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Performance objectives and performance criteria – Two sides of the food chain*

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Over the last decade, the approach to food safety control by governments has been changing. For public health protection and the facilitation of fair trade, governments have chosen to follow the framework of risk analysis. Risk analysis helps risk managers in governmental functions to decide on food safety control measures in a structured, open and transparent way. New terms and concepts have been introduced to describe public health goals (i.e. Appropriate Level of Protection – ALOP;

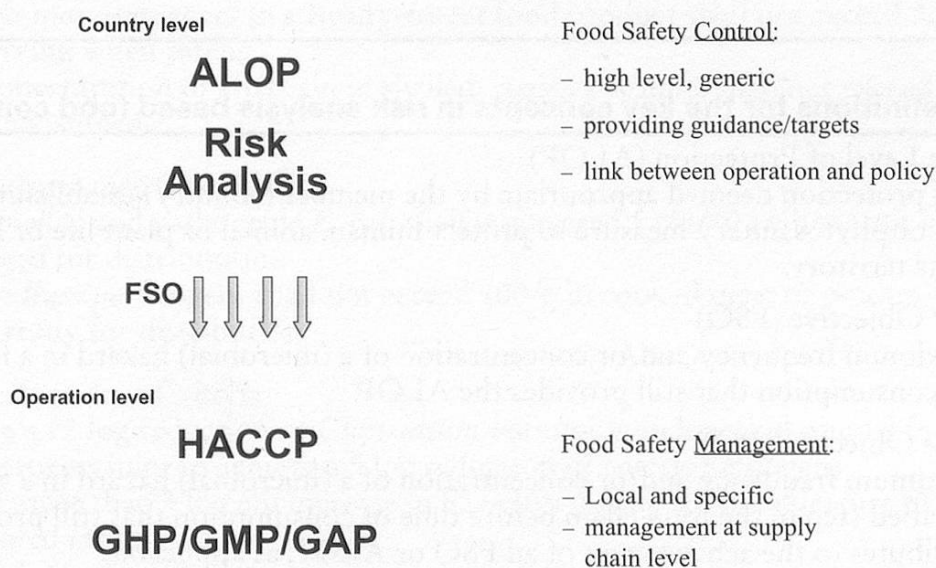


Figure 1 The management of food safety takes place at country and operational level
The FSO forms the bridge between governmental or country level food control policy (articulated as ALOP or public health goals) and operational level food safety management.

* Presented at the 36th Symposium of the Swiss Society of Food Hygiene, Zurich, 8 October 2003

definition in table 1) or the stringency of hazard control in food operations (i.e. Food Safety Objective – FSO; working definition in table 1). These terms have been described in this journal in the preceding presentations of Robert L. Buchanan and Martin Cole. Importantly, through stipulating FSOs which define the hazard level of the final product at consumption, governments provide guidance to relevant food chains about the stringency expected in operational hazard control (figure 1). While food operations that manage the safety of their products in my opinion do not need to change much in terms of the basic running of their food safety management system, they will need to be able to design their operations in such a way that the food at the moment it is eaten complies with the FSO, the hazard level tolerated at consumption. Some hypothetical examples of FSO values are given in table 2. Food chains often consist of a sequence of individual steps (e.g. primary production, transport, manufacturing, storage, retail, preparation for consumption) and in many instances there are a number of different parties (e.g. farmers, transporters, food companies, retailers, food service, consumers) that manage the quality and safety at individual steps. While the management of individual steps is managed by existing generic concepts (i.e. Good Agricultural Practice, Good Manufacturing Practice, Good Hygiene Practice, Hazard Analysis Critical Control Point) and specific concepts (i.e. microbiological criteria, control measures, process criteria) some new concepts have been introduced that are to be used to bridge from governmental food control policy to food safety management in the chain namely:

Table 1

Working definitions for the key concepts in risk analysis based food control

Appropriate Level of Protection (ALOP)

Level of protection deemed appropriate by the member (country) establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.

Food Safety Objective (FSO)

The maximum frequency and/or concentration of a (microbial) hazard in a food at the time of consumption that still provides the ALOP.

Performance Objective (PO)

The maximum frequency and/or concentration of a (microbial) hazard in a food at a specified step in the food chain before time of consumption that still provides or contributes to the achievement of an FSO or ALOP, as applicable.

Performance Criterion (PC)

The effect of one or more control measure(s) needed to meet or contribute to meeting a PO.

Control Measures (CM)

Any action and activity that can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level (it can be microbiological specifications, guidelines on pathogen control, hygiene codes, microbiological criteria, specific information (e.g. labelling), training, education, and others).

- Performance Objective (PO), which is equivalent to FSO, specifying hazard levels that are tolerable, but are set at one or more specific steps earlier in the food chain (working definition in table 1). POs are linked to the FSO and, when proposed by governments, can be viewed as a kind of milestones that governments provide as guidance in order to help meet the FSO. However, POs can also be decided on by operational food safety managers as an integral part of the design of the production of a food in a supply chain. Some hypothetical examples of PO values are given in table 2.
- Performance Criterion (PC), which indicates the change in hazard level required at a specific step in order to reduce the hazard level at the start of the step (H_0) to a level at the end of the step that complies with the PO or the FSO when it is at the chain end (working definition in table 1). PCs in general will be decided on by food safety managers as key points in the design of the production of a food in a supply chain. PCs can be achieved by one or more control measures and as such are a reflection of the concrete management measures that assure a product is safe and produced to the proper specifications. Some PC examples are given in table 2.

Table 2

Example guidance values at consumption (FSO) or earlier in a food chain (PO)

Example Food Safety Objectives

- *Listeria monocytogenes* in a Ready-to-eat food product shall not exceed 3.5 log cfu/serving when eaten.
- The concentration of aflatoxin in shelled, roasted peanuts shall not exceed 15 µg/kg when consumed.

Example Performance Objectives

- *Salmonellae* and pathogenic *E. coli* shall not exceed 1 cfu/10 l when fruit juice is packaged for distribution.
- *Clostridium perfringens* shall not exceed 100/g in cooked meat or poultry products when ready for distribution.

Example Performance Criteria

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

Example control measures

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

Example process criteria

- 20 minutes at 121 °C for proteolytic *C. botulinum* cook
- 10 min at 90 °C for non-proteolytic *C. botulinum* cook
- 2 minutes at 70 °C for pasteurisation

With respect to milestones, there are two discrete elements: one Food Safety Objective at the time of consumption and one or more Performance Objective(s), as required, at earlier points in the food chain. These milestones are not intended to be enforced but should provide guidance to designing the correct operational control measures at the step in the chain that the POs govern. Complying with the hazard level tolerated at the moment of consumption (FSO) is a shared responsibility for all parties together and requires an appropriate design of the complete chain which is helped by specifying POs and PCs as food control guidance targets or food safety management measures at relevant points in the production chain.

Figure 2 gives an overview of how various guidance milestones and operational measures relate to each other in an imaginary food supply chain. Operational measures may include single Control Measures (CM) or sets of control measures working in concert (within the design of the food safety performance at the step) to achieve a certain effect, termed PC, on the hazard level in the food product when leaving the step. There are many different types of control measures, instigated by regulation or chosen by the industry, the proper functioning of which needs to be monitored and verified by the industry. The stringency in the control of the food safety system(s) operating in the food chain should be such that any exposure of the public at time of consumption does not unduly add to the public health burden but will still comply to the ALOP or any other form of public health goal articulated.

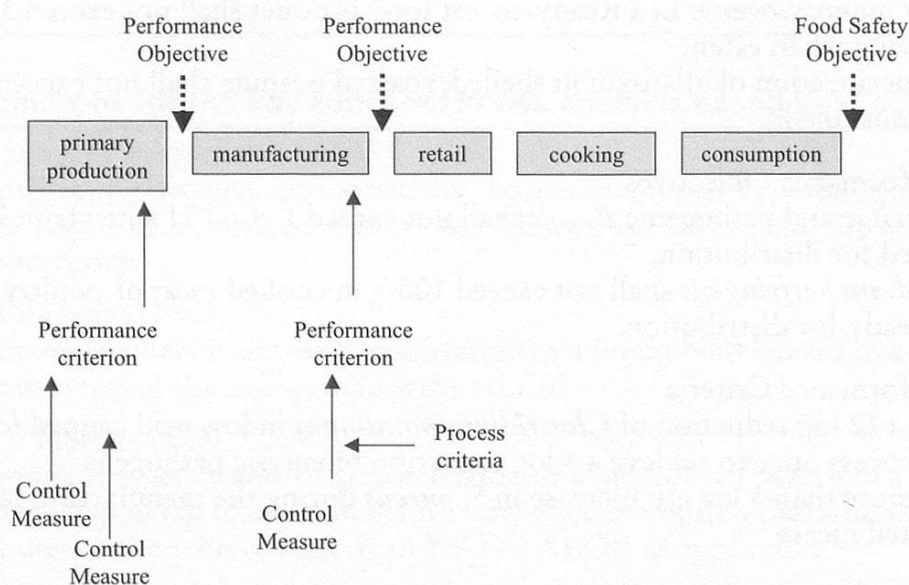


Figure 2 An overview of how governmental or country level guidance along an imaginary food chain links in with operational level measures at relevant points

The guidance is given in the form of FSO or PO values stipulated by the appropriate food control function. The operational level measures are embedded in the food safety management systems operated in the chain, such as GHP, GMP, and HACCP.

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

- It is the only guidance point that is directly related to the actual public health impact. Without consumption of the product there is no exposure of the consumer to the hazard and no health implication. When POs are determined, obviously, they have to be articulated with a good understanding of the events before and after the point that the PO is valid for and that have an influence on the hazard level, but there is still the possibility that a food is not consumed or the events following the PO are different in the actual case.
- It is valid for all different types of supply chains producing a particular product. Food chains can be very different in their infrastructure, partnerships, logistics and level of hazard control exercised at specific points. Nevertheless, whatever the infrastructure, the FSO now defines the hazard level that should not be surpassed at consumption which actually assures a form of equivalence in the level of safety provided in the food product as well as a specific stringency in the overall chain management.
- It is the value that should lead the development of PO values earlier in the chain. Whereas the FSO gives guidance to the stringency required overall, it is more or less left open how compliance to the FSO is achieved. In other words, it is left flexible how a food chain structures and organises itself to produce the food such that it is in compliance. This avoids undue external constraints on the food chains and allows them to produce within their internal constraints (e.g. with respect to technologies, materials, processes, chain organisation, intended market) as long as compliance is evidenced. It also fosters innovation, as not only conventional technologies and processes can be applied. Where deemed necessary, governments can choose to mandate specific PCs or control measures as appropriate defaults, as is currently done for certain control measures.

Performance criteria are the specific operational, supply chain measures at specific step(s) that result in meeting the objective for that step, the PO. When a PC is effective at time of consumption (e.g. a required minimum heat treatment during preparation which causes a specific reduction in the hazard level) it actually is the FSO that is met. Such a PC can be part of the product design, but can be relied upon

only under specific conditions. PCs can be about a required reduction of the hazard, avoiding increase (limit to 0) or assuring a minimal increase.

The conceptual equation that the ICMSF has introduced (1, 2, see lecture of Martin Cole in this journal) helps to think about how the incoming hazard level (H_0) is modulated by one or more control measures (CM) delivering the PC (which is the net of hazard growth and reduction at a step) in order to comply with the PO and the FSO. For example, when the outcome of a manufacturing step should be $-3 \log \text{ cfu/g}$ ($=\text{PO}$), and when it is known that the incoming contamination level is $3 \log \text{ cfu/g}$ ($=H_0$), a 6 log reduction of the hazard level ($=\text{PC}$) would be needed which can be accommodated by a heating process ($=\text{CM}$). When in this example re-contamination after heating is a potential issue, additional CMs need to be taken to avoid recontamination for instance by assuring physical separation of raw and treated product or by using in-pack heating. When re-contamination cannot be avoided, but the formulation can be adapted to minimise growth of the hazard to $1 \log \text{ cfu/g}$, a stronger heat treatment that causes a 7D reduction would allow for the additional 1 log margin required. To compensate for process variability and to ensure that PO and FSO are consistently met, the food chain may choose to design in a conservative hazard control level and implement more stringent performance criteria for their end-products (refs. FSO) or intermediate products (refs. PO) than would be necessary to be at par with PO and FSO values.

Summary

Performance Objectives and Performance Criteria are two new concepts introduced in the context of risk analysis based food safety control, and complement concepts already introduced such as Food Safety Objectives with respect to food safety control and Control Measures and Process Criteria regarding operational food safety management. All concepts together help government to give guidance to food chains about the expected safety of food products and at the same time help food chains to design their food production and food safety management systems such that there is compliance with this expectation.

Zusammenfassung

Mit den «Performance Objectives» und «Performance Criteria» werden zwei neue Konzepte in den Rahmen der auf einer Risiko Analyse aufbauenden Kontrolle der Lebensmittelsicherheit eingeführt. Die Konzepte sind als Ergänzungen zu den bereits existierenden Konzepten «Food Safety Objectives» der öffentlichen Lebensmittelkontrolle und «Control Measures» und «Process Criteria» im operativen, industriellen Bereich anzusehen. In Ihrer Gesamtheit helfen diese Konzepte den Regierungen Richtlinien über die erwartete Sicherheit der Lebensmittel aufzustellen, und helfen gleichzeitig den verschiedenen Mitglieder der Nahrungskette, die notwendigen Massnahmen zur Erfüllung der Vorgaben einzuführen.

Résumé

Deux nouveaux concepts ont été introduits dans le cadre de la sécurité alimentaire, les «Performance Objectives» et «Performance Criteria». Ils doivent être considérés comme compléments aux concepts déjà existants, tels les «Food Safety Objectives» pour les services publics et les «Control Measures» et «Process Criteria» dans le domaine opérationnel et industriel. Ces concepts permettent aux autorités gouvernementales de définir la sécurité attendue tout au long de la chaîne alimentaire et contribue de cette manière à l'introduction de mesures adéquates permettant d'atteindre ce but.

Key words

Performance objective, performance criteria, food safety objective, appropriate level of protection

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