



Food Safety
AUTHORITY OF IRELAND

27

GUIDANCE NOTE

**Guidance Note on the Enforcement
of Commission Regulation (EC)
No 2073/2005 on Microbiological
Criteria for Foodstuffs**

Guidance Note No. 27: Guidance Note on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs

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Published by:
Food Safety Authority of Ireland
Abbey Court
Lower Abbey Street
Dublin 1

Tel: +353 1 817 1300 Fax: +353 1 817 1301
Email: info@fsai.ie Website: www.fsai.ie

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CONTENTS

1. BACKGROUND	1
2. SCOPE	2
3. NATIONAL LEGISLATION	3
4. COMMISSION REGULATION (EC) NO 2073/2005, AS AMENDED	4
5. WHO MUST COMPLY WITH THE REGULATION AND WHAT MUST THEY DO?	8
6. RESPONSIBILITIES OF THE COMPETENT AUTHORITY	11
7. CHECKLIST FOR ASSESSING COMPLIANCE	12
8. SUPPORTING INFORMATION FOR THE CHECKLIST	26
Identifying Relevant Criteria	27
Sampling and Testing Food	41
Taking Action on Unsatisfactory Results	65
Analysing Trends in Results	69
Environmental Monitoring	71
Labelling	79
Demonstrating Compliance with Relevant Criteria throughout the Shelf-life	83
9. TAKING OFFICIAL SAMPLES TO CHECK COMPLIANCE WITH THE CRITERIA	86
APPENDIX 1. FOOD CATEGORIES LISTED IN THE REGULATION WITH EXAMPLES OF FOOD	91
APPENDIX 2. OTHER LEGAL MICROBIOLOGICAL STANDARDS	103
APPENDIX 3. MICROBIOLOGICAL GUIDELINES	104

Disclaimer: This Guidance Note is not legally binding and should be read in conjunction with Commission Regulation (EC) No 2073/2005 (as amended) and other relevant European and national legislation. This Guidance Note is intended as a general guide for enforcement officers when assessing a food business operator's compliance with the Regulation. Enforcement officers must assess each food business operator's compliance with the Regulation on a case-by-case basis.

I. BACKGROUND

Microbiological criteria for foodstuffs are set in Commission Regulation (EC) No 2073/2005 (as amended). Regulation (EC) No 852/2004 (as amended) which lays down general rules for food business operators on the hygiene of foodstuffs, requires food business operators to comply with microbiological criteria for foodstuffs. Regulation (EC) No 853/2005 (as amended) which sets specific hygiene rules for foods of animal origin also requires that food business operators ensure compliance with microbiological criteria.

Regulation (EC) No 178/2002 (as amended) lays down general food safety requirements, according to which food must not be placed on the market if it is unsafe (Article 14). The food safety criteria set in Commission Regulation (EC) No 2073/2005 (as amended) define the microbiological acceptability of food placed on the market. If the results of testing against these food safety criteria are unsatisfactory, the product or batch of foodstuffs must be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002.

Regulation (EC) No 852/2004 (as amended) also requires food business operators to put in place, implement and maintain, a permanent procedure or procedures based on HACCP principles¹. Commission Regulation (EC) No 2073/2005² (as amended) requires food business operators to perform testing as appropriate against the microbiological criteria set out in its Annex I when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.

With respect to official controls, Regulation (EC) 882/2004 (as amended) lays down general rules for performance of official controls to verify food business operators' compliance with food and feed law. Regulation (EC) No 854/2004 (as amended) lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. Commission Regulation (EC) No 2074/2005 (as amended), lays down implementing measures for certain products of animal origin under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004.

All legislation and Food Safety Authority of Ireland (FSAI) publications referred to in this Guidance Note are available from the FSAI's website:

- Legislation at: www.fsai.ie/legislation.html
- FSAI publications at: www.fsai.ie/resources_publications.html

¹ The HACCP requirement does not apply to primary producers. However, guides to good practice should encourage the use of appropriate hygiene practices at farm level. For other types of food business, the Regulation allows for flexibility in relation to implementation of the HACCP requirement. It recognises that in food businesses undertaking low-risk activities, the prerequisite hygiene requirements are sufficient to control food safety without the need to develop a HACCP-based system. Additionally, the Regulation allows for business to follow recognised guides to good practice where typical hazards and controls have been identified

² Commission Regulation (EC) No 2073/2005 as amended, will most often be referred to as 'the Regulation' in the remainder of this Guidance Note

2. SCOPE

This Guidance Note provides guidance for competent authorities³ on the enforcement of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, and its corrections and amendments published up to 7 March 2014:

- Corrigendum (OJ L278, p32, 10/10/2006) to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, p1, 22/12/2005)
- Corrigendum (OJ L283, p62, 14/10/2006) to Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338, p1, 22/12/05)
- Commission Regulation (EC) No 1441/2007 (OJ L322, p12, 07/12/2007) of 5 December 2007
- Commission Regulation (EC) No 365/2010 (OJ L107, p9, 29/04/2010) of 28th April 2010 as regards Enterobacteriaceae in pasteurised milk and other pasteurised liquid dairy products and *Listeria monocytogenes* in food grade salt
- Commission Regulation (EU) No 1086/2011 (OJ L281, p7, 28/10/2011) of 27 October 2011 amending Annex II to Regulation (EC) No 2160/2003 and Annex I to Commission Regulation (EC) No 2073/2005 as regards *salmonella* in fresh poultry meat
- Commission Regulation (EU) No 209/2013 (OJ L69, p19, 12/03/2013) of 11 March 2013 amending Commission Regulation (EC) No 2073/2005 of 15 November 2005 as regards microbiological criteria for sprouts and the sampling rules for fresh poultry meat
- Commission Regulation (EU) No 1019/2013 (OJ L282, p46, 24/10/2013) of 23 October 2013 amending Annex I to Regulation (EC) No 2073/2005 as regards histamine in fishery products
- Commission Regulation (EU) No 217/2014 of 7 March 2014 amending Regulation (EC) No 2073/2005 as regards *salmonella* in pig carcasses

It is likely that the Regulation will be reviewed, revised or supplemented in the future in order to take account of developments in science, technology and methodology, changes in prevalence and contamination levels, changes in the population of vulnerable consumers, as well as the possible outputs from risk assessments.

³ The FSAI has produced Guidance Note 26: Guidance for Food Business Operators on the Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

3. NATIONAL LEGISLATION

Regulation (EC) No 2073/2005 has been transposed into national legislation by the following statutory instruments⁴:

I. For food business supervised by the Health Service Executive (HSE)⁵

- European Union (Microbiological Criteria for Foodstuffs) Regulations, 2012 (S.I. No 474 of 2012), amended by:
 - i. European Union (Microbiological Criteria for Foodstuffs) (Amendment) Regulations, 2013 (S.I. No. 301 of 2013)
 - ii. European Union (Microbiological Criteria for Foodstuffs) (Amendment) Regulations, 2014 (S.I. No. 15 of 2014)

2. For food businesses supervised by the Department of Agriculture, Food and Marine (DAFM), the Sea-Fisheries Protection Authority (SPFA) and local authorities:

- European Communities (Food and Feed Hygiene) Regulations, 2009 (S.I. No. 432 of 2009), amended by:
 - i. European Communities (Food and Feed Hygiene) (Amendment) Regulations, 2010 (S.I. No. 312 of 2010)
 - ii. European Communities (Food and Feed Hygiene) (Amendment) Regulations, 2012 (S.I. No. 164 of 2012)
 - iii. European Communities (Food and Feed Hygiene) (Amendment) (No 2) Regulations, 2012 (S.I. No 362 of 2012)

⁴ Does not include national legislation published after 6 June 2014

⁵ For food businesses that are supervised by the Health Service Executive and approved under Regulation (EC) No 853/2004, the relevant statutory instrument is S.I. No. 432 of 2009 (as amended)

4. COMMISSION REGULATION (EC) NO 2073/2005, AS AMENDED

The aim of the Regulation is to enhance the safety of food and to facilitate fair trade by harmonising microbiological criteria that can be used to assess the acceptability of food. The Regulation sets requirements for:

- a) Sampling frequency (how often foods should be sampled and tested)
- b) The analytical method to use when testing food
- c) Interpreting test results
- d) Action to take if test results are unsatisfactory
- e) Analysing trends in test results
- f) Conducting environmental monitoring
- g) Labelling
- h) Conducting studies to ensure compliance with relevant criteria throughout the shelf-life

4.1 Foods included in the Regulation

The Regulation sets legal microbiological criteria for certain foods, broadly categorised as:

- Ready-to-eat foods
- Carcasses
- Fresh poultry meat
- Minced meat
- Meat preparations
- Meat products
- Mechanically separated meat
- Dairy products
- Egg products
- Live bivalve molluscs
- Fishery products
- Cooked crustaceans and molluscan shellfish
- Pre-cut fruit and vegetables (ready-to-eat)
- Sprouts and sprouted seeds
- Unpasteurised fruit and vegetable juices (ready-to-eat)

Appendix I of this Guidance Note lists the food categories set in the Regulation and examples of the types of food which fall into each of these food categories.

4.2 Foods and Microorganisms not included in the Regulation

The Regulation does not set criteria for every combination of food and microorganism (its toxin or metabolite), but this does not mean that combinations not listed in the Regulation are not a food safety concern. For example, the Regulation does not set criteria for shiga-toxin producing *E. coli* (STEC)⁶ in cheese made from unpasteurised milk or Hepatitis A in berries.

Appendix 2 of this Guidance Note lists other legal microbiological criteria.

Appendix 3 lists guideline microbiological criteria against which the acceptability of food can be assessed in the absence of legal criteria.

4.3 Food Safety Criteria and Process Hygiene Criteria

The Regulation sets two types of microbiological criteria:

- 1) **Food safety criteria**
- 2) **Process hygiene criteria**

Food safety criteria are used to assess the safety of a product or batch of foodstuffs. Process hygiene criteria are used to assess the hygienic functioning of production processes. The differences between these two types of microbiological criteria are described in Table I.

If the results of testing against either type of criteria are unsatisfactory, food business operators must take the appropriate action specified in the Regulation.

⁶ STEC is also referred to as verotoxigenic *E. coli* or verocytotoxigenic *E. coli* (VTEC)

Table 1. Differences between Food Safety Criteria and Process Hygiene Criteria

	Food Safety Criteria	Process Hygiene Criteria
Where the criteria are listed in the Regulation	Annex I, Chapter 1	Annex I, Chapter 2
What the criteria are used to assess	Acceptability of a batch of food in terms of safety	Hygienic functioning of production processes
Where the criteria apply	Products placed on the market during their shelf-life (in most cases ^(a))	At the end of the manufacturing process (in most cases ^(b))
What type of microorganism the criteria apply to	Pathogens, their toxins or metabolites (in most cases ^(c))	Indicator microorganisms (in most cases ^(d))
When test results are unsatisfactory, the food business operator must (according to Article 7 of the Regulation):	<ul style="list-style-type: none"> • Notify the competent authority • Withdraw or recall the implicated product or batch of foodstuffs in accordance with Article 19 of Regulation (EC) no 178/2002^(e) • Take the corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers • Take measures to find the cause of the unsatisfactory results • Take measures to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place 	<ul style="list-style-type: none"> • Take the actions laid down in Annex I, Chapter 2 which specify the action to take in case of unsatisfactory results for each process hygiene criterion • Take the corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers • Take measures to find the cause of the unsatisfactory results • Take measures to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place

^(a) One limit (absence in 25g) for *Listeria monocytogenes* in ready-to-eat food applies before the food has left the immediate control of the food business operator who has produced it (food category 1.2)

^(b) Differs for carcasses (food categories 2.1.1-2.1.5); certain cheeses (food categories 2.2.2-2.2.4); ready-to-eat pre-cut fruit and vegetables (food category 2.5.1); and ready-to-eat unpasteurised fruit and vegetable juices (food category 2.5.2)

^(c) There is a food safety criterion for the indicator *E. coli* in live bivalve molluscs and live echinoderms, tunicates and gastropods (food category 1.25)

^(d) There is a process hygiene criterion for *Salmonella* in carcasses (food categories 2.1.3-2.1.5); for coagulase positive staphylococci in cheese (food categories 2.2.3-2.2.5), milk powder and whey powder (food category 2.2.7), and shelled and shucked products of cooked crustaceans and molluscan shellfish (food category 2.4.1); and for *Bacillus cereus* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age (food category 2.2.11)

^(e) Subject to restrictions, the Regulation makes provision to reprocess food that is unsatisfactory for food safety criteria or to use it for purposes other than those for which it was originally intended (Article 7)

4.4 Components of a Microbiological Criterion

Each microbiological criterion in the Regulation specifies the:

1. **Food category** to which the criterion applies
2. **Microorganism** (or their toxin or metabolite) to which the criterion applies
3. **Sampling plan** which specifies:
 - 'n' (the number of samples to be tested)
 - 'm' (a lower limit) and **M** (an upper limit). Or in some cases a single limit where $m=M$ (for example, 'absence in 25g'), and
 - 'c' which is the number of samples that are permitted to have results above a single limit (if the criterion states that $m=M$) or between m and M (if the criterion sets them as two separate limits)
4. **Analytical reference method** which should be used to test the sample (an alternative method may be used subject to certain conditions)
5. **Stage** where the criterion applies (for example, on the market or at the end of manufacturing)
6. **Action** to be taken if results are unsatisfactory⁷

All the components of a microbiological criterion must be taken into consideration when assessing compliance with the Regulation. For example, the Regulation sets down limits for specific microorganisms, their toxins or metabolites in specific food categories at specific points in the food chain. These limits cannot be applied to alternative points in the food chain. This includes samples taken for official control purposes.

⁷ The action in case of unsatisfactory results is stated in Article 7 of the Regulation. For process hygiene criteria, additional information on action in case of unsatisfactory results is stated in Annex I, Chapter 2

5. WHO MUST COMPLY WITH THE REGULATION AND WHAT MUST THEY DO?

This Guidance Note on the enforcement of Commission Regulation (EC) No 2073/2005 (as amended) sets out a checklist of questions (Section 7) which can be used by enforcement officers to assess a food business operator's compliance with the Regulation. Section 8 provides supporting information for each of the questions in the checklist.

The level of activity that is required by a food business operator to comply with the Regulation will vary depending on the type of food business.

5.1 Who must Comply?

The Regulation applies to all food business operators, except those that *only* handle food for which no relevant criteria are set in the Regulation.

Article 3 of the Regulation states:

“Food business operators shall ensure that foodstuffs comply with the relevant microbiological criteria set out in Annex I. To this end the food business operators at each stage of food production, processing and distribution, including retail, shall take measures, as part of their procedures based on HACCP principles together with the implementation of good hygiene practice, to ensure the following:

- (a) that the supply, handling and processing of raw materials and foodstuffs under their control are carried out in such a way that the process hygiene criteria are met,*
- (b) that the food safety criteria applicable throughout the shelf-life of the products can be met under reasonably foreseeable conditions of distribution, storage and use.”*

5.2 How can Food Businesses Operators Comply?

The Regulation has most impact on food business operators that **produce, manufacture** or **package** food for which criteria are set in the Regulation. Depending on the type of food produced, manufactured or packaged by these food businesses, the food business operator may need to:

1. **Identify criteria in the Regulation** that are relevant to the food they manufacture, package or produce
2. **Test** (where appropriate) the food they produce, manufacture or package to check it complies with the relevant criteria
3. **Take the appropriate action** if test results are unsatisfactory
4. **Analyse trends** in their test results
5. **Conduct environmental monitoring**

6. **Label with the instruction to cook thoroughly**, if they manufacture or pack minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked
7. **Demonstrate** the food complies with relevant criteria throughout its shelf-life

The FSAI has produced *Guidance Note 26: Guidance for Food Business Operators on the Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.*

5.3 Primary Producers and HACCP

Although Regulation (EC) No 853/2004 (as amended) exempts primary producers from putting in place, implementing and maintaining a permanent procedure based on HACCP principles, the Regulation does set food safety criteria for primary products that are:

1. Ready-to-eat foods (food categories 1.2 and 1.3)
2. Sprouted seeds (food category 1.18)
3. Sprouts (food category 1.29), and
4. Live bivalve molluscs and live echinoderms, tunicates and gastropods (food categories 1.17 and 1.25)

Primary producers can ensure compliance with the relevant food safety criteria by taking account of these criteria as part of their good hygiene practice (GHP) and good agricultural practice (GAP).

5.4 Food Businesses applying HACCP Flexibility

Regulation (EC) No 852/2004 (as amended) allows the HACCP-based procedures to be implemented with flexibility⁸. It recognises that in food businesses undertaking low-risk activities, the prerequisite hygiene requirements are sufficient to control food safety without the need to develop a HACCP-based system. Additionally, Regulation 852 allows for business to follow **recognised national guides to good practice** where typical hazards and controls have been identified, such as:

- I.S. 341:2007⁹ Hygiene in Food Retailing and Wholesaling (NSAI, 2007)
- I.S. 340:2007¹⁰ Hygiene in the Catering Sector (NSAI, 2007)

If food businesses correctly implement the control measures in the guide to good hygiene practice recommended for their type of business, this should ensure that the relevant criteria can be met, provided the business is not conducting an additional activity or activities not covered by the guide.

Businesses may also use guides developed by competent authorities to assist them to develop their own HACCP-based procedures, for example:

- Safe Catering – Your Guide to Making Food Safely (FSAI, 2012)
- Food Safety Workbook for Farmhouse Cheesemakers (FSAI, 2010)

⁸ See European Commission Guidance Document on Implementation of procedures based on the HACCP principles, and facilitation of the implementation of the HACCP principles in certain food businesses (available at www.fsai.ie). Also FSAI Guidance Note 11, Assessment of HACCP Compliance (Revision 2)

^{9, 10} The most recent version should be used

6. RESPONSIBILITIES OF THE COMPETENT AUTHORITY

Competent authorities, in accordance with Regulation (EC) No 882/2004, must verify food business operators' compliance with the Regulation. They can do this in a number of ways including:

- a) Auditing HACCP-based procedures and good hygiene practice
- b) Assessing the food business operator's sampling and testing schemes
- c) Checking laboratory test reports
- d) Assessing the adequacy of the corrective and preventive actions
- e) Inspection
- f) Monitoring
- g) Surveillance
- h) Taking official control samples of food for testing¹¹

In this Guidance Note:

- **Section 7** contains a checklist to assist enforcement officers when they are assessing a food business operator's compliance with the Regulation
- **Section 8** contains supporting information for the questions in the checklist
- **Section 9** provides guidance on taking official samples of food to check compliance with microbiological criteria set in the Regulation

¹¹ The European Commission has produced a Guidance Document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs (available at www.fsai.ie). In addition, Regulation (EC) No 854/2004, laying down specific rules on official controls on products of animal origin intended for human consumption (as amended) requires that, with respect to fishery products (food categories 1.26, 1.27 and 1.27a) random testing for histamine should be carried out to verify compliance with the permitted levels laid down under Community legislation and that, with respect to pig carcasses, official sampling is carried out in addition to food business operators' testing in order to verify food business operators' correct implementation of the process hygiene criterion for *Salmonella* on pig carcasses (food category 2.1.4)

7. CHECKLIST FOR ASSESSING COMPLIANCE

This section of the Guidance Note contains a **checklist**¹² that enforcement officers can use when assessing a food business operator's compliance with the Regulation. **Supporting information** for each question in the checklist is provided in Section 8.

The checklist guides enforcement officers to look at how the food business operator has:

- Identified relevant criteria (Questions 1 and 2)
- Sampled and tested food (Questions 3 - 9)
- Taken action when test results were unsatisfactory (Questions 10 and 11)
- Analysed trends in their test results (Question 12)
- Conducted environmental monitoring (Questions 13 and 14)
- Complied with the Regulation's labelling requirement (Question 15)
- Demonstrated compliance with relevant criteria throughout the shelf-life (Question 16)

The checklist is for guidance only and enforcement officers must assess each food business operator's compliance with the Regulation on a case-by-case basis.

¹² The checklist is also available at www.fsai.ie

Checklist to be used when assessing compliance with Commission Regulation EC (No) 2073/2005 on microbiological criteria for foodstuffs (as amended)

Supporting information relevant to each question is provided in Section 8 of FSAI's Guidance Note No. 27

QUESTION	ANSWER	COMMENT
Identifying relevant criteria		
I: Does the food business operator produce, manufacture or package foods for which there are relevant criteria in the Regulation?	<input type="checkbox"/> Yes <input type="checkbox"/> No – checklist doesn't apply to this food business operator	
I (a): Is this food business operator a caterer or retailer that only produces, manufactures or packages food that will be consumed within two days after production?	<input type="checkbox"/> Yes – checklist doesn't apply to this food business operator <input type="checkbox"/> No	
I (b): Is the food business operator a primary producer of live bivalve molluscs and live echinoderms, tunicates and gastropods?	<input type="checkbox"/> Yes – checklist doesn't apply to this food business operator <input type="checkbox"/> No	
I (c): Has the food business operator identified all food safety criteria that are relevant to the food they produce, manufacture or package? (Annex I, Chapter 1 of the Regulation)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I (d): Has the food business operator identified all process hygiene criteria that are relevant to the food they produce, manufacture or package? (Annex I, Chapter 2 of the Regulation)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I (e): Has the food business operator documented the relevant criteria as part of their HACCP-based procedures and good hygiene practice?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
2: Does the food business operator produce, manufacture or package ready-to-eat food?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q3	
2 (a): Has the food business operator documented the ready-to-eat status of the food they produce, manufacture or package?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2 (b): With respect to <i>L. monocytogenes</i> , has the food business operator determined and documented if the ready-to-eat food falls into food category 1.1, 1.2 or 1.3 in Annex I, Chapter I of the Regulation?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Sampling and testing food		
3: Does the food business operator produce, manufacture or package food for which the Regulation sets a sampling frequency?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q4	
3 (a): Does the food business operator take samples of food and test them according to the rules set in the Regulation?	<input type="checkbox"/> Yes – go to Q4 <input type="checkbox"/> No	
3 (b): Does the food business operator use a reduced frequency of sampling derogation?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3 (c): Does the food business operator have evidence to back up their decision to use a reduced frequency of sampling derogation?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3 (d): Can the food business operator show that their decision to use a reduced frequency of sampling derogation was authorised by the competent authority?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
4: Does the food business operator produce, manufacture or package food for which there is a relevant criterion, but for which the Regulation does not set a sampling frequency?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q5	
4 (a): Has the food business operator conducted a risk assessment to decide if – and how often – they need to take samples of food and test them to check compliance with the relevant criteria?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q4d	
4 (b): Has the food business operator documented this risk assessment?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4 (c): Has the food business operator determined (based on their risk assessment) that they don't need to test food in order to check compliance with the relevant criteria?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4 (d): Does the food business operator use means other than testing food to validate or verify that their HACCP-based procedures and good hygiene practice are working properly?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5: Has the food business operator described and documented what constitutes a batch for each of their end-products?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
6: When testing food, does the food business operator collect and test the number of sample units (n) specified in the criterion's sampling plan?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Food business operator doesn't test food to check compliance – go to Q13	
6 (a): Does the food business operator take these sample units from the same batch?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6 (b): Does the food business operator ensure samples are representative of the batch and do not introduce sampling bias?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6 (c): Does the laboratory provide a separate result record for each sample unit (n) tested?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
7: Was sufficient volume/ mass of food tested to check compliance with the criterion?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
8: Does the laboratory test samples using the analytical reference method specified in the Regulation?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q8b	
8 (a): Does the laboratory use the most up-to-date version of the reference method?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
8 (b): Does the laboratory test the samples using an alternative method?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q9	
8 (c): Was the alternative method validated against the most recent edition of the analytical reference method specified in the Regulation?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
8 (d): If the alternative method was a rapid (proprietary) method, was it certified by a third party in accordance with the protocol set out in ISO 16140:2003 or other internationally accepted similar protocols?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	
8 (e): If using an alternative method other than those above (8c & 8d), was the method validated according to internationally accepted protocols?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable – go to Q9	
8 (f): If using an alternative method other than those above (8c & 8d), was the method's use authorised by the competent authority (in conjunction with the FSAI and/or relevant reference laboratory, as necessary)?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
9: Does the food business operator interpret test results correctly?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Taking action on unsatisfactory results		
10: Has the food business operator received unsatisfactory test results for a food safety criterion?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q11	
10 (a): Did the food business operator notify the competent authority?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10 (b): Had the batch of food reached the consumer?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q10d	

QUESTION	ANSWER	COMMENT
<p>10 (c): Did the food business operator recall the batch of food and:</p> <ul style="list-style-type: none"> • Notify trade customers • Notify consumers • Remove the food from the distribution chain • Remove food from consumers (if necessary to protect public health)? 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>10 (d): Did the food business operator withdraw the batch of food, and:</p> <ul style="list-style-type: none"> • Notify trade customers • Remove the food from the distribution chain? 	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>10 (e): Did the food business operator take the corrective actions defined in their HACCP-based procedures?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>10 (f): Did the food business operator take any other actions necessary to protect the health of consumers?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not necessary	
<p>10 (g): Did the food business operator take measures to find the cause of the unsatisfactory results?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>10 (h): Did the food business operator take measures to prevent the recurrence of the unacceptable microbiological contamination (e.g. modifications to the HACCP-based procedures or other food hygiene control measures in place)?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<p>10 (i): Did the food business operator reprocess the batch of food?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q10k	

QUESTION	ANSWER	COMMENT
10 (j): Was the reprocessing treatment sufficient to eliminate the hazard of concern?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10 (k): Did the food business operator use the batch of food for purposes other than for which it was originally intended?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q11	
10 (l): Did the food business operator take into account their HACCP-based procedures and good hygiene practice when deciding on this alternative use?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
10 (m): Was the alternative use authorised by the competent authority?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
11: Has the food business operator received unsatisfactory test results for a process hygiene criterion?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q12	
11 (a): Did the food business operator take actions laid down in Annex I, Chapter 2? (This specifies the action to take in case of unsatisfactory results for each process hygiene criterion)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
11 (b): Did the food business operator take the corrective actions defined in their HACCP-based procedures?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
11 (c): Did the food business operator take any other actions necessary to protect the health of consumers?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not necessary	
11 (d): Did the food business operator take measures to find the cause of the unsatisfactory results?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
11 (e): Did the food business operator take measures to prevent the recurrence of the unacceptable microbiological contamination, e.g. modifications to the HACCP-based procedures or other food hygiene control measures in place?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Analysing trends in results		
12: Does the food business operator analyse trends in their test results?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
12 (a): Does/will the food business operator take timely appropriate actions to remedy the situation when they observe a trend towards unsatisfactory results in order to prevent microbiological risks occurring?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Environmental monitoring		
13: Does the food business operator manufacture dried infant formulae or dried foods for special medical purposes intended for infants below six months which pose a <i>Cronobacter</i> spp. (<i>Enterobacter sakazakii</i>) risk?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q14	
13 (a): Does the food business operator document their environmental sampling and testing programme? (Good practice)	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
13 (b): Does the food business operator take samples of the processing areas and equipment to test for Enterobacteriaceae?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13 (c): Has the food business operator determined a sampling frequency?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13 (d): Does the food business operator take samples of the processing areas and equipment in accordance with ISO standard 18593?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13 (e): Does the food business operator sample appropriate sites in the production facility?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13 (f): Does the food business operator pre-determine and document the appropriate action to take in the case of unsatisfactory results?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13 (g): Does the food business operator take appropriate action in the case of unsatisfactory results?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
13 (h): Does the food business operator monitor trends in their test results?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
Q14: Does the food business operator produce, manufacture or package ready-to-eat food which may pose a <i>L. monocytogenes</i> risk for public health?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q15	
I4 (a): Does the food business operator take samples from processing areas and equipment to test for <i>L. monocytogenes</i> ?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I4 (b): Does the food business operator document their environmental sampling and testing programme? (Good practice)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I4 (c): Does the food business operator take samples from processing areas and equipment according to the EU Guidelines on sampling the food processing area and equipment for the detection of <i>Listeria monocytogenes</i> ? (Best practice)	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I4 (d): Does the food business operator take samples from the appropriate sites in the food processing environment?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I4 (e): Does the food business operator take samples at the appropriate time during production?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I4 (f): Does the food business operator use the appropriate sampling swab and sampling method?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I4 (g): Does the food business operator sample a large enough surface area?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
14 (h): Does the food business operator test samples for <i>L. monocytogenes</i> using EN ISO 11290-1 or valid alternative method according to Article 5 of the Regulation?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
14 (i): Has the food business operator determined a sampling frequency?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
14 (j): Has the food business operator pre-determined and documented the appropriate action to take if <i>L. monocytogenes</i> is detected?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
14 (k): Does/will the food business operator take appropriate action if <i>L. monocytogenes</i> is detected?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
14 (l): Does the food business operator monitor trends in their test results?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Labelling		
15: Does the food business operator manufacture or package minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked?	<input type="checkbox"/> Yes <input type="checkbox"/> No – go to Q16	
15 (a): Has the food business operator clearly labelled the product to inform the consumer that the product must be thoroughly cooked before consumption?	<input type="checkbox"/> Yes <input type="checkbox"/> No	

QUESTION	ANSWER	COMMENT
Compliance with relevant criteria throughout the shelf-life		
I6: Has the food business operator set a shelf-life of the foods they produce, manufacture or pack?	<input type="checkbox"/> Yes <input type="checkbox"/> No – end of questionnaire	
I6 (a): Can the food business operator demonstrate that the food they produce, manufacture or package complies with the relevant criteria throughout its shelf-life?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
I6 (b): Has the food business operator determined the physico-chemical characteristics of their product (such as pH, water activity, salt content, concentration of preservatives and type of packaging) taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not necessary	
I6 (c): Has the food business operator consulted available scientific literature and research data regarding the growth and survival characteristics of the microorganisms of concern?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not necessary	
I6 (d): Has the food business operator conducted predictive mathematical modelling established for the food in question, using critical growth or survival factors for the microorganisms of concern in the product?	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not necessary	

QUESTION	ANSWER	COMMENT
<p>16 (e): Has the food business operator carried out tests (i.e. challenge studies) to investigate the ability of appropriately inoculated microorganisms of concern to grow or survive in the product under different reasonably foreseeable storage conditions?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not necessary</p>	
<p>16 (f): Has the food business operator carried out durability studies to evaluate the growth or survival of the microorganism of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use?</p>	<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not necessary</p>	

8. SUPPORTING INFORMATION FOR THE CHECKLIST

This section of the Guidance Note provides **supporting information** for the checklist questions listed in Section 7. The checklist questions look at how the food business operator has:

- Identified relevant criteria (Questions 1 and 2)
- Sampled and tested food (Questions 3 - 9)
- Taken action when test results were unsatisfactory (Questions 10 and 11)
- Analysed trends in their test results (Question 12)
- Conducted environmental monitoring (Questions 13 and 14)
- Complied with the Regulation's labelling requirement (Question 15)
- Demonstrated compliance with relevant criteria throughout the shelf-life (Question 16)

Q1 & 2 Identifying Relevant Criteria

Question 1: Does the food business operator produce, manufacture or package foods for which there are relevant criteria in the Regulation?

From the outset, food business operators should identify if they **produce, manufacture or package** foods for which there are relevant criteria in the Regulation. Enforcement officers should check that the food business operator has:

- Identified all food safety criteria that are relevant to the food they produce, manufacture or package? (Annex I, Chapter 1 of the Regulation)
- Identified all process hygiene criteria that are relevant to the food they produce, manufacture or package? (Annex I, Chapter 2 of the Regulation)
- Documented the relevant criteria as part of their HACCP-based procedures and good hygiene practice

The Regulation's food categories and examples of foods which fall into these categories are summarised in Appendix I.

More than one criterion may apply to a particular foodstuff.

Example 1: A food business that slices and packages ready-to-eat shredded iceberg lettuce with a shelf-life of four days must ensure it complies with the:

1. Process hygiene criterion for *E. coli* (food category 2.5.1)
2. Food safety criterion for *L. monocytogenes* (food category 1.3)
3. Food safety criterion for *Salmonella* (food category 1.19)

Example 2: A food business that produces ready-to-eat, chilled smoked mackerel with a shelf-life of 20 days must ensure it complies with the:

1. Food safety criterion for *L. monocytogenes* (food category 1.2) and
2. Food safety criterion for histamine (food category 1.26)

On the other hand, there may be no relevant criterion for a particular food in the Regulation because the Regulation does not set microbiological criteria for all types of food (Section 4.2). Even if the Regulation does not apply to a particular food, the food business operator must still ensure that they comply with their obligation under Regulation (EC) No 178/2002 (as amended) to place safe food on the market. With respect to microbiology, the food business operator should have identified any microbiological hazards associated with their food product and put in place measures, through their HACCP-based procedures and good hygiene practice, to eliminate or reduce these hazards to an acceptable level. If there are no relevant microbiological criteria in the Regulation, the acceptability of the food may be assessed against other legal or guideline microbiological criteria (Appendix 2 & 3).

INFORMATION SPECIFIC TO:

Primary producers

The Regulation sets food safety criteria for primary products that are:

1. Ready-to-eat foods¹³ (food categories 1.2 and 1.3)
2. Sprouted seeds (food category 1.18)
3. Sprouts (food category 1.29), and
4. Live bivalve molluscs and live echinoderms, tunicates and gastropods (food categories 1.17 and 1.25)

Primary producers of ready-to-eat foods, (e.g. mushrooms, lettuce, sprouts/sprouted seeds) must identify and document the criteria relevant to their products.

However, primary producers, (i.e. harvesters) of live bivalve molluscs and live echinoderms, tunicates and gastropods do not need to identify the criteria relevant to their products. This is because these products may only be placed on the market for retail sale via a dispatch centre¹⁴, where the health mark must be applied¹⁵. It is the responsibility of the dispatch centre to identify and demonstrate compliance with the relevant microbiological criteria. The dispatch centre should follow 'Information specific to manufacturers and packagers' in this Guidance Note.

Manufacturers and packagers

Food business operators that manufacture or package foods must identify if there are any criteria applicable to their end-products.

Wholesalers and distributors

Food businesses that only perform wholesale or distribution activities do not need to identify the microbiological criteria in the Regulation relevant to the foods they handle. This is the responsibility of the food business operator that produced, manufactured or packaged that food.

¹³ Some primary products are ready-to-eat (see Question 2 for guidance on determining ready-to-eat status)

¹⁴ 'Dispatch centre' means any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs fit for human consumption – Regulation (EC) No 853/2004 (as amended)

¹⁵ Annex III, Section VII, Regulation (EC) No 853/2004 (as amended)

Caterers

In general, caterers do not need to identify if the Regulation sets microbiological criteria relevant to the foods they cook or prepare. This is because caterers, for the most part, produce food that is eaten immediately or soon after preparation.

However, a caterer should identify if there are any criteria in the Regulation relevant to their end-products if they:

- Produce, manufacture or package food that will be consumed **more than two days**¹⁶ after production
- Cook food using a time/temperature combination that is different to those set in national guides to good hygiene practice such as I.S. 340

Retailers

In general, retailers do not need to identify if the Regulation sets microbiological criteria relevant to the foods they sell. This is the responsibility of the food business operator that produced, manufactured or packaged that food.

As for caterers, if retailers produce, manufacture or package food that will be eaten immediately, or eaten within two days after preparation, (e.g. sandwiches, mixed salads) they do not need to identify if there are any relevant criteria in the Regulation.

However, a retailer should identify if there are any criteria in the Regulation relevant to their end-products if they:

- Produce, manufacture or package food that will be consumed **more than two days**¹⁷ after production
- Cook food using a time/temperature combination that is different to those set in national guides to good hygiene practice such as I.S. 341

^{16,17} Two days is based on the general food safety advice for leftovers where food can be cooked and refrigerated for up to two days. Day of production can be regarded as Day 0. Therefore, if food is produced on a Monday (Day 0), Tuesday is Day 1 after production and Wednesday is Day 2 after production

Question 2: Does the food business operator produce, manufacture or package ready-to-eat food?

When a food business operator is identifying if there are any microbiological criteria in the Regulation which are relevant to the foods they **produce, manufacture or package** (Question 1), they must decide if they intend any food(s) to be ready-to-eat. Enforcement officers should check that the food business operator has:

- Determined if they produce, manufacture or package ready-to-eat food
- Documented the ready-to-eat status of the food they produce, manufacture or package
- With respect to *L. monocytogenes*, determined and documented if the ready-to-eat food falls into food category 1.1, 1.2 or 1.3 in Annex I, Chapter I of the Regulation

Ready-to-eat food

Ready-to-eat food poses a microbiological risk because it is consumed without any further microbiocidal treatment, such as cooking. The Regulation sets microbiological criteria specific to ready-to-eat food along with additional rules on environmental monitoring (Question 14) and shelf-life studies (Question 16). Ready-to-eat food is defined in the Regulation as:

“...food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level, microorganisms of concern;”

See Figure 1 for a food business operator’s decision tree for determining the ready-to-eat status of the food they manufacture or produce.

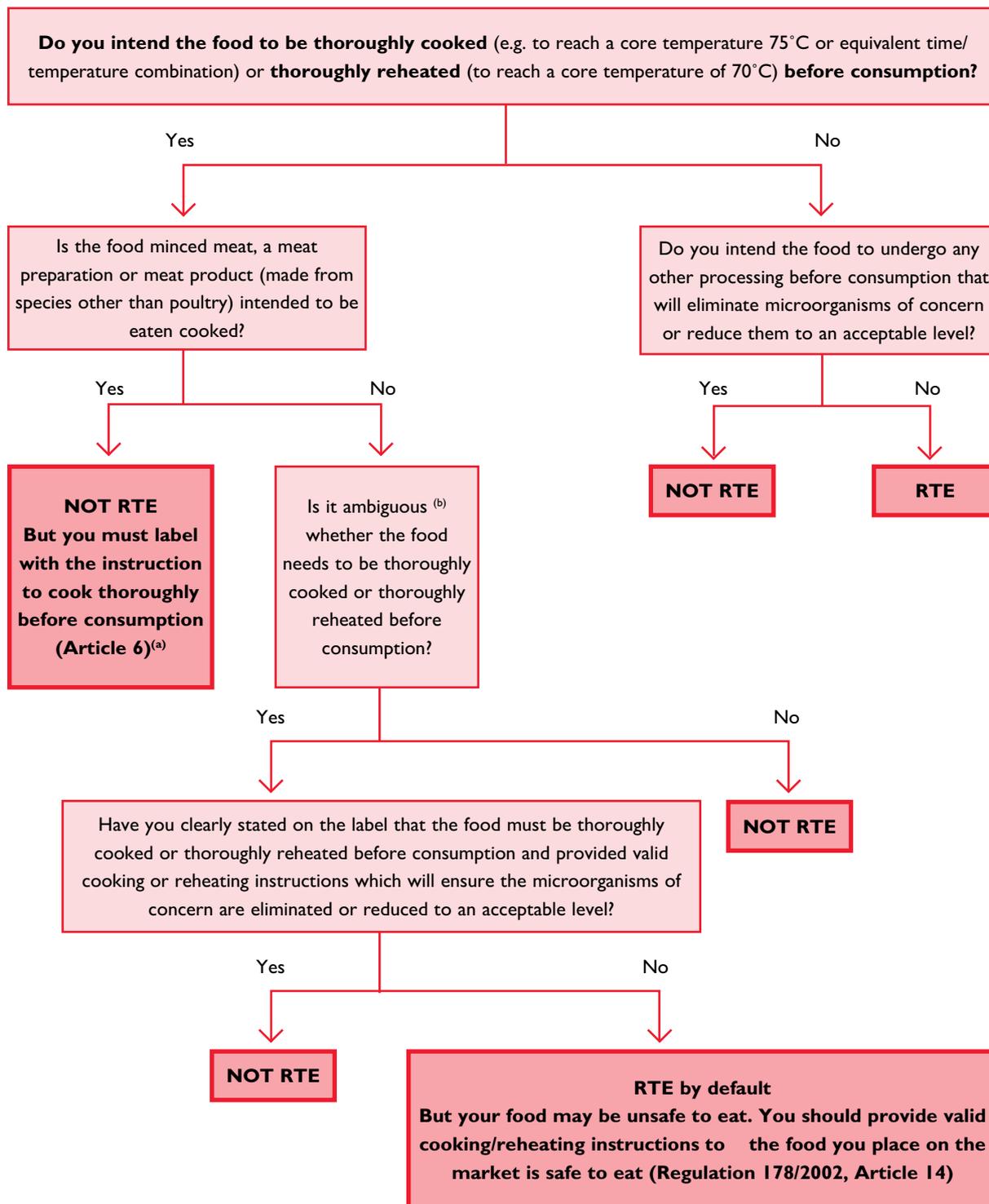


Figure 1: Food business operator’s decision tree for determining the ready-to-eat status of the food they produce, manufacture or package

^(a) Although the labelling requirement in Regulation 2073/2005 does not apply to minced poultry, poultry preparations and poultry products intended to be eaten cooked, the FSAI recommends that these products are also labelled with the instruction to cook thoroughly before consumption. See Q15 for more information on the Regulation’s labelling requirements

^(b) Consumers or other food business may believe that some foods are ready-to-eat because of their appearance, e.g. flash fried chicken nuggets

Cooking/reheating instructions

Thoroughly cooking food, so that its core reaches a temperature of 75°C (or equivalent time/temperature combination), is considered effective to achieve a 6-D reduction in the number of *Listeria monocytogenes* cells. Of the foodborne pathogens that do not form spores, *L. monocytogenes* is regarded as the most heat resistant. Therefore, other non-spore forming pathogens that may be present in the food should also be destroyed by this process. Food business operators may use alternative time/temperature combinations as long as they achieve the same lethal effect as 75°C instantaneously. Scientifically accepted alternative time/temperature combinations include: 70°C for 2 minutes, 67°C for 5 minutes and 64°C for 12 minutes and 37 seconds¹⁸.

Thoroughly reheating foods that have already been cooked to achieve a core temperature of $\geq 70^{\circ}\text{C}$ ¹⁹ is also considered effective to eliminate microorganisms of concern or reduce them to an acceptable level. Foods which are intended to be reheated for palatability purposes but will not reach a core temperature of 70°C are considered ready-to-eat.

If a food business operator does not intend a food they produce, manufacture or package to be ready-to-eat, they should label it with the instruction that it should be thoroughly cooked or thoroughly reheated before consumption and provide clear, valid cooking or reheating instructions.

Clear and valid cooking instructions are particularly important for food which, because of its appearance, a consumer or another food business may think is ready-to-eat, for example, flash-fried chicken nuggets.

When clear, valid cooking/reheating instructions are provided, the food should not be considered ready-to-eat unless labelling states that the food may also be consumed as it is sold, without further cooking or reheating.

Instruction to ‘wash before consumption’

Most salad leaves, and many herbs, are consumed without cooking. Even if they are labelled with an instruction to wash before consumption, they are considered ready-to-eat. Although washing can reduce microbial contamination on the plant’s surface, it is not effective to eliminate microorganisms of concern or reduce them to an acceptable level because some pathogens can become internalised within the plant’s tissue.

¹⁸ For other equivalent time/temperature combinations, see the FSAI’s Guidance Note 20: Industrial Processing of Heat-Chilled Foods

¹⁹ Reheating temperature cited in I.S. 340:2007 (Hygiene in the catering sector) and I.S. 341: 2007 (Hygiene in retailing and wholesaling)

Ability to support the growth of *Listeria monocytogenes*

With respect to *L. monocytogenes*, the Regulation lists three categories of ready-to-eat food:

- **Food category 1.1:** Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes
- **Food category 1.2:** Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes
- **Food category 1.3:** Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes

By default, ready-to-eat foods are considered food category 1.2 if:

- a) They do not fall into food category 1.1, or
- b) The food business operator cannot demonstrate they fall into food category 1.3

Foods that fall into food category 1.3

So long as the ready-to-eat food is not intended for infants or for special medical purposes (food category 1.1), it is considered unable to support the growth of *L. monocytogenes* if:

- 1) Its shelf-life is less than five days²⁰
- 2) Its pH is ≤ 4.4
- 3) Its water activity is ≤ 0.92
- 4) Its pH is ≤ 5.0 and its water activity is ≤ 0.94
- 5) It is a frozen food
- 6) Its growth potential is $\leq 0.5 \log_{10}$ cfu/g

Other types of ready-to-eat food can fall into food category 1.3 if the food business operator can provide scientific justification for their decision. If a food business operator considers a food they produce, manufacture or package is unable to support the growth of *L. monocytogenes*, enforcement officers should assess the food business operator's decision on a case-by-case basis. Enforcement officers may seek advice from the FSAI if there is any uncertainty.

²⁰ This means the total shelf-life of the product. Day of production can be regarded as Day 0 (see page 35)

Shelf-life of less than five days

Ready-to-eat food with a shelf-life less than five days is considered unable to support the growth of *L. monocytogenes*. This decision is related to the lag phase of *L. monocytogenes* and is based on the Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health on *Listeria monocytogenes* (1999)²¹. A ready-to-eat food with a shelf-life less than five days (so long it is not intended for infants or for special medical purposes) automatically falls into food category I.3, regardless of its pH, water activity etc.

Given that ready-to-eat foods with a shelf-life of five days or more may not fall into food category I.3, it is important that the number of days on a food’s shelf-life is calculated in a consistent manner by food business operators and enforcement officers. The day of production or packaging is taken as Day 0²² with the number of days on the shelf-life calculated as per Figure 2.

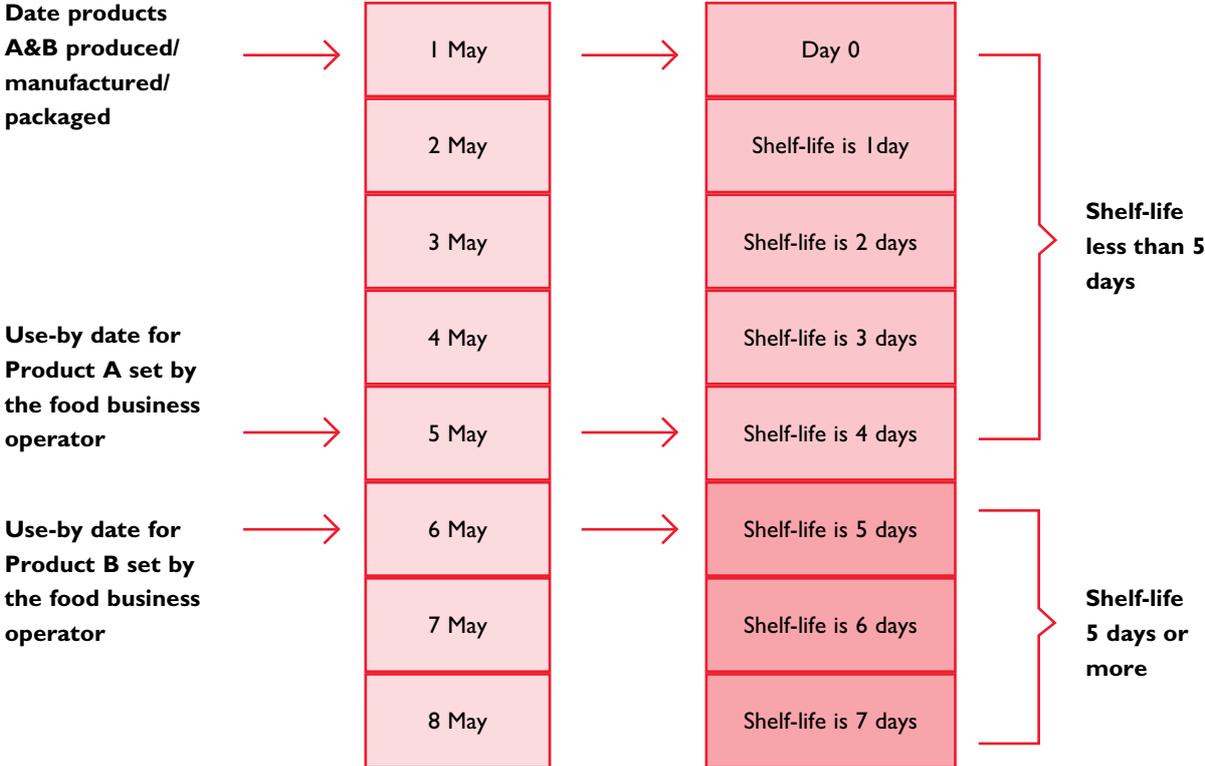


Figure 2: How to determine if a food’s shelf-life is less than five days

²¹ Available at http://ec.europa.eu/food/fs/sc/scv/out25_en.pdf
²² Day 0=day of production or packaging according to European Commission Guidance on shelf-life studies for ready-to-eat foods (available at www.fsai.ie)

pH of foods

A food's ability to support the growth and survival of microorganisms is influenced by its pH. The pH scale extends from 0 to 14, where 7 is neutral, below 7 is acidic and above 7 is alkaline. Most microorganisms grow best at or near pH 7. Table 2 lists average pH values for some foods.

It is recommended that pH is measured according to ISO 2917:1999²³ or other applicable method. Typically, pH is measured on macerated food and therefore is an average. In multi-component foods (such as plated meals, sandwiches, mixed salads etc.) each component may have a different pH value. The laboratory may need to measure the pH of each component separately (as far as possible) in order to assess if any component of the food can support *L. monocytogenes* growth. Taking coleslaw as an example, mayonnaise has a low pH which may not support *L. monocytogenes* growth, but cabbage (with a higher pH) could.

It may also be necessary for the laboratory to measure the pH of food products over its shelf-life because pH can vary with time due to microbial activity and production composition or formulation. Some foods products may be more prone to pH change than others, including vegetables, fresh meats, poultry and mould/smear ripened cheese.

²³ ISO 2917:1999 Meat and meat products – Measurement of pH – Reference method (available to purchase at: www.iso.org)

Table 2: Average pH values of some foods

Approx. pH range	Food
2.0 – 2.2	Lemon juice
2.0 – 2.5	Vinegar
3.6 – 3.8	Tomato ketchup
3.8 – 4.0	Apple/Fruit juices
4.0 – 4.5	Tomatoes Beer Wine
4.2 – 4.5	Cottage cheese Yoghurt Mayonnaise
4.5 – 5.1	Bananas
5.2 – 5.9	Cheddar cheese
5.3 – 5.8	Bread
5.4 – 6.5	Canned vegetables
5.5 – 5.9	Fresh beef steaks
5.6 – 6.6	Bacon
5.8 – 6.0	Fresh poultry
6.0 – 6.2	Fresh pork Potatoes
6.1 – 6.4	Butter
6.2 – 7.3	Cows' milk
6.6 – 6.8	Fresh fish
6.6 – 7.0	Fresh shellfish
7.0 – 7.8	Fresh eggs
7.0	Pure water
≥8.0	Baking soda

From: *FSAI Guidance Note No. 18 – Validation of Produce Shelf-life (Revision 1)*. These values are approximations only. Laboratory analysis of a foodstuff is required in order to determine an accurate pH measurement.

Water activity of foods

Water activity (a_w) is a measure of the amount of freely available water within a food. The water activity of most foods ranges from 0.2 for very dry foods to 0.99 for moist fresh foods (Table 3). Foods with a low water activity cannot support microbial growth because microorganisms need water to grow. Pathogenic and spoilage bacteria do not grow in food with a water activity of less than 0.85, but yeasts and moulds can grow at water activities as low as 0.6. The water activity of a food can be altered by drying, freezing or adding solutes or ions.

The standard method for determining water activity is ISO 21807:2004²⁴. Most individual foods have a homogenous water activity, therefore homogenisation with a mincer is unnecessary. Indeed, homogenisation is inadvisable because the sample material may become hot and give off water so the water activity measured will no longer be representative of the foodstuff examined.

One exception is fermented meat products (for example, fermented sausage and ham) in which a water activity gradient is formed between the inside and outside because of drying. For these foods, water activity can be measured in the inside and outside regions, or even at points distributed over the cross-section. Another exception is water-in-oil emulsions, e.g. margarines, which have heterogeneous water activity, even if they are homogenised.

The water activity of multi-component foods will vary between components. It may be necessary for the laboratory to measure the water activity of each component separately (as far as possible) in order to assess if any component of the food can support *L. monocytogenes* growth.

²⁴ ISO 21807:2004 Microbiology of food and animal feeding stuffs – Determination of water activity (available to purchase at: www.iso.org)

Table 3: Approximate water activity values of some foods

Approx a_w range	Food
1.0	Distilled water
≥ 0.98	Fresh meats, poultry, fish and eggs Fresh milk Fresh fruit and vegetables Fruit and vegetable juices
$\geq 0.93 - 0.98$	Cured meats Fresh breads Cheddar cheese Cold-smoked salmon
$\geq 0.8 - 0.93$	Dry and fermented sausages Dry cheeses Margarine Fruit juice concentrate Maple syrup
0.7 - 0.8	Soy sauce (will vary depending on salt concentration)
≥ 0.65	Dried meat, e.g. beef jerky
$\geq 0.6 - 0.85$	Dried fruit Jam Honey Flour
$\geq 0.3 - 0.6$	Biscuits Dry noodles Dry pasta Crisps
0.4 - 0.5	Whole egg powder
$\geq 0.2 - 0.3$	Dried vegetables Dried soups Breakfast cereals Milk powders
≤ 0.2	Coffee powder

From: *FSAI Guidance Note No. 18 – Validation of Produce Shelf-life (Revision 1)*. These values are approximations only. Laboratory analysis of a foodstuff is required in order to determine an accurate water activity measurement.

Frozen food

Frozen food (during the period it remains frozen) falls into food category 1.3 because *L. monocytogenes* cannot grow at the recommended holding temperatures for frozen food²⁵. However, if the manufacturer or producer intends the frozen food to be defrosted before consumption, e.g. frozen cheesecake, and the shelf-life of the defrosted food is five days or longer, this food may fall into food category 1.2 if the defrosted food can support the growth of *L. monocytogenes*.

Growth potential

Challenge tests can be used to determine the growth potential of a food. Foods with a growth potential:

- **$\leq 0.5 \log_{10}$ cfu/g** are classified as unable to support the growth of *L. monocytogenes* and fall into food category 1.3
- **$> 0.5 \log_{10}$ cfu/g** are considered able to support the growth of *L. monocytogenes* and fall into food category 1.2

The Commission has published two guidance documents on using challenge tests to determine the growth potential of food (both available at www.fsai.ie):

1. **For food business operators:** Guidance Document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
2. **For laboratories:** Technical Guidance Document on shelf-life laboratory durability and challenge studies for *Listeria monocytogenes* in ready-to-eat foods

²⁵ Minimum temperature for *L. monocytogenes* growth is -1.5°C

Q3 – 9 Sampling and Testing Food

Question 3: Does the food business operator produce, manufacture or package food for which the Regulation sets a sampling frequency?

For some types of food, Annex I, Chapter 3 of the Regulation lays down sampling frequencies (which state how often food business operators should take samples for testing) and sampling rules (which state how those samples should be taken). Enforcement officers should check if a food business operator:

- Produces, manufactures or packages food for which the Regulation sets a sampling frequency
- Takes samples and tests them according to the rules set in the Regulation
- Uses a reduced frequency of sampling derogation
- Has evidence to back up any decision to use a reduced frequency of sampling derogation
- Can demonstrate that any decision to use a reduced frequency of sampling derogation was authorised by the competent authority

The Regulation sets sampling frequencies and rules for:

1. Carcasses of cattle, pigs, sheep, goats, horses
2. Poultry carcasses, portions and fresh poultry meat
3. Minced meat intended to be eaten raw
4. Minced meat made from poultry meat intended to be eaten cooked
5. Minced meat made from species other than poultry intended to be eaten cooked
6. Meat preparations intended to be eaten raw
7. Meat preparations made from poultry meat intended to be eaten cooked
8. Meat preparations made from species other than poultry intended to be eaten cooked
9. Mechanically separated meat
10. Preliminary testing of seeds for sprouting
11. Sprouts

Flow diagrams describing these sampling rules and frequencies are available at www.fsai.ie.

Derogations from set sampling frequencies

When justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses and establishments producing minced meat, meat preparations and fresh poultry meat in small quantities may be exempted from the sampling frequencies set down in the Regulation.

If the food business operator uses a reduced frequency of sampling derogation, enforcement officers should check that the food business operator:

- Has evidence to back up this decision to reduce the frequency of testing, and
- Can show that the new approach was authorised by the competent authority

When conducting this risk analysis, the competent authority should take account of the:

- Operational hygiene at the establishment
- Sanitation of premises and equipment
- Results of previous microbiological or other hygiene checks
- Design and maintenance of premises and equipment
- Training, experience and competence of personnel
- Number and distribution of customers supplied by the establishment
- Risk categorisation of customer
- Throughput of the premises
- Inter-operational variation
- HACCP compliance

Guidelines on reduced sampling frequencies are available at www.fsai.ie:

1. Cross-Agency Hygiene Package Implementation Working Group. Recommendation No. 5 Version 1. Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in low throughput premises
2. Minimum sampling frequencies for butcher shops producing minced meat and meat preparations in small quantities (this document is applicable to butcher shops supervised by environmental health officers)

Question 4: Does the food business operator produce, manufacture or package food for which there is a relevant criterion, but for which the Regulation does not set a sampling frequency?

Once a food business operator has identified that there are criteria in the Regulation that are relevant to the food they produce, manufacture or package, they must then decide if they need to test that food to check if it complies with those criteria. And if they do need to test food, how often should they test it.

The Regulation (Article 4) states:

“Food business operators shall perform testing as appropriate against the microbiological criteria set out in Annex I, when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.”

If a food business operator produces, manufactures or packages a food for which there is a relevant criterion in the Regulation, but for which the Regulation does not set a sampling frequency, the food business operator must determine the appropriate sampling frequency based on a risk assessment.

Enforcement officers should check if a food business operator:

- Produces, manufactures or packages food for which there are relevant criteria in the Regulation, but for which the Regulation does not set a sampling frequency
- Has conducted a risk assessment to decide if – and how often – they need to take samples of food and test them to check compliance with the criteria
- Has documented this risk assessment
- Has determined (based on their risk assessment) that they don't need to test food in order to check compliance with the criteria
- Uses other means to validate or verify that their HACCP-based procedures and good hygiene practice are working properly

Validation and verification

Food business operators can validate and verify that their HACCP-based procedures and good hygiene practice are working effectively by means other than testing the food.

For example, a food business operator can validate (or prove) their cooking critical control point (CCP) by obtaining evidence that the cooking time and temperature they use is effective to eliminate microorganisms of concern. Scientifically accepted time/temperature combinations that the core of the food must achieve to achieve a 6 D reduction in *L. monocytogenes*²⁶, include: 75°C instantaneously, 70°C for two minutes, 67°C for five minutes etc. Other equivalent time/temperature combinations are cited in the FSAI's *Guidance Note No. 20: Industrial Processing of Heat-Chill Foods*.

Food business operators can verify (or check) that this CCP is being met by periodically reviewing the monitoring results and verifying that the necessary corrective action was taken on occasions where the critical limits were not met.

Food category 1.1 and food category 1.3 foods which do not need to be regularly tested for *L. monocytogenes*

The Regulation (under footnote 4 of Annex I, Chapter I, food safety criteria) states that the following types of ready-to-eat food in **food categories 1.1²⁷ and 1.3²⁸** do not require regular testing against the criterion (for *L. monocytogenes*):

- Those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, when recontamination is not possible after this treatment (for example, products heat treated in their final package)
- Fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds
- Bread, biscuits and similar products
- Bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products
- Sugar, honey and confectionery, including cocoa and chocolate products
- Live bivalve molluscs and
- Food grade salt

²⁶ *L. monocytogenes* is regarded as the most heat resistant non-spore-forming foodborne pathogen. Therefore, cooking procedures that are effective to destroy *L. monocytogenes* will destroy other non-spore-forming pathogens should they be present in the food

²⁷ Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes

²⁸ Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes

Testing of these foods may be required in special circumstances, for example during an outbreak investigation, or on suspicion of food poisoning or food processing failure.

Note: footnote 4 does not apply to food category 1.2 foods 'Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes'.

Risk assessment to determine sampling frequency

It is not possible for the competent authority to set standard sampling frequencies for all types of food or food business. In order to determine what level of testing (sampling frequency) is appropriate for a particular foodstuff or food business, the food business operator should conduct a risk assessment. Based on the risk assessment, the food business operator can decide:

- If they need to test food to check compliance with the criteria
- How often they should test samples (appropriate sampling frequency)

Enforcement officers should assess the appropriateness of the sampling frequency determined by a food business operator on a case-by-case basis.

The food business operator's risk assessment should take the following points into consideration:

1. The microbial hazard(s) of concern in the foodstuffs

The food business operator should identify the microbial hazards of concern in the foodstuff. Microbial hazards can arise from microorganisms, their toxins or their metabolites. Information on microbial hazards can be obtained from scientific literature, competent authorities, Government departments, research institutes, international organisations etc. Relevant information includes data collected from clinical studies, epidemiological studies, environmental studies, microbiological surveillance and studies on the survival and growth of microorganisms through the food chain.

2. The susceptibility of the population consuming the food

Food business operators should take into account the susceptibility of the population or sub-population for which the foodstuff is intended, such as:

- Is the food intended for infants (e.g. baby food, infant formula)?
- Will the food be served to people with reduced immune systems (e.g. hospital patients, nursing home residents)?

3. The intended use of the foodstuff

Food business operators should take into account the instructions for use of the foodstuff, i.e. is the food ready-to-eat when placed on the market or does it require cooking or other processing before consumption which is effective to eliminate the microorganisms of concern or reduce them to an acceptable level?

4. Nature of the business

Food business operators should take into account the nature of the business, i.e. the types/mix of foodstuffs and the volume of food being handled. Regarding the latter, it is important to remember that 'low volume' does not automatically mean 'low-risk'. Further information on the risk categorisation of certain food businesses is provided in the FSAI's *Guidance Note No. 1 Guidance for the Health Service Executive on the Inspection of Food Businesses*.

5. Environmental monitoring

Food business operators should take into account, the results from environmental monitoring as the presence of environmental contaminants, such as *L. monocytogenes*, increases the risk of end-product contamination.

6. HACCP-based procedures and good hygiene practice

Food business operators should take into account the robustness of their HACCP-based procedures and good hygiene practice. In general, an established system will be more robust than a new system. This can be demonstrated by examining historical data, such as the results of previous testing or previous monitoring records at critical control points.

Reducing or increasing sampling frequencies

Food business operators should adapt the frequency of sampling to the nature and size of the food business. The sampling frequencies appropriate for one establishment may not be appropriate for another establishment even if they carry out similar activities.

Provided that the safety of foodstuffs is not compromised, a food business operator may be able to justify reducing the initial sampling frequency they set if results of past testing of food (historical results) show continual compliance with the relevant criteria. This verifies that the HACCP-based procedures and good hygiene practice are working properly. Results of environmental monitoring may also be taken into account to demonstrate that cleaning and disinfection procedures in place limit the chance of post-processing contamination.

On the other hand, if test results are unsatisfactory, or if the food business operator changes their procedures based on HACCP and good hygiene practice, the sampling frequency may need to be increased to verify the effectiveness of any corrective actions or modifications.

INFORMATION SPECIFIC TO:

Primary producers

The main responsibility of testing food lies with the food business operator that produces, manufactures or packages that food. Enforcement officers should check that primary producers who produce:

- Sprouts**, adhere to the sampling frequency set in the Regulation
- Ready-to-eat fresh produce**, have conducted a risk assessment to determine the sampling frequency and have documented this risk assessment

Primary producers of live bivalve molluscs and live echinoderms, tunicates and gastropods are not required to conduct sampling and testing against the microbiological criteria in the Regulation, since these products cannot be placed on the market until they go through a dispatch centre²⁹. It is the responsibility of the dispatch centre to conduct a risk assessment to determine the sampling frequency and have documented this risk assessment. Dispatch centres should follow information specific to manufacturers and packagers in this Guidance Note.

Manufacturers and packers

The main responsibility of testing food lies with the food business operator that produces, manufactures or packages the food. Enforcement officers should check that food business operators that manufacture or package food for which there are relevant criteria in the Regulation, but for which the Regulation does not set a sampling frequency have:

- Conducted a risk assessment to decide if – and how often – they need to take samples of food and test them to check compliance with the criteria, and
- Documented this risk assessment

If the food business operator has determined (based on a risk assessment) that they don't need to test food in order to check compliance with the criteria, enforcement officers should check that the food business operator:

- Uses other means to validate or verify that their HACCP-based procedures and good hygiene practice are working properly, e.g. use a guide to good hygiene practice specific to their sector/product

²⁹ Annex III, Section VII, Regulation (EC) No 853/2004 (as amended)

Wholesalers and distributors

Food business operators that only carry out wholesale or distribution activities are not required to test the food they handle to check it complies with the relevant criteria. Enforcement officers should check that the food business operator:

- Uses other means to validate or verify that their HACCP-based procedures and good hygiene practice are working properly, e.g. use a guide to good hygiene practice specific to their sector/product

Caterers

In general, caterers do not need to test the food they cook or prepare to check it complies with the Regulation. This is because caterers, for the most part, produce food that is eaten immediately or within two days³⁰ after preparation. Enforcement officers should check that the food business operator can demonstrate that they:

- Use other means to validate or verify that their HACCP-based procedures and good hygiene practice are working properly (for example use a guide to good hygiene practice such as I.S. 340:2007)

However, caterers do need to take the same testing approach as manufacturers and packers if they:

- Produce, manufacture or package food that will be consumed more than two days³¹ after production, or
- Cook food using a time/temperature combination that is different to those set in guides to good hygiene practice such as I.S. 340:2007

^{30, 31} Two days is based on the general food safety advice for leftovers where food can be cooked and refrigerated for up to two days. Day of production can be regarded as Day 0. Therefore, if food is produced on a Monday (Day 0), Tuesday is Day 1 after production and Wednesday is Day 2 after production

Retailers

In general, retailers do not need to test food they sell to check it complies with the Regulation. This is the responsibility of the food business operator that produced, manufactured or packaged it.

Likewise, if a retailer produces, manufactures or packages food that is intended to be eaten immediately, or within two days after preparation, (e.g. sandwiches, mixed salads) they do not need to test that food to check it complies with the Regulation. Enforcement officers should check that the food business operator can demonstrate that they:

- Use other means to validate or verify that their HACCP-based procedures and good hygiene practice are working properly, e.g. use a guide to good hygiene practice such as I.S. 341:2007

However, retailers do need to take the same testing approach as manufacturers and packers if they:

- Produce, manufacture or package food that will be consumed more than two days³² after production, or
- Cook food using a time/temperature combination that is different to those set in guides to good hygiene practice such as I.S. 341:2007

³² Two days is based on the general food safety advice for leftovers where food can be cooked and refrigerated for up to two days. Day of production can be regarded as Day 0. Therefore, if food is produced on a Monday (Day 0), Tuesday is Day 1 after production and Wednesday is Day 2 after production

Question 5: Has the food business operator described and documented what constitutes a batch for each of their end-products?

Competent authorities should check food business operators that produce, manufacture or package food for which there are relevant criteria have:

- Described** what constitutes a batch for each of their end-products, and
- Documented** the batch description as part of their HACCP-based procedures and good hygiene practice

Under the Regulation, a 'batch' is defined as a group or set of identifiable products obtained from a given process under practically identical circumstances, and produced in a given place within one defined production period.

Food business operators need to describe clearly what constitutes a batch for each of the products they produce, manufacture or package because the Regulation states how many samples should be collected and tested from each batch when assessing compliance with a criterion.

The Regulation (Article 7) also requires the food business operator to withdraw or recall a batch of food for which the testing results for a food safety criterion are unsatisfactory. Note: depending on the nature of the non-compliance or the food business operator's definition of a batch, multiple batches may need to be included in the withdrawal or recall.

See the FSAI's *Guidance Note No. 10 Product Recall and Traceability (Revision 3)* for information on determining batch size.

Question 6: When testing food, does the food business operator collect and test the number of sample units (n) specified in the criterion's sampling plan?

Each criterion specifies a sampling plan. Enforcement officers should check the food business operator:

- Collects the number of sample units (n) specified in each criterion's sampling plan
- Takes these sample units from the same batch (Question 5)
- Ensures samples are representative of the batch and do not introduce sampling bias
- Receives a separate laboratory result for each sample unit (n) tested

Compliance with the criterion can only be verified if the correct number of sample units (n) specified in the Regulation are tested, e.g. n=5, n=30 etc.

Example: When testing a batch of dried follow-on formula for *Salmonella* to assess compliance with the criterion for food category I.23:

- The food business operator should take 30 sample units (n=30) of at least 25g each (the limit is absence of *Salmonella* in 25g)
- Each of the 30 sample units should be taken from the same batch
- Each sample unit should be representative of the batch – i.e. no sampling bias
- The laboratory must perform 30 individual tests for the presence of *Salmonella*
- The laboratory must return 30 individual test results (showing either absence or presence of *Salmonella* in 25g)
- As c=0, a batch of dried infant formula complies with the criterion if the result of all 30 sample units is absence of *Salmonella* in 25g

Representative sample

According to the Regulation, 'representative sample' means:

“a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample;”

Reducing the number of samples

The Regulation does allow food business operators to reduce the number of sample units stated in the sampling plans set out in the Regulation, but only if they have historical documentation that can demonstrate that they have effective HACCP-based procedures. However, the FSAI strongly advises against reducing the number of sample units.

If the food business operator does have suitable historical documentation and has satisfactory HACCP-based procedures and good hygiene practice, the FSAI advises that the food business operator should reduce the sampling frequency (how often samples are tested), rather than the number of sample units tested on each sampling session. This is because reducing the number of sample units reduces the stringency of the sampling plan, making it less likely that pathogens will be detected if they are present.

Pooling samples

The Regulation requires samples to be pooled (composited) for:

- Cattle, sheep, goat and horse carcasses (food categories: 2.1.1 & 2.1.3)
- Pig carcasses (food categories: 2.1.2 & 2.1.4)
- Poultry carcasses/portions (2.1.5)
- Live bivalve molluscs and live echinoderms, tunicates and gastropods (food category 1.25)

For other food categories, the Regulation only allows pooling³³ of samples if studies are available which demonstrate equivalence of results between the analysis of pooled sample units and the analysis of individual sample units. These studies must be undertaken for each food matrix/microorganism combination and must be approved by the competent authority on the basis of evidence shown. To date, few or no studies of this nature have been undertaken.

³³ Article 5 (5) “Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees.”

Question 7: Was sufficient volume/mass of food tested to check compliance with the criterion?

Some criteria state how much food is to be tested, for example 'absence in 25g' or 'absence in 10g'. Enforcement officers should check laboratory test results to ensure that:

- The correct mass/volume of sample was tested to assess compliance with the relevant criteria.

Examples:

- **10 x 25g** samples are required to be tested for *L. monocytogenes* for food category 1.1 – ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes
- **30 x 10g** samples are required to be tested for *Cronobacter* spp. for food category 1.24 – dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age
- A minimum of 10 individual animals to be pooled to give 100g of flesh and intra-valvular liquid required to be tested for *E. coli* for food category 1.25 – live bivalve molluscs and live echinoderms, tunicates and gastropods.

If not enough sample is tested, compliance with the criterion cannot be confirmed. For example, if the criterion requires 'absence in 25g' and the laboratory reported 'absence in 20g', this result does not demonstrate compliance with the criterion.

It is advisable that the food business operator provides the laboratory with slightly more than the required sample size to ensure the laboratory has sufficient sample to test in order to check compliance with the criterion. Food business operators should confirm the minimum amount required with the laboratory carrying out the testing.

Question 8: Does the laboratory test samples using the analytical reference method specified in the Regulation?

Each criterion specifies the analytical reference method to use when testing food. An alternative method may be used subject to certain conditions. Enforcement officers should check the laboratory reports to determine if the laboratory:

- Tested the sample using the analytical reference method specified in the Regulation
- Used the most up-to-date version of the reference method
- Tested the sample using an alternative method
- Used an alternative method that has been validated against the most recent edition of the analytical reference method specified in the Regulation
- Used a rapid (proprietary) method, it has been certified by a third party in accordance with the protocol set out in ISO 16140:2003³⁴ or other internationally accepted similar protocols
- Used an alternative method other than those above, the method was:
 - Validated according to internationally accepted protocols, and
 - Their use was authorised by the competent authority (in conjunction with the FSAI and/or relevant reference laboratory, as necessary)

Analytical reference methods

An analytical reference method is specified in the Regulation for each criterion. Most of these methods have been developed by the International Organization for Standardization (ISO) and are updated regularly. If the laboratory uses the reference method specified in the Regulation, they must use the most recent edition of this method. The ISO website (www.iso.org) lists the most recent version of their reference methods.

Enforcement officers should check the laboratory test report to see if the analytical reference number is stated. It is best practice for the laboratory to cite the test method they used on the laboratory report. Sometimes the laboratory will cite an in-house SOP (standard operating procedure) number instead of the analytical reference method. This number can be cross-checked against the laboratory's 'Scope of accreditation' which is available on the website of their accreditation body (see Accreditation, page 57). Enforcement officers can check with the official laboratories, or the FSAI, if they need further clarification.

³⁴ ISO 16140:2003 Microbiology of food and animal feeding stuffs – Protocol for the validation of alternative methods (available to purchase at: www.iso.org)

Alternative analytical methods

Food business operators are allowed to use alternative analytical methods (appropriate to the food matrix under examination), as long as the alternative method provides equivalent results to the reference method. Alternative analytical methods may have advantages over the reference method, such as a shorter time-to-result or easier to use.

AFNOR* and MICROVAL* are two organisations that validate and certify alternative analytical methods according to the requirements of the Regulation. Lists of validated/certified alternative methods are available on their websites.

If the food business operator wishes to use analytical methods other than those validated and certified as described above, the methods must:

- Be validated according to internationally accepted protocols, and
- Have been authorised for use by the competent authority (in conjunction with the FSAI and/or relevant reference laboratory, as necessary)

Alternative sampling and testing procedures

Food business operators may use other sampling and testing procedures³⁵ if they can demonstrate, to the satisfaction of the competent authority (in conjunction with the FSAI and/or relevant reference laboratory), that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses.

Although for each criterion in the Regulation the test parameter is specified, Article 5 (5) does allow, food business operators to test against alternative microorganisms and related microbiological limits or for analytes other than microbiological ones – but this is only allowed for process hygiene criteria, not for food safety criteria.

* <http://nf-validation.afnor.org/en>

* <http://www.nen.nl/MicroVal-validation/Certificates.htm>

³⁵ Article 5 (5) Food business operators may use other sampling and testing procedures, if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. Those procedures may include use of alternative sampling sites and use of trend analyses

Accreditation

Accreditation is the formal recognition of a laboratory's competence to conduct testing in compliance with the international standard ISO 17025³⁶. Compliance with this standard requires laboratories to demonstrate competence, impartiality and integrity.

It is **best practice** that the laboratory analysing samples for food business operators is accredited to conduct the analytical method on the required food matrix, but this is not a legal requirement³⁷. If accreditation of the specific method and matrix is not available, it is best practice to choose a laboratory that is accredited to use the relevant method in other food matrices or a laboratory that has been accredited for a broad range of test methods.

The Irish National Accreditation Board (INAB) is the national body with responsibility for accreditation of laboratories in Ireland. Each accredited laboratory is issued with a certificate of accreditation that lists the analytical tests (including the basis of the method and relevant food matrix) for which the laboratory is accredited. A laboratory's accreditation status can be checked on INAB's website at: www.inab.ie.

Laboratories operating outside of Ireland are not accredited by INAB, but by other accreditation bodies such as the United Kingdom Accreditation Service (UKAS).

Accreditation provided by these accreditation bodies is equivalent if they are signatory to the European Co-operation for Accreditation (EA) multi-lateral agreement for testing.

³⁶ ISO 17025: General requirements for the competence of testing and calibration laboratories (available to purchase at: www.iso.org)

³⁷ However, laboratories carrying out analysis for official controls should be accredited in accordance with EN ISO/IEC 17025 on 'General requirements for the competence of testing and calibration laboratories' (see Section 9, Taking official samples to check compliance with the criteria)

Food category 1.2 – correct test to use

Food category 1.2 (ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes) is unique in that it sets two limits for *L. monocytogenes*: 100 cfu/g or absence in 25g. Each limit requires a different test:

- EN/ISO 11290-2³⁸ (the enumeration test) for the 100 cfu/g limit
- EN/ISO 11290-1³⁹ (the detection test) for the absence in 25g limit

Enforcement officers should check that the food business operator has determined the relevant limit applicable to the food depending on whether or not:

- The food was sampled when it was still under the control of the food business operator who produced it, and
- The food business operator who produced the food has studies to show how *L. monocytogenes* will grow in the food during the course of its shelf-life

This is because the correct test to use is determined by the relevant limit.

See Decision Tree (Figure 3).

³⁸ EN/ISO 11290-2: Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of *Listeria monocytogenes* – Part 2: Enumeration method (available to purchase at www.iso.org)

³⁹ ISO 11290-1: Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of *Listeria monocytogenes* – Part 1: Detection method (available to purchase at www.iso.org)

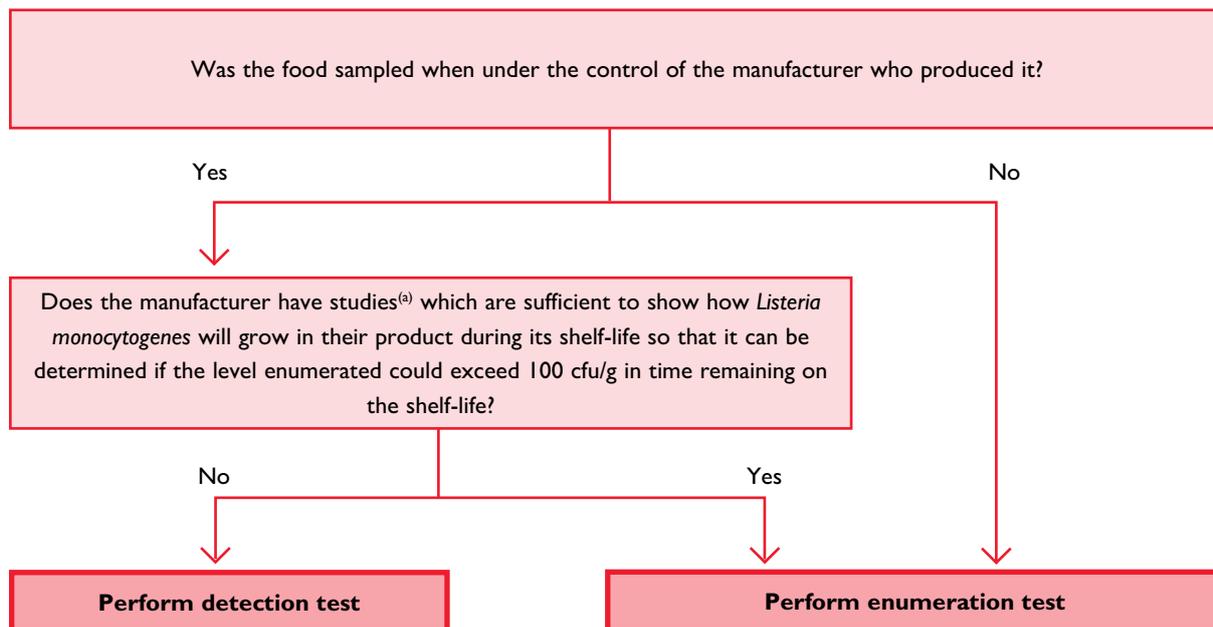


Figure 3: Decision tree to determine which test to perform when assessing compliance of foods that fall into food category 1.2

(a) The types of study suitable for this purpose are referred to in Annex II of the Regulation. See also Question 16 of this Guidance Note.

Question 9: Does the food business operator interpret test results correctly?

Enforcement officers should check the food business operator's laboratory test reports to determine if the food business operator:

- Interprets test results correctly

It is important that food business operators interpret the results correctly because test results are used to assess if the batch of food from which the sample came is compliant or not compliant with the Regulation. The food business operator is required to take action when test results are unsatisfactory (Questions 10 and 11), or the results are approaching unsatisfactory (Question 12).

Example: Testing food category 2.1.6 (minced meat) for *E. coli*:

- Sampling plan is $n=5$, $c=2$
- Limits are: $m=50$ cfu/g and $M=500$ cfu/g
- Results are satisfactory if all five results are ≤ 50 cfu/g
- Results are acceptable if a maximum of two results are between 50 and 500 cfu/g and the remaining results are ≤ 50 cfu/g
- Results are unsatisfactory if one or more result is >500 cfu/g or more than two results are between 50 and 500 cfu/g

Example: Testing food category 1.27 (fishery products, except those in food category 1.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine) for histamine:

- The sampling plan is $n=9$, $c=2$, although single samples ($n=1$) may be taken at retail level
- The limits are: $m=200$ mg/kg and $M=400$ mg/kg
- For batch samples ($n=9$), the results are satisfactory if:
 - a. The mean value observed ≤ 200 mg/kg, and
 - b. No more than two results are between 200 and 400mg/kg, and
 - c. No value is >400 mg/kg
- For a single retail sample ($n=1$) the result is satisfactory if it ≤ 400 mg/kg
- For batch samples ($n=9$) the results are unsatisfactory if:
 - a. The mean value observed is >200 mg/kg, or
 - b. More than two results are between 200 and 400mg/kg, or
 - c. One or more result is >400 mg/kg
- For a single retail sample ($n=1$) the result is unsatisfactory if it is >400 mg/kg

Interpreting *L. monocytogenes* enumeration results for food category 1.2

The Regulation sets two criteria for foods which fall into food category 1.2 (ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes). Table 4 shows how both criteria have a different:

- Limit
- Analytical reference method
- Stage where the criterion applies, and
- Conditions under which the criterion applies

Table 4: Food category 1.2 criteria

	First criterion	Second criterion
Limit	100 cfu/g	Absence in 25 g
Analytical reference method	EN/ISO 11290-2 (enumeration test)	EN/ISO 11290-1 (detection test)
Stage	Products placed on the market during their shelf-life	Before the food has left the immediate control of the food business operator who has produced it
Circumstances under which the criterion applies	See footnote 5, Chapter I: “This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life.”	See footnote 7, Chapter I: “This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.”

Footnote 5 in Annex I, Chapter I of the Regulation states that the 100 cfu/g limit only applies if the food business operator can demonstrate that the limit of 100 cfu/g will not be exceeded throughout the shelf-life. However, this means that the Regulation (as it stands) does not actually set a *L. monocytogenes* limit for food category 1.2 food:

- That is sampled after it has left the immediate control of the food business operator that produced it, and
- The food business operator that produced it cannot demonstrate that the limit of 100 cfu/g will not be exceeded throughout the shelf-life

The FSAI has written to the European Commission seeking clarification on this gap in the Regulation because samples such as those described above are often tested by another food business, e.g. retailers or wholesalers, or by enforcement officers.

While the Regulation doesn't actually set a limit for *L. monocytogenes* in category 1.2 for food sampled under the circumstances described above, Article 14 of Regulation 178/2002 applies where food shall not be placed on the market if it is unsafe. Unsafe food must be recalled or withdrawn in accordance with Article 19 of Regulation (EC) No 178/2002. In this instance, where a food business operator cannot demonstrate compliance with the Regulation, a risk assessment should be carried out using *FSAI Guidance Note No. 10 (Revision 3)* to determine if the food is unsafe in accordance with Article 14 of Regulation (EC) No 178/2002. Figure 4 is a decision tree for interpreting *L. monocytogenes* enumeration results for foods that fall into food category 1.2.

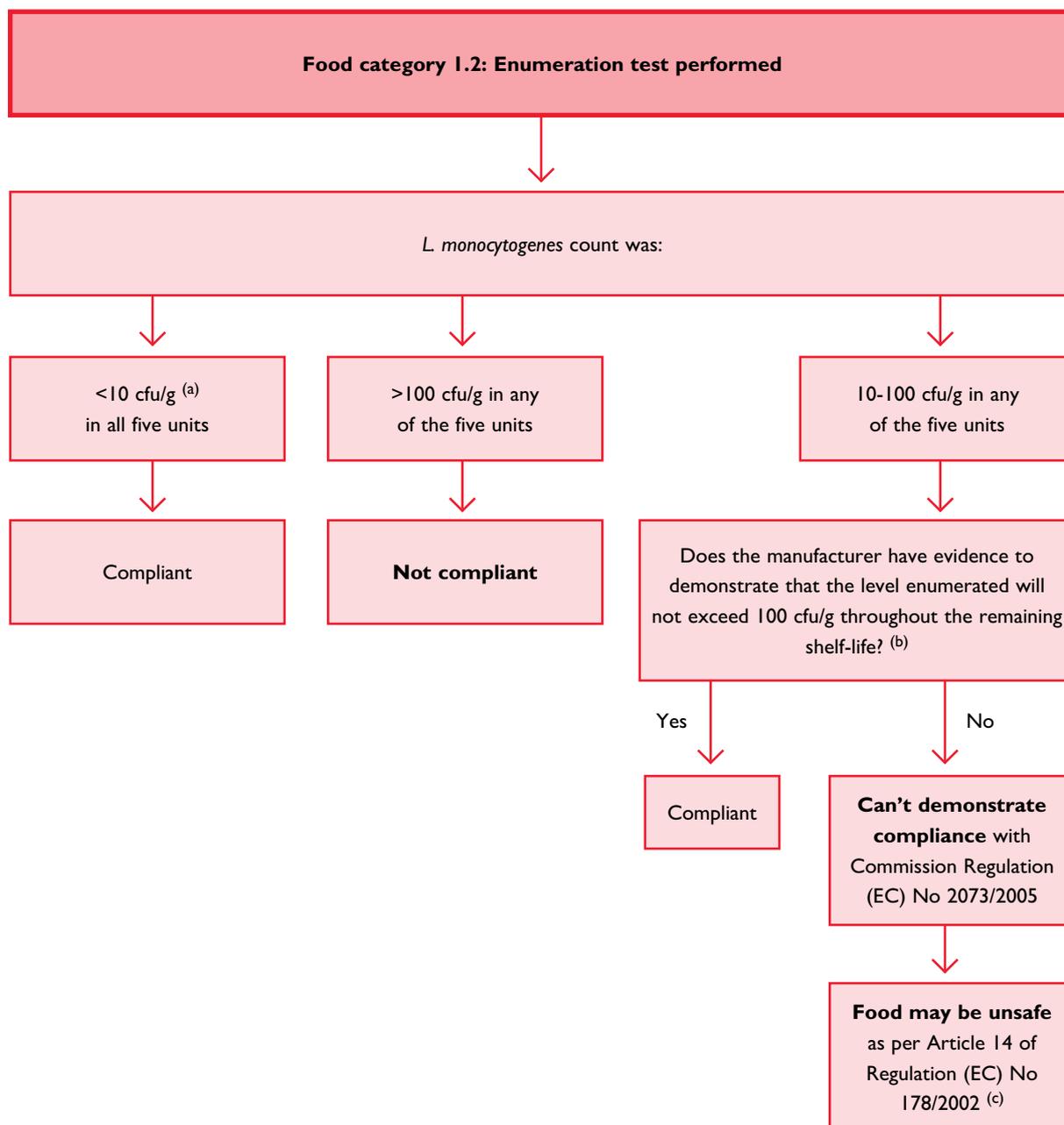


Figure 4: Decision tree for interpreting *L. monocytogenes* enumeration results for foods that fall into food category 1.2

^(a) <10 cfu/g is lowest result that can be reported using the enumeration test. The enumeration test cannot return a result of: 0, 1, 2, 3, 4, 5, 6, 7, 8, or 9 cfu/g. The lowest count it can return is 10 cfu/g (limit of enumeration). A result of <10 cfu/g means the sample is: 1) not contaminated with *L. monocytogenes*, or 2) contaminated with a very low number of *L. monocytogenes* which is below the limit of enumeration

^(b) The types of study which will provide this evidence are referred to in Annex II of the Regulation. See also Question 16 of this Guidance Note

^(c) Competent authorities should conduct a risk assessment – in accordance with FSANZ's *Guidance Note 10 Product Recall and Traceability (Revision 3)* – to determine if the food is unsafe under Article 14 of Regulation (EC) No 178/2002. Information provided by the food business operator should be considered as part of this risk assessment. If it is determined that the batch of food is unsafe, it must be recalled/withdrawn in accordance with Article 19 of Regulation (EC) No 178/2002 (see Question 10).

Interpreting *Salmonella* results

The Regulation sets criteria requiring absence of *Salmonella* (of any serotype) in various different food categories. However, food category 1.28 (fresh poultry meat) only requires absence of *Salmonella* Typhimurium or *Salmonella* Enteritidis.

The Regulation lists EN/ISO 6579 as the reference analytical method to detect *Salmonella*. Except for food category 1.28, biochemical confirmation using the ISO method is sufficient to confirm that a suspect isolate belongs to the genus *Salmonella* and the sample is non-compliant with the criterion (the isolate does not need to be serotyped).

However, if *Salmonella* is detected in a food category 1.28 sample, the isolate must be serotyped according to the White-Kaufmann-Le Minor scheme to determine if it is *S. Typhimurium* or *S. Enteritidis* before the sample can be categorised as compliant or non-compliant with the criterion.

Measurement of uncertainty

At Community level, no implementing measures have been established on how the measurement of uncertainty (MU) should be taken into account when interpreting enumeration results from microbiological analyses of foodstuffs. MU does not apply to absence/presence results.

With respect to food safety criteria (for which unsatisfactory results require a withdrawal/recall for the implicated batch), numerical microbiological results apply to three food categories:

- Food category 1.2 – *L. monocytogenes* limit of 100 cfu/g
- Food category 1.3 – *L. monocytogenes* limit of 100 cfu/g
- Food category 1.25 – *E. coli* limit of 230 MPN/100g

MU linked to microbiological analyses is one of the factors affecting the test result. How the MU should be taken into account when interpreting the test results against the statutory limit is a complex issue. This is particularly the case in microbiological analyses, as the calculation of the MU is not as developed in this sector as in the chemical side and as the MUs in microbiological analyses tend to be high, often of the order of 0.5-1.0 log units.

According to the strategy for setting microbiological criteria for foodstuffs in Community legislation, the general policy is that food business operators should always regard all test results above the limits as unacceptable regardless of the MU involved, whereas in the official controls, the MU could be taken into account in order to be sure beyond reasonable doubt that the batch in question does not comply with the criterion⁴⁰.

⁴⁰ Available at: http://ec.europa.eu/food/food/biosafety/salmonella/discussion_paper_en.pdf

Q10 & II Taking Action on Unsatisfactory Results

Question 10: Has the food business operator received unsatisfactory test results for a food safety criterion?

If the results of testing against a food safety criterion are unsatisfactory, the Regulation specifies the action that the food business operator must take (Figure 5). Enforcement officers should check that the food business operator has:

- Notified the competent authority
- Withdrawn or recalled the implicated product or batch of foodstuffs in accordance with Article 19 of Regulation (EC) No 178/2002
- Taken the corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers
- Taken measures to find the cause of the unsatisfactory results
- Taken measures to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place

Reprocessing the food

If the food is on the market, but not yet at retail level, the Regulation makes provision for it to be reprocessed. This processing may not be carried out by a food business operator at retail level. Enforcement officers should check that the reprocessing:

- Was not carried out by a food business operator at retail level
- Treatment was sufficient to eliminate the hazard in question

Using food for an alternative purpose

The food business operator may use the batch of food for purposes other than those for which it was originally intended. Enforcement officers should check that the:

- Alternative use does not pose a risk for public or animal health
- Food business operators took into account their HACCP-based procedures and good hygiene practice when deciding on this alternative use
- Alternative use was authorised by the competent authority

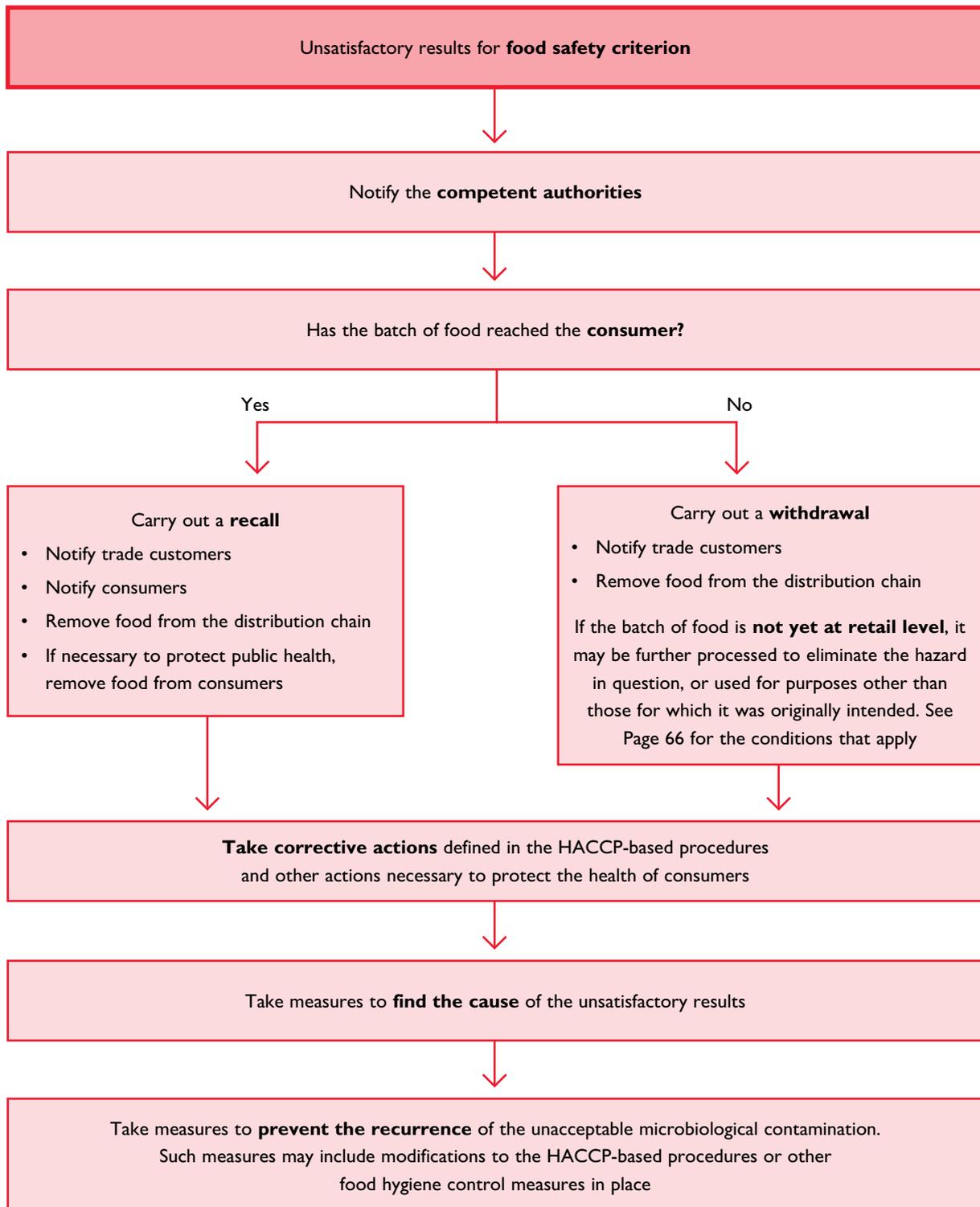


Figure 5: Action required by the food business operator when results are unsatisfactory for a food safety criterion

Question 11: Has the food business operator received unsatisfactory test results for a process hygiene criterion?

If the results of testing against a process hygiene criterion are unsatisfactory, the Regulation specifies the action that the food business operator must take (Figure 6). Enforcement officers should check that the food business operator has taken:

- The actions laid down in Annex I, Chapter 2 – this specifies the action the food business operator should take in case of unsatisfactory results for each process hygiene criterion
- The corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers
- Measures to find the cause of the unsatisfactory results
- Measures to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place

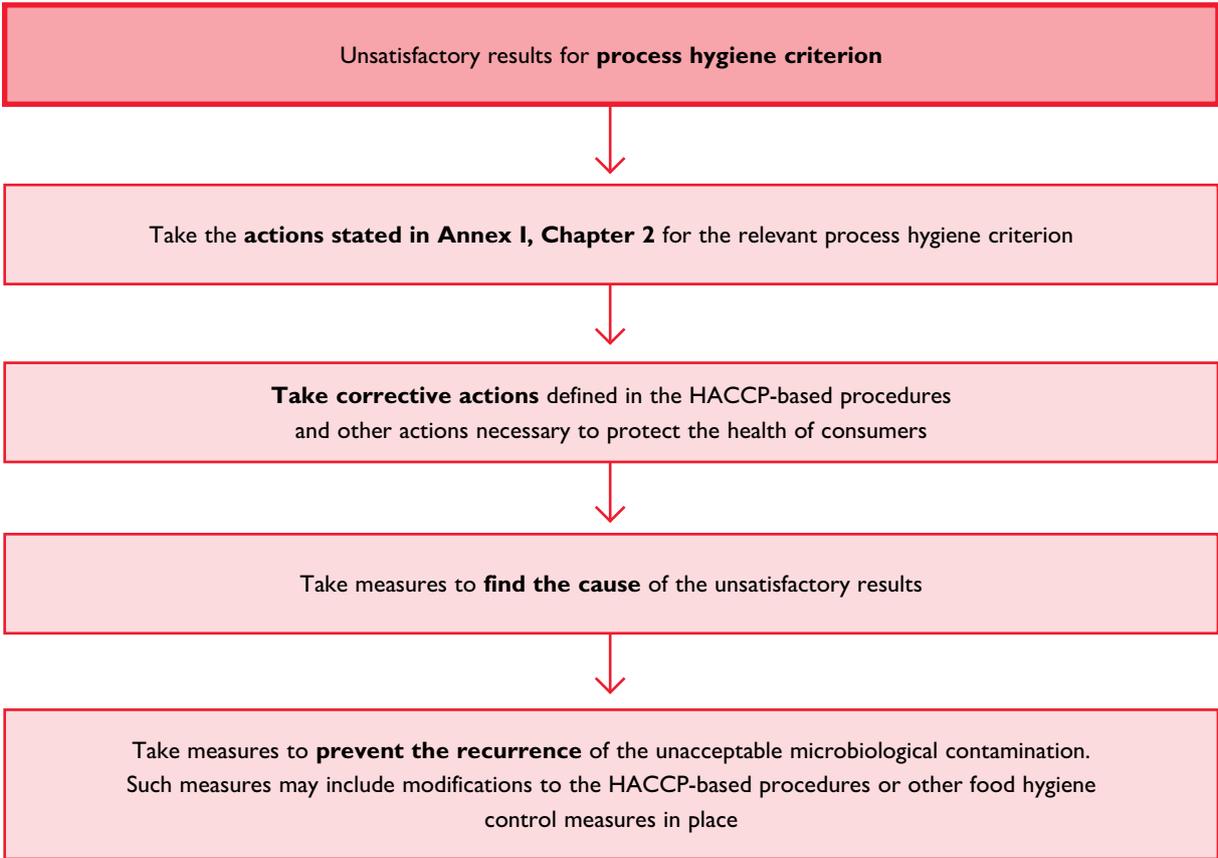


Figure 6: Action required by the food business operator when results are unsatisfactory for a process hygiene criterion

Q12 Analysing Trends in Results

Question 12: Does the food business operator analyse trends in their test results?

Enforcement officers should check that the food business operator:

- Analyses trends in their test results, and
- Takes (will take) timely appropriate actions to remedy the situation, when they observe a trend towards unsatisfactory results in order to prevent microbiological risks occurring

Analysis of trends

The Regulation requires that food business operators analyse trends in their test results (Article 9).

“Food business operators shall analyse trends in the test results. When they observe a trend towards unsatisfactory results, they shall take appropriate actions without undue delay to remedy the situation in order to prevent the occurrence of microbiological risks.”

By analysing trends in the results of food testing, food business operators can gauge if their HACCP-based procedures and good hygiene practice are working effectively. Food business operators can also gauge how their cleaning and sanitising regime is working by analysing trends in the results of any environmental sampling carried out (see Questions 13 and 14). Analysis of trends can also be used as historical evidence to reduce sampling frequencies.

Enumeration results can be analysed by plotting the results on a graph (Figure 7). For enumeration results, analysing trends will highlight if test results are approaching unsatisfactory, so that the food business operator can take action to remedy the situation before the results reach unsatisfactory levels. Food business operators could also set intermediate microbiological limits at which they take action before results become unsatisfactory.

Absence/presence results can be analysed by tabulating the results because it is not easy to represent these types of results on a graph.

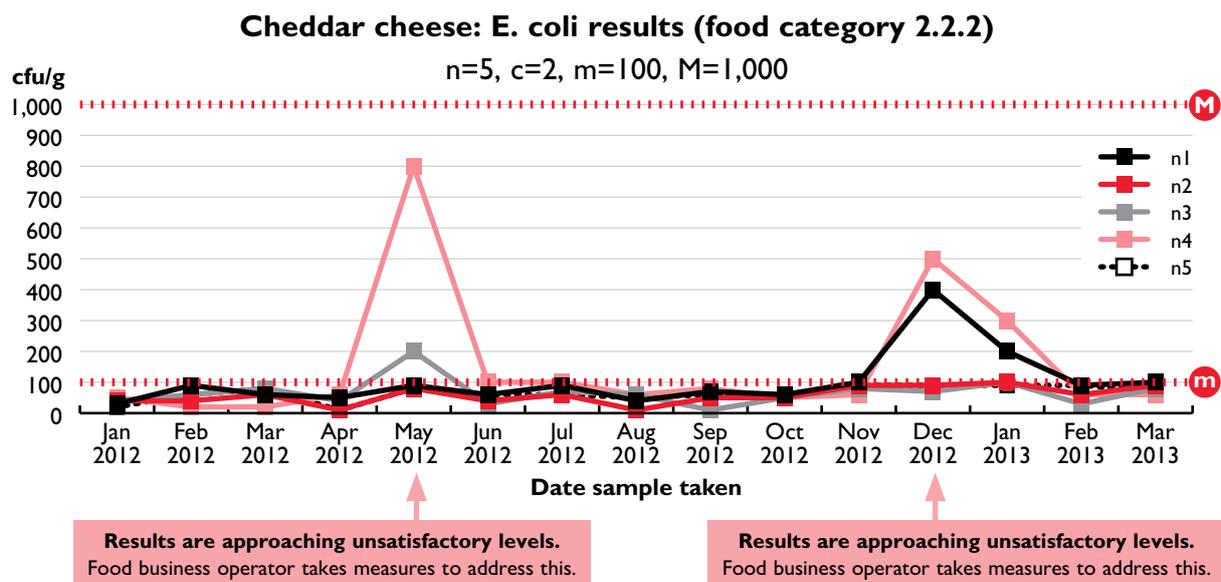


Figure 7: Example of how enumeration results can be plotted on a graph so that it is easier to observe trends. Each time a new test result is received it can be added to the graph

Q13 & 14 Environmental Monitoring

Question 13: Does the food business operator manufacture dried infant formulae or dried foods for special medical purposes intended for infants below six months which pose a *Cronobacter* spp. (*Enterobacter sakazakii*) risk?

If a food business operator manufactures dried infant formulae or dried foods for special medical purpose intended for infants below six months which pose an *Cronobacter* spp. (*Enterobacter sakazakii*)⁴¹ risk, enforcement officers should check that the food business operator:

- Documents their environmental sampling and testing programme (good practice)
- Takes samples of the processing areas and equipment to test for Enterobacteriaceae
- Takes samples of the processing areas and equipment in accordance with ISO standard 18593⁴²
- Takes samples of the processing areas and equipment at an appropriate frequency
- Takes samples of the processing areas and equipment at appropriate sites in the production facility
- Pre-determines and documents the appropriate action to take in the case of unsatisfactory results
- Takes appropriate action in the case of unsatisfactory results
- Monitors trends in their test results

***Enterobacteriaceae* levels**

Enterobacteriaceae is used as an indicator for *Cronobacter* spp. and other pathogens. The Regulation specifies that samples are taken in accordance with ISO standard 18593.

Post-process food contact surfaces should be free of Enterobacteriaceae contamination. Non-food contact surfaces may have varying numbers of Enterobacteriaceae depending on the site sampled and the nature of food manufacturing processes in the plant. Generally, dry plant environments should have fewer than 10³ Enterobacteriaceae per 100 cm². However, each plant should determine the microbiological criteria that best meet the needs of its processes⁴³.

⁴¹ Due to a change in taxonomy, the name of *Enterobacter sakazakii* in Regulation (EC) No 2073/2005 was changed to *Cronobacter* spp. (*Enterobacter sakazakii*). This was amended by Commission Regulation (EU) No 365/2010

⁴² ISO 18593:2004 Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs (available to purchase at: www.iso.org)

⁴³ D.L. Zinc (1995) Enterobacteriaceae and the Food Plant Environment. 3 Messenger Micro, Volume IV. Available at <http://multimedia.3m.com/mws/mediawebsserver?6666660Zjcf6IVs6EVs6666PO2COrrrrQ->

Frequency of environmental monitoring

The Regulation does not state how often a food business operator should take samples from processing areas and equipment used in food production. A generic sampling frequency cannot be specified due to the variability of processing facilities and their practices. Food business operators should determine how often to conduct environmental monitoring based on a risk assessment (see page 46). Sampling frequencies will be specific to each establishment and therefore a generic sampling frequency cannot be specified due to the variability of processing facilities and their practices.

Sampling sites

Food business operators should determine what sites to sample throughout their establishment (from raw material intake to final dispatch) taking into account previous microbiological results from environmental monitoring. Sampling should be focused at sites where contamination is most likely to occur – including both food contact and non-food contact surfaces.

Question 14: Does the food business operator produce, manufacture or package ready-to-eat food which may pose a *L. monocytogenes* risk for public health?

If the food business operator produces, manufactures or packages ready-to-eat food that may pose a *L. monocytogenes* risk for public health, enforcement officers should check that the food business operator:

- Takes samples from processing areas and equipment to test for *L. monocytogenes*
- Documents their environmental sampling and testing programme
- Takes samples from processing areas and equipment according to the EU guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*⁴⁴ i.e.:
 - Takes samples from the appropriate sites in the food processing environment
 - Takes samples at the appropriate time during production
 - Uses the appropriate sampling swab and sampling method
 - Samples a large enough surface area
 - Tests the samples for *L. monocytogenes* using EN ISO 11290-1 or validated alternative method according to Article 5 of the Regulation
- Takes samples from processing areas and equipment at an appropriate frequency
- Pre-determines and documents the appropriate action to take if *L. monocytogenes* is detected
- Takes the appropriate action when *L. monocytogenes* is detected
- Monitors trends in their test results
- Documents their environmental sampling and testing programme

The FSAI's report '**The Control and Management of *Listeria monocytogenes* Contamination of Food**' gives advice on how to conduct an environmental monitoring programme for *L. monocytogenes*, including advice on frequency of sampling, environmental sampling sites, action to take on the detection of *L. monocytogenes* (on food contact and non-food contact surfaces) and investigating the source of contamination.

⁴⁴ Available at www.fsai.ie

Sampling for *L. monocytogenes*

The Regulation specifies the ISO standard 18593⁴⁵ as the reference method for taking samples from food, the processing environment and equipment. However, this standard does not give sufficient guidance specific for *L. monocytogenes* detection so the EU Reference Laboratory for *L. monocytogenes* published guidelines on sampling food processing area and equipment for *Listeria monocytogenes*⁴⁶. While not a legal requirement, it is best practice for food business operators conducting environmental monitoring for *L. monocytogenes* to follow the EU guidelines.

The EU guidelines prescribes best practice on where, how and when wipe sampling should be performed to detect *L. monocytogenes* on surfaces of ready-to-eat food processing areas and equipment. The guidelines specify best practice for the:

1. Choice of sampling locations in the production facility
2. Time at which sampling should be performed during production
3. The sampling method to use (including the type of swab and diluents)
4. The area to be sampled
5. Transport and storage of samples
6. The analytical test method to use, and
7. Expression of results

⁴⁵ ISO 18593:2004 Microbiology of food and animal feeding stuffs – Horizontal methods for sampling techniques from surfaces using contact plates and swabs (available to purchase at www.iso.org)

⁴⁶ Available at www.fsai.ie

Sampling locations

Food business operators should determine what sites to sample throughout their establishment (from raw material intake to final dispatch) taking into account previous microbiological results from environmental monitoring.

The EU's guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes* gives advice on where to take samples when conducting environmental monitoring for *L. monocytogenes*. Sampling should be focused at sites where contamination is most likely to occur – including both food contact and non-food contact surfaces. These include hard to reach places such as holes or crevices in fibrous, porous, rusting and hollow materials and poorly cleanable equipment.

Frequency of environmental monitoring

The Regulation does not state how often a food business operator should take samples from processing areas and equipment used in food production. Neither is sampling frequency specified in the EU guidelines on sampling the food processing area and equipment for the detection of *Listeria monocytogenes*. However, the guidance document does state that sampling should be done frequently in areas where the food product is exposed to contamination, but it may be useful to also sample, less frequently, in areas where it is not (storage areas).

A generic sampling frequency cannot be specified due to the variability of processing facilities and their practices. Food business operators should determine how often to conduct environmental monitoring based on a risk assessment (see page 46). Sampling frequencies will be specific to each establishment and therefore, a generic sampling frequency cannot be specified due to the variability of processing facilities and their practices.

INFORMATION SPECIFIC TO:

Primary producers

Environmental monitoring should be carried out by primary producers that produce:

- Ready-to-eat foods that pose a *L. monocytogenes* risk for public health, or
- Sprouts/sprouted seeds

Ready-to-eat foods (food category 1.3)

For food category 1.3, footnote 4 of Annex I, Chapter I, Food safety criteria, states that regular testing against the criterion (for *L. monocytogenes*) is not required in normal circumstances for fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds. The same logic should be applied to environmental monitoring by food business operators producing ready-to-eat primary produce that falls into food category 1.3.

Sprouts/sprouted seeds

Sprouts/sprouted seeds are a ready-to-eat food which may pose a *L. monocytogenes* risk to public health. Commission Regulation (EU) No 209/2013 (preamble 13) states:

*“Sprouts should be considered to be ready-to-eat food, as they can be consumed without the need for cooking or other processing, which would otherwise be effective in eliminating or reducing to an acceptable level pathogenic micro-organisms. Food business operators producing sprouts should therefore comply with the food safety criteria for ready-to-eat food laid down in Union legislation, **including the sampling of processing areas and equipment** as part of their sampling scheme.”*

Environmental monitoring is not required for producers of canned or jarred sprouts because the production process eliminates the risk of *L. monocytogenes*.

Manufacturers and packers

Environmental monitoring should be carried out by food business operators that produce, manufacture or package ready-to-eat food which may pose a *L. monocytogenes* risk for public health. Food business operators that produce, manufacture or package other types of food may need to carry out environmental monitoring if this is necessary to ensure that the criteria are met.

Wholesalers and distributors

There is no requirement for food business operators that only carry out wholesale or distribution activities to conduct environmental monitoring.

Caterers

The Regulation requires food business operators that manufacture ready-to-eat food which may pose a *L. monocytogenes* risk for public health. In general, caterers that produce, manufacture or package ready-to-eat food do not need to conduct environmental monitoring if the food is consumed immediately, or within two days after production (as this reduces the *L. monocytogenes* risk for public health). However, environmental monitoring should be carried out by caterers that produce, manufacture or package ready-to-eat food which may pose a *L. monocytogenes* risk for public health and which will be consumed more than two days⁴⁷ after production).

Retailers

Food business operators that are involved in retail activities only are not required to conduct environmental monitoring. Likewise, retailers do not need to conduct environmental monitoring if they produce, manufacture or package food that will be eaten immediately, or within two days after production (as this reduces the *L. monocytogenes* risk to health). However, environmental monitoring should be carried out by retailers that produce, manufacture or package ready-to-eat food which may pose a *L. monocytogenes* risk for public health and which will be consumed more than two days⁴⁸ after production).

^{47, 48} Two days is based on the general food safety advice for leftovers where food can be cooked and refrigerated for up to two days. Day of production can be regarded as Day 0. Therefore, if food is produced on a Monday (Day 0), Tuesday is Day 1 after production and Wednesday is Day 2 after production.

Q15 Labelling

Question 15: Does the food business operator comply with the labelling rules set in the Regulation?

If a food business operator manufactures or packages minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked, enforcement officers should check that the food business operator:

- Clearly labels the product to inform the consumer that the product must be thoroughly cooked before consumption

The Regulation (Article 6) requires that minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked, must be clearly labelled to inform the consumer of the need for thorough cooking before eating. This labelling requirement does not apply to:

- a. Minced meat or meat preparations made from poultry meat⁴⁹, or
- b. Minced meat or meat preparations (from any species) intended to be eaten raw

Instead, the Regulation sets stricter microbiological criteria for these two food types.

Pre-packaged products

For pre-packaged products supplied by a manufacturer or packer to another food business, information on the need to cook thoroughly can be provided on commercial documentation supplied along with the food and not actually on the label. This is because Council Directive 2000/13/EC allows for conditions of use to be provided on the commercial documentation.

Products sold loose

For food sold loose, the FSAI recommends that when selling to the final consumer, information on the need to cook thoroughly is provided:

- a. On a notice near the point-of-sale
- b. On the label printed by the weighing scales, or
- c. In any other manner in which the food business operator can clearly communicate the required information to the consumer

⁴⁹ Although the labelling requirement in the Regulation does not apply to minced poultry, poultry preparations and poultry products intended to be eaten cooked, the FSAI recommends that these products are also labelled with the instruction to cook thoroughly before consumption.

INFORMATION SPECIFIC TO:

Primary producers

The Regulation does not set any labelling requirements for primary producers.

Manufacturers and packers

Enforcement officers should check that food business operators that manufacture or pack minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked:

- Clearly label the product to inform the consumer that the product must be thoroughly cooked before consumption

Wholesalers and distributors

The Regulation does not set any labelling requirements for food business operators that only carry out wholesale and distribution activities.

Caterers

The Regulation does not set any labelling requirements for caterers. However, enforcement officers should check that:

- Caterers follow the cooking instructions set by the manufacturer on the label or in the accompanying documentation (where provided)

Retailers

Enforcement officers should check that retail butchers that manufacture or pack minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked:

- Clearly label the product to inform the consumer that the product must be thoroughly cooked before consumption. This information can be:
 - Printed on pre-packaged products
 - On a notice near to the point-of-sale
 - On the label printed by the weighing scales, or
 - In any other manner in which the food business operator can clearly communicate the required information to the consumer

Enforcement officers should check that retailers (including butchers) that buy in ready-prepared minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked:

- Ensure that the products are clearly labelled to inform the consumer that the product should be cooked thoroughly before consumption. This information can be:
 - Printed on pre-packaged products
 - On a notice near to the point-of-sale
 - On the label printed by the weight scales, or
 - In any other manner in which the food business operator can clearly communicate the required information to the consumer

Q16 Demonstrating Compliance with Criteria throughout the Shelf-life

Question 16: Can the food business operator demonstrate that the food they produce, manufacture or package complies with the relevant criteria throughout its shelf-life?

If a food business operator produces, manufactures or packages food for which there are relevant criteria in the Regulation, enforcement officers should check that the food business operator can:

- Demonstrate that the food they produce, manufacture or package complies with the relevant criteria throughout its shelf-life

The food safety criteria relevant to a food must be met throughout its shelf-life under reasonable foreseeable conditions of distribution, storage and use (Article 3). As necessary, food business operators that manufacture the product must conduct studies to investigate compliance with the relevant criteria throughout the shelf-life. The types of studies referred to are listed in Annex II of the Regulation.

In order to investigate compliance with the relevant criteria, food business operators may have (as necessary):

- Determined the physico-chemical characteristics of their product (such as pH, water activity, salt content, concentration of preservatives and type of packaging) taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life
- Consulted available scientific literature and research data regarding the growth and survival characteristics of the microorganisms of concern
- Conducted predictive mathematical modelling established for the food in question, using critical growth or survival factors for the microorganisms of concern in the product
- Carried out tests, i.e. challenge studies, to investigate the ability of appropriately inoculated microorganisms of concern to grow or survive in the product under different reasonably foreseeable storage conditions
- Carried out durability studies to evaluate the growth or survival of the microorganism of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use

Food business operators may collaborate in conducting these studies.

FSAI Guidance Note No.18

The FSAI *Guidance Note No.18: Validation of Product Shelf-life (Revision 1)*, outlines best practice for the validation of product shelf-life and is applicable to all food business operators manufacturing or packaging food products which require a 'use-by' date.

L. monocytogenes and shelf-life

Although the requirement to demonstrate compliance with the relevant criteria throughout the shelf-life applies to all foods for which food safety criteria are set in the Regulation, it is particularly relevant to ready-to-eat foods that are able to support the growth of *L. monocytogenes* and that may pose a *L. monocytogenes* health risk for public health. This is because *L. monocytogenes* can grow at refrigeration temperatures.

The European Commission has issued guidance documents on shelf-life studies in relation to *L. monocytogenes*, both are available at www.fsai.ie.

Guidance for food business operators

Title: *Guidance document on Listeria monocytogenes shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs*

Aim: To help food business operators:

- Demonstrate to the satisfaction of the competent authority that their products will comply with the Regulation until the end of the shelf-life
- Understand the range of different approaches available to help establish a safe product shelf-life in relation to *L. monocytogenes*
- Decide the appropriate approach for shelf-life testing for their products
- Classify their products into ready-to-eat foods in which *L. monocytogenes* can or can't grow during their shelf-life

Guidance for laboratories

Title: *Technical guidance document for conducting shelf-life studies on Listeria monocytogenes in ready-to-eat foods*

Aim: To provide recommendations to laboratories on how to select, implement and perform the tests required, e.g. challenge test, durability studies etc.

9. TAKING OFFICIAL SAMPLES TO CHECK COMPLIANCE WITH THE CRITERIA

Although food business operators are responsible for ensuring that their products meet the criteria set in the Regulation, in some cases enforcement officers may wish (will need⁵⁰) to take samples of food to check compliance with the relevant criteria. Official sampling must be undertaken in accordance with the European Commission guidance document on official controls under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs⁵¹ and Regulation 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

The aim of the Commission's guidance document on official controls is to give guidance on:

- Official sampling
- Requirements of official laboratories
- Analysis methods to be used for official samples, and
- Microbiological criteria applied to official samples

9.1 Official Sampling versus a Food Business Operator's Sampling

Official sampling should not replace sampling which should have been undertaken by the food business operator. If official sampling and testing is carried out, it is best practice for the enforcement officer to provide the food business operator with a copy of the laboratory certificate for their records. At the very least, copies of the laboratory certificate, along with an accompanying report, should be provided to the food business operator in the case of a non-compliance (Article 9 of Regulation 882/2004).

9.2 Inform the Food Business Operator that Official Samples are being taken

The competent authority must establish a procedure which ensures that, during the official sampling, the food business operator or his representative is always aware of his right to obtain samples for a supplementary expert opinion. This right of the food business operator should always be respected. The decision taken by the food business operator should be recorded in the sampling report.

The competent authority should inform the food business operator about the limitations of supplementary sampling for microbiological analysis, e.g. the results may be of limited value as the distribution of microorganisms within a sample is often heterogeneous and thus it is not uncommon for results to differ (Section 9.2 of European Commission Guidance Document on official controls under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs).

⁵⁰ Regulation (EC) No 854/2004 (as amended) requires that, with respect to fishery products (food categories 1.26, 1.27 and 1.27a) random testing for histamine should be carried out to verify compliance with the permitted levels laid down under Community legislation and that, with respect to pig carcasses, official sampling is carried out in addition to food business operators' in order to verify food business operators' correct implementation of the process hygiene criterion for *Salmonella* on pig carcasses (food category 2.1.4)

⁵¹ Available at www.fsai.ie

9.3 Sampling Frequency

Except for pig carcasses⁵², no fixed sampling and testing frequency has been set for official controls in the Community legislation. The need for official sampling and testing should be assessed when competent authorities are planning their sampling strategy and aim of sampling in the context of their multi-annual national control plans according to Article 41 of Regulation (EC) No 882/2004.

9.4 Risk-based Approach

Regulation (EC) No 882/2004 requires that official controls to verify compliance with food law, are carried out regularly, on a risk basis with appropriate frequency. Documented procedures must be put in place for official controls, to ensure that they controls are carried out uniformly and are of a consistently high quality. Microbiological sampling and testing for official control purposes, must also be carried out using a documented, risk-based approach.

9.5 Sampling Plans/Sample Numbers

Official samples must be taken in accordance with the sampling plans specified in Annex I of Regulation (EC) No 2073/2005, for example $n=1$ ⁵³, $n=5$, $n=9$, $n=30$, $n=50$. However, at retail level, single samples are permitted if the sampling is being conducted for monitoring/surveillance purposes. This is because it may not always be possible to obtain sufficient number of samples from the same batch of food.

Monitoring is the performance of routine microbiological analysis aimed at detecting microbiological contamination of foodstuffs from which useful prevalence data may emerge.

Surveillance is the performance of routine microbiological analysis aimed at detecting microbiological contamination of foodstuffs for the purpose of applying appropriate control measures. Such control measures are normally determined in advance by the competent authority. One of the main objectives of surveillance is to follow-up unsatisfactory results with an investigation and possible enforcement action.

⁵² Regulation (EC) No 854/2004 as amended by Commission Regulation (EC) No 218/2014 (Article 2)

⁵³ $n=1$ for food category 1.27a (Fish sauce produced by fermentation of fishery products) because fish sauce is a liquid product in which histamine is expected to be evenly distributed. The Regulation also states that single samples may be taken at retail level for food categories 1.26 (Fishery products from fish species associated with a high amount of histidine) and 1.27 (Fishery products, except those in food category 1.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine)

To avoid excessive waste, official samples from large food items, e.g. whole legs of ham, whole wheels of cheese, 5kg bags of chopped ready-to-eat vegetables, whole tuna etc., the required number of sample units specified in the criterion's sampling plan may be taken from that one food item. Enforcement officers should record that samples have been taken in this manner on the sample submission form.

9.6 Transport of Samples to the Laboratory, Storage and Starting the Analysis

Standardised procedures for the transport of samples to the laboratory, the storage and the starting of the analysis are presented in ISO/DIS 7218: Microbiology of food and animal feeding stuffs – general rules for microbiological examinations.

ISO/DIS 7218 does not set a maximum time limit for transporting foods that are not stable at ambient temperature to the laboratory. However, given the potential for change in the levels of the target organisms, it is recommended that this type of sample should arrive at the laboratory within 36 hours after sampling. According to the above-mentioned ISO/DIS document, the microbiological analysis should be started as soon as possible upon receipt at laboratory, preferably within 24 hours. It is recommended that analysis is started, as a rule, within 48 hours of taking the sample, unless the testing protocol specifically states otherwise.

For highly perishable fresh, refrigerated products, the following additional guidance is given:

- During transport and storage, freezing temperatures must be avoided
- Pre-packed food should be stored at or below the storage temperature given on the label
- In case of examination at a later stage, e.g. for checking compliance of a pre-packed food at end of shelf-life, the samples should be stored at the laboratory under the recommended conditions given on the label

9.7 Laboratory and Test Methods

Testing should be carried out in official laboratories only. Official laboratories should be accredited in accordance with EN ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories'.

When testing foodstuffs against the criteria, official laboratories should use the most recent version of the analytical reference method specified in the Regulation, e.g. when testing pre-cut fruit and vegetables for *Salmonella*, the most recent version of ISO 6579 should be used.

Official laboratories may use alternative analytical methods to the reference method specified in the Regulation, provided that the alternative method is validated/certified according to the rules set down in Article 5 of the Regulation (see Question 8).

9.8 Appropriate Testing (testing against the food safety or process hygiene criteria?)

The point of the food chain specified for each criterion in the Regulation is also applicable to limits of results of official controls, e.g. the limits set for a process hygiene criterion should not be applied to food sampled at retail level.

Food safety criteria: Where foods are placed on the market (this includes imported food) testing should be conducted to assess compliance with the relevant food safety criteria.

Process hygiene criteria: Foodstuffs sampled during, or at the end of manufacturing, should be tested against the relevant process hygiene criteria.

Note that '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). Thus, foodstuffs ready for distribution from a processing/manufacturing establishment can also be tested against the food safety criteria.

Foods placed on the market should not be tested against process hygiene criteria.

9.9 Interpretation of Results

Results should be interpreted as outlined in Chapter 1 and Chapter 2, Annex I of the Regulation (see Question 9).

Note: According to the strategy for setting microbiological criteria for foodstuffs⁵⁴ in Community legislation, measurement of uncertainty (MU) could be taken into account in order to be sure beyond reasonable doubt that the batch in question does not comply with the criterion.

9.10 Action to be taken in the Case of Unsatisfactory Results

If the test results of official samples are unsatisfactory, enforcement officers should take the action outlined below.

⁵⁴ Available at: http://ec.europa.eu/food/food/biosafety/salmonella/discussion_paper_en.pdf

9.10.1 Results unsatisfactory for a food safety criterion:

- Notify the FSAI of the result. If necessary, the FSAI will immediately notify the Commission under the rapid alert system for food and feed (RASFF)
- Notify the food business operator of the result
- Ensure the food business operator takes the necessary corrective action (see Question 10)

9.10.2 Results unsatisfactory for a process hygiene criterion:

- Notify the food business operator of the result (it is not necessary to notify the FSAI)
- Ensure the food business operator takes the necessary corrective action (see Question 11)

APPENDIX I. FOOD CATEGORIES LISTED IN THE REGULATION WITH EXAMPLES OF FOOD

Food Category		Examples of Food	Further Information
I.1	Ready-to-eat foods intended for infants and ready-to-eat foods for special medical purposes	<ul style="list-style-type: none"> • Infant formula • Follow-on formula • Weaning foods • Energy dense tube feeds • Powdered, high protein supplement for hypoproteinaemia patients • Highly fortified milk-based drinks for specialised use, e.g. to treat malnutrition. 	<p>Footnote 4 in Annex I, Chapter I of the Regulation: Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods:</p> <ul style="list-style-type: none"> • Those which have received heat treatment or other processing effective to eliminate <i>L. monocytogenes</i>, when recontamination is not possible after this treatment, e.g. products heat treated in their final package • Fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds • Bread, biscuits and similar products • Bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products • Sugar, honey and confectionery, including cocoa and chocolate products • Live bivalve molluscs • Food grade salt
I.2	Ready-to-eat foods able to support the growth of <i>L. monocytogenes</i> , other than those intended for infants and for special medical purposes	By default, ready-to-eat food that does not fall into food category I.1 or I.3.	

Food Category	Examples of Food	Further Information
<p>1.3 Ready-to-eat foods unable to support the growth of <i>L. monocytogenes</i>, other than those intended for infants and for special medical purposes</p>	<p>Ready-to-eat food with:</p> <ul style="list-style-type: none"> • Shelf-life less than 5 days • pH ≤4.4 • Water activity ≤0.92 • pH ≤5.0 combined with water activity ≤0.94 • Frozen food (during the period that they remain frozen) • Foods with a growth potential ≤0.5 Log₁₀ cfu/g • Other foods based on scientific justification <p>Some examples:</p> <ul style="list-style-type: none"> • Ice-cream • Milk powders • Some cheeses • Some yoghurts 	<p>Other foods may be considered unable to support the growth of <i>L. monocytogenes</i> subject to scientific justification (Footnote 8 in Annex I, Chapter I of the Regulation).</p> <p>Footnote 4 in Annex I, Chapter I of the Regulation: Regular testing against the criterion is not required in normal circumstances for the following ready-to-eat foods:</p> <ul style="list-style-type: none"> • Those which have received heat treatment or other processing effective to eliminate <i>L. monocytogenes</i>, when recontamination is not possible after this treatment, e.g. products heat treated in their final package • Fresh, uncut and unprocessed vegetables and fruits, excluding sprouted seeds • Bread, biscuits and similar products • Bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products • Sugar, honey and confectionery, including cocoa and chocolate products • Live bivalve molluscs • Food grade salt

Food Category		Examples of Food	Further Information
1.4	Minced meat and meat preparations intended to be eaten raw	<ul style="list-style-type: none"> • Steak tartare • Carpaccio 	According to Regulation (EC) No 853/2004: 'Minced meat' means boned meat that has been minced into fragments and contains less than 1% salt. 'Meat preparations' means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.
1.5	Minced meat and meat preparations made from poultry meat intended to be eaten cooked	<ul style="list-style-type: none"> • Raw turkey mince • Raw turkey burgers • Raw chicken sausages • Raw chicken stir-fry • Raw duck breasts in Chinese-style sauce • Raw Cajun-spiced chicken pieces • Raw stuffed chicken breasts • Flash-fried chicken which remains raw in the centre • Marinated fresh poultry that has not been marinated completely through to the centre 	
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	<ul style="list-style-type: none"> • Raw lamb mince • Raw beef burgers • Raw pork sausages • Raw beef stir-fry • Raw lamb chops in Greek-style sauce • Raw stuffed pork loin • Flash-fried meat which remains raw in the centre • Marinated fresh meat that has not been marinated completely through to the centre 	Labelling requirement (Article 6) applies. See Q15.

Food Category		Examples of Food	Further Information
I.7	Mechanically separated meat (MSM)	<ul style="list-style-type: none"> • Mechanically separated meat 	According to Regulation (EC) No 853/2004, 'Mechanically separated meat' or 'MSM' means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.
I.8	Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the <i>Salmonella</i> risk	<ul style="list-style-type: none"> • Air-dried smoked duck • Partially fermented sausages • Parma ham • Chorizo • Salami 	According to Regulation (EC) No 853/2004, 'Meat products' means processed products resulting from the processing of meat or from the further processing of such processed products, so that the cut surface shows that the product no longer has the characteristics of fresh meat.
I.9	Meat products made from poultry meat intended to be eaten cooked	<ul style="list-style-type: none"> • Breaded chicken fillets that have been completely cooked through to the centre (but require further cooking) • Fresh poultry meat marinated completely through to the centre (but requires further cooking) 	
I.10	Gelatine and collagen	See food category description	
I.11	Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	See food category description	The criterion does not apply to cheese, butter and cream for which the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and water activity of the product where appropriate, there is no <i>Salmonella</i> risk (see footnote 10 of Annex I, Chapter I of the Regulation).
I.12	Milk powder and whey powder	See food category description	

Food Category		Examples of Food	Further Information
I.13	Ice-cream, excluding products where the manufacturing process or the composition of the product will eliminate the <i>Salmonella</i> risk	See food category description	The criterion only applies to ice cream that contains milk ingredients (see footnote 11 of Annex I, Chapter I of the Regulation).
I.14	Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the <i>Salmonella</i> risk	See food category description	<p>According to Regulation (EC) No 853/2004, 'Egg products' means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.</p> <p>This criterion applies to the processed egg only, and does not apply to foods that use egg as an ingredient, e.g. omelettes, chocolate mousse, meringues, egg mayonnaise sandwiches etc. Some of these types of food may fall into food category I.15.</p> <p>Eggs produced under the Bord Bia quality assurance scheme (or other similar schemes) do not eliminate the <i>Salmonella</i> risk.</p>
I.15	Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the <i>Salmonella</i> risk	<ul style="list-style-type: none"> • Ice-cream containing raw egg • Tiramisu containing raw egg • Chocolate mousse containing raw egg • Icing containing raw egg • Mayonnaise containing raw egg 	Eggs produced under the Bord Bia quality assurance scheme (or other similar schemes) do not eliminate the <i>Salmonella</i> risk.

Food Category		Examples of Food	Further Information
1.16	Cooked crustaceans and molluscan shellfish	<ul style="list-style-type: none"> • Cooked crab • Cooked lobster • Cooked crayfish • Cooked shrimp • Cooked prawns • Cooked mussels • Cooked oysters • Cooked clams • Cooked scallops • Cooked barnacles • Cooked whelks 	
1.17	Live bivalve molluscs and live echinoderms, tunicates and gastropods	<ul style="list-style-type: none"> • Live oysters • Live clams • Live scallops • Live mussels • Live edible sea urchins • Live sea cucumbers • Live snails • Live whelk • Live limpets 	
1.18	Sprouted seeds (ready-to-eat)	<ul style="list-style-type: none"> • Sunflower • Pea 	<p>Sprouted seeds are obtained from the germination of seeds and usually involve a pre-soaking germination stage. They are usually grown in growing rooms, rather than conventional environments. True leaves may be produced.</p> <p>Sprouts (food category 1.29) are a subset of 'sprouted seeds'. For sprouts, the seed is consumed and true leaves are not produced, i.e. only cotyledons/seed leaves are present.</p>

Food Category		Examples of Food	Further Information
I.19	Pre-cut fruit and vegetables (ready-to-eat)	<ul style="list-style-type: none"> • Sliced apple • Chopped melon • Halved cucumber • Shredded lettuce • Diced onion • Shredded cabbage 	This criterion does not apply to whole, un-cut fruit and vegetables, e.g. whole lettuce, whole apples, whole melons, herbs growing in pots. This criterion does not apply to non-ready-to eat products.
I.20	Unpasteurised fruit and vegetable juices (ready-to-eat)	<ul style="list-style-type: none"> • Unpasteurised fruit juice • Unpasteurised vegetable juice • Unpasteurised smoothies 	This criterion does not apply to non-ready-to eat products or to pasteurised products.
I.21	Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Applies to cheeses described in food categories: 2.2.3 2.2.4 2.2.5	
I.22	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	See food category description	
I.23	Dried follow-on formulae	See food category description	
I.24	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	See food category description	

Food Category		Examples of Food	Further Information
I.25	Live bivalve molluscs and live echinoderms, tunicates and gastropods	<ul style="list-style-type: none"> • Live oysters • Live clams • Live scallops • Live mussels • Live edible sea urchins • Live sea cucumbers • Live snails • Live whelk • Live limpets 	
I.26	Fishery products from fish species associated with a high amount of histidine	Particularly fish species of the family: <ul style="list-style-type: none"> • <i>Scombridae</i> (tunas, albacore, bonitos, mackerels, seerfishes and wahoo) 	
I.27	Fishery products, except those in food category I.27a, which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine	<ul style="list-style-type: none"> • <i>Clupeidae</i> (herrings, sardines, menhadens, pilchards and shads) • <i>Engraulidae</i> (anchovies) • <i>Coryfenidae</i> (dolphin fish) • <i>Pomatomidae</i> (blue fish) • <i>Scombresosidae</i> (Billfish, King Gars, Saury) 	
I.27a	Fish sauce produced by fermentation of fishery products	See food category description	
I.28	Fresh poultry meat	Fresh meat from: <ul style="list-style-type: none"> • Breeding flocks of <i>Gallus gallus</i> • Laying hens • Broilers, and • Breeding and fattening flocks of turkeys 	The criterion does not apply to other poultry such as duck, or fresh meat from other birds, such as: goose, quail, ostrich, pheasant, pigeon.

Food Category		Examples of Food	Further Information
1.29	Sprouts	<ul style="list-style-type: none"> • Alfalfa • Fenugreek • Bean sprouts 	<p>Sprouts are defined in legislation (Commission Implementing Regulation (EU) No 208/2013) as products obtained from the germination of seeds and their development in water or another medium, harvested before the development of true leaves and which is intended to be eaten whole, including the seed.</p> <p>Sprouts are a subset of 'sprouted seeds' (see food category 1.18). For sprouts, the seed is consumed and true leaves are not produced, i.e. only cotyledons/seed leaves are present.</p>
2.1.1	Carcases of cattle, sheep, goats and horses	See food category description	
2.1.2	Carcases of pigs	See food category description	
2.1.3	Carcases of cattle, sheep, goats and horses	See food category description	
2.1.4	Carcases of pigs	See food category description	
2.1.5	Poultry carcasses of broilers and turkeys	See food category description	
2.1.6	Minced meat	<ul style="list-style-type: none"> • Raw minced beef • Raw minced turkey • Raw minced pork • Raw minced chicken • Raw minced lamb 	According to Regulation (EC) No 853/2004 'Minced meat' means boned meat that has been minced into fragments and contains less than 1% salt.
2.1.7	Mechanically separated meat (MSM)	• Mechanically separated meat	According to Regulation (EC) No 853/2004, 'Mechanically separated meat' or 'MSM' means the product obtained by removing meat from flesh-bearing bones after boning or from poultry carcasses, using mechanical means resulting in the loss or modification of the muscle fibre structure.

Food Category		Examples of Food	Further Information
2.1.8	Meat preparations	<ul style="list-style-type: none"> • Steak tartare • Carpaccio • Raw minced meat • Raw beef burgers • Raw chicken stir-fry • Raw Cajun-spiced chicken pieces • Raw stuffed pork loin • Flash-fried meat which remains raw in the centre • Marinated fresh meat that has not been marinated completely through to the centre 	According to Regulation (EC) No 853/2004, 'Meat preparations' means fresh meat, including meat that has been reduced to fragments, which has had foodstuffs, seasonings or additives added to it or which has undergone processes insufficient to modify the internal muscle fibre structure of the meat and thus to eliminate the characteristics of fresh meat.
2.2.1	Pasteurised milk and other pasteurised liquid dairy products	See food category description	The criterion does not apply to products intended for further processing in the food industry.
2.2.2	Cheeses made from milk or whey that has undergone heat treatment	See food category description	
2.2.3	Cheeses made from raw milk	See food category description	
2.2.4	Cheeses made from milk that has undergone a lower heat treatment than pasteurisation and ripened cheeses made from milk or whey that has undergone pasteurisation or a stronger heat treatment	See food category description	The criterion does not apply to cheeses for which the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.
2.2.5	Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment	See food category description	The criterion does not apply to cheeses for which the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.

Food Category		Examples of Food	Further Information
2.2.6	Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	See food category description	
2.2.7	Milk powder and whey powder	Milk powder and whey powder that is not intended for further processing in the food industry	The criterion does not apply to products intended for further processing in the food industry.
2.2.8	Ice-cream and frozen dairy desserts	Ice-cream and frozen dairy desserts that contain milk ingredients	The criterion does not apply to ice-cream or frozen desserts that do not contain milk ingredients.
2.2.9	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	See food category description	
2.2.10	Dried follow-on formulae	See food category description	
2.2.11	Dried infant formulae and dried dietary foods for special medical purposes intended for infants below six months of age	See food category description	
2.3.1	Egg products	<ul style="list-style-type: none"> • Hard boiled eggs • Pasteurised liquid eggs • Pasteurised dried egg • Pasteurised egg white • Whole pickled eggs • Eggs in brine 	<p>According to Regulation (EC) No 853/2004, 'Egg products' means processed products resulting from the processing of eggs, or of various components or mixtures of eggs, or from the further processing of such processed products.</p> <p>This criterion applies to the processed egg only, and does not apply to foods that use egg as an ingredient, e.g. omelettes, chocolate mousse, meringues, egg mayonnaise sandwiches etc.</p>

Food Category		Examples of Food	Further Information
2.4.4	Shelled and shucked products of cooked crustaceans and molluscan shellfish	Shelled and shucked: <ul style="list-style-type: none"> • Cooked crab • Cooked lobster • Cooked crayfish • Cooked shrimp • Cooked prawns • Cooked mussels • Cooked oysters • Cooked clams • Cooked scallops • Cooked barnacles 	The criterion does not apply to cooked products still in their shell.
2.5.1	Pre-cut fruit and vegetables (ready-to-eat)	<ul style="list-style-type: none"> • Sliced apple • Chopped melon • Halved cucumber • Shredded lettuce • Diced onion • Shredded cabbage 	This criterion does not apply to whole, un-cut fruit and vegetables, e.g. whole lettuce, whole apples, whole melons, herbs growing in pots. This criterion does not apply to non-ready-to eat products.
2.5.2	Unpasteurised fruit and vegetable juices (ready-to-eat)	<ul style="list-style-type: none"> • Unpasteurised fruit juice • Unpasteurised vegetable juice • Unpasteurised smoothies 	This criterion does not apply to non-ready-to eat products or to pasteurised products.

APPENDIX 2. OTHER LEGAL MICROBIOLOGICAL STANDARDS

Outside of the Regulation, other legal microbiological standards have been set in legislation. Table 5 lists legal microbiological criteria for drinking water and raw milk.

Table 5: Other Legal Microbiological Criteria for Food/Water^(a)

Type of Food	European Legislation	Irish Legislation
Raw milk	Regulation (EC) No 853/2004	S.I. No. 432 of 2009 (as amended)
Drinking water Spring water 'Other' water (bottled)	Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption	S.I. No. 122 of 2014, S.I. No. 225 of 2007 (as amended)
Natural mineral water	Directive 2009/54/EC of the European parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters	S.I. No. 225 of 2007 (as amended)

^(a) List does not take into account amendments made or new legislation introduced after 9 May 2014

In addition, Commission Regulation (EC) No 669/2009 (as amended) requires increased level of official controls (including laboratory analysis) on imports of certain feed and food of non-animal origin. Regulation (EC) No 854/2004 (as amended) lays down microbiological criteria which competent authorities use to classify live bivalve mollusc production and relaying areas.

APPENDIX 3.MICROBIOLOGICAL GUIDELINES

Mandatory microbiological criteria are set in legislation, but not all combinations of food and microorganism are covered. Guideline microbiological criteria have been published which provide guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. These guidelines can be used if legal microbiological criteria are not set for a particular combination of food and microorganism.

Commonly used microbiological guidelines include:

1. Guidance Note 3: Guidelines for the Interpretation of Results of Microbiological Analysis of Some Ready-to-Eat Foods Sampled at Point-of-Sale (FSAI, 2014)
2. Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods (Health Protection Agency, 2009)⁵⁵
3. Microorganisms in Foods 8: Use of Data for Assessing Process Control and Product Acceptance (International Commission on Microbiological Specifications for Foods, 2011)⁵⁶

Food businesses may also set microbiological specifications which suppliers must meet as part of purchase agreements.

Action required when Results of Testing against Guideline Criteria are Unsatisfactory

In the absence of legal microbiological criteria, the microbiological acceptability of food can be assessed against guideline microbiological criteria. The action required when unsatisfactory results are obtained after testing against guideline criteria depends on the microorganism and type of food tested. For example, the presence of a pathogen in a ready-to-eat food usually means that the food does not meet food safety requirements (Article 14, Regulation 178/2002) and must be withdrawn/recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, unsatisfactory results when testing for hygiene indicators (such as aerobic colony counts or Enterobacteriaceae) do not necessarily mean the food is unsafe to eat. While a withdrawal or recall of the food is may not be required, food business operators need to investigate the cause and take corrective action to prevent unsatisfactory results from reoccurring.

⁵⁵ Available at www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1259151921557

⁵⁶ Available to purchase at www.icmsf.org/publications/books.html

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Food Safety Authority of Ireland
Abbey Court, Lower Abbey Street,
Dublin 1

Údarás Sábháilteachta Bia na hÉireann
Cúirt na Mainistreach, Sráid na Mainistreach Íocht.,
Baile Átha Cliath 1

Tel: +353 1 817 1300

Fax: +353 1 817 1301

Email: info@fsai.ie

Website: www.fsai.ie

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