Food Safety
AUTHORITY OF IRELAND

MICROBIAL FACTSHEET SERIES

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Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs – Information for Manufacturers/Processors

This factsheet outlines the main issues to be considered by manufacturers/processors to ensure compliance with Regulation (EC) No 2073/2005. It should be read in conjunction with the Food Safety Authority of Ireland's (FSAI) *Guidance Note No. 26 – Guidance for Food Business Operators on the Implementation of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs.*

1. Background

Under General Food Law (Regulation (EC) No 178/2002), all food business operators have a legal obligation to produce safe food.

In addition:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs requires manufacturers/processors to adopt hygiene measures (this includes compliance with relevant microbiological criteria) and to put in place, implement and maintain a permanent procedure or procedures based on HACCP principles, and
- Regulation (EC) No 853/2004 lays down additional hygiene rules for foods of animal rules

2. Criteria Specified in Commission Regulation (EC) No 2073/2005

Annex I of Commission Regulation (EC) No 2073/2005 lays down **food safety** and **process hygiene criteria** for specific combinations of foodstuffs and microorganisms, their toxins or metabolites.

Food safety criteria are:

- Used to assess the safety of a product or batch of foodstuffs. They generally apply throughout the shelf-life of foodstuffs placed on the market[1] (irrespective of whether the foodstuffs are produced within the EU or imported from a third country)
- Established for microorganisms (usually pathogenic microorganisms), their toxins or metabolites in various food commodities, e.g. *Listeria monocytogenes* in ready-to-eat foods, staphylococcal enterotoxin in certain cheeses, milk powder and whey powder

[1] 'Placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves (Article 3.8 of Regulation 178/2002 on General Food Law)

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Process hygiene criteria are:

- Used to assess the correct functioning of production processes. They are applicable to foodstuffs either during or at the end of the manufacturing process
- Established for microorganisms (usually indicator[2] microorganisms) in various food commodities, e.g. *E. coli* in minced meat, *Enterobacteriaceae* in egg products

- Further information on food safety and process hygiene criteria is provided Part A, Section 2.
- Information specific to the food safety criterion for *L. monocytogenes* in ready-to-eat food is provided in Part B, Section 2 of the guidance note.

3. How do Manufacturers/Processors comply with this Regulation?

The first step is to check if any of the criteria, i.e. process hygiene or food safety criteria, specified in the Regulation are relevant to your ingredients or your end products.

If criteria are relevant to your ingredients, you must:

- Ensure you are supplied with ingredients meeting these criteria. You can do this by undertaking supplier audits/inspections, setting microbiological specifications (which at a minimum meet the legal requirements of Regulation (EC) No 2073/2005) and periodic testing of incoming ingredients

If criteria are relevant to your end products, you must:

- Implement measures as part of your procedures based on HACCP principles and good hygiene practices to ensure compliance
- Sample foodstuffs and test against the relevant criteria, as appropriate, when you are validating and verifying your procedures based on HACCP principles and good hygiene practices. **Note:** in some instances, other means of validation and verification may be more appropriate than sampling and testing, e.g. demonstrating that the thickest part of a cooked dish reaches 75°C or above. You should choose the most appropriate means

Further information is provided in Part B, Sections 1 and 3 of the guidance note.

[2] Indicator microorganisms per se do not pose a risk to public health; however, they indicate that the food has been i) exposed to conditions which increase the risk of pathogen contamination or ii) held under conditions conducive for pathogen growth.

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4. Sampling and Testing of Foodstuffs

When you sample foodstuffs and test against the relevant criteria, there are legal requirements you must follow and recommended best practice requirements.

i) Sampling frequency

Sampling frequencies are specified in the Regulation for carcasses, minced meat, meat preparations and mechanically separated meat. For all other foodstuffs, you must define a production batch and determine an appropriate frequency for sampling and testing based on risk assessment (there is no obligation to test every production batch).

Further information is provided in Part B, Sections 3.2 and 3.3 of the guidance note.

ii) Number of samples to be obtained from the production batch being sampled

This is specified in the Regulation for each criterion.

Further information is provided in Part B, Section 3.4 of the guidance note.

iii) The laboratory and the analytical method used by the laboratory

It is recommended that you use the services of an accredited laboratory. You must ensure the laboratory uses the correct analytical method to analyse your foodstuff. **Note:** Products can be placed on the market prior to results being returned from the laboratory.

Further information is provided in Part B, Section 3.5 of the guidance note.

iv) Interpretation of results and action to be taken in the case of unsatisfactory results

Interpretation of results is essential to determine compliance or non compliance of your production batch with the criterion.

- Failure to comply with a food safety criterion requires withdrawal or recall of the production batch from the market.
- Failure to comply with a process hygiene criterion requires the implementation of hygiene based corrective actions.

Further information is provided in Part B, Sections 3.6 and 3.8 of the guidance note.

v) Analysis of trend

You should look for trends in your test results by plotting your results on a graph and following the results over a period of time. If the trend approaches an unsatisfactory result, you must take action to prevent the occurrence of microbiological risk.

Further information is provided in Part B, Section 3.7 of the guidance note.

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What about microorganisms (their toxins or metabolites) not specified in the Regulation?

It is your legal obligation to produce safe food. Therefore, if microorganisms (their toxins or metabolites) other than those listed in this Regulation, pose a risk to your foodstuffs, you should implement measures as part of your procedures based on good hygiene practices and HACCP principles to control them. These procedures must be validated and verified. Furthermore, these microorganisms (their toxins or metabolites) should be addressed, as appropriate, in the microbiological specifications set for your suppliers.

Further information is provided in Part B, Section 3.9 of the guidance note.

Your sampling and testing programme should be outlined in a documented procedure or standard operating procedure and should include all of the issues outlined in this section.

5. Shelf-life Studies

You are obliged to conduct shelf-life studies, as necessary, to demonstrate compliance with the food safety criteria throughout the shelf-life. This applies particularly to ready-to-eat foods that are able to support the growth of *L. monocytogenes* and that may pose a risk for public health.

For pre-packaged products, Council Directive 2000/13 EC lays down specific requirements for shelf-life declaration, i.e. the date of minimum durability, in the form of a 'best-before' or 'use-by' date. Some pre-packaged products are exempt from the shelf-life declaration under this legislation; however, it is recommended that where a food safety criterion exists in Commission Regulation (EC) No 2073/2005, it is best practice to include shelf-life declaration on these labels. Additional information on the general labelling requirements for shelf-life is outlined in Section 2.1.5.5 of *The Labelling of Food in Ireland 2007*.

Further information on shelf-life studies is provided in Part B, Section 4.0 of the guidance note.

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6. Environmental Monitoring

Environmental sampling is a legal requirement in:

i) Establishments manufacturing ready-to-eat foods which may pose a *Listeria monocytogenes* risk for public health (monitoring should be conducted for *L. monocytogenes*)

ii) Establishments manufacturing dried infant formulae or dried foods for special medical purposes intended for infants below 6 months which pose a *Cronobacter* spp. (*Enterobacter sakazakii*) risk (monitoring should be conducted for *Enterobacteriaceae*)

iii) Other establishments when necessary for ensuring foodstuffs comply with the relevant food safety and process hygiene criteria

Further information is provided in Part B, Section 5.0 of the guidance note.

7. Labelling Requirements

Article 6 of the Regulation lays down labelling requirements for minced meat and meat preparations made from species other than poultry which are intended to be eaten cooked. Batches of these foodstuffs can only be placed on the market if they are clearly labelled by the manufacturer to inform the consumer of the need for thorough cooking prior to consumption.

Further information is provided in Part B, Section 6.0 of the guidance note.

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Reference Source

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1)
http://www.fsai.ie/uploadedFiles/Consol_Reg2073_2005.pdf

Food Safety Authority of Ireland (FSAI) (2011) Guidance Note No.26 Guidance for Food Business Operators on the implementation of Commission Regulation (EC) No 2073/2005 on the Microbiological Criteria for Foodstuffs

Food Safety Authority of Ireland (FSAI) (2010) Guidance Note No. 10 Product Recall and Traceability (Revision 2)
http://www.fsai.ie/gn10productrecallandtraceabilityrevision2.html.

Food Safety Authority of Ireland (FSAI) (2011) Guidance Note No.18 Validation of product shelf-life (Revision 1)
http://www.fsai.ie/Guidancenote18validationofproductshelfliferevision1.html

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1)
http://www.fsai.ie/uploadedFiles/Consol_Reg178_2002(1).pdf

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1)
http://www.fsai.ie/uploadedFiles/Consol_Reg852_2004.pdf

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)
http://www.fsai.ie/uploadedFiles/Consol_Reg853_2004(1).pdf

Other Factsheets in this Series

Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs – Information for Retailers

Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs – Information for Primary Producers of Horticultural Products

Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs – Information for Caterers