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# Microbiological criteria – Purpose and limitations\*

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Microbiological criteria represent one form of acceptance criteria. Ideally they should be based upon a Food Safety Objective (FSO), i.e. a statement of the maximum frequency and/or concentration of microbiological hazards in a food. While similar at first impression, FSOs and microbiological criteria are quite different in function and content as summarised in the following table 1.

The establishment of meaningful and logic microbiological criteria is a complex process, which is, however, not always performed correctly. Microbiological criteria define the acceptability of a product based on the presence/absence or number of microorganisms (and/or their toxins) per unit(s) of mass, volume, area or lot.

Three types of microbiological criteria can be differentiated, although Codex Alimentarius only recognises one.

- Microbiological Standard – a mandatory criterion that is included into a law or ordinance
- Microbiological Guideline – an advisory criterion used to inform food manufacturers on levels which can be achieved when applying best practices
- Microbiological Specification – a part of a commercial agreement between a buyer and a supplier

Such microbiological criteria may be mandatory or advisory depending on their use. Microbiological Standards should be established according to the principles outlined by Codex Alimentarius (1). Mandatory microbiological criteria are applied by regulatory authorities at defined points of the food chain where they are expected to improve the degree of consumer protection. In the case of food processors, microbiological criteria can assist in checking for compliance with existing regulations and in verifying and/or validating the efficacy of their preventive measures, i.e. Good Hygiene Practices (GHP) and Hazard Analysis and Critical Control Point (HACCP).

Safety of food products is thus principally ensured by control at sources, product design and process control. End product testing alone cannot ensure safe foods – this is due to the limitations of sampling plans.

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Table 1

**Comparison of the characteristics of microbiological FSOs and microbiological criteria**

<i>Food Safety Objective (FSO)</i>	<i>Microbiological Criterion</i>
A goal for process design to obtain acceptable food	A statement of conditions that differentiates acceptable from unacceptable lots of food
Applied to food processing operations	Applied to individual lots or consignments of food products
Components: Maximum frequency and/or Concentration of a hazard	Components: Microorganism (toxin) of concern Sampling plan Analytical unit Analytical method Microbiological limits Number of analytical complying with limits
Can be used to establish microbiological criteria	Cannot be used to establish FSOs
Used only for food safety (hazards)	Can be used for food safety and quality
Based on what risk managers believe will ensure the supply of safe foods	Based on a FSO or on what risk managers believe will ensure a safe or acceptable food
Can be used to drive changes in food processes to improve overall safety	Can be used to drive changes in food process to ensure individual lots or consignments will meet established criteria
Suitable for the assessment of the food safety system of a manufacturer	Not very suitable for assessing a food safety system of a manufacturer. Provides only information on a present lot, not on future or past ones
A high level of confidence is possible when processes are designed and validated to meet a FSO	Confidence may be less certain if a FSO is not used when processes are designed and validated to meet criteria

Microbiological criteria should be established following the principles of Codex and thus be based on sound scientific analysis and if possible on a risk assessment. They should be established in a transparent way such as to ensure fair trade. They should also be reviewed on a regular basis to take into account changes in the scientific knowledge, in processing technologies as well as the occurrence of emerging pathogens.

A microbiological criterion should only be established when there is a definite need and where application is practical. A certain number of elements need to be included in the considerations:

- The evidence of actual or potential hazards to health;
- The microbiological status of the raw materials;
- The effect of processing on the microbiological content of a food;
- The likelihood and consequences of microbial contamination and/or growth during subsequent handling, storage and use;
- The intended use of the food;
- The category(s) of consumers concerned;
- The cost-benefit ratio associated with the application of the particular criterion;
- The need to inform personnel along the entire food chain.

Microbiological criteria consist of different elements:

- The microorganism of concern (and/or their toxins) and the reason for that concern;
- Where appropriate indicators can be included;
- Appropriate microbiological limits defined for specific point(s) of the food chain;
- The number of analytical units that should conform to the established limits;
- A sampling plan defining the number of samples taken, methods of sampling and handling as well as the size of the analytical unit;
- The analytical methods of detection and/or quantification.

## Summary

This paper describes the differences between Food Safety Objectives (FSO) and microbiological criteria. It describes further the process of the establishment of microbiological criteria on the base of the principles outlined by the Codex Alimentarius.

## Zusammenfassung

Dieser Beitrag diskutiert die Unterschiede zwischen «Food Safety Objectives» (FSO) und mikrobiologischen Kriterien. Es wird ausserdem die Prozedur für das Festlegen mikrobiologischer Kriterien auf Grund der Prinzipien des Codex Alimentarius beschrieben.

## Résumé

Cette contribution discute les différences entre les «Food Safety Objectives» (FSO) et les critères microbiologiques. En outre la procédure pour l'établissement des critères microbiologiques sur la base des principes du Codex Alimentarius est décrite.

## Key words

Microbiological criteria, food safety objectives, sampling plans

## References

- 1 *Codex Alimentarius*: Principles for the establishment and application of microbiological criteria for foods. CAC/GL21-1997 [ftp://ftp.fao.org/codex/standard/en/CXG\\_021e.pdf](ftp://ftp.fao.org/codex/standard/en/CXG_021e.pdf)

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