

# Microbiological Criteria for Foodstuffs

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# Microbiological Criteria: The UK perspective

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- A role for microbiological criteria
- Regulation 2073/2005 Regulation on Microbiological criteria for foodstuffs
- Current issues



## Role for microbiological criteria - limitations

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Microbiological testing alone cannot guarantee the safety of food.

- Limitations in sampling
- Limitations in methodology; and
- Uneven distribution of micro organisms throughout the food



## Role for microbiological criteria – preventative approach

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Food safety is primarily achieved by a structured, preventative approach (Good Manufacturing Practice and food safety management practices based on HACCP principles)

Identify the hazards and risks associated with a food or food process and put in place systems to control these.



# Role for microbiological criteria - definitions

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## Codex

A microbiological criterion for food defines the acceptability of a product or a food lot, based on the absence or presence, or number of micro organism including parasites, and/or quantity of their toxins/metabolites, per units of mass, volume area or lot.

## SCF and SCVPH (EU)

Similar definition but refers also to acceptability of the process



## Role for microbiological criteria – definitions (2)

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### Food Safety Criteria

Criteria defining the acceptability of a product or batch of foodstuff applicable to products ready to be placed on the market or are already on the market

### Process Hygiene Criteria

Criteria indicating the acceptable functioning of the production process. A level of contamination which indicates corrective action is required to maintain the hygiene of the process.



## Role for microbiological criteria

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Microbiological criteria are tools that can be used in assessing the safety and quality of foods.

They give guidance on the acceptability of foodstuffs and processes and should be used to help **validate and verify food safety management procedures.**



# Role for microbiological criteria – relationship with HACCP

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- Risk assessment will identify harmful micro organisms which may be associated with a particular food product (hazards).
- Businesses will then establish approaches to control those hazards and monitor the process to ensure it is working correctly. Testing against microbiological criteria is one of the ways of validating and verifying the controls.
- Testing may not be required as other monitoring approaches may be more effective (e.g. time/temperature profiles).
- If testing is to be carried out the business should determine the level of testing within their HACCP plan i.e. How often do they need to test to ensure the process is working effectively and the hazard is being controlled?



# Role for microbiological criteria - sources

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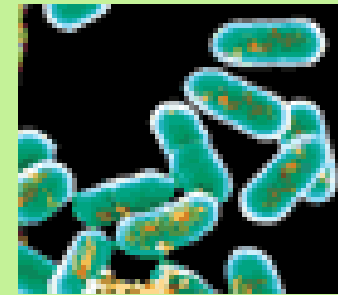
A range of microbiological criteria are applied to food. Some of these are specified in legislation (Regulation 2073/2005) and others are applied to help meet the more general requirement that food should not be placed on the market if it is unsafe (Regulation 178/2002).

- Regulation 2073/2005
- HPA ready-to-eat foods guidelines
- IFST/CCFRA guidelines
- APHA/HPA protocol for imported foods
- Customer specifications
- Industry guides
- etc, etc





## The EU Regulation on Microbiological Criteria (Reg. (EC) No. 2073/2005)



- Supports the Food Hygiene Regulations
- Guidance on the acceptability of food and manufacturing process
- Reviews previous criteria and sets down new criteria for certain products



# Regulation 2073/2005 - History

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Provides microbiological criteria to replace those provided in the commodity-based legislation that were consolidated into the Food Hygiene Regulations which came into force January 11 2006.

Criteria in the previous legislation were:

- Developed 5-10 years ago
- Contained many inconsistencies
- Few standard methods
- Didn't take account of prevalence



# Regulation 2073/2005 – establishing the criteria

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The commission established a clear strategy for setting the criteria (SANCO)1252/2001 Rev11)

- should be established and applied only where there is a definite need and their application is practical
- mandatory criteria should only apply to those products and/or points of the food chain where no other more effective tools available and where they are expected to improve consumer protection
- micro organisms selected for criteria should be widely accepted as relevant (as pathogens or indicator organisms) to the food or process
- An EFSA opinion is required if new criteria are to be set or existing criteria are revised



# Regulation 2073/2005 - who is affected?

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- Applies to ALL food business operators (fbo) involved in the production and handling of food



- Also applies to Competent Authority



# Regulation 2073/2005 – The criterion

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Regulation 2073/2005 establishes Food Safety Criteria and Process Hygiene criteria. Each criterion consists of a number of components:

- A statement on the microorganisms/toxin/metabolite of concern including justification for the criterion
- Analytical method
- Sampling plan (number of samples and sample unit size)
- microbiological limits at specified point in food chain
- the number of analytical units that should conform to those limits
- The commodity to which the criterion applies
- the points in the food chain where the criterion applies
- actions to be taken when the criterion is not met.



## Regulation 2073/2005 – key messages

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- The Regulation does not require routine testing or set a minimum level of testing, except for meat and meat preps etc.
- It should not lead to an increase in end product testing or positive release.
- Criteria should be used within context of food safety management procedures (HACCP) to validate and verify food safety management systems.
- Sampling and testing is not always required to demonstrate compliance – evidence that processes are functioning correctly e.g. safer food better business.



## Regulation 2073/2005 – key messages (2)

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- A business should establish the level of sampling required to demonstrate compliance with the Regulation within its HACCP plan taking account of historical data and other relevant information.
- Sampling and testing requirements should be adapted to reflect the nature and size of the business.
- To fully comply with the Regulation, the specified corrective action must be carried out – failure to meet the criteria alone is not an offence.



## Regulation 2073/2005 - the Competent Authority

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- The Competent Authority must ensure businesses comply with the Regulation.
- Sampling and testing is only one of measures available to determine compliance.
- Compliance cannot be determined without full assessment of the food safety management procedures, supporting sampling and testing regimes and testing data.
- The Competent Authority should generally only take additional samples if they have concerns about business' procedures or there has been insufficient testing by the business.



# Regulation 2073/2005 - failing to meet the criteria

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A business must carry out the specified corrective action if a food fails to meet the relevant criteria. All failures will result in a review of the food safety management procedures

- **FOOD SAFETY CRITERIA** - the product will not be placed on the market or will be withdrawn/recalled from the market
- **PROCESS HYGIENE CRITERIA** - proposes corrective action for improved production.





## Regulation 2073/2005 – implementation in the UK

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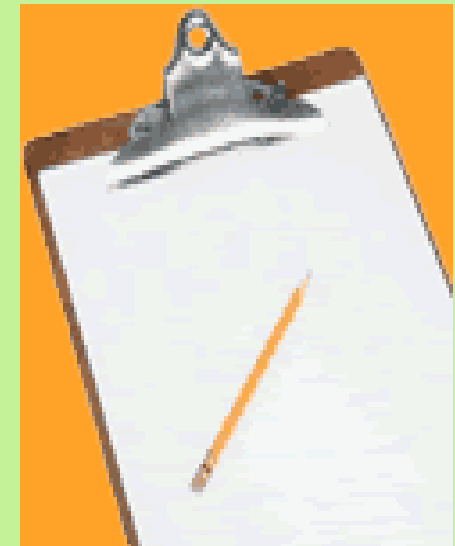
- Regulation applies directly. SI required to make it an offence not to comply with the Regulation.
- Implemented through SI 2006 No. 14 (The Food Hygiene (England) Regulations) which implements the food hygiene legislation.
- Regulation came into force 11 January 2006.
- Agency guidance is available at [www.food.gov.uk](http://www.food.gov.uk)



## Current issues - guidance

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- Issued guidance on the Regulation when it came into force
- Engaging stakeholders to revise guidance – more user friendly and take account of practical experience with the Regulation – issue revised version for comment April and finalised guidance available Autumn
- FAQ section for web site



## Current issues - methods



- Regulation includes requirements for laboratories and standard methods
- Can use alternative methods (including rapid methods or commercial kits) as long as demonstrate equivalence according to ISO or other internationally accepted standards.
- Working with stakeholders to clarify requirements and questions arising e.g. validation of methods, certification by a third party and UKAS accreditation



## Current issues – Activities in Europe

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Activity has continued since the Regulation came into force. Main activities since 1 Jan 2006:

- Commission guidance on microbiological sampling and testing for official controls
- National criteria
- New criteria for infant formula (*B.cereus*) and follow-on formula (*Enterobacteriaceae* and *Salmonella*)
- *Campylobacter*
- Carcass sampling



## Current issues – Activities in Europe (2)

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Commission proposal for revision to the Regulation which includes:

- Clarification of *Listeria* criteria
- *Bacillus cereus* process hygiene criteria for infant formula
- Changes to the infant formula criteria (separating *Enterobacteriaceae* and *Salmonella* and *Enterobacter sakazakii* criteria)
- Food safety (*Salmonella*) and process hygiene (*Enterobacteriaceae*) criteria for follow on formula
- Harmonised approach to carcass testing
- New reference method for staph enterotoxin

Amendments to the zoonoses legislation



## Summary

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- Microbiological testing alone cannot guarantee the safety of food.
- Microbiological criteria will help validate and verify food safety management systems
- The business should determine the appropriate level of testing by asking how often they need to test to show their processes are functioning correctly.
- In some cases no testing will be required.



## Summary (2)

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- Sampling and testing is only one of measures available to determine compliance with Regulation 2073/2005.
- A full assessment of the food safety management procedures, supporting sampling and testing regimes and testing data must be carried out to assess compliance
- The Enforcement Authority should generally only take additional samples if they have concerns about business' procedures or there has been insufficient testing by the business.



**Thank you for listening**



