

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

This factsheet outlines the main issues to be considered by retailers 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 retailers 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.

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 market¹ (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 indicator² 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 Retailers comply with this Regulation?

The first step is to identify the criteria which are relevant.

If criteria are relevant to the ingredients or other foodstuffs supplied to your retail establishment, you must:

- Ensure these ingredients/foodstuffs meet the relevant 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 sampling and testing

If criteria are relevant to your end products, i.e. foodstuffs which require no further processing and are sold directly to the customer or foodstuffs processed in your deli/butcher counter, you must also:

- Implement measures as part of your procedures based on HACCP principles and good hygiene practices to ensure compliance with the relevant criteria
- 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

If you are producing minced meat or meat preparations you must follow the sampling frequencies specified in Annex II of the Regulation. However, establishments producing these commodities in small quantities may be exempt from these sampling frequencies when justified on the basis of a risk analysis and consequently authorised by the competent authority. Further information and reference sources on these exemptions are provided in the guidance note.

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, Section 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

For foods prepared on your premises, you should look for trends in your test results (where possible) 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.

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

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

It is your legal obligation to ensure the safety of the foodstuff you sell. Therefore, if microorganisms (their toxins or metabolites) other than those listed in this Regulation pose a risk, you must 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

The food business operator responsible for the manufacturer of a product must conduct studies, as necessary, to investigate compliance with the food safety criteria throughout the product 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. You should bear this in mind:

- i) For your own branded products and
- ii) If you prepare foodstuffs (either loose or pre-packaged) for sale in your deli/butcher counter

Please note that:

- i) Shelf-life studies are not necessary for foods produced for immediate consumption
- ii) 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, on pre-packaged products. 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*.

Finally, it is good practice to implement good stock rotation to ensure foodstuffs are not sold after their date of minimum durability.

Further information is provided in Part B, Section 4.0 of the guidance note.

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6. Environmental Monitoring

Retailers should be aware that environmental monitoring is mandatory 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) Other establishments when necessary for ensuring foodstuffs comply with the relevant food safety and process hygiene criteria

Although environmental monitoring may not always be necessary in the food preparation areas of retail establishments, retailers should bear in mind, the legislative requirements when dealing with suppliers.

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.

- If you are supplied with any of these commodities which are pre-packaged, you must ensure that appropriate labelling has been applied by the manufacturer.
- If you are selling any of these commodities loose, you must apply a relevant point-of-sale notice.

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](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

Other Factsheets in this Series

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

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

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