Microbiological criteria in food control

FOOD QUALITY AND SAFETY - Prof. Angel Angelov, Assoc. Prof. Velitchka Gotcheva

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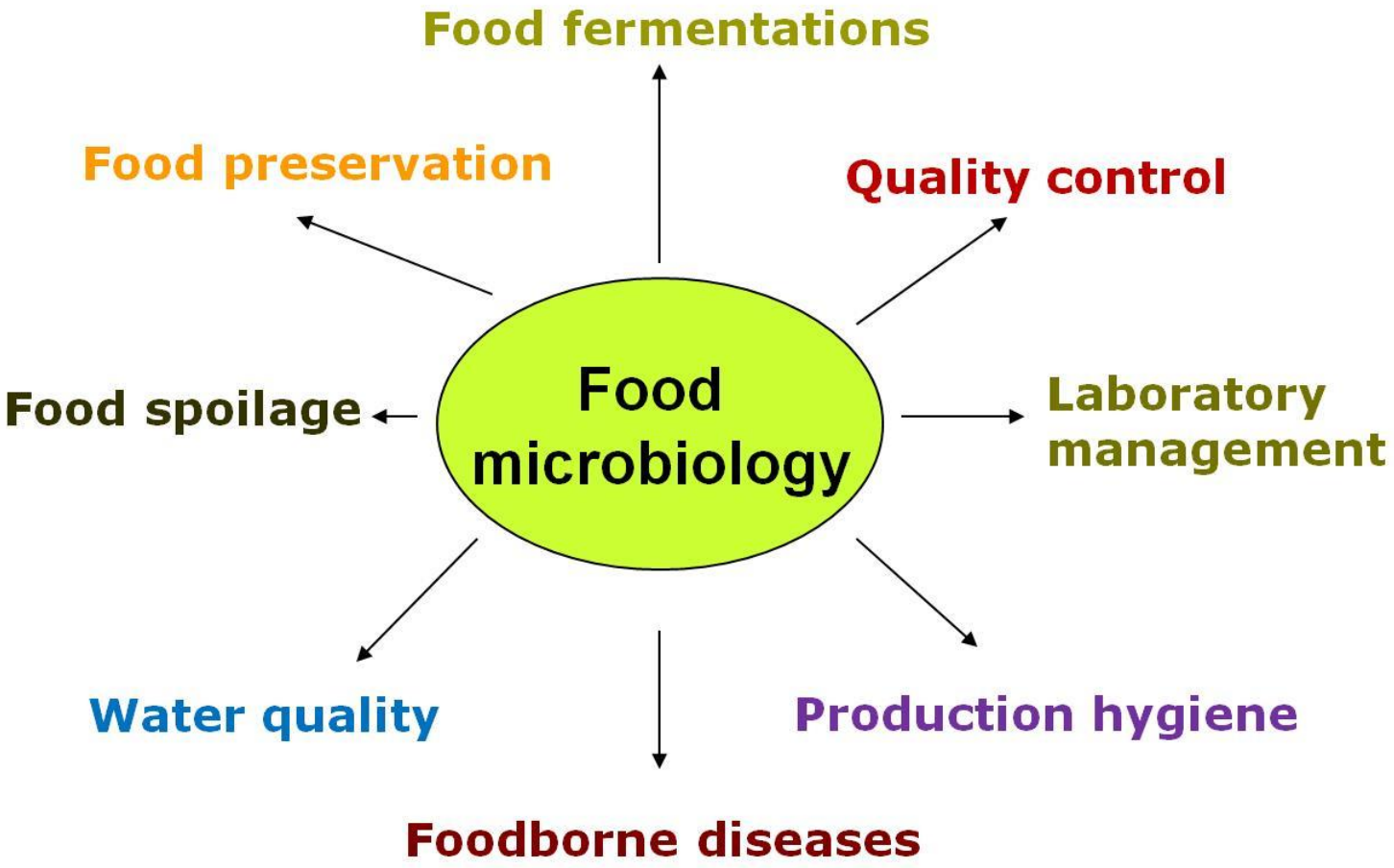
Food microbiology



Microbiology in food safety

Food safety is assured by:

- Control at the source
- Product design and process control
- Application of Good Manufacturing and Hygienic Practices during production, processing (including labelling), handling, distribution, storage, sale, preparation and use in conjunction with the application of the HACCP system

Microbiological analysis

- Hygiene control of production
- Detection of possible hazards from pathogens
- Estimation of the potential shelf life of the product
- Potential health risk to consumers
- Control of end product – not sufficient! → control at various stages of production

Microbiological analysis

- Total viable count (total number of microorganisms)
- Presence or absence of certain organisms
- Levels of indicators
- Presence or absence of specific pathogens
- Levels of specific pathogens

Microbiological criteria - definition

International Commission on the Microbiological Specifications for Foods (ICMSF)

"A microbiological criterion for food 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."

Microbiological criteria - functions

- Consumer health protection
- Ensure that food reaching consumer has an adequate shelf life
- Show that food has been manufactured under conditions of GMPs

Microbiological criteria - functions

Guard against economical losses caused by

- Rejection of product by another manufacturer or retailer
- Rejection of product by a national agency with possible legal consequences
- Legal costs and loss of product credibility and market status

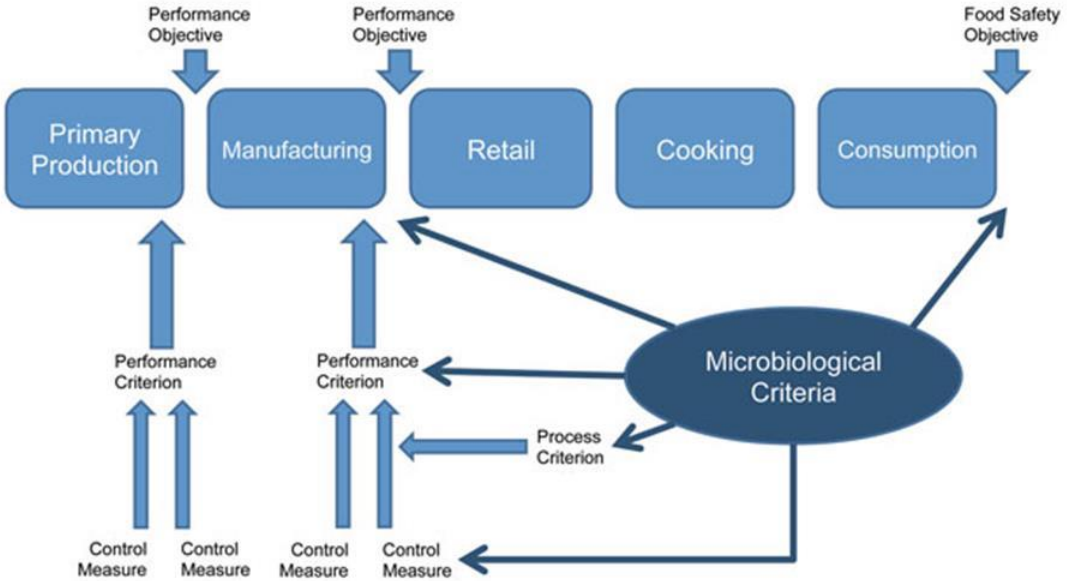
Microbiological criteria - components

- A statement of the microorganisms of concern and/or their toxins/metabolites and the reason for that concern
- The analytical methods for their detection and/or quantification
- A plan defining the number of field samples to be taken and the size of the analytical unit
- Microbiological limits considered appropriate to the food at the specified point(s) of the food chain
- The number of analytical units that should conform to these limits

Microbiological criteria - components

A microbiological criterion should also state:

- The food to which the criterion applies
- The point(s) in the food chain where the criterion applies;
- Any actions to be taken when the criterion is not met



Microbiological criteria - components

Example: Regulation 2073/2005

Chapter 2. Process hygiene criteria

2.1. Meat and products thereof

Food category	Micro-organisms	Sampling plan (1)		Limits (2)		Analytical reference method (3)	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.6. Minced meat	Aerobic colony count (7)	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E.coli (8)	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

Microbiological criteria – purpose and applications

- Formulate design requirements
- Indicate the required microbiological status of raw materials, ingredients and end-products at any stage of the food chain
- Examination of foods, including raw materials and ingredients

Microbiological criteria – purpose and applications

- Verification of the efficacy of HACCP-based systems and Good Hygienic Practices
- Define distinction between acceptable and unacceptable raw materials, ingredients, products, lots, by regulatory authorities and/or food business operators
- Determine that processes are consistent with the General Principles of Food Hygiene

Application by regulatory authorities

- Define and check compliance with the microbiological requirements
- Mandatory microbiological criteria - apply to those products and/or points of the food chain where no other more effective tools are available, and where they are expected to improve the degree of protection offered to consumer
- Product-type specific and only applied at the point of the food chain as specified in the regulation

Application by food business operators

- Check compliance with regulatory provisions
- Formulate design requirements and examine end-products as one of the measures to verify and/or validate the efficacy of a HACCP plan
- Criteria - specific for the product and the stage in the food chain at which they will apply
- May be stricter than criteria used for regulatory purposes and should, as such, not be used for legal action
- Normally not used to monitor CCPs

General considerations for establishment and application of microbiological criteria

- Need for criterion is demonstrated (e.g. by epidemiological evidence that the food may represent a public health risk and that a criterion is meaningful for consumer protection)
- Criterion should be technically attainable by applying Good Manufacturing Practices

General considerations for establishment and application of microbiological criteria

To fulfil the purposes of a microbiological criterion, consideration should be given to: (1)

- Evidence of actual or potential hazards to health
- Microbiological status of the raw material(s)
- Effect of processing on the microbiological status of the food
- Likelihood and consequences of microbial contamination and/or growth during subsequent handling, storage and use

General considerations for establishment and application of microbiological criteria

To fulfil the purposes of a microbiological criterion, consideration should be given to: (2)

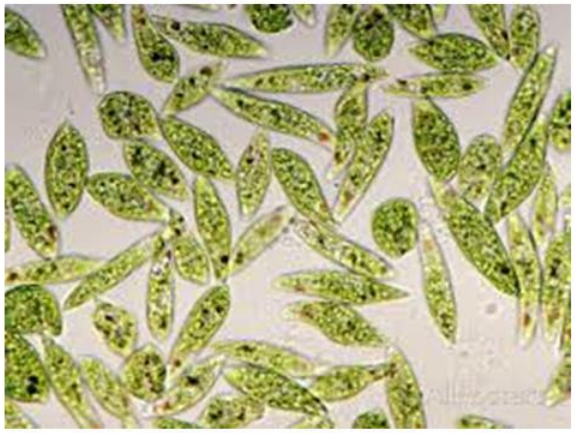
- Consumer groups concerned
- Cost/benefit ratio associated with the application of the criterion
- Intended use of the food.

Number and size of analytical units per lot tested should be as stated in the sampling plan and should not be modified.

A lot should not be subjected to repeated testing in order to bring the lot into compliance.

Microbiological aspects of criteria

- Bacteria, viruses, yeasts, moulds, and algae
- Parasitic protozoa and helminths
- Their toxins/metabolites



Microbiological aspects of criteria

- Microorganisms included in a criterion should be widely accepted as relevant - as pathogens, as indicator organisms or as spoilage organisms - to the particular food and technology
- Where pathogens can be detected directly and reliably, consideration should be given to testing for them in preference to testing for indicator organisms
- If a test for an indicator organism is applied, there should be a clear statement whether the test is used to indicate unsatisfactory hygienic practices or a health hazard

Microbiological methods

- Methods with statistically established reliability (accuracy, reproducibility, inter- and intra-laboratory variation)
- Preference to methods validated for the commodity concerned
- Methods to determine suitability for consumption of highly perishable foods, or foods with a short shelf-life, should be chosen so that the results of microbiological examinations are available before the foods are consumed or exceed their shelf-life

Microbiological limits

- Limits used in criteria should be based on microbiological data appropriate to the food and should be applicable to a variety of similar products
- Based on data gathered at various production establishments operating under Good Hygienic Practices and applying the HACCP system
- Consideration of the risk associated with the microorganisms

Microbiological limits

- Likelihood of uneven distribution of microorganisms in the food
- Variability of the analytical procedure
- For absence of a particular microorganism, size and number of the analytical unit (as well as the number of analytical sample units) should be indicated

Sampling plans

Considerations for choice of a sampling plan:

- Sampling procedure and the decision criteria to be applied to a lot, based on examination of a prescribed number of sample units and subsequent analytical units of a stated size by defined methods
- No sampling plan can ensure the absence of a particular organism
- Administratively and economically feasible

Sampling plans

Considerations for choice of a sampling plan:

- Risks to public health associated with the hazard
- Susceptibility of the target group of consumers
- Heterogeneity of distribution of microorganisms where variables sampling plans are employed
- Acceptable quality level and the desired statistical probability of accepting a non-conforming lot

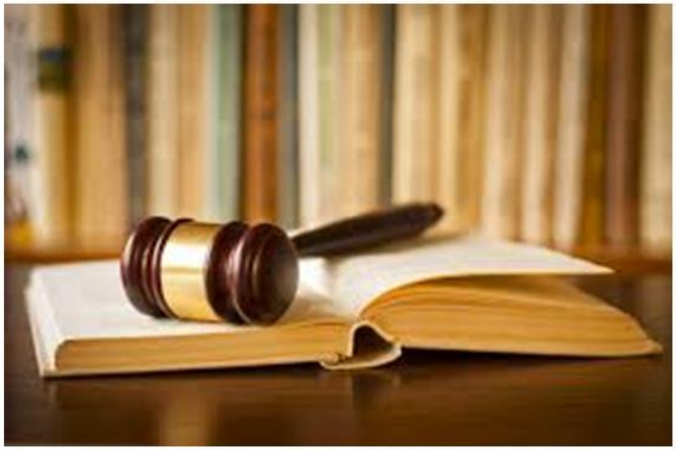
Types of criteria

ICMSF (International Commission on Microbiological Specifications for Foods)

- Microbiological standards
- Microbiological guidelines
- Microbiological specifications

Microbiological standards

- Part of national legislation, must be complied with
- Aim to ensure safety, sometimes quality of foods
- Defined for pathogens, in some cases for indicator microoganisms



Microbiological guidelines

- Guide to manufacturers and others as to the levels of microorganisms that are generally not exceeded under conditions of GMPs and/or appropriate storage
- Guidelines are often “in house”, varying from one manufacturer to another even for same product
- May be used to ensure that HACCP is operating correctly

Microbiological guidelines

- Microbiological specifications of the finished product
- Provides the necessary hygiene status
- Includes MO causing spoilage and / or food diseases
- Microbiological instructions for hygiene monitoring

Microbiological specifications

- Criteria used for contractual agreements
- May be recommendations by national or international agencies
- Normally based on acceptance sampling (any lots exceeding the specification are rejected)

Microbiological indicators

- **Process indicators** - microorganisms that confirm the effectiveness of a process - plate count, total coliforms
- **Hygiene indicators** - microorganisms that indicate faecal contamination - termotolerant coliforms or *E. coli*. Their presence implies the presence of pathogenic microorganisms.

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

- Applies since January 1st, 2006
- First European document setting international (European) microbiological criteria for food safety criteria and process hygiene
- Before: national regulations, company specifications, Codex Alimentarius guidelines
- (18) International guidelines for microbiological criteria in respect of many foodstuffs have not yet been established

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

Food safety criteria – Annex I, Chapter 1

- *Listeria monocytogenes* (ISO 11290-1,2)
- *Salmonella* (ISO 6579)
- *Escherichia coli* (ISO 16469-1,2,3)
- *Cronobacter (Enterobacter) sakazakii* (ISO/TS 22964)
- Staphylococcal enterotoxins (European screening method of the CRL for milk)
- Histamine (HPLC method)

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

Process hygiene criteria – Annex I, Chapter 2

- Aerobic colony count (ISO 4833)
- *Enterobacteriaceae* (ISO 21528-1,2)
- Salmonella (EN/ISO 6579)
- *Escherichia coli* (16469-1,2,3)
- Coagulase-positive staphylococci (*Staphylococcus aureus*) (ISO 6888-1,2)

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

Food safety and process hygiene criteria for foods of animal origin:

- Meat and meat products
- Milk and dairy products
- Egg products
- Fish and fish products

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

Food category	Micro-organisms (toxins)	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfac-tory results
		n	**c**	**m**	**M**			

- **n** = number of units comprising the sample
- **c** = number of sample units giving values between **m** and **M**
- **satisfactory**, if all the values observed are **< m**,
- **acceptable**, if a maximum of c/n values are between **m** and **M**, and the rest of the values observed are **< m**,
- **unsatisfactory**, if one or more of the values observed are **>M** or more than c/n values are between **m** and **M**.

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

No food safety and process hygiene criteria for:

- Ready meals (soups, sauces, second dishes, salads, appetizers, desserts) and semi-products
- Baby foods (cereal-based foods, canned foods)
- Cereal, fruit and vegetable foods (natural, dried, frozen)
- Spices
- Sterilized canned foods

Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs

No food safety and process hygiene criteria for:

- Mayonnaise and emulsified products
- Confectionery, chocolate and cocoa products
- Pastry
- Soft drinks
- Food additives
- Starter cultures (except dairy)

Problems with the use of microbiological criteria

- Cost
- Sampling – difficult to ensure samples are representative of the batch, risk of accepting defective batches
- Destructive analysis – cost; tested samples can not be re-tested
- Change of microbiological status of foods during distribution and storage
- Testing time – sometimes several days to obtain result, for perishable foods - only retrospective, even with rapid methods results may not be immediately available

Problems with the use of microbiological criteria

- Laboratory overload
- Difficult to defend microbiological test results in court
- Variation in testing – rarely taken into account, plate counts – 95% confidence limits of ± 0.5 log cycle; 95% confidence limits for MPN techniques are very wide
- Reliability of test procedures – isolation of MO of concern, false positives, new pathogens