reduction in incidence of listeriosis annually reported in a given system) and
5. ALOP as not increasing the incidence of domestically acquired human cases of a particular disease annually reported (e.g. salmonellosis in Finland, Norway and Sweden).

2.1 Assessing whether the Appropriate Level of Protection is met

When ALOPs are set, it will also be necessary to be able to assess whether the ALOP is met. This should be clearly planned when ALOPs are set since improvements e.g. in reporting systems may increase the numbers of reported human cases although the safety level in the food production has remained the same or even improved. On the contrary, if the reporting system remains more or less the same, the trend e.g. decrease, can be followed.

For example, if an ALOP is defined as a certain percentage of reduction of a given food borne disease, data on human cases should be collected to demonstrate that the number of these food borne cases actually has decreased after setting of this ALOP. The challenges will be encountered if current reporting systems are not sensitive enough to provide valid data. Furthermore, it must be realised that the level of underreporting human cases varies between hazards and also between the countries. It is also important to know what the share of food-related cases out of all human cases is.

Although the assessment whether ALOP is met or not may be difficult as described above, it is an important element of the overall food safety policy.

3. FOOD SAFETY OBJECTIVES, PERFORMANCE OBJECTIVES AND PERFORMANCE CRITERIA

FSOs and POs are risk management targets that can be used to ensure that the established ALOP is achieved. FSOs and POs, as ALOPs, should be set individually by countries, with consideration of the present sanitary situation.

To establish an FSO data on exposure and dose-response relationship are essential. Furthermore data describing the importance of different sources of infection should be available.

Whereas ALOP is a public health goal based on both scientific information and socio-economical aspects, an FSO is the target in foods at the time of consumption linked to the ALOP. An FSO reflects the stringency that governmental food safety control deems necessary for operational food safety management to implement. In this respect, an FSO is an important communication tool for the overall management of the food chain as it articulates the expected level of control of hazard levels in the food chain. The use of FSO as an overall target at the time of consumption of a food product provides flexibility to the producers in the way this target is achieved (Gorris, 2005).

The establishment of an FSO requires good cooperation between public health and food control authorities. Basically, an FSO should articulate the overall goal of the food chain to achieve the set ALOP. On the other hand, an FSO should also be realistic i.e. it should be technically possible to produce food where the set FSO is achieved.

While the FSO is a target at the point of consumption, the PO is a target at a specified step in the food chain before the time of consumption. Both the FSO and PO contribute to an ALOP.

Setting of FSOs and POs can be based on:

1. Risk assessment
2. Practical experience and scientific data and
3. The precautionary principle

Ideally, a risk assessment should have been performed before an FSO/PO is set. The assessment would typically estimate the effect of different steps in production chain on the level of contamination at specified points in the food chain and thereby on the risk. In this way, for foods where this is relevant, e.g. broiler carcasses, POs can be set for those steps where they would be most useful targets for achieving the ALOP. For other foods, e.g. ready-to-eat foods, the setting of an FSO may be useful. Importantly, if a quantitative risk assessment has been developed, the effect of increasing/decreasing the FSO/PO can be simulated. This is useful for decision making and also enables e.g. cost-benefit analyses.

In many countries, POs have effectively been established without being named POs. Such POs, have not been based on quantitative risk assessment, but on scientific data and practical experience. In Finland, Norway and Sweden, the overall annual goal is that the *Salmonella* prevalence in live food producing animals (cattle, poultry and swine) and domestically produced products thereof, should not exceed 1% at the national level. The targets (POs), which are "absence of *Salmonella*", have been set in primary production (e.g. faecal samples from animals before being sent for slaughter) as well as in cutting plants (swabs and, from poultry, neck skin samples). If *Salmonella* is detected, stringent control measures e.g. stamping out must be applied. These programmes were established without the quantitative knowledge on the effect of different POs on the incidence of domestically acquired salmonellosis. The idea of not increasing the incidence of salmonellosis attributable to pork, beef, poultry meat and eggs is to be regarded as an ALOP.

According to the SPS agreement, the precautionary principle, if justified, may also be applied when setting sanitary and phytosanitary measures. An example of this would be BSE and the target of "absence" of any Specific Risk Materials (SRMs) in meat.

Performance criteria (PC) may be used to ensure that FSOs and POs are being met. According to the CAC definition, performance criterion means 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. Performance criteria are often translated into process criteria and product criteria, by industry or competent authorities. For example, if a PC indicates that a heat treatment should provide a 5-log reduction of a hazard, then the corresponding process criterion would stipulate e.g. the specific time and temperature combinations that would be needed to achieve the PC. Similarly, if a PC requires that an acidification treatment of

a food product reduces 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.

PC are generally set by individual food business. However, performance criteria may also be set by national governments, for a specific control measure, where its application by the industry is generally uniform and/or as advice to food business that are not capable of establishing performance criteria themselves (CAC, 2005). The existence of such PC ensures that the food safety system is transparent and thus provides evidence of equivalence in accordance with the WTO/SPS agreement.

3.1 Assessing whether the Food Safety Objectives, Performance Objectives and Performance Criteria are met

FSOs and POs are targets and compliance with FSO/POs will not necessarily have to be performed by the establishment of a microbiological criterion and testing. Other efficient means to ensure that FSOs and POs are met, are the setting of performance criteria and/or process/product criteria as appropriate. Thus, in ensuring compliance with a given FSO/PO the first thing is to decide at which level (single product, single company or in a country) and at which point in time (every day, rolling window, years) the FSO/PO should be verified. The fact that there are several possibilities may create confusion about the use and the implementation of these tools in risk management.

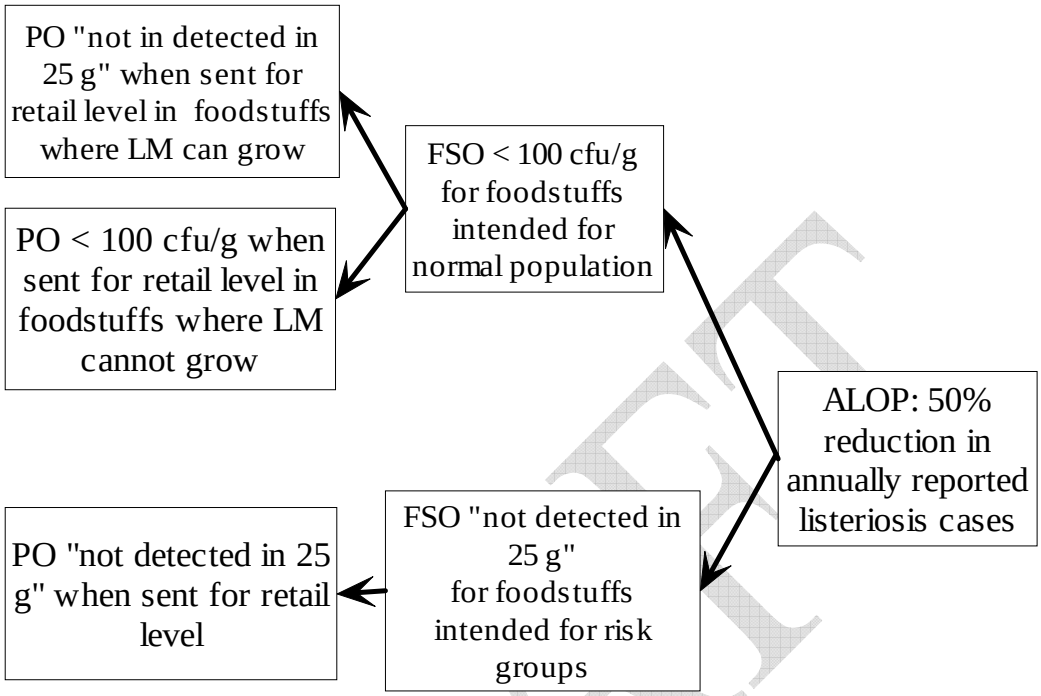
3.2 Examples

3.2.1 Use of objectives of *Listeria monocytogenes* in ready-to-eat foods

Depending on how the ALOP is expressed and its intention, one or more FSOs may be needed. For example, if an ALOP is 50% reduction in reported listeriosis cases, an FSO may be set both for foodstuffs intended for normal population and for foodstuffs intended for vulnerable groups (e.g. the elderly, the immunocompromised) (Figure 1). Since *L. monocytogenes* cannot grow in all type of foodstuffs, different targets could be set for different food categories. In those foodstuffs where *L. monocytogenes* cannot grow, a PO of the same level as the FSO could be set. However, if *L. monocytogenes* can grow, the PO should be lower than the FSO in order to guarantee that the FSO will not be exceeded.

This approach could be further simplified if data available indicated that there is not a significant difference of risk for normal vs. vulnerable groups, or that the level of protection would be the same with “absence” and <100 CFU/g. The FAO/WHO risk assessment for *L. monocytogenes* in ready-to-eat foods concluded that a more strict criterion of “not detected in 25 g” does not provide a higher level of protection than that “the numbers should not exceed 100 CFU/g” (ICMSF 2005; WHO/FAO, 2004). A risk assessment performed by WHO/FAO also showed that an FSO of 100 or 1000 CFU/g will result in very few cases of human listeriosis if compliance with the FSO is ensured.

Figure 1. Illustration of possible setting of different FSOs and POs based on one ALOP related to hazard-food combination.

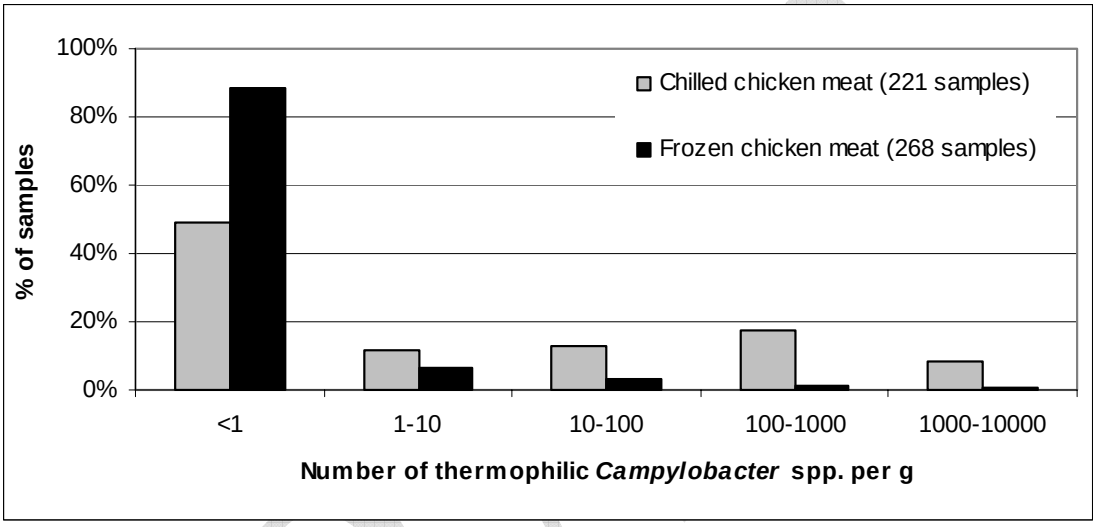


3.2.2 Use of objectives for *Campylobacter* spp. in raw poultry

Risk assessments have estimated that the concentration of *Campylobacter* spp. in raw poultry product has a great impact on the risk to the consumer of contracting campylobacteriosis (Rosenquist *et al.*, 2003; Nauta *et al.*, 2005). The primary risk was associated with handling of raw poultry together with other ready-to-eat foods like salad (chicken meals). Simulations using the Danish model designed to predict the effect of different mitigation strategies predicted that the incidence of campylobacteriosis associated with consumption of chicken meals could be reduced 30 times by effecting a 2 log reduction of the number of *Campylobacter* spp. on the chicken carcasses. To obtain a similar reduction of the incidence, the flock prevalence would have to be reduced approximately 30 times (e.g. from 60% to 2%) or the kitchen hygiene improved approximately 30 times (e.g. from 21% not washing the cutting board to 0.7%). The risk arises mainly through cross-contamination from raw poultry meat to ready-to-eat products, such as salads. Since FSO by definition only applies to products at the point of consumption, this is neither a practical nor efficient risk management tool for raw poultry meat. Instead, for these products, the setting of a PO for the concentration of *Campylobacter* spp. in raw poultry at the end of processing could, at least in theory, be considered as a relevant and practical risk management option. Thus, having surveillance data on the concentration of *Campylobacter* on fresh poultry carcasses (Figure 2) a PO could be to move the

distribution to the left by lowering the concentration of *Campylobacter* spp. on all carcasses i.e. *x* log units by a physical or chemical decontamination procedure. Another possibility is to express a PO as a percentage of carcasses, which is allowed to exceed a certain number i.e. less than *x* percent of the carcasses may contain more than *y Campylobacter*/g. In all cases, verifying that you are in compliance with the PO will be a challenge. Ensuring compliance with the PO could either be performed as national surveys with certain intervals or could be performed continuously at the single slaughterhouses. Continuously surveillance will require extensive testing.

Figure 2. The number of thermophilic *Campylobacter* in Danish produced and imported chicken products from retail outlets in Denmark, 2003.



For this reason, the introduction of a Performance Criterion (PC) may be more practical. A PC may be set, requiring the manufacturer to introduce a treatment that will allow a reduction of the numbers of *Campylobacter* on the raw products of a defined magnitude, e.g., 2 log reduction by freezing or another decontamination procedure with the result that the incidence of campylobacteriosis in humans is also reduced (30 times according to Rosenquist *et al.*, 2003). Setting a PC for specific subgroups e.g. carcasses arising from *Campylobacter* positive flocks (scheduling) is also an option.

4. MICROBIOLOGICAL TESTING AND ESTABLISHMENT OF MICROBIOLOGICAL CRITERIA

4.1. Microbiological testing

Microbiological tests can be used for a range of purposes (Annex, Table 1) and it is important to consider the purpose of testing before deciding which microbiological tests and sampling plans are used. The intended purpose determines the type of test (indicator or pathogen), the method (rapidity, accuracy, repeatability, reproducibility etc.), the sample (line-residue, end-product), the interpretation of the result, and any action to be taken (e.g. rejection of a lot, or merely readjustment of the process). Annex Table 1 (ICMSF, 2005) illustrates some aspects of microbiological testing but

it should not be regarded as being exclusive.

It is important to note that food safety can be ensured only through the widespread implementation of HACCP[7] principles in the food industry, together with GHP[8] / GMP[9], and testing is used as one of many tools to verify that the HACCP or GHP/GMP is well implemented and that the possible hazards are eliminated or controlled.

It has become accepted practice to select raw materials containing low numbers of the microbes of concern by choice of suppliers with a good history, supported by microbiological testing. Those low numbers are eliminated/controlled by the formulation, the process applied, and the storage conditions, commonly stored under refrigeration for a limited shelf-life.

In some foods, both the prevalence and numbers of pathogens is low, making routine traditional testing ineffective. Sometimes microbiological tests are made for another organism ("indicator", "surrogate"), the presence of which reflects the occurrence of the pathogen at much lower levels (e.g. Enterobacteriaceae for *Salmonella*).

Similarly, indicator organisms can be used to monitor the hygiene of the processing environment (e.g. Enterobacteriaceae during the manufacture of infant formulae).

Random testing of foods can be used as a tool to ensure that a given FSO/PO is met. Establishment of a MC should be done in all circumstances where testing is an efficient tool to ensure that the FSO/PO is met.

Tightened sampling is applied e.g. if there is not adequate information about conditions under which the food has been produced. This typically involves testing either larger samples or more samples i.e. the sampling plan becomes a more severe test.

Investigational sampling is applied where there is increased concern (e.g. that a process deviation has occurred, or the food is from a producer with a record of inconsistent controls) and attempts to determine whether or not there is evidence of such failure. Such testing is commonly done by the manufacturer.

Microbiological testing might be necessary to validate the reduction of a microbial hazard obtained by a given process. This is particularly desirable whenever the lethal effect of the process cannot be easily predicted from the scientific data available; for instance for processes involving a complex combination of factors or in the case of new technologies with limited scientific background.

Multiplication of microbial hazards (or production of the hazard if it is a microbial toxin produced in foods) can occur during the shelf life of food products, between processing and consumption. The performance criterion to meet the FSO in that

[7] Hazard Analysis and Critical Control Points
[8] Good Hygiene Practices
[9] Good Manufacturing Practices

example might be “no growth”, “no toxin production” or “the extent of growth lower than a certain limit”. Whenever the food composition permits growth of the microbial hazard, the processing criterion must be an appropriate combination of storage duration and storage temperature during shelf life. If scientific information available does not permit the prediction of the fate of the hazard in the product in relation to time and temperature, microbiological testing might be needed to validate the storage duration as a function of the anticipated storage temperature.

For instance, procedures have been proposed (AFSSA, 2005; Regulation (EC) N° 2073/2005) to test the extent of growth of *Listeria monocytogenes* in ready-to-eat foods. Testing might involve naturally contaminated food product (assuming that the microbial hazard is frequent enough) or food artificially inoculated. The major difficulty is the anticipation of the temperature regime during storage.

Surveillance can be used to measure compliance (Annex Table 1) but also for other purposes such as research and risk assessment. If the prevalence of a pathogen is high, and numbers are also high (e.g. thermophilic *Campylobacter* spp. in some flocks and on carcasses of poultry), low numbers of tests are adequate to monitor / survey that contamination. However, when the prevalence is low, and numbers are also low (e.g. *Salmonella* spp. on cattle and lamb carcasses), such low levels of testing stand little chance of detecting the occasional and low contamination. The extent of sampling and testing in surveillance should be based on some understanding of the likely occurrence of the microbe(s) of concern.

4.2 Microbiological criteria

Microbiological criteria defines “the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot” (Codex 1997). According to the new Regulation on microbiological criteria[10], a microbiological criterion means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of microorganisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

Regulation (EC) N° 2073/2005 sets down the microbiological criteria for certain microorganisms to be complied with by food business operators. This means that these criteria are enforceable against food business operators, which have to evaluate the need and frequency of sampling and testing on a case-by-case basis when fixed rules are not set down in the Regulation. In the new Regulation the European Commission defines two types of microbiological criteria:

- **Food safety criteria**, which define the acceptability of food products placed on the market. These criteria apply to the products placed on the market. If the criteria are not met the product/batch has to be withdrawn from the market.

[10] Regulation 2073/2005, OJ L338, 22/12/2005, p1

- **Process hygiene criteria**, which define the acceptable functioning of the production process. These criteria apply during the production process. If the criteria are not met the control measures to be taken are usually improvement of production hygiene and selection of raw material.

These microbiological criteria give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. The use of microbiological criteria should form an integral part of the implementation of HACCP-based procedures and other hygiene control measures.

Furthermore in the new regulation the EC emphasises that safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of GHP and application of procedures based on HACCP principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures.

Microbiological criteria should not be confused with FSO and PO. FSO and PO are targets and define the acceptable limits in the frequency/number of the hazard in foods. Setting microbiological criterion is one of the possible means to verify that these targets are met. In many cases, FSO and PO can be defined but microbiological criteria are not considered efficient to meet these targets. Therefore, absence of a microbiological criterion in the Regulation for a foodborne pathogenic bacteria and a food category does not mean that microorganisms do not represent a hazard. It means that setting a microbiological criterion is not in that case, an efficient method to control that established FSOs/POs are met. Examples of opinions of SCVPH and EFSA regarding setting of microbiological criteria and FSO/PO are shown in Table 2 (Annex). Since the concept of MC and FSO/PO has been evolving the terminology in all former opinions might not necessarily be consistent.

Regulation (EC) No 178/2002 lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe. Food business operators have an obligation to withdraw unsafe food from the market. In order to contribute to the protection of public health and to prevent differing interpretations the EC has established harmonised food safety criteria on the acceptability of food, in particular as regards the presence of certain pathogenic micro-organisms.

The Codex Alimentarius Commission (1997) laid down principles for the establishment and application of microbiological criteria for foods. However, some of these principles are not applicable with these concepts (FSO etc) and the new EC definition for criteria. In some circumstances, microbiological criteria are not appropriate to ensure that FSOs/POs are met i.e. when there are other more efficient means to control the risk or, when there are no efficient and cost-effective detection methods available considering the occurrence of the pathogen.

In particular, whenever the microorganism of concern can be controlled in a predictable, measurable and reliable way by food processing, food composition or food storage conditions, setting a PC (which can be defined by process or food criteria) is usually more effective to meet an FSO than setting a microbiological criterion. In other cases, i.e. whenever there is no adequate information about

conditions under which the food is produced, microbiological criteria might be particularly useful to verify the safety of the products or of the process.

5. CONCLUSIONS

- ALOP is a statement of the public health goals that is achieved by the food safety measures applied in a country, i.e. a quantification of the disease burden within a country linked to the implementation of food safety measures. The setting of an ALOP is a risk management decision under governmental responsibility taking into account both scientific knowledge and other aspects such as socio-economical factors in a country.
- Examples of different types of ALOPs are shown below:
  - ALOP as an incidence of human cases of a particular disease annually reported (e.g. 1 case of *L. monocytogenes* per 100,000 inhabitants),
  - ALOP as a hazard-foodstuff combination (e.g. an incidence of human listeriosis cases caused by consumption of frankfurter),
  - ALOP as a hazard-group of foodstuffs combination (e.g. an incidence of human listeriosis cases caused by consumption of ready-to-eat foods where growth is possible),
  - ALOP as the reduction in the incidence of human cases of a particular disease annually reported (e.g. a 50% reduction in incidence of listeriosis annually reported in a given system)
  - ALOP as not increasing the incidence of domestically acquired human cases of a particular disease annually reported (e.g. salmonellosis in Finland, Norway and Sweden).
- Although the assessment of whether ALOP is met or not may be difficult, it is an important element of the overall food safety policy.
- FSOs and POs are risk management targets that can be used to ensure that the established ALOP is achieved. While the FSO is a target at the point of consumption, the PO is a target at a specified step in the food chain before the point of consumption.
- Performance criterion means 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.
- When FSOs and POs are established it is important to decide how they should be verified i.e. by which means, at which level, and at which point in time. FSOs and POs are targets and define the acceptable limits in the frequency/number of the hazards in foods. They are, however, not necessarily going to be verified by testing.
- FSOs/POs are tools to communicate to the industry what the expected food safety outcome of the process is at a specified point in the food chain.

- A microbiological criterion means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of microorganisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.
- The FSOs and POs only represent targets while a microbiological criterion consists of more specific elements such as the analytical method, the sampling plan, microbiological limit(s), the specified point of the food chain where the limit(s) apply, the number of analytical units that should confirm to the limit(s) and the actions to be taken when the criterion is not met.
- Food safety is ensured through the implementation of HACCP principles in the food industry, together with GHP / GMP, and microbiological testing is used only as one of many tools to verify that the HACCP or GHP/GMP is well implemented and that the possible hazards are eliminated or controlled.
- Microbiological criteria as a tool for defining the acceptance of an end product could be used if there is not adequate information about conditions under which the food has been produced and stored. This typically involves microbiological testing either larger samples or more samples.
- In some circumstances, microbiological criteria are not appropriate to ensure that FSOs/POs are met i.e. when there are more efficient means to control the risk or, when there are no efficient and cost-effective detection methods considering the occurrence of the pathogen.
- Microbiological testing can be used for a range of purposes and it is important to consider the purpose before deciding which microbiological tests are used.

6. RECOMMENDATIONS

- The implicit ALOPs should be replaced by explicit ALOPs in order to be able to better link the FSOs, POs etc to the ALOP.
- FSOs and/or POs should be established for the most important pathogens/food combinations and be followed by establishment of microbiological criteria, performance criteria, process and product criteria as appropriate. As such, MC may provide an objective means of verifying that a PO, PC (or a FSO) is met.
- MC should still be used in assessing compliance of tested lots or consignments of food where there is no adequate information available about conditions under which the food was produced. MC should also find utility to verify the continuing effectiveness of all parts of a food safety control system.

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ANNEX

Table 1. Some examples of microbiological testing (ICMSF, 2005)

Type of testing	**Purpose**	**User**	**Sample type**	**Sampling plan**	**Microbes**
Acceptance	Lot inspection	Government	End-products	Attributes	Pathogens/Indicators
Acceptance	Verification, lots (batches) of known history	Government	End-products	Attributes	Pathogens/Indicators
		Industry	Raw materials	Attributes	Pathogens/Indicators
Monitoring, checking	CCPs, Lines	Industry	Line samples	Variables Attributes	Indicators
Environmental sampling	Line, environments	Industry	Residues, dust, water	Finding source of contamination	Indicators
Verification	HACCP	Industry	End-products	Attributes	Pathogens/Indicators
Surveillance	Compliance	Government/Industry	Products in commerce	Attributes [usually with n=1]	Pathogens
Investigation	Food chain	Government/Industry	All types of samples	Finding source of contamination	Pathogens

Table 2. Scientific opinions in the context with microbiological criteria in EU in 1999-2004 given by SCF, SCVPH and BIOHAZ.

Microbe	Recommendation on criteria/other objectives	Reference
Microbiological criteria	Criteria should be based on formal risk assessment and internationally approved principles. The criteria should be relevant and effective in relation to consumer health protection.	SCVMPH, 1999a
Listeria monocytogenes	Concentration should be below 100 cfu/g	SCVMPH, 1999b; SCF agreed 2000
Pathogenic *Vibrio vulnificus* and *Vibrio parahaemolyticus* in raw and undercooked seafood	No support for setting criteria for pathogenic *Vibrio vulnificus* and *Vibrio parahaemolyticus*	SCVMPH, 2001
Norwalk like viruses (NLV)	Conventional faecal indicators are unreliable for demonstrating presence or absence of NLV and as indicator for purification. *E.coli* instead of faecal coliforms should be used as indicators.	SCVMPH, 2002
Specifications for gelatine SCF	Sufficient to apply mandatory criterion only for salmonella.	SCF, 2002
Verotoxigenic *E. coli* (VTEC) in foodstuffs	End product criteria are unlikely to reduce risk for the consumers. Microbiological guidelines for faecal contamination can contribute.	SCVMPH, 2003a
Staphylococcal enterotoxins in milk products, particularly cheeses	Revision of criteria for coagulase positive staphylococci in cheeses, raw milk intended for processing and powdered milk should be revised.	SCVMPH, 2003b

Microbe	Recommendation on criteria/other objectives	Reference
Salmonella in foodstuffs	High risk foods were identified. The decision on criteria should be based on the ability to protect consumers and its feasibility.	SCVMPH, 2003c
Enterobacter sakazakii and salmonella in infant formula	Performance objective (PO) for powdered infant formula and follow-on-formula, aiming at very low levels of *Salmonella* and *E. sakazakii*, is introduced. Verification of PO is conformed by testing for Enterobacteriaceae in the environment and in the product.	EFSA, 2004 (BIOHAZ Panel)
Clostridium spp. in foodstuffs	The setting of microbiological criteria is not regarded as a cost-effective control measure and efforts should concentrate on establish HACCP based systems with effective process controls and assured refrigerated storage for a defined time.	EFSA, 2005a (BIOHAZ Panel)
Campylobacter in animals and foodstuffs	Setting microbiological standards for *Campylobacter* in poultry meat products at retail level appear not to be cost-effective as this would imply unnecessary testing of end products. For poultry, the setting of a performance objective (PO)/target for *Campylobacter* is a relevant option. In primary production, the PO/target would be the proportion of infected flocks (flock prevalence). In the slaughter plant, the PO/target could be the proportion of contaminated final raw carcasses and/or the numbers of *Campylobacter* on them.	EFSA, 2005b (BIOHAZ Panel)
Bacillus cereus and *Bacillus spp.* in foodstuffs	For the development of new food product, or food product that support growth of B. cereus, either by their nature or their conditions of storage (e.g. extended shelf life), processors should ensure that numbers of B. cereus between 103 and 105 per g are not reached at the stage of consumption under anticipated conditions of storage and handling. This should also apply for dehydrated foods reconstituted by hot water before consumption.	EFSA 2005c (BIOHAZ Panel)