

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

This factsheet outlines the main issues to be considered by primary producers of horticultural products 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 primary producers of horticultural products to adopt hygiene measures (this includes compliance with relevant microbiological criteria).

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

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

Process hygiene criteria indicate the acceptable functioning of the production process. Process hygiene criteria are not established in the Regulation for primary horticultural products¹.

Food safety criteria define the acceptability of a product or batch of foodstuffs. Regarding primary horticultural products, food safety criteria are established for:

- *Salmonella* spp. in sprouted seeds²
- *L. monocytogenes* in ready-to-eat foods, i.e.

Ready-to-eat foods **able** to support the growth of *L. monocytogenes* and

Ready-to-eat foods **unable** to support the growth of *L. monocytogenes*

¹ 'Primary products' means products of primary production including products of the soil, of stock farming, of hunting and fishing (Regulation (EC) No 852/2004). At primary production, primary products are often subject to operations to ensure a better presentation, e.g. washing of vegetables, removing leaves from vegetables, sorting of fruit etc. These are considered normal routine operations. On the other hand, other operations may be carried out on the farm which are likely to alter the products and/or introduce new hazards e.g. the peeling of potatoes, the slicing of carrots, the bagging of salads and the application of preservation gases. These operations are not considered normal routine operations at the level of primary production. Products arising from these operations are not considered primary products.

² For further information on sprouted seeds, please consult the FSAI factsheet entitled 'Factsheet on Safe Production of Ready-To-Eat Sprouted Seeds'

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To establish whether a criterion for *L. monocytogenes* is applicable, primary producers must:

- Determine whether their primary product is ready-to-eat or not-ready-to-eat (note: Sprouted seeds produced using the control measures outlined in the FSAI 'Guidelines on Safe Production of Ready-to-Eat Sprouted Seeds' are considered ready-to-eat and should be labelled as 'ready to-eat'. Sprouted seeds that are not produced using these control measures should be labelled 'cook before consumption' and are not-ready-to-eat).

If a primary product is classified as ready-to-eat, primary producers must then;

- Determine whether it is **able** or **unable** to support the growth of *L. monocytogenes*.

Note: The Regulation classifies ready-to-eat fresh, uncut and unprocessed vegetables (this does not include sprouted seeds) as products **unable** to support the growth of *L. monocytogenes*. It states that regular testing for this pathogen is not required.

- 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 Primary Producers of Horticultural Products comply with this Regulation?

If a food safety criterion is applicable to your primary horticultural product, you must:

- Implement procedures as part of your good hygiene practices and good agricultural/horticultural practices to ensure compliance³
- Sample foodstuffs and test against the relevant criteria, as appropriate, when you are validating and verifying these procedures. Note: in some instances, other means of validation and verification may be more appropriate than sampling and testing. You should choose the most appropriate means.

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

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

You must define a production batch and determine an appropriate frequency of 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.

³ Some primary producers also implement procedures based on hazard analysis and critical control point principles (HACCP), although this is not a legal requirement.

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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.

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.

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, e.g. VTEC, pose a risk to your primary product, you should implement procedures as part of your good agricultural/aquaculture practices and good hygiene practices to control them.

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.

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5. Shelf-life Studies

As a primary producer you are obliged to conduct shelf-life studies, as necessary, to investigate compliance with the food safety criteria throughout the shelf-life. In particular, this applies to ready-to-eat foods able to support the growth of *L. monocytogenes*. Example: Food safety criteria are established for *Salmonella* spp. and *L. monocytogenes* in ready-to-eat sprouted seeds. Therefore, shelf-life studies should be conducted to investigate compliance with these criteria.

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

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

Regarding primary products, environmental monitoring would be particularly appropriate in pack-houses handling raw and ready-to-eat products where cross contamination could occur and in pack-houses handling high risk products such as ready-to-eat sprouted seeds.

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

7. What about Processed, i.e. Cut, Sliced or Shredded, Fruit and Vegetables

Fruit and vegetables which have been cut, sliced or shredded are not considered primary products and are not the focus of this factsheet. However, producers of these products should be aware that both process hygiene criteria, i.e. *E. coli* in ready-to-eat pre-cut fruit and vegetables and *E. coli* in ready-to-eat unpasteurised fruit and vegetable juices, and food safety criteria (*L. monocytogenes* in ready-to-eat foods, *Salmonella* spp. in ready-to-eat pre-cut fruit and vegetables and *Salmonella* spp. in ready-to-eat unpasteurised fruit and vegetable juices) apply. Producers involved in these operations should also consult another factsheet in this series entitled 'Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs – Information for Manufacturers/Processors'

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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>

Food Safety Authority of Ireland (FSAI) (2011) Guidelines on Safe Production of Ready-To-Eat Sprouted Seeds (Sprouts)

<http://www.fsai.ie/WorkArea/DownloadAsset.aspx?id=10772>

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

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](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 Caterers

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