Opinion of the Scientific Panel on Biological Hazards on microbiological criteria and targets based on risk analysis[1]

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BIOHAZ Panel members

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SUMMARY

The BIOHAZ Panel has undertaken this self-tasking issue aiming to provide an overview of the different concepts and their use with special considerations to the applicability of microbiological criteria and targets in the food chain at EU-level based on risk analysis. Recognizing that risk-based food safety management is still evolving, this document should be subject to periodical review.

Food safety management has developed from official, prescriptive control/inspection and compliance testing to goal-orientated systems which are more flexible in their implementation. The structured approach of HACCP which requires producers to identify hazards and eliminate or control them at Critical Control Points (CCP) together with controls at primary production, GHP and GMP and controlled conditions of distribution and sale, has changed the purposes of microbiological testing and microbiological criteria.

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.

Whilst ALOP represents the current public health status in relation to food safety, public health goals are intended to inspire actions to improve the future public health status and reduce disease burden. The original purpose of the FSO and PO was to translate the ALOP into levels of hazards in the food chain that can be communicated to and managed by the food industry. The FSOs and POs only represent limits 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.

Microbiological criteria are useful for validation and verification of HACCP-based processes and procedures, and other hygiene control measures. In addition microbiological criteria are used to assess the acceptability of a batch of food, including the circumstances where there is insufficient knowledge of production conditions e.g. at port of entry. In EU legislation, they are also used as a way to communicate the level of hazard control that should be achieved. Meeting microbiological criteria offers some assurance that particular pathogens are not present at unacceptably high concentrations, but does not guarantee "absence" of those pathogens.

Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs introduces two different types of criteria; Food Safety Criteria and Process Hygiene Criteria. An advantage of establishing food safety criteria for pathogenic microorganisms is that harmonised standards on the acceptability of food are provided for both authorities and industry within the EU and for products imported from third countries. Food safety criteria will impact the entire food chain, as they are set for products placed on

the market. Risk of recalls and the economic loss as well as loss of consumer confidence will be a strong motivation to meet the criteria. Therefore food safety criteria are assumed to have an effect on food safety and public health where there is an actual or perceived risk. However, it is not possible to evaluate the extent of public health protection provided by a specific food safety criterion. Microbiological testing alone may convey a false sense of security due to the statistical limitation of sampling plans, particularly in the cases where the hazard presents an unacceptable risk at low concentrations and/or low and variable prevalences. Food safety is a result of several factors. Microbiological criteria should not be considered without other aspects of EU food legislation, in particular HACCP principles and official controls to audit food business operators' compliance.

Process hygiene criteria communicate the expected outcome of a process as end-manufacturing or end- product criteria. They define the expected final outcome of the processes, but they neither characterize nor differentiate between the processes themselves.

Regulation (EC) No 2160/2003 on the control of *Salmonella* and other specified food-borne zoonotic agents, aims to ensure that proper and effective measures are taken to detect and control *Salmonella* and other zoonotic agents at all relevant stages of production, processing and distribution, including in feed, in order to reduce their prevalence and the risk they pose to public health. The use of targets at different stages of production could lead to a decrease in the prevalence of certain pathogens along the food chain. This is expected to have a positive impact on food safety and public health although the reduction of the risk remains to be estimated.

The BIOHAZ Panel recommended that studies on the reduction of risk obtained by introduction of food safety criteria, process hygiene criteria and targets should be encouraged. When developing guidelines for the use of FSO/PO in Codex, already existing terms in current legislation (i.e. the EU legislation on microbiological criteria and targets) need to be taken into account in order to avoid too many different terms been used to address the same issues. It is also recommended that the goal for risk management is established before evaluating possible control options, including the establishment of microbiological criteria and their purpose.

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BACKGROUND

On 30 March 2006, EFSA published and requested comments on the draft guidance document of BIOHAZ Panel on microbiological criteria, testing and other objectives, as a self-tasking mandate. The closure date of the consultation was 7 June 2006.

Fourteen submissions of public comments were received from food processors, distributors, scientific societies and member states food safety authorities. EFSA and the Panel on Biological Hazards (BIOHAZ) wish to acknowledge and express gratitude to those who provided comments.

EFSA and the BIOHAZ Panel took into consideration all the received comments but realized that the issue was more complex and controversial than anticipated. EFSA and the BIOHAZ Panel therefore agreed the amendment of the terms of reference as well as the title of the mandate as it is explained following.

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 Alimentarius Commission (CAC, 2004). The purpose of this opinion is to:

- Provide an overview of systems of food safety management including microbiological criteria.
- Provide a short description of the current Codex concepts, viz. Appropriate Level of Protection (ALOP), Food Safety Objective (FSO), Performance Objective (PO), Performance Criteria (PC) and microbiological criteria.
- Describe the types of microbiological criteria (food safety criteria, process hygiene criteria) and targets contained in the EU legislation in regard to public health.
- Consider the application of microbiological criteria and targets in the food chain at the EU level based on risk analysis.

DEFINITIONS

The Codex Alimentarius has developed new concepts for food safety. The associated definitions, adopted by Codex Alimentarius Commission (CAC) in 2005 and in the case of ALOP by WTO (1994) 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[2].

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)[3].

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].

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 including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot[4].

In the new European Regulation[5] 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 WTO, 1994
3 CAC, 2005a
4 CAC, 1997
5 Regulation (EC) No 2073/2005, OJ L 338, 22.12.2005, p. 1, corrected by OJ L 278, 10.10.2006, p. 32, and OJ L 283, 14.10.2006, p. 62.

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[6]

Precautionary principle: Article 7 of the Regulation 178/2002 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.

[6] According to the Regulation (EC) 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 International Commission on Microbiological Specifications for Foods (ICMSF, 1986) and the Codex Alimentarius (CAC, 1997). 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.

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.

On 1st January 2006 the European Commission (EC) adopted the new regulation on microbiological criteria for foodstuffs[7]. That 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. 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 provide an overview of the different concepts and their use with special considerations to the applicability of microbiological criteria and targets in the food chain at EU-level based on risk analysis.

Although much of the text found in this document may be a repetition of what is stated in already existing documents, EFSA and the BIOHAZ Panel have found it necessary and useful to compile this information and thereby provide a comprehensible overview and interpretation of the different concepts.

Recognizing that risk-based food safety management is still evolving, this document should be subject to periodical review.

[7] Regulation (EC) No 2073/2005, OJ L 338, 22.12.2005, p. 1, corrected by OJ L 278, 10.10.2006, p. 32, and OJ L 283, 14.10.2006, p. 62.

2. Overview of systems of food safety management including microbiological criteria

It has been the practice for governments to develop and enact basic food laws, and to set standards for safety and quality, including composition and labelling. The organisation of inspection and compliance vary widely in different countries but it is essential that government and industry work together constructively.

Powers have been given to local government inspectors to sample in factories to ensure that codes of Good Manufacturing Practice (GMP) and Good Hygienic Practice (GHP) are followed and meet regulations, and at retail and in food service establishments. Food Safety/Food Hygiene Regulations commonly cover general requirements for food premises (hygienic design, construction operation and sanitation of premises and equipment, hygiene of food preparation and processing operations, education and training of personnel).

At first religious edicts, and subsequently laws, governing collection, processing and handling of food, have been produced by national and international bodies to protect the public from fraud, adulteration and illness. Compliance has been largely by inspection, although shortcomings have long been recognised. Laws often contain vague terms that are open to different interpretations by inspectors. Sometimes factors important to food safety were given less importance than factors that were largely aesthetic or a matter of opinion.

In the 1950's it was not uncommon for canned foods to be incubated at elevated temperatures to assure the effectiveness of the canning process. Similarly, food products with a long shelf-life were often sampled and tested microbiologically to ensure the absence, or low levels, of key microorganisms before being released for distribution and sale. However, the sampling plans used were unable to detect hazards/defects occurring at low frequencies and negative results did not guarantee complete absence, e.g. from pathogens.

Many food processes and practices developed after a problem occurred e.g. spoilage during transportation or human illness, its microbiological cause was identified, and a method determined to control it. For example, pasteurised milk was introduced in Denmark in 1870 and in the US in 1874; frozen meats were first transported from Australia to the UK in the 1880s; drinking water was chlorinated in the UK in 1905.

As the scientific basis for safe food processing was strengthened, particular hazards were identified and processes for their control designed e.g. heat processing for low acid canned foods to eliminate spores of *Clostridium botulinum*; milk pasteurisation processes to eliminate *Mycobacterium tuberculosis* and *Coxiella burnetii*; heat processes to eliminate *Escherichia coli* O157:H7 and *Listeria monocytogenes* from meat products.

In the 1960's an alternative approach to food control was developed, initially to ensure microbiologically safe foods for US astronauts. The Hazard Analysis Critical Control Point (HACCP) approach (Baumann, 1974) offered a rational and structured approach to the control of food safety by identifying the hazards, their severity and risk; determining critical control points (CCPs) that will eliminate or control those hazards; establishing procedures that check that the CCPs are under control; and identifying appropriate corrective actions should they not be (ICMSF, 1988). Experience quickly

showed that the HACCP approach was more effective and more reliable than inspection and acceptance testing and it has been adopted by the food industry worldwide. The adoption of the HACCP approach, with its records of details of the raw materials and processes applied, has greatly reduced the need for microbiological testing and limited to the validation and verification purposes.

In 1962 a Joint FAO/WHO Codex Alimentarius Commission (Codex) was established to protect the health of consumers and to ensure fair practices in international food trade. Members develop documents that are a consensus based on available science, taking into account the needs of the food industry and the impact on international trade.

During the last decades increased numbers of cases of illness due to *Salmonella* and *Campylobacter* have been reported. The reasons for this might be several including changes in agricultural practices, changes in lifestyle as well as improved analytical methods and reporting systems. It should be emphasised that ensuring safe foods is the consequence of several practices rather than a single process or event. Such practices include healthy animals, feed free from known pathogens, clean water, crops not contaminated by human waste, minimising microbial contamination during slaughter / harvesting and post-harvest handling. Food processes often contain a step to eliminate the hazard(s) of concern while distribution and storage conditions minimise multiplication of those pathogens.

2.1. HACCP based analysis *vs* risk based analysis

With the World Trade Organization (WTO) agreement in 1994, 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, 1994). 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.

In January 2000 the European Commission adopted the “White Paper on Food Safety” (European Commission, 2000) which set out a strategy for a radical revision of the Community's food safety hygiene rules in order to harmonize and simplify detailed and complex hygiene requirements previously contained in a number of Council Directives covering the hygiene of foodstuffs and the production and placing on the market of products of animal origin.

Regulation (EC) No 178/2002 was subsequently adopted in January 2002 and it holds the cornerstone of this strategy. The key principles of this new food safety law include i) a comprehensive and integrated approach to food safety throughout the whole food chain (from farm to table), ii) the precautionary principle, iii) food operators right through the food chain will bear primary responsibility for food safety, iv) the

establishment of traceability at all stages of production, processing and distribution, iv) the transparency through public consultation and information and v) the requirement of food law and any subsequent measures to be based on risk analysis, except where it is not appropriate to the circumstances or nature of the measure.

Hygiene package legislation[8] lays down minimum hygiene requirements; official controls are in place to check food business operators' compliance and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles. Regulation (EC) No 2073/2005[9] on microbiological criteria for foodstuffs is an implementing measure of the new food hygiene legislation applicable since January 2006. The main principle of the new legislation is that the safety of food 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 for validation and verification of HACCP procedures. Therefore, Community microbiological criteria have been set down in the new Regulation for defining the acceptability of the process as well as defining the safety of the food.

Food safety management has evolved from an approach relying strongly on end-product testing to an approach based on process control, which is primarily **Hazard-Based**. In the Hazard Analysis Critical Control Points – HACCP system, decisions, standards and actions are based on objective and verifiable information on relevant hazards and are aimed at eliminating or reducing exposure to such hazards, with the expectation that there will be a reduction in risk. More recently, there is a growing need for **Risk-Based** food safety management systems. In such a system, decisions, standards and actions are based on specific knowledge of risks and are aimed at achieving an established level of health protection and should be explained and validated in these terms. This development has been fuelled by the establishment of the World Trade Organization (WTO) and the Sanitary and Phytosanitary (SPS) Agreement (WTO, 1994).

In the HACCP system, a decision must be taken on how identified hazards are controlled. There is no established criterion for what is acceptable, or what is not acceptable. In practice, different approaches are taken. Hulebak and Schlosser (2002) describe the US approach to establishing HACCP in meat production. These authors identify evisceration and dehiding as CCPs in beef slaughter. Visual inspection is proposed as the major control strategy, and several corrective actions including trimming of visually contaminated areas, reducing line speed, increasing the number of staff or improving their training level are proposed as corrective actions. Whilst such actions have intuitive appeal, it is very difficult to establish a direct link to the level of health protection related to their implementation. Furthermore, criteria based on such considerations are arbitrary, and difficult to standardize. Against this back-ground, the risk-based approach to food safety management can be seen as an addition to the hazard-based approach. Whether such an addition is needed and efficient depends on the situation. Some examples where risk based approaches may have added value are:

[8] Regulation (EC) No 852/2004 on the hygiene of foodstuffs, OJ No L 226, 25.6.2004, p. 3 and Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, OJ No L 226, 25.6.2004, p.22

[9] Regulation (EC) No 2073/2005, OJ L 338, 22.12.2005, p. 1, corrected by OJ L 278, 10.10.2006, p. 32, and OJ L 283, 14.10.2006, p. 62.

- In situations where equivalence as defined in the SPS agreement should be demonstrated;
- To evaluate how public health goals can be met;
- In situations where different risk management options should be compared for their effectiveness and/or efficiency;
- In situations where a series of options is necessary to control risks.

As a conclusion, the management of food safety has evolved from official, prescriptive, inspection and compliance testing, to goal-orientated systems which are more flexible in their implementation. The structured approach of HACCP which requires producers to identify hazards and eliminate or control them at Critical Control Points (CCP) together with controls at primary production, GHP and GMP and controlled conditions of distribution and sale, has changed the purposes of microbiological testing and microbiological criteria.

3. Appropriate level of protection and public health goals

3.1. Appropriate level of protection

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".

The ALOP is defined in the SPS Agreement (WTO, 1994) as follows:

> *"The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."*

An ALOP represents the current public health status in relation to food safety and not some future objective. Because the currently achieved public health status may change (for example, new technologies may change the level of a contaminant in a food), an ALOP may change over time. Further guidance in this area has been provided by WTO Committee on Sanitary and Phytosanitary Measures (WTO, 2005).

Quantifying the ALOP may not be an easy task. The main source of information is public health surveillance, in particular to establish the current level of foodborne illness. Many countries use laboratory-confirmed cases as the primary source of information (EFSA, 2005;2006). These cases represent only a small fraction of the total disease incidence and ideally, additional information is available to calibrate the so-called surveillance pyramid. The sensitivity of the surveillance may vary between countries and within one country by time. Because most foodborne pathogens can also be transmitted by other routes (e.g. the environment or direct contact with animals), it is also necessary to establish the fraction of all cases that is attributable to food, and within the food category which food types are associated with exposure. This process

is called source attribution and applies information from various sources such as outbreak studies, analytical epidemiology, microbial subtyping and risk assessment (Batz et al., 2005).

An evaluation whether a product in the international trade will provide the same level of protection to the population in the importing country, can also be based on public health surveillance but this would require a high level of detail in the available data. An example is the Danish *Salmonella* source account, which differentiates between domestically produced and imported meats (Hald, et al., 2004). In many cases, it may not be possible or desirable to evaluate equivalence by surveillance as this is by definition a *post hoc* approach. Alternatively, the evaluation can be based on data regarding the occurrence of pathogens in the imported food product as input to a risk assessment approach. Likewise, a risk assessment approach can also be used to evaluate if the current level of protection will continue to be met when changes in the food production system are foreseen.

ALOPs may range from general to specific, depending upon the level of source attribution. An example of a general ALOP could be the current level of *Salmonella* infections in a country (an example of an ALOP was the incidence of *Salmonella* in Finland and Sweden when they joined the European Union). An example of a specific ALOP was the background level of cryptosporidiosis in the USA as a basis for establishing levels of treatment for drinking water (Regli et al., 1991).

An ALOP can be expressed on different levels. The most common level is (the incidence rate in) the entire population in a country, but this may not be the most appropriate expression to evaluate food safety. If only a small proportion of the population consumes a particular food, the risk to those consumers may be a more meaningful basis to express the ALOP. To evaluate products from individual companies, the risk per serving is the appropriate level as this is independent of the market share of a company.

3.2. Public health goals

Public health goals are different from ALOP and are intended to inspire actions to improve the future public health status and reduce disease burden. The concept of public health goals has been introduced by the consultation of the Joint FAO/WHO Expert meeting held in Kiel (FAO/WHO, 2006) and has not yet been formally defined by Codex Alimentarius. Public health goals will usually be set by government or public health bodies, with a varying degree of input from stakeholders, and imply some consideration of the current health status and disease burden (in the population as a whole or in vulnerable sub-populations). In setting goals consideration may also be given to possible interventions and how achievement of the goal is to be measured. Maintenance of current levels of health protection is also an important public health goal when evaluating changes in food production systems and technologies and also when judging the equivalence of different measures in different countries.

An example of a public health goal is the target set by the UK Food Standards Agency to reduce the incidence of foodborne disease by 20% by April 2006 (FSA, 2001).

When a public health goal is established as a risk reduction target, a well designed microbiological risk assessment (MRA) can establish the magnitude of exposure

reduction that would need to be achieved by changes in control measures in order for the public health goal to be met and in future become the ALOP.

The assessment whether the public health goals are met will typically be based on public health surveillance. Also for this purpose, it is necessary to assess the sensitivity of the public health surveillance system. In particular it must be known if there are changes over time that affect the numbers of reported human cases. If the reporting system remains more or less the same, the trend e.g. decrease, can be interpreted as a result from interventions. For example, if a public health goal 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 goal. Although the assessment whether public health goals are met or not may be difficult as described above, it is an important element of the overall food safety policy.

4. Microbiological criteria in the Codex Alimentarius

A microbiolological criterion for food, according to Codex Alimentarius (CAC, 1997), "*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*". The decision on setting a microbiological criterion should be based on its ability to protect the health of consumers and it must be technically attainable by applying good manufacturing practices.

It must be stressed that in the Codex definition (CAC, 1997), microbiological criteria include (i) the analytical methods for the detection and /or quantification of the hazard, (ii) a sampling plan defining the number of field samples to be taken and the size of the analytical unit, (iii) the microbiological limits considered appropriate to the food at a specified point of the food chain and (iv) the number of analytical units that should conforms to these limits. A microbiological criterion according to the Codex definition is a tool used to assess foods by batch sampling and microbiological testing against a limit. Therefore, setting a microbiological criterion does not only mean that the food must comply with a microbiological limit, but also that compliance will be verified by testing samples. Setting a microbiological criterion also implies to define actions to be taken when the criteria is not met.

Before the 1997 Codex definition, three categories of limits verified by microbiological testing were defined:

- *Standards*, for regulatory and mandatory requirements;
- *Specifications* for requirements agreed among food business operators and
- *Guidelines* used by processors to assess the efficacy of Good Hygienic Practices (GHP) and HACCP.

The Codex Alimentarius (CAC, 1997) defines two applications of microbiological criteria. By regulatory authorities, on the one hand, to check compliance with the microbiological limits and to reject (or take any other appropriate action) the non-compliant food lots, which corresponds to Standards. By food business operators, on

the other hand, as one of the measure to verify efficacy of HACCP plan or good manufacturing practices which corresponds to Guidelines and Specifications.

The Codex Alimentarius (CAC, 1997) specifies that the sampling plan should define *"the probability of detecting microorganisms in a lot"* and insist on the limit of sampling plans stating that *"no sampling plan can ensure the absence of a particular organism"*. For any sampling plan there is a risk of accepting an unacceptable lot and this risk is high if the proportion of defective units in the lot is low. For instance, with a sample of 10 units tested, there is a 90% chance of accepting a lot containing 1% defective units whereas there is a 35% chance of accepting a lot containing 10% defective units (ICMSF, 1986). The risk can be reduced by increasing the number of units in the sample tested (ICMSF, 1986).

The Codex Alimentarius (CAC, 1997) also specifies that microbiological criteria shall apply where *"no other more effective tools are available"* to improve the degree of protection offered to the consumer and that microbiological criteria *"are not normally suitable for monitoring critical limits"*. Safety of foods is principally assured by a preventive approach, *i.e.* control at the source, product design and process control, application of GHP at all stage of the food chain, in conjunction with application of the HACCP system. For instance, one-line measurements of physical and chemical parameters designed to control microbiological hazards should always be preferred to microbiological testing, whenever such parameters are available.

5. Microbiological criteria and targets in the European legislation

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) No 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 EU Regulation, the following topics related to the microbiological criteria are described:

- Microorganisms of concern, toxins and metabolites: *Listeria monocytogenes*, *Salmonella* spp., *Enterobacter sakazakii*, *Escherichia coli*, staphylococcal enterotoxins, histamine;
- The analytical reference methods, mainly EN/ISO methods, although equivalent methods are expressly permitted;
- The sampling-plan: number of units comprising the sample, number of sample units giving values over limits;

[10] Regulation (EC) No 2073/2005, OJ L 338, 22.12.2005, p. 1, corrected by OJ L 278, 10.10.2006, p. 32, and OJ L 283, 14.10.2006, p. 62.

- Limits (e.g. absence in 10g, 25g, less than 100/g);
- The food category: ready-to-eat, minced meat intended to be eaten raw or cooked, cheeses, butter and cream made from raw milk, milk and whey powders, ice-cream, egg products, live bivalve molluscs, echinoderms, tunicates and gastropods, sprouted seeds ready to eat, pre-cut fruit and vegetables, unpasteurised fruit and vegetable juices, some fishery products;
- The point in the food chain where the criterion applies;
- Any actions to be taken when the criterion is not meet: the product or batch of foodstuffs shall be withdrawn or recalled, or in certain circumstances may be submitted to further processing by a treatment eliminating the hazard in question (article 7), or improvement on process hygiene.

An EU **Food Safety Criterion** defines the acceptability of food products. 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.

An EU **Process Hygiene Criterion** gives guidance on, and being is an indicator of, the acceptable functioning of HACCP-based manufacturing, handling and distribution processes. It sets indicative contamination values above which corrective actions are required in order to maintain the hygiene of the process in compliance with food law.

6. Microbiological targets

Regulation (EC) No 2160/2003[11] on the control of *Salmonella* and other specified food-borne zoonotic agents, aims to ensure that proper and effective measures are taken to detect and control *Salmonella* and other zoonotic agents at all relevant stages of production, processing and distribution, including in feed, in order to reduce their prevalence and the risk they pose to public health. Those specific requirements should be based on targets for the reduction of the prevalence of these agents in animal populations, mainly at the level of primary production and, where appropriate at other stages of the food chain, including in food and feed. This procedure requires fully harmonized baseline studies to be conducted throughout the Community. The Member States are obliged to establish national control programmes to meet the targets set and these control programmes have to be approved by the Commission.

In this Regulation, the targets consist of a numerical expression of the maximum percentage of epidemiological units remaining positive and (or) the minimum percentage of reduction in the number of epidemiological units remaining positive. The testing schemes necessary to verify the achievement of the target should be defined by the Commission.

Actually, the EU provisions request the setting of Community targets have been proposed for all *Salmonella* serotypes with public health significance at the primary production step for breeding flocks of *Gallus gallus* and breeding herds of pigs, and for laying hens, broilers and turkeys. Interestingly, targets should also be fixed for all

[11] Regulation (EC) No 2160/2003; OJ L 325, 12.12.2003, 1-15.

Salmonella serotypes with public health significance, at the slaughter step, for herds of slaughter pigs. To achieve these targets, minimum sampling scheme is required describing the animal population and the phases of production which sampling must cover. Moreover the sampling plan, the size and the number of analytical units, and the analytical methods are proposed.

7. Description of the Codex concepts: Food Safety Objectives, Performance Objectives and Performance Criteria

A guidance document for the conduct of Microbiological Risk Management has been on the agenda in Codex Committee on Food Hygiene for several years. The title of the document is "Proposed draft principles and guidelines for the conduct of Microbiological Risk Management" and the document is at step 8 of the procedure (CAC, 2007).

In connection to this work three new terms Food Safety Objectives, Performance Objectives and Performance Criteria have been defined by Codex (CAC, 2005a) as follows:

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).

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.

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.

The reason for the introduction of these new "intermediate" terms are explained in the Codex document (CAC, 2005b) and is shown in Annex of this document.

At the 38th Session of the Codex Committee on Food Hygiene (CCFH), Houston, USA, 4-9 December 2006, there was broad agreement about the fact that the part of the document dealing with the new concepts on metrics (such as Food Safety Objectives, Performance Objectives and Process and Product Criteria) could not be finalised on the basis of available data, including the results of the Kiel expert meeting (FAO/WHO, 2006). The part dealing with metrics was split from the main body of the document and will be further worked at by a Working Group led by France. On the other hand, the main body of the document could be finalized and forwarded to the Codex Commission for final adoption at Step 8.

The original purpose of the FSO and PO was to translate the ALOP into levels of hazards in the food chain that can be communicated to and managed by the food industry.

The FSO and PO only represent limits 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.

The FSO/PO concept is more recent and less well understood than microbiological criteria and needs to be further elaborated to be a useful risk management tool.

8. Advantages and disadvantages with the current food safety criteria, process hygiene criteria and targets

8.1. Food safety criteria

Food safety criteria have been defined only for the pathogens/foodstuffs combinations (Regulation (EC) 2073/2005) for which testing samples placed on the marked was considered an efficient contribution to public health. This does not mean that in other cases the pathogen does not represent a risk for food safety, but merely that microbiological criteria were not considered as an efficient mean to improve food safety.

A microbiological safety criterion sets a clear standard for what is acceptable. According to Regulation (EC) No 178/2002 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. However, it is often not possible to distinguish between safe and unsafe food since risks will always exist. Without microbiological criteria industry, as well as authorities, would have to make judgment on each case in question, inevitably leading to unofficial agreements on when and which actions would be required.

The setting of microbiological safety criteria provides a harmonized approach to the acceptability of foods.

The food safety criteria affect the entire food chain from farm to table, even if they in the present legislation currently are set for foods placed on the market. The industry must design the production to meet these criteria, because if they do not there is a risk of withdrawal, with economic loss as well loss of public goodwill. Therefore food safety criteria can be assumed to have an effect of food safety and public health where there is an actual or perceived risk. However, it is not possible to evaluate the extent of public health protection provided by a specific food safety criterion.

Food Safety Criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. The safety of food is mainly ensured by a preventive approach, such as implementation of GHP and application of procedures based on HACCP principles. In EU legislation, food safety criteria are also used as a way to communicate the level of hazard control that should be achieved.

Due to the statistical limitation of sampling plans, microbiological testing alone may give a false sense of security unless sufficient number of samples is tested over time. Most food safety criteria are based on two class sampling plans with 5 or 10 units tested per sample, except for infant formulae where 30 units should be tested (Regulation (EC) 2073/2005). Therefore, for pathogens present in food lots at a low frequency, the risk of not detecting contaminated food lots is high (ICMSF, 1986;2005). In these cases efficiency of food safety criteria to improve consumer protection will be low. The primary reason for the Scientific Committee for Veterinary measures relating to Public Health (2003) to consider that the setting of microbiological criteria for human pathogenic *Escherichia coli* and for *E. coli*

O157:H7, was not appropriate, was their sporadic occurrence and low prevalence in foods (SCVPH, 2003). Development of new detection methods, however, may permit an increase in the number of units tested, as well as the sensitivity, thereby improving the sensitivity of sampling plans. However, meeting targets earlier in the food chain may be more effective in controlling such hazards.

Food safety is a result of several factors. Microbiological criteria should not be considered without other aspects of EU food legislation, in particular HACCP principles and official controls to audit food business operators' compliance.

In order to establish food safety criteria, it is a prerequisite that methods to properly detect the hazard are available at a reasonable cost. Inherent in this is that hazards must be accurately defined, or the result may be that food batches are erroneously considered unsafe.

Regulation (EC) No 2073/2005 on microbiological criteria does not prescribe any sampling/testing frequencies except for minced meat, mechanically separated meat and meat preparations.

While this leaves flexibility[12] to tailor the intensity of testing according to the risk, it also leaves the possibility of inconsistency in testing and control. It is not possible to quantitatively link food safety criteria, as they are used, to risk. In order to establish such a link, it would be necessary to specify sampling frequencies and compliance criteria. Furthermore, information should be available on the variability of the numbers of pathogens in different batches of the food product.

8.2. Process hygiene criteria

The process hygiene criteria indicated in the Regulation are largely based on so-called two- or three-class sampling plans.

Regulation (EC) No 2073/2005 defines process hygiene criterion (PHC) as "a criterion indicating the acceptable functioning of the production process. 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". However, because:

a) the set contamination values in most cases are applicable only to the product at the end of the manufacturing process and

b) they are not related to the (normally highly variable) initial contamination values of the raw materials at the individual operator level,

the nature of the PHC is similar to that of so-called "end-product" criteria. In other words, most given PHC actually do not provide information on initial contamination versus final ratios in the processes, but only on the process outcomes. This might be either an advantage or a disadvantage depending whether the purpose is to microbiologically characterize the process itself, or to characterize the microbiological status of the final product only.

[12] Regulation (EC) No 852/2004 on the hygiene of foodstuffs, OJ No L 226, 25.6.2004, p. 3 and Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin, OJ No L 226, 25.6.2004, p.22

PHC alone are not sufficient to characterize the acceptability of a process. Their use is an integral part of the implementation of HACCP-based procedures and other hygiene control measures, including for validation and verification purposes. According to Article 4 of Regulation (EC) No 852/2004, food business operators are to comply with microbiological criteria. In most cases, food business operators decide themselves the necessary sampling and testing frequencies as part of their hygiene control procedures based on HACCP principles. However, for some processes, testing frequencies are given in the EU regulations. It is important to note that the regulations allow testing against alternative (indicator) micro-organisms (and related microbiological limits) or against analytes other than microbiological ones.

8.3. Targets

Targets have been already incorporated in the European legislation for *Salmonella* in flocks of breeding and laying hens of *Gallus gallus*.

In breeding hens the target is less than 1% of flocks remaining positive for *Salmonella* Enteritidis, *Salmonella* Typhimurium, *Salmonella* Hadar, *Salmonella* Virchow and *Salmonella* Infantis by the end of 2009 (Regulation (EC) No 1003/2005[13] implementing Regulation (EC) No 2160/2003[14] as regards a Community target for the reduction of the prevalence of certain *Salmonella* serotypes in breeding flocks of *Gallus gallus* and amending Regulation (EC) No 2160/2003).

In flocks of laying hens, incremental percentage reductions have been agreed on with regard to *Salmonella* Enteritidis and *Salmonella* Typhimurium (Commission Regulation (EC) No 1168/2006[15] of 31 July 2006 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus* and amending Regulation (EC) No 1003/2005).

Based on a baseline study on the prevalence of *Salmonella* in laying hen flocks of *Gallus gallus*[16], the European Commission and Member States have agreed reduction targets. Every Member State will have to work towards reducing the number of egg laying hens infected with *Salmonella* spp. by a specific minimum percentage each year, with steeper targets set for Member States with higher levels of *Salmonella*. The legislation applies from 1 August 2006 and the first target deadline is set for 2008. The following annual percentage reduction targets are set for *Salmonella* in egg-laying hens until the flock prevalence is below 2%:

[13] Regulation (EC) No 1003/2005, OJ L 170, 1.7.2005, p. 12-17
[14] Regulation (EC) No 2160/2003, OJ L 325, 12.12.2003, p. 1-15
[15] Regulation (EC) No 1168/2006, OJ L 211, 1.8.2006, p. 4-8
[16] The European Food Safety Authority (EFSA) has published a preliminary report on findings of a baseline study of *Salmonella* spp. in egg laying hens. (Ref) The purpose of this study is to establish the current *Salmonella* prevalence to assist the European Community in setting targets for reduction of this pathogen (as required by Regulation (EC) No. 2160/2003). The ultimate aim is to achieve a prevalence of 2% or less in egg laying hens. The baseline study demonstrated that the overall *Salmonella* spp. prevalence in Member States ranged from 0% to a maximum of 79.5%. The prevalence for the two *Salmonella* serovars responsible for the majority of human illness (*Salmonella* Enteritidis and *Salmonella* Typhimurium) ranged from 0% to a maximum of 62.5%.

- 10% reduction if the prevalence of *Salmonella* in the preceding year was below 10%;
- 20% if the prevalence of *Salmonella* in the preceding year was 10-19%;
- 30% if the prevalence of *Salmonella* in the preceding year was 20-39%;
- 40% if the prevalence of *Salmonella* in the preceding year was over 40%.

The aim is to ensure particularly rapid progress in those member states with a higher incidence of *Salmonella* in laying hens.

The baseline studies recommend some parameters (sampling schemes, analytical methods) to measure the level of reduction of targeted microorganisms.

The use of these targets at different stages at production could lead to a decrease of the prevalence of certain pathogens along the food chain. This is expected to have a positive impact on food safety and public health although the reduction of the risk remains to be estimated.

In addition it could be said that the implementation of sanitary measures at the farm level should be efficient not only against the targeted microorganisms (e.g. *Salmonella* spp.) but also against other pathogens and, in that way, should improve the microbiological status of the food.

9. CONCLUSIONS

ToR 1: Provide an overview of systems of food safety management including microbiological criteria.

- Food safety management has developed from official, prescriptive control/inspection and compliance testing to more goal-orientated systems which are more flexible in their implementation. The structured approach of HACCP which requires producers to identify hazards and eliminate or control them at Critical Control Points (CCP) together with controls at primary production, GHP and GMP and controlled conditions of distribution and sale, has changed the purposes of microbiological testing and microbiological criteria.

ToR 2: Provide a short description of the current Codex concepts, viz. Appropriate Level of Protection (ALOP), Food Safety Objective (FSO), Performance Objective (PO), Performance Criteria (PC) and microbiological criteria.

- ALOP is defined in the SPS-agreement and represents the current public health status in relation to food safety.
- Public health goals differ from ALOP and are intended to inspire actions to improve the future public health status and reduce disease burden.
- The original purpose of the FSO and PO was to translate the ALOP into levels of hazards in the food chain that can be communicated to and managed by the food industry.
- The FSOs and POs only represent limits 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.

ToR 3 & ToR 4: a) Describe the types of microbiological criteria (food safety criteria, process hygiene criteria) and targets contained in the EU legislation in regard to public health and **b)** Consider the application of microbiological criteria and targets in the food chain at the EU level based on risk analysis.

Microbiological criteria

- Microbiological criteria are useful for validation and verification of HACCP-based processes and procedures, and other hygiene control measures.
- In addition microbiological criteria are used to assess the acceptability of a batch of food, including the circumstances where there is insufficient knowledge of production conditions e.g. at port of entry.
- Microbiological criteria are also used in EU legislation as a way to communicate the level of hazard control that should be achieved.
- Meeting microbiological criteria offers some assurance that particular pathogens are not present at unacceptably high concentrations, but does not guarantee "absence" of those pathogens.

Food Safety Criteria

- An advantage of establishing food safety criteria for pathogenic microorganisms is that harmonised standards on the acceptability of food are provided for both authorities and industry within the EU and for products imported from third countries.
- Food safety criteria will impact the entire food chain, as they are set for products placed on the market. Risk of recalls and the economic loss as well as loss of consumer confidence will be a strong motivation to meet the criteria. Therefore food safety criteria are assumed to have an effect on food safety and public health where there is an actual or perceived risk. However, it is not possible to evaluate the extent of public health protection provided by a specific food safety criterion.
- Microbiological testing alone may convey a false sense of security due to the statistical limitation of sampling plans, particularly in the cases where the hazard presents an unacceptable risk at low concentrations and/or low and variable prevalences.
- Food safety is a result of several factors. Microbiological criteria should not be considered without other aspects of EU Food legislation, in particular HACCP principles and official controls to audit food business operators' compliance.

Process hygiene criteria

- Process hygiene criteria communicate the expected outcome of a process as end-manufacturing or end-product criteria.
- Process hygiene criteria define the expected final outcome of the processes, but they neither characterise nor differentiate between the processes themselves.

Targets

- The use of targets at different stages of production could lead to a decrease in the prevalence of certain pathogens along the food chain. This is expected to have a positive impact on food safety and public health although the reduction of the risk remains to be estimated.

10. RECOMMENDATIONS

- Studies on the reduction of risk obtained by introduction of food safety criteria, process hygiene criteria and targets should be encouraged.
- It is recommended that when developing guidelines for the use of FSO/PO in Codex, already existing terms in current legislation (i.e. the EU legislation on microbiological criteria and targets) need to be taken into account in order to avoid too many different terms been used to address the same issues.
- It is recommended that the goal for risk management is established before evaluating possible control options, including the establishment of microbiological criteria and their purpose.

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ANNEX

The reason for the introduction of FSO, PO, PC are explained in the Codex document as follows:

The increasing adoption of risk analysis is allowing more quantitative and transparent approaches for relating ALOP to the required stringency of the food safety control system, and for the comparison of MRM options for their suitability and, possibly, equivalence. This has allowed the development of new MRM tools such as FSO, PO and PC and the enhancement of the scientific basis of existing MRM tools such as microbiological criteria (MC).

It is difficult to relate control measures directly to an ALOP, particularly when it is implicit or expressed in qualitative terms (such as "reasonable certainty of no harm"[17]), and not in quantitative terms (such as a "number of illnesses/year"). Therefore the concept of FSO has been introduced. Effective MRM typically requires that additional risk-based milestones be established at particular steps in the food chain to ensure the ultimate food safety outcome. As a means of addressing this need, PO and PC have been introduced.

There is a hierarchy between the concepts of FSO, PO and PC. Conceptually, an FSO is derived from the ALOP, whereas a PO and/or a PC are derived from an FSO. However, also in the absence of an ALOP or an FSO, the concepts of PO and PC may be potential options for risk managers to guide the establishment of process requirements in operational practice. The availability of a MRA can help in deciding upon the need and for choosing the best step where to apply PO, PC or particular control measures.

a. Food Safety Objective (FSO)

A food safety objective is defined as ***"****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)". 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 MRAs. FSOs are seldom verifiable as regulatory standards as they apply at the time of consumption. They 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 observation of the public health status, mainly with the help of epidemiological surveys (see section 8). The other is based on experimental or other scientific evidence 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:

[17] See OECD document

- *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 the safety of certain products;*
- *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).*
- *Notably, FSOs may not be universally common and may take into account regional differences.*

b. Performance Objective (PO)

A performance objective is 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 or ALOP, as applicable".

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 mediate 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. An MRA can assist in determining such relationships.*

An MRA 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 their food safety control system such that the PO (set by government or the individual food business) and the FSO (set by government) are met, the individual food business) will have to make provisions respecting their 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. The 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, …) and the intended use of the end products (domestic consumer handling, …). Although POs are generally not intended to be verified by analytical means, compliance with POs may need to be verified by other means, such as:

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

c. Performance Criterion (PC)

A performance criterion is defined as "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".

PCs are generally set by individual food business. However, PCsmay 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.

The PC can be expressed e.g., in terms of a desired reduction (or acceptable increase) in the concentration and/or frequency of a hazard in the course of a particular control measure, e.g. the result of a particular treatment.

Generally, PC either relate to a control measure with a microbiocidal and/or microbiostatic effect. A PC for a microbiocidal control measure (e.g. heat treatment) expresses the desired reduction of the microbial population that occurs during the application of the control measure. A PC for a microbiostatic control measure (e.g. chilling) expresses the maximum increase in the microbial population that is acceptable under the various conditions during which the measure is applied.

Such PCs are often translated by industry or sometimes by competent authorities, into process criteria[18] or product criteria. For example, if a PC indicated 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 combination(s) that would be needed to achieve the PC. Similarly, if a PC required that an acidification treatment of a food 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. The concepts of process criteria and product criteria have been long recognised and used by industry and competent authorities.

[18] *For the purposes of this document a process criterion is understood to mean " 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" and a product criterion is understood to mean "a 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."*