Guidance on the Practical Implementation of the EC Regulation on Microbiological Criteria for Foodstuffs

BRITISH RETAIL CONSORTIUM

CFA
CHILLED FOOD ASSOCIATION

EDITION 1.2
6 DECEMBER 2006

Published by Chilled Food Association Ltd, P.O. Box 6434, Kettering, NN15 5XT, UK

Typeset in Arial 10

ISBN-13 978-1-901798-13-5
ISBN-10 1-901798-13-5

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FOREWORD

This guidance is intended to help food business operators (manufacturers and retailers) to understand the requirements of the Commission Regulation on Microbiological Criteria for Foodstuffs ('the Regulation'), providing additional detail to that given in the Food Standards Agency's own guidance documents.

The purpose of the Regulation is to protect public health and provide harmonised reference points for Food Business Operators (FBOs). It relates to the General Food Law (178/2002/EC) that obliges FBOs to withdraw or recall unsafe food from the market. It states that safety is ensured by a preventative approach such as employing good hygiene practices and use of Hazard Analysis and Critical Control Point (HACCP) principles. This guidance assumes FBOs have working knowledge of this approach.

The Regulation generally relates to finished manufactured foods and not to ingredients or raw materials used to manufacture that food. However, FBOs producing/supplying raw materials may be affected by the Regulation through the application of criteria and corrective actions required by their customers' food safety management plans.

With the exception of raw minced meat, meat preparations, certain meat products intended to be cooked and mechanically separated meat, the Regulation does not specify the frequency of sampling/testing, and it is for the FBO to decide the appropriate level of sampling/testing to help validate and verify their food safety management systems, e.g. HACCP.

This guidance document is separated into two parts:

Part A is an overview of the requirements of the Regulations.
Part B provides interpretation of Annex I (the microbiological criteria) for both food safety and process hygiene. The tables in this section are taken directly from the regulation and include relevant footnotes for clarity. The interpretations appear below the table in blue text.

The guidance has been prepared by the Chilled Food Association with support from:

British Retail Consortium
British Frozen Food Federation
British Meat Processors Association
Campden and Chorleywood Food Research Association
Food Standards Agency
Health Protection Agency
Provision Trade Federation

This guidance will be updated as required in light of practical experience.

6 December 2006
Version 1.2

The Regulation provides for further criteria to be added in the future and businesses must ensure that they are aware of any changes.

The issuing organisations seek to ensure the information and guidance they provide is correct, but accept no liability in respect thereof. Such information and guidance are not substitutes for specific legal or other professional advice.

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PART A - OVERVIEW OF THE REQUIREMENTS OF THE REGULATIONS

1. The Purpose of Microbiological Criteria

Microbiological criteria are intended to give some degree of assurance that food is safe and of suitable quality, and that it will remain so to the end of its shelf life provided it is handled appropriately.

The EC Regulation on Microbiological Criteria for Foodstuffs requires FBOs to use the criteria given in the Regulation when carrying out validation and verification checks as part of food safety management systems based on HACCP principles.

It should be noted that it is not an offence *per se* to breach the criteria set out in the Regulations.

2. The Purpose of Microbiological Testing

The safety of food is neither guaranteed nor controlled by microbiological testing. Microbiological testing can be used to validate and monitor processes and verify Critical Control Points (CCPs) identified through HACCP. Microbiological testing of final product alone cannot be relied upon to demonstrate product safety and may be insufficient to demonstrate due diligence.

The EC Regulation on Microbiological Criteria for Foodstuffs simply requires food business operators to ensure their products comply with microbiological criteria, testing against microbiological criteria as appropriate “when they are validating or verifying the correct functioning of their procedures based on HACCP principles and good hygiene practice.”

It is important to note that the Regulations are not intended to create additional testing requirements since validating/verification testing is a standard part of HACCP. The Regulation should also not lead to an increased reliance on or positive release.

3. The Legal Context

The Commission Regulation on Microbiological Criteria for Foodstuffs (2073/2005/EC), hereafter referred to as “the Regulation”, applies from 1 January 2006.

The Regulation is pursuant to the Regulation on the Hygiene of Foodstuffs (Regulation No. 852/2004/EC) and to the General Food Law (Regulation No. 178/2002/EC).

The Regulation on Microbiological Criteria for Foodstuffs is subject to future review in order to take account of developments in microbiology and food safety.

A copy of the Regulation and any future amendments to it can be obtained from the Europa website at: www.europa.eu.int/eur-lex.

The Regulation is implemented locally through Food Hygiene (No. 2) Regulations 2005 in the constituent countries of the UK. This implementing legislation includes, for example, requirements for FBOs to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles and to take the measures laid down in paragraphs (2) to (4) of Article 7 of the Microbiological Criteria Regulation when the results of testing against the Food Safety Criteria are unsatisfactory.

4. Requirements for Food Business Operators

The following are minimum legal requirements:

- There is an obligation within 178/2002/EC to withdraw or recall unsafe food from the market.

- If the Food Safety Criteria given in Annex I, Chapter 1 of the Regulation are not met, the product is deemed as 'unsatisfactory'. Under 178/2002/EC there is an obligation on the Brand Owner to withdraw unsafe food from the market and to notify the Competent Authority. Further action may include product recall by the Brand Owner. This would be agreed on a case by case basis in consultation with the Competent Authority.

- Food Business Operators must analyse trends in the test results.

- When a trend towards unsatisfactory results is found, or if the Process Hygiene Criteria given in Annex I, Chapter 2 of the Regulation are exceeded then appropriate investigation and corrective action is required. Corrective action is to include the actions specified in the Annex I of the Regulation (see pages 17-52 of this guidance) together with other corrective actions defined in the Food Business Operator's HACCP-based procedures and other actions necessary to protect the health of consumers. In addition, the Food Business Operator shall take measures to find the cause of the unsatisfactory results in order 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. Environmental monitoring can form part of the investigatory action undertaken to prevent a reoccurrence of an exceedance. No notification is required in the case of a Process Hygiene Criterion being exceeded.

- A food management preventative approach such as employing good hygiene practices and a system based on HACCP principles must be in place. Food testing against the appropriate criteria should be undertaken, if appropriate, when verifying or validating HACCP.

- The Regulation stipulates a minimum frequency of sampling and testing for carcases, minced meat, meat preparations, meat products covered in Annex I of the Regulation that are intended to be eaten cooked and mechanically separated meat. For more details of these requirements see Part B of this document section 8 (Food Safety Criteria) and section 9 (Process Hygiene Criteria).

- Where there are no frequencies defined by the Regulation (all except carcases, minced meat, meat preparations, meat products covered in Annex I of the Regulation that are intended to be eaten cooked and mechanically separated meat), sampling and testing frequencies should be determined by the Food Business Operator based on HACCP principles. Evidence to support the sampling/testing regime should be held on file and available on request to the Competent Authority.

- Raw minced meat, raw meat preparations and raw poultry meat products intended to be cooked must be clearly labelled by the manufacturer informing the consumer of the need for thorough cooking prior to consumption.

- If official control testing (for example by a Port Health Authority) is conducted on a product from outside the EU the Food Safety Criteria will be used as a minimum requirement.

- Alternative methods to those prescribed in the Regulation may be used as long as those methods provide equivalent results validated against the reference method given in Annex I of the Regulation. Alternative methods must be:

    a. validated against the reference method, and if a commercial kit, certified by a third party using an internationally accepted protocol, i.e. ISO 16140 or a similar protocol
    Or
    b. validated by an internationally accepted protocol and authorised by the Competent Authority.

- Environmental monitoring is one important tool when investigating why hygiene criteria and/ or food safety criteria are not met.

- Processing areas and equipment used in the manufacture of ready-to-eat foods must be monitored for *Listeria monocytogenes*.

- Processing areas and equipment used in the manufacture of dried infant formula and related products must be monitored for *Enterobacteriaceae*.

5. Recommendations for Food Business Operators

In addition to the legal obligations Food Business Operators should also consider the following:

- Sampling of the production and processing environment is required to monitor hygiene in relation to ready-to-eat foods. *Listeria* spp is considered a suitable hygiene indicator for *Listeria monocytogenes*. If *Listeria* spp are detected the particular species must be identified. Aerobic colony counts can be useful in validating factory cleaning procedures.

- Laboratories carrying out official controls must be accredited. FBOs should use an appropriately accredited laboratory to conduct microbiological testing. Laboratories should take part in relevant external proficiency testing schemes.

6. Selected Definitions

Batch

This is defined in Article 2 (e) of the Regulation for the microbiological criteria for foodstuffs (2073/2005/EC) 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.

The food business operator must define the batch. Batch size is a key point to consider in any risk management action.

Brand Owner

The Brand Owner is a Food Business Operator and is the person or organisation that has legal responsibility for the product.

For the purpose of this guidance document, for pre-packed products, this would normally be the brand on the food package.

Competent Authority

For the purpose of the microbiological criteria for foodstuffs Regulation, in the UK the Competent Authority is the Food Standards Agency. Enforcement is undertaken on its behalf by the Local Authority, Port Health Authority and the Meat Hygiene Service.

Egg Products

Directive (853/2004/EC) defines egg products as “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”. They may be liquid, concentrated, dried, crystallized, frozen, quick frozen or coagulated.

Food for Infants

Means food intended to meet fully or partially the nutritional requirements of children under the age of 12 months. It includes both infant formulae and follow-on formulae as defined in Directive 91/321/EC.

Food Business Operator (FBO)

A FBO is defined in the General Food Law Regulation (178/2002/EC) as the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

Meat Preparations

"Meat Preparations", as defined in Regulation 853/2004/EC, 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.

Meat Products

"Meat Products", as defined in Regulation 853/2004/EC, 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.

Minced Meat

"Minced Meat", as defined in Regulation 853/2004/EC, means boned meat that has been minced into fragments and contains less than 1% salt.

Placing on the Market

The General Food Law Regulation (178/2002/EC) defines Placing on the Market as: "The holding of food or feed for the purpose of sale, including offering for sale or any other form or transfer, whether free of charge or not, and sale, distribution, and other forms or transfer themselves."

In practice this means food is placed on the market if it has left the control of the primary manufacturer.

Product Recall

Means any measure aimed at achieving the return of the product that has already been supplied to or made available to consumers.

Product Withdrawal

Means any measure aimed at preventing the distribution, display or offer of a product.

Proficiency Testing

The determination of laboratory testing performance by means of interlaboratory test comparisons.

Ready-to-eat Food

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

For the purpose of this guidance ready-to-eat means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or reheating.

For example, ready meals labelled to be reheated are outside the scope of the Regulation. Smoked salmon, sandwiches and products not requiring such processing prior to consumption are within the scope of the Regulation.

Reference Method

This refers to the laboratory method in Annex I of the Regulation, which is normally international, i.e. an EN/ISO standard.

Shelf life

As defined in the Regulations as "Either the period corresponding to the period preceding the "use by" or the minimum durability date".

In practice this means the period during which the product maintains its microbiological safety and sensory qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other inhibitory or inhibiting factors that may be used.

Small Establishments and Slaughterhouses

Small minced meat and meat preparation establishments produce up to an average 2 metric tonnes a week.

Small poultry meat establishments hand fewer than 7,500,000 birds a year.

Small red meat slaughterhouses handle fewer than 25,000 livestock units a year.

Terms Used in the Criteria Tables

The following definitions apply to the criteria tables (sections 8 and 9) when the detection (presence/absence) of specific pathogens is being tested for (i.e. a two-class sampling plan):

Limit m: This is the maximum acceptable level

Sampling Plan n: The number of samples from the batch which are tested

Sampling Plan c: The number of samples that are allowed to exceed m

The following definitions apply to the criteria tables (sections 8 and 9) when enumeration of the microorganism being tested for is required (i.e. a three-class sampling plan):

Limit m: This level is the target normally achieved using HACCP and good hygienic practice.

Limit M: This is the maximum acceptable level

Sampling Plan n: The number of samples from the batch which are tested

Sampling Plan c: The number of samples that are allowed to have results between m and M

7. Sampling Plans and Frequencies

The Regulation gives sampling plans to which the criteria in its Annex (I) are to be applied.

Testing or sampling frequencies are defined in the Regulation for minced meat, meat preparations and mechanically separated meat. For all other product types, the Food Business Operator should determine sampling and microbiological testing frequency.

HACCP principles must be applied when manufacturing all products. The management of the microbiological risks at each stage of manufacturing process must be considered.

Key stages include:

- Ingredients/ raw material
- Factory - design, hygiene of equipment and people
- Manufacturing process targeting appropriate organism/s
- Packaging
- Storage temperature and shelf life
- Intended use
- Food safety studies related to similar products

More information on the practical application of HACCP can be found in CFA's 'Best Practice Guidelines for the Production of Chilled Food'.

Microbiological testing may be appropriate at certain stages to verify that the HACCP is adequate, operational and effectively in control. Monitoring raw materials and factory hygiene may also be important. Final product microbiological testing against microbiological criteria is often used to verify that the overall process is in control.

When deciding the frequency of microbiological tests against criteria the following should be considered. For example for raw materials:

- The microbiological hazards and risks associated with the raw material.
- Knowledge and confidence in the supplier/ producer of the raw material.
- The risk associated with the volume of the raw material used.
- Historical data.

The supplier/ producer of the raw material should be producing using HACCP principles, which should minimise the risks, associated with the raw materials.

The more confidence you have in the raw material supplier/ producer the less testing is required. Confidence can be achieved by:

- Auditing the supplier/ producer and their HACCP including their microbiological checks

and/ or

- Increasing the frequency of checks until sufficient historical data is available.

Microbiological testing can be used to verify a HACCP plan. As the HACCP plan is more established and more satisfactory test results are obtained the frequency of testing may be reduced based on historical data.

If anything significant is changed in the production of the product such as raw material source, formulation or processing, the HACCP should be reviewed and it may be appropriate to increase test frequency.

It is the view of the Food Standards Agency that where testing is not part of validation or verification of procedures based on HACCP principles then there is no requirement to conduct such additional testing under the Regulation and the specific requirements of Annex I of the Regulation do not apply.

More information on sampling and testing can be found in CFA's 'Microbiological Testing and its Interpretation Guidance', ISBN-13 978-1-901798-10-4.

PART B – INTERPRETATION OF ANNEX I (THE CRITERIA)

The Regulation sets Food Safety Criteria and Process Hygiene Criteria, which are detailed in sections 8 and 9, respectively.

8. Food Safety Criteria Index

Criteria have been set for *Escherichia coli*, *Enterobacter sakazakii, Listeria monocytogenes, Salmonella* spp, *Staphylococcus* enterotoxin and histamine.

The following is an index of the microbiological criteria tables taken from Annex I Chapter 1 of the Regulation.

The tables have been separated so that each section can be referred to in isolation. Some product examples have been given to assist in deciding which tables are relevant.

Ready to Eat Foods

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.1	*Listeria monocytogenes* in ready-to-eat foods intended for infants and special medical purposes	Ready-to-eat baby foods Ready-to-eat foods intended for infants less than 12 months old Ready-to-eat dietary food for special medical purposes for infants less than 6 months old
1.2	*L. monocytogenes* in ready-to-eat foods able to support the growth of *L.monocytogenes* other than those in 1.1.	Chilled ready-to-eat products with more than 5 days life Pre-packed delicatessen products Pre-packed sliced cooked meat Smoked salmon Pate Soft Cheese
1.3	*L. monocytogenes* in ready-to-eat foods unable to support the growth of *L.monocytogenes* other than those in 1.1.	Ice cream Yoghurt Hard Cheese Products with a pH of less than 4.4, e.g. coleslaw Products with shelf life of less than 5 days e.g. sandwiches and some unpackaged delicatessen products if prepared in store

Minced Meat and Meat Preparations

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.4	*Salmonella* in minced meat and meat preparations intended to be eaten raw	Steak tartare
1.5	*Salmonella* in minced meat and meat preparations made from poultry meat intended to be cooked	Chicken/Turkey Mince Turkey kebabs Chicken nuggets if not fully cooked by the manufacturer
1.6	*Salmonella* in minced meat and meat preparations made from other species than poultry intended to be cooked	Minced beef, sausages, burgers, minced lamb kebabs, minced pork
1.7	*Salmonella* in Mechanically separated meat (MSM)	

Meat and Products Thereof

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.8	*Salmonella* in meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the *Salmonella* risk	Salami Parma ham Cold smoked duck
1.9	*Salmonella* in meat products made from poultry meat intended to be eaten cooked	Turkey bacon
1.10	*Salmonella* in gelatine and collagen	

Milk and Dairy Products

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.11	*Salmonella* in cheeses, butter and cream made from raw milk or milk that has undergone a lower heat-treatment than pasteurisation	Roquefort, Brie de Meaux
1.12	*Salmonella* in milk powder and whey powder	Dried milk powder
1.13	*Salmonella* in ice cream, excluding products where the manufacturing process or the composition of the product will eliminate the *Salmonella* risk	Ice cream made from unpasteurised ingredients
1.21	*Staphylococcal* enterotoxins in cheeses, milk powder and whey powder, as referred to in the coagulase-positive *staphylococci* criteria in Chapter 2.2 of Annex I of the Regulation	Cheese, excluding processed cheese and non fermented cheese.

Infant Formula and dried dietary foods for infants for special medical purposes

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.22 1.23	*Salmonella* and *Enterobacter sakazakii* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age, as referred to in the *Enterobacteriaceae* criterion in Chapter 2.2 of Annex I of the Regulation	

Egg Products

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.14	*Salmonella* in egg products, excluding products where the manufacturing process or the composition of the product will eliminate the *Salmonella* risk	Unpasteurised liquid egg
1.15	*Salmonella* in ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the *Salmonella* risk	Mayonnaise and meringues made with unpasteurised egg

Fishery Products and Shellfish

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.16	*Salmonella* in cooked crustaceans and molluscan shellfish	Mussels, prawns, shrimp, lobster, crab
1.17	*Salmonella* in live bivalve molluscs and live echinoderms, tunicates and gastropods	Oysters, clams, sea urchins, winkles, whelks
1.24	*E.coli* in live bivalve molluscs and live echinoderms, tunicates and gastropods	Oysters, clams, sea urchins, winkles, whelks
1.25	Histamine in fishery products from fish species associated with a high amount of histidine	Tuna, mackerel, sardines, mahi mahi
1.26	Histamine in fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine	Anchovies

Produce

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
1.18	*Salmonella* in sprouted seeds (ready-to-eat)	Cress, ready-to-eat beansprouts
1.19	*Salmonella* in pre-cut fruit and vegetables (ready-to-eat)	Prepared ready-to-eat salads, prepared ready-to-eat fruit
1.20	*Salmonella* in unpasteurised fruit and vegetable juices (ready-to-eat)	Freshly squeezed unpasteurised juices

The Food Safety Criteria

Food Safety - Ready-to-eat foods: infant foods and foods for special medical purposes

There are very specific criteria requirements for *Listeria* monocytogenes in ready-to-eat foods intended for infants and for special medical purposes:

Food category and criterion number		Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
			n	C	M	M		
1.1	Ready-to-eat foods intended for infants and ready-to eat foods for special medical purposes	*Listeria monocytogenes*	10	0	Absence in 25 g		EN/ISO 11290-1	Products placed on the market during their shelf-life

The Regulation states that regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods:

- those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, 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

Interpretation of Requirements:

Positive release testing for L.monocytogenes *is not required.*

Results indicating the presence of L. monocytogenes *in 25g of these products are considered to be an unacceptable food safety risk and products must be withdrawn from the market and the competent authority notified.*

The sampling plan given above may be revised if the food business operator can demonstrate by historical documentation and data that effective HACCP based procedures are in place. A preventative approach such as environmental monitoring should be demonstrated.

Figure 1: Decision tree showing the application of *Listeria monocytogenes* criteria for ready-to-eat foods other than infant foods and foods for special medical purposes

For all ready-to-eat foods not designed for infants or for special medical purposes the decision tree below can be used to identify the type of criteria applicable. The specific criteria can be found in the appropriate later sections of this guidance.

Is the product ready-to-eat? i.e. 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

→ NO → No criterion for *L. monocytogenes* applies

↓ YES

Is the product one of the following? [i.e. referred to in footnote 4 of the Regulation]

- Product which has received heat treatment or other processing to eliminate *L. monocytogenes*, when recontamination is not possible
- Fresh, uncut and unprocessed vegetables and fruit (excluding sprouted seeds)
- Bread, biscuits and similar products
- Bottled or packed waters, soft drinks, beer, cider, wine, spirits and similar products
- Sugar, honey, confectionery, including cocoas and chocolate products
- Live bivalve molluscs

→ YES → No criterion for *L. monocytogenes* applies

↓ NO

Is the product:

- pH $\leq$ 4.4 or
- $a_W \leq 0.92$ or
- pH $\leq$ 5.0 and an $a_W \leq 0.94$ or
- shelf life of <5 days or
- frozen at $\leq$-12ºC

→ YES → Product is unable to support the growth of *L. monocytogenes*.

Limit of 100 cfu/g applies when placed on the market throughout shelf life

↓ NO

Are scientific/modelling, historical or other data (e.g. end of life testing) available to demonstrate that the product will not support the growth of *L. monocytogenes*?

→ YES → Limit of 100 cfu/g applies when placed on the market throughout shelf life

↓ NO

Is data available to show that *L. monocytogenes* will not exceed 100 cfu/g at the end of shelf life under expected storage conditions?

→ YES → Establish shelf life to ensure that limit of 100 cfu/g not exceeded when placed on the market throughout shelf life under expected storage conditions

↓ NO

EITHER carry out studies to show that *L. monocytogenes* will not exceed 100 cfu/g at the end of shelf life under expected storage conditions, **OTHERWISE** a limit of 0 cfu/25g applies before the food has left the immediate control of the producing FBO

Food Safety - Ready-to-eat foods able to support the growth of Lm

Food category and criterion number	Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
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	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2	Products placed on the market during their shelf-life
		5	0	Absence in 25 g		EN/ISO 11290-1	Before the food has left the immediate control of the food business operator, who has produced it

The criterion of 100 cfu/g applies 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 should be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of the shelf-life.
The criterion of absence in 25g applies 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.
Article 3.2 of the Regulation states: "As necessary the food business operators responsible for the manufacture of the product shall conduct studies in accordance with Annex II in order to investigate compliance with the criteria throughout the shelf life"
Annex II states:

– "specifications for physico-chemical characteristics of the product, such as pH, a_w, salt content, concentration of preservatives and the type of packaging system, taking into account the storage and processing conditions, the possibilities for contamination and the foreseen shelf-life; and
– consultation of available scientific literature and research data regarding the growth and survival characteristics of the micro-organisms of concern.

When necessary on the basis of the above-mentioned studies, the food business operator shall conduct additional studies, which may include:

– predictive mathematical modelling established for the food in question, using critical growth or survival factors for the micro-organisms of concern in the product;
– tests to investigate the ability of the appropriately inoculated micro-organism of concern to grow or survive in the product under different reasonably foreseeable storage conditions;
– studies to evaluate the growth or survival of the micro-organisms of concern that may be present in the product during the shelf-life under reasonably foreseeable conditions of distribution, storage and use.

The above-mentioned studies shall take into account the inherent variability linked to the product, the micro-organisms in question and the processing and storage condition.

Interpretation of Requirements:

To determine how to apply the criteria for these products refer to page 17 Figure 1 (Decision Tree Showing Application of* Listeria monocytogenes *(Lm) Criteria for Ready-to-eat foods other than Infant Foods and Foods for Special Medical Purposes)

The Food Business Operator (manufacturer and/or brand owner) should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP. Positive release testing for L.monocytogenes *is not required.*

This criterion applies in general to chilled ready-to-eat foods.

(continued…)

The exclusions listed in the Regulation under criterion 1.1 apply, i.e.:

- *those which have received heat treatment or other processing effective to eliminate* L. monocytogenes*, 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*

Additional products that will not support the growth of L. monocytogenes *also include foods with:*

- *a pH ≤4.4 or*
- *an a_w ≤0.92*
- *a shelf life of less than 5 days*
- *a pH ≤5.0 and an a_w ≤ 0.94*

Frozen foods at less than -12°C will not support the growth of L. monocytogenes.

n = the number of samples to be taken from a given process under practically identical circumstances and produced in a given place within one defined production period. ***Samples can be composited together****.*

Results indicating that levels of L. monocytogenes *are more than 100 cfu/g are considered to be an unacceptable food safety risk and products must be withdrawn from the market and the Competent authority notified.*

If L. monocytogenes *is detected in 25g or at levels of no more than 100 cfu/g, in product either before dispatch from the manufacturing site or when already on the market, there must be evidence to demonstrate that the level will not exceed 100cfu/g within the shelf life under expected storage conditions (see next page).* ***If this evidence is available notification is not required*****.**

The section on studies, whilst applicable to a range of different microorganisms in foods is of most relevance to L.monocytogenes *(particularly criteria 1.2 and 1.3) in the context of these criteria.*

Manufacturers of ready-to-eat foods should understand how L.monocytogenes *behaves in their product, as determined by the products formulation, storage conditions, packaging and shelf life. The factors deemed to be critical in controlling development of* L.monocytogenes *must be identified, controlled and monitored (e.g. in a hard cheese, salt, moisture, pH and acidity are likely to be the most significant factors restricting growth of* L.monocytogenes*. Tolerances and limits for these parameters should be specified and controlled.*

Effective HACCP, good hygienic procedures and environmental monitoring for Listeria *spp are a critical component of* Listeria *management.*

(continued…)

Should Lm *be found to be present in a ready-to-eat food there are is a hierarchy of options available to manufacturers to determine how* L.monocytogenes *would behave in the product:*

1. Historical data

Historical data provides the best indication of the behaviour of an organism in food. When present, Listeria *has usually contaminated the product from the environment. In a factory environment, natural contaminants are likely to be stressed and will grow slower than those that have been grown for use in inoculation studies (as is the case in models and challenge testing). Data on the levels of* Listeria *present throughout and at the end of shelf life can be used to assess its potential for growth. For example, if* Listeria *was detected in a cooked meat product at the beginning of shelf life at a level of <10 cfu/g, and end of life data on a representative sample from the same batch showed levels remained at no more than 100 cfu/g, then the data help demonstrate that from a* Listeria *perspective the product remains safe over its shelf life. Under such circumstances, a low level (e.g. <10 cfu/g) detection during shelf life should not need to be notified, withdrawn or recalled.*

This approach is considered to be the most valid providing that end of life samples have either followed the normal route of distribution, storage and retail, (e.g. sampling from the shelf for retail products) or have been stored at temperatures closely simulating those conditions. The limitation of this method is that for most of the time Listeria *should be absent in product; it can therefore be difficult, or take time to acquire such data. It also provides no information on safe shelf life for new products, particularly if a new product is introduced that is significantly different from those usually produced at the manufacturing site.*

2. Outbreak and scientific data

Much information is available in the scientific literature researching growth of organisms in foods. These data may be used to support the safety of a product over its life. The main disadvantage is that it may be difficult to find information that closely resembles the formulation, processing and storage conditions of the product in question. However, it may be possible to demonstrate through these data that the product type in question has not previously been linked to an outbreak. Such data may support the safety of a particular product/product group but is not a replacement for HACCP, an effective Listeria *management/monitoring plan, and the establishment of a safe shelf life using the studies detailed here.*

3. Predictive Mathematical Modelling

Predictive models enable the user to enter key physicochemical factors such as the pH, water activity (primarily defined by the salt content) of the product in question, and its storage temperature. A prediction is then obtained showing how, over time the organism would be expected to grow. The main disadvantage of predictive models is that they are developed based on growth of organisms in broths, which is frequently faster than growth in real food systems, which can result in predicted shelf lives being shorter than may be achieved in reality, particularly in low acid, high water activity products.

Predictive models are cheap or free, failsafe and quick to use. However, they need some interpretation in their use. A number of models are available, e.g. Growth Predictor, which is freely available at: http://www.ifr.ac.uk/Safety/GrowthPredictor/default.html. In Growth Predictor, the water activity is directly linked to salt, which can affect accuracy when predicting growth in products where the water activity is predominantly influenced by sugar or low moisture.

4. Challenge testing

***Challenge tests are not required to be carried out if any of the above information is available**. Challenge testing is the process of inoculating the organism of interest into the product in question and observing its growth over time, by monitoring at selected time intervals. This MUST be conducted in an appropriately accredited laboratory. To conduct a challenge test well requires expert knowledge to ensure that the strains chosen are relevant, the inoculum is correctly applied with minimal interference to the product's characteristics and ensuring that the inoculum is fully recoverable. A well-conducted challenge test can provide more accurate information than models about an organism's behaviour in a specific food product. Key disadvantages of challenge testing are that a change in formulation may require a repeat challenge test if the formulations are significantly different, the status of inoculated cells will not be the same as in reality (i.e. not stressed) therefore growing quicker than in reality and that the test assumes that the product is contaminated during production, whereas HACCP/GMP are designed to prevent/minimise contamination.*

(continued…)

Food Safety - Ready-to-eat foods unable to support the growth of Lm

Food category and criterion number	Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
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	*Listeria monocytogenes*	5	0	100 cfu/g		EN/ISO 11290-2	Products placed on the market during their shelf-life
The Regulations state that regular testing against the criterion is not useful in normal circumstances for the following ready-to-eat foods: • those which have received heat treatment or other processing effective to eliminate *L. monocytogenes*, 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 Products with pH ≤ 4.4 or $a_w \leq 0.92$, products with pH ≤ 5.0 and $a_w \leq 0.94$, products with a shelf-life of less than 5 days are automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.							

Interpretation of Requirements:

To determine how to apply the criteria for these products refer to page 17 Figure 1 (Decision Tree Showing Application of* Listeria Monocytogenes *(Lm) Criteria for Ready-to-eat foods other than Infant Foods and Foods for Special Medical Purposes)

The Food Business Operator (manufacturer and/or brand owner) should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP. Positive release testing for L.monocytogenes *is not required.*

This criterion applies to products that will not support the growth of L.monocytogenes *but in which this organism could survive at levels of more than 100 cfu/g.*

As stated in the Regulation products belonging to in this category include foods with:

- *a pH ≤4.4 or*
- *an a_w ≤0.92*
- *a shelf life of less than 5 days*
- *a pH ≤5.0 and an a_w ≤ 0.94*

Levels of L. monocytogenes *of more than 100 cfu/g isolated in product are considered to be a food safety risk. Such products must be withdrawn from the market and competent authority must be notified.*

(continued…)

Food Safety - Minced Meat and Meat Preparations

Food category and criterion number		Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
			n	c	m	M		
1.4	Minced meat and meat preparations intended to be eaten raw	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.5	Minced meat and meat preparations made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence In 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.6	Minced meat and meat preparations made from other species than poultry intended to be eaten cooked	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.7	Mechanically separated meat (MSM)	*Salmonella*	5	0	Absence in 10 g		EN/ISO 6579	Products placed on the market during their shelf-life

Sampling frequencies for minced meat, meat preparations and mechanically separated meat

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations or mechanically separated meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

In the case of sampling for *Salmonella* analyses of minced meat, meat preparations and carcases, the frequency can be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks. The salmonella sampling frequency may also be reduced if there is a national or regional salmonella control programme in place and if this programme includes testing that replaces the above-described sampling. The sampling frequency may be further reduced if the national or regional salmonella control programme demonstrates that the salmonella prevalence is low in animals purchased by the slaughterhouse.

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses and establishments producing minced meat and meat preparations in small quantities may be exempted from these sampling frequencies.

The definition for **mechanically separated meat** (MSM) refers to MSM produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III of Regulation No 853/2004/EC of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

Note: MSM is the same as mechanically recovered meat. (MRM).

Interpretation of Requirements:

Unlike the criteria for other product types the testing frequencies for minced meat and meat preparations are a statutory requirement under the microbiological criteria for foodstuffs Regulation for Food Business Operators. A minimum of one batch of one product type of minced meat or meat preparation must be sampled once a week per production site. Establishments producing minced meat and meat preparations in small quantities (e.g. premises not requiring approval) are exempt from these sampling frequencies.

The day of the week sampling takes place must be changed each week so that all production days are sampled over time.

During the course of producing the batch to be tested, 5 separate samples must be taken spaced out across the production run. This is so that a representative sample of the batch is obtained. A representative sample of a batch cannot be taken at retail level.

Samples can be combined and tested for Salmonella *spp unless the transitional derogation is in place (see next page). This means that a total sample size of 125g (5 x 25g samples) and 50g (5 x 10g samples) must be tested using 1:10 dilution detailed in the reference method.*

Minced Meat and Meat preparations intended to be eaten raw:

Salmonella *must not be detected in 25g from any of the 5 samples. If* Salmonella *is detected (i.e. confirmed) the product must be withdrawn or recalled from sale (see section 5 - Selected Definitions), and the Competent Authority notified,*

Minced Meat and Meat preparations intended to be eaten cooked:

Until 1st January 2010 Salmonella *must not be detected from any of the 5 samples each of 10g. If* Salmonella *is detected(i.e. confirmed) the product should be withdrawn from sale (see section 5 - Selected Definitions) and the Competent Authority notified unless a Transitional Derogation is in place and the product is on the home market (see below).*

(continued…)

All minced meat and meat preparations must be clearly labelled by the manufacturer indicating the need for thorough cooking prior to consumption. Either the provision of cooking instructions sufficient to achieve thorough cooking or a statement that the product requires cooking is considered to be suitable.

If satisfactory Salmonella results (Salmonella not detected) are obtained for 30 consecutive weeks the frequency of testing can be reduced from weekly to fortnightly

The testing frequency can be further reduced if there is a national or regional Salmonella control programme in place that demonstrates that the prevalence of salmonella in the animals/meat used to produce minced meat and meat preparations is low (Seek advice from the Competent Authority).

The Transitional Derogation (granted until 31st December 2009) allows continued sale of minced meat, meat preparations and meat products intended to be cooked provided no more than one of the 5 samples tests positive for Salmonella (the samples must therefore be tested separately) and:

- *Product produced under the Derogation must bear a 'special mark' and can only take advantage of the derogation in the country where it is produced and sold. Exported product must not bear the special mark.*
- *That the product label includes the following 'special mark' indicating that the product is produced under the derogation:*

Products produced under the Transitional Derogation and those not produced under the Derogation are allowed to be produced within the same production area at the same time.

From 1st January 2010, for minced meat and meat preparations made from poultry meat, Salmonella must not be detected in 25g from any of the 5 samples tested and from that date there is no longer a requirement to label with cooking instructions. Until that date, all minced meat and meat preparations must be clearly labelled by the manufacturer indicating the need for thorough cooking prior to consumption. The provision of cooking instructions sufficient to achieve thorough cooking satisfies this requirement.

Food Safety - Meat and products thereof

Food category and criterion number	Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
		n	C	m	M		
1.8 Meat products intended to be eaten raw, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf life
1.9 Meat products made from poultry meat intended to be eaten cooked	*Salmonella*	5	0	From 1.1.2006 Absence in 10 g From 1.1.2010 Absence In 25 g		EN/ISO 6579	Products placed on the market during their shelf life
1.10 Gelatine and collagen	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

Interpretation of Requirements:

The Food Business Operator (manufacturer and/or brand owner) should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP. Positive release testing for Salmonella *is not required.*

Note that there is no Salmonella *criterion for ready-to-eat foods containing both products of plant origin and processed products of animal origin.*

1.8 Meat products intended to be eaten raw:

Salmonella *must not be detected in 25g. If* Salmonella *is detected(i.e. confirmed) the product must be withdrawn or recalled from sale (see section 5 - Selected Definitions), and the Competent Authority notified.*

(continued…)

1.9 Meat products made from poultry meat intended to be eaten cooked:

Until 1st January 2010 Salmonella *must not be detected from any 1 of 5 10g samples. If Salmonella is detected (i.e. confirmed) the product may be withdrawn from sale (see section 5 - Selected Definitions) and the Competent Authority notified unless a Transitional Derogation is in place in the manufacturing country. The Transitional Derogation (which may be granted until 31st December 2009) allows continued sale of meat products intended to be cooked provided no more than 1 of 5 samples tests positive for* Salmonella *and that:*

- *Product produced with the 'special mark' can only take advantage of the derogation in the country where it is produced and sold. Where the 'special mark' appears on the packaging of exported product the derogation is not available overseas and the higher* Salmonella *standard is applicable. Exported product must not bear the special mark.*
- *That the product label includes the following 'special mark' indicating that the product is produced under the derogation:*

From 1st January 2010 Salmonella must not be detected in 25g from any 1 of 5 samples tested.

Until 1st January 2010 all these meat products must be clearly labelled by the manufacturer indicating the need for thorough cooking prior to consumption. The provision of cooking instructions sufficient to achieve thorough cooking or a statement that the product requires cooking is considered to be suitable.

Food Safety – Milk and Dairy Products

Food category and criterion number		Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
			n	C	m	M		
1.11	Cheeses, butter and cream made from raw milk or milk that has undergone a lower heat-treatment than pasteurisation*	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.12	Milk powder and whey powder*	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.13	Ice cream♦, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.21	Cheeses, milk powder and whey powder, as referred to in the coagulase-positive staphylococci criteria in Chapter 2.2 of this Annex	Staphylococcal enterotoxins	5	0	Not detected in 25g		European screening method of the CRL for Milk ♣	Products placed on the market during their shelf-life

* Excluding products when the manufacturer can demonstrate to the satisfaction of the competent authorities that, due to the ripening time and a_w of the product where appropriate, there is no salmonella risk.

♦ Only ice creams containing milk ingredients.

♣ Reference: Hennekinne et al., J. AOAC Internat. Vol. 86, No 2, 2003.

Interpretation of Requirements:

The Food Business Operator should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP.

1.11/ 1.12 – A heat treatment lower than pasteurisation would be less than 71.7°C for 15 seconds or the thermal equivalent. Products excluded for this food category are those products in which it is shown by robust scientific evidence that Salmonella *cannot survive.*

If the results obtained exceed the above criteria they are unsatisfactory and the affected product must be withdrawn from the market. The Competent Authority must also be notified.

Food Safety - Infant Formula and dried dietary foods for special medical purposes intended for infants

Food category and criterion number	Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
1.22 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age, as referred to in the *Enterobacteriaceae* criterion in Chapter 2.2 of this Annex	*Salmonella*	30	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.23 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age, as referred to in the *Enterobacteriaceae* criterion in Chapter 2.2 of this Annex	*Enterobacter sakazakii*	30	0	Absence in 10 g		ISO/DTS 22964	Products placed on the market during their shelf-life

Interpretation of Requirements:

The Food Business Operator should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP.

If the results obtained exceed the above criteria they are unsatisfactory and the affected product must be withdrawn from the market. The Competent Authority must also be notified.

Food Safety - Egg Products

Food category and criterion number		Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
			n	c	m	M		
1.14	Egg products, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
1.15	Ready-to-eat foods containing raw egg, excluding products where the manufacturing process or the composition of the product will eliminate the salmonella risk	*Salmonella*	5	0	Absence in 25 g or ml		EN/ISO 6579	Products placed on the market during their shelf-life

Interpretation of Requirements:

The Food Business Operator should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP.

If the results obtained exceed the above criteria they are unsatisfactory and the affected product must be withdrawn from the market. The Competent Authority must also be notified.

Food Safety - Fishery products and shellfish

Food category and criterion number		Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
			n	c	m	M		
1.16	Cooked crustaceans and molluscan shellfish	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.17	Live bivalve molluscs and live echinoderms, tunicates and gastropods	*Salmonella*	5	0	Absence in 25g		EN/ISO 6579	Products placed on the market during their shelf-life
1.24	Live bivalve molluscs and live echinoderms, tunicates and gastropods	*E. coli*[*]	1 ♦	0	<230 MPN / 100g of flesh and intra-valvular liquid		ISO TS 16649-3	Products placed on the market during their shelf-life
1.25	Fishery products from fish species associated with a high amount of histidine♣	Histamine	9 ♠	2	100 mg/kg	200 mg/kg	HPLC♥	Products placed on the market during their shelf-life
1.26	Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of histidine♣	Histamine	9	2	200 mg/kg	400 mg/kg	HPLC♥	Products placed on the market during their shelf-life

(continued…)

Food Safety - Fishery products and shellfish

* *E. coli* is used here as an indicator of faecal contamination.
♦ A pooled sample comprising a minimum of 10 individual animals.
♣ Particularly fish species of the families: *Scombridae, Clupeidae, Engraulidae, Coryfenidae, Pomatomidae, Scombresosidae.*
♠Single samples may be taken at retail level. In such a case the presumption laid down in Article 14(6) of Regulation No 178/2002/EC, according to which the whole batch should be deemed unsafe, shall not apply.
♥ References: 1. Malle P., Valle M., Bouquelet S. Assay of biogenic amines involved in fish decomposition. J. AOAC Internat. 1996, 79, 43-49.
Duflos G., Dervin C., Malle P., Bouquelet S. Relevance of matrix effect in determination of biogenic amines in plaice (*Pleuronectes platessa*) and whiting (*Merlangus merlangus)*. J. AOAC Internat. 1999, 82, 1097-1101.

Histamine in fishery products from fish species associated with a high amount of histidine:
– satisfactory, if the following requirements are fulfilled
  1. the mean value observed is ≤m
  2. a maximum of c/n values observed are between m and M
  3. no values observed exceed the limit of M,
– unsatisfactory, if the mean value observed exceeds m or more than c/n values are between m and M or one or more of the values observed are >M.

Interpretation of Requirements:

The Food Business Operator should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP.

If the results obtained exceed the above criteria they are unsatisfactory and the affected product must be withdrawn from the market. The Competent Authority must also be notified.

Food Safety - Produce

Food category and criterion number		Microorganisms/ their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
			n	c	m	M		
1.18	Sprouted seeds (ready-to-eat)*	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.19	Pre-cut fruit and vegetables (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life
1.20	Unpasteurised fruit and vegetable juices (ready-to-eat)	*Salmonella*	5	0	Absence in 25 g		EN/ISO 6579	Products placed on the market during their shelf-life

* Preliminary testing of the batch of seeds before starting the sprouting process or the sampling to be carried out at the stage where the highest probability of finding *Salmonella* is expected.

Interpretation of Requirements:

The Food Business Operator should decide the testing frequency based on HACCP principles, testing should be used to verify HACCP.

Ready-to-eat products included in this category are taken to be washed and ready-to-eat. Products requiring washing prior to consumption are not included in this category.

If the results obtained exceed the above criteria they are unsatisfactory and the affected product must be withdrawn from the market. The Competent Authority must also be notified.

9. Process Hygiene Criteria Index

Criteria have been set for aerobic colony count, Enterobacteriaceae, Salmonella, *E.coli*, and coagulase positive Staphylococci.

The following is an index of the microbiological criteria tables taken from Annex I Chapter 2 of the Regulation.

The tables have been separated so that each section can be referred to in isolation. Some product examples have been given to assist in deciding which tables are relevant.

Meat and products thereof

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
2.1.1 2.1.3	Aerobic Colony Count, *Enterobacteriaceae* and *Salmonella* on carcases of cattle, sheep, goats and horses	Whole or split, before chilling or cutting
2.1.2 2.1.4	Aerobic Colony Count, *Enterobacteriaceae* and *Salmonella* on carcases of pigs	Before chilling and cutting
2.1.5	*Salmonella* on poultry carcases of broilers and turkeys	Whole, after chilling
2.1.6	Aerobic Colony Count and *E. coli* in minced meat	See definition
2.1.7	Aerobic Colony Count and *E. coli* in mechanically separated meat (MSM)	
2.1.8	*E.coli* in meat Preparations	Burgers, raw sausages

Milk and Dairy Products

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
2.2.1	*Enterobacteriaceae* in pasteurised milk and other pasteurised liquid dairy products	
2.2.2	*E.coli* in cheeses made from milk or whey that has undergone heat treatment	
2.2.3	Coagulase-positive *staphylococci* in cheese made from raw milk	
2.2.4	Coagulase-positive *staphylococci* in 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	
2.2.5	Coagulase-positive *staphylococci* in ripened soft cheeses (fresh cheeses) made from milk or whey	

	that has undergone pasteurisation or a stronger heat treatment	
2.2.6	*E.coli* in butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	
2.2.7	*Enterobacteriaceae* and coagulase-positive staphylococci in milk powder and whey powder	
2.2.8	*Enterobacteriaceae* in ice cream and frozen dairy desserts	Arctic roll, pavlova, cheesecake, frozen yogurt, tiramisu.

Infant formula and dried dietary food for infants for special medical purposes

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
2.2.9	*Enterobacteriaceae* in dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age	

Egg Products

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
2.3.1	*Enterobacteriaceae* in egg products	See definition

Fishery Products and Shellfish

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
2.4.1	*E.coli* and coagulase-positive *staphylococci* in shelled and shucked products of cooked crustaceans and molluscan shellfish	Oysters, clams, winkles

Produce

Criterion No.	Organism and Food Category	Examples (not an exhaustive list)
2.5.1	*E.coli* in pre-cut fruit and vegetables (ready-to-eat)	Prepared ready-to-eat salads, prepared ready-to-eat fruit
2.5.2	*E.coli* in unpasteurised fruit and vegetable juices (ready-to-eat)	Freshly squeezed unpasteurised juices

The Process Hygiene Criteria

Process Hygiene - Meat and products thereof

Food category and criterion number	Microorganisms	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.1 Carcases of cattle, sheep, goats and horses	Aerobic colony count			3.5 log cfu/cm^2 daily mean log	5.0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			1.5 log cfu/cm^2 daily mean log	2.5 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
2.1.2 Carcases of pigs	Aerobic colony count			4.0 log cfu/cm^2 daily mean log	5.0 log cfu/cm^2 daily mean log	ISO 4833	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
	Enterobacteriaceae			2.0 log cfu/cm^2 daily mean log	3.0 log cfu/cm^2 daily mean log	ISO 21528-2	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls
The limits (m and M) apply only to samples taken by the destructive method. The daily mean log is calculated by first taking a log value of each individual test result and then calculating the mean of these log values.								
Sampling plan: see section on next page								

(continued…)

Process Hygiene - Meat and products thereof (continued)

Sampling rules for carcases of cattle, pigs, sheep, goats and horses

The destructive and non-destructive sampling methods, the selection of the sampling sites and the rules for storage and transport of samples are described in standard ISO 17604 (Microbiology of food and animal feeding stuffs – Carcase sampling for microbiological analysis).

Five carcases shall be sampled at random during each sampling session. Sample sites should be selected taking into account the slaughter technology used in each plant.

When sampling for analyses of Enterobacteriaceae and aerobic colony counts, four sites of each carcase shall be sampled. Four tissue samples representing a total of 20 cm^2 shall be obtained by the destructive method. When using the non-destructive method for this purpose, the sampling area shall cover a minimum of 100 cm^2 (50 cm^2 for small ruminant carcases) per sampling site.

When samples are taken from the different sampling sites on the carcase, they shall be pooled before examination.

Guidelines for sampling

More detailed guidelines on the sampling of carcases, in particular concerning the sampling sites, may be included in the guides to good practice referred to in Article 7 of Regulation No 852/2004/EC of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs.

Sampling frequencies for carcases

The food business operators of slaughterhouses shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

The sampling frequency of carcases for Enterobacteriaceae and aerobic colony count analyses may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks. If any subsequent results exceed M, then sampling frequency should return to weekly.

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses producing small quantities may be exempted from these sampling frequencies.

Table 1: Sampling frequency for red meat carcasses

Category		Average annual throughput of cattle, pigs sheep, goats, horses - **livestock units**[1]	Sampling frequencies	
			Initial Frequency	**Reduced Frequency if results are satisfactory**
Standard establishments	**1**	Over 25,000 a year *(25,000 = 500 x 50 weeks)*	***Enterobacteriaceae* and ACC:** 5 carcases once a week for 6 weeks for each species (6 x 5 = 30 samples/ species)	***Enterobacteriaceae* and ACC:** 5 carcases once every 2 weeks for each species,
			***Salmonella*:** 5 carcases once a week for 30 weeks, for each species (30 x 5 = 150 samples/species)	***Salmonella*:** 5 carcases once every 2 weeks, for each species
Small establishments	**2**	Below 25,000 but over 7,500 a year *(7,500 =150 x 50 weeks)*	***Enterobacteriaceae* and ACC:** 5 carcases once a week for 2 weeks for each species (5 x 2 = 10 samples/ species)	***Enterobacteriaceae* and ACC:** 5 carcases once every 4 weeks
			***Salmonella*:** 5 carcases once every 4 weeks,	
	3	Below 7,500 but over 1,500 a year *(1,500 = 30 x 50 weeks)*	***Enterobacteriaceae* and ACC:** 5 carcases once a week for 2 weeks per species (5 x 2 = 10 samples/ species)	***Enterobacteriaceae* and ACC:** 5 carcases on one day every 12 weeks, for each species
			***Salmonella*:** not required	
	4	Below 1,500 cattle, pigs sheep, goats, horses a year (ex-low throughput)	***Enterobacteriaceae* and ACC:** 5 consecutive carcases of each species handled. (5 samples per species)	***Enterobacteriaceae* and ACC:** 5 consecutive carcases of each species, 1 year after the last test for that species.
			***Salmonella*:** not required	

The meat database www.ukmeat.org is useful for calculation of trend results.

[1] 1 soliped; 1 adult bovine animal; 2 other bovine animals; 5 swine of over 100kg live weight; 7 other swine; 10 sheep or goats; 20 lambs or piglets of under 15kg live weight.

Process Hygiene - Meat and products thereof (continued)

Food category and criterion number	Microorganisms	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.3 Carcases of cattle, sheep, goats and horses	*Salmonella*	50	2	Absence in the area tested per carcase		EN/ISO 6578	Carcases after dressing but before chilling	Improvements in slaughter hygiene, review of process controls and origin of animals
2.1.4 Carcases of pig	*Salmonella*	50	5	Absence in the area tested per carcase		EN/ISO 6579	Carcases after dressing but before chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin
2.1.5 Poultry carcases of broilers and turkeys	*Salmonella*	50	7	Absence in 25 g of a pooled sample of neck skin		EN/ISO 6579	Carcases after chilling	Improvements in slaughter hygiene and review of process controls, origin of animals and biosecurity measures in the farms of origin
For points 2.1.3 – 2.1.5 m=M The 50 samples are derived from 10 consecutive sampling sessions in accordance with the sampling rules and frequencies laid down in this Regulation The number of samples where the presence of salmonella is detected. The c value is subject to review in order to take into account the progress made in reducing the salmonella prevalence. Member States or regions having low salmonella prevalence may use lower c values even before the review								

Interpretation

After each sampling session, the results of the last ten sampling sessions (50 results) are assessed, e.g. a moving window - after 10 weeks new results are produced. These results should then be used to determine whether the process hygiene criteria have been met.

(continued...)

Sampling rules for carcases of cattle, pigs, sheep, goats and horses

The destructive and non-destructive sampling methods, the selection of the sampling sites and the rules for storage and transport of samples are described in standard ISO 17604 (Microbiology of food and animal feeding stuffs – Carcase sampling for microbiological analysis).

When sampling for *Salmonella* analyses, an abrasive sponge sampling method shall be used. The sampling area shall cover a minimum of 100 cm² per site selected.

When samples are taken from the different sampling sites on the carcase, they shall be pooled before examination.

Sampling rules for poultry carcases

See note for criterion 2.1.5 above, regarding sample numbers.

For the *Salmonella* analyses, a minimum of 15 carcases shall be sampled at random during each sampling session and after chilling. A piece of approximately 10 g from neck skin shall be obtained from each carcase. On each occasion the neck skin samples from three carcases shall be pooled before examination in order to form 5 x 25 g final samples.

Guidelines for sampling

More detailed guidelines on the sampling of carcases, in particular concerning the sampling sites, may be included in the guides to good practice referred to in Article 7 of Regulation No 852/2004/EC of the European Parliament and of the Council of 29 April 2004 on the Hygiene of Foodstuffs.

Sampling frequencies for carcases

The food business operators of slaughterhouses shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

In the case of sampling for *Salmonella* analyses of carcases, the frequency can be reduced to fortnightly if satisfactory results have been obtained for 30 consecutive weeks. If any subsequent results exceed M, then sampling frequency should return to weekly. The salmonella sampling frequency may also be reduced if there is a national or regional salmonella control programme in place and if this programme includes testing that replaces the above-described sampling. The sampling frequency may be further reduced if the national or regional salmonella control programme demonstrates that the salmonella prevalence is low in animals purchased by the slaughterhouse.

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses producing small quantities may be exempted from these sampling frequencies.

Table 2: Sampling frequency for poultry slaughterhouses

Category		Average annual throughput of turkeys and broilers	Sampling frequencies	
			Initial Frequency	Reduced Frequency if results are satisfactory
Standard establishments	1	Over 7,500,000 a year *(7,500,000 = 150,000 x 50 weeks)*	***Salmonella***: 5 carcases once a week for 30 weeks, for each species (30 x 5 = 150 samples/species)	***Salmonella***: 5 carcases once every 2 weeks, for each species (30 x 5 = 150 samples)
Small establishments	2	Below 7,500,000 but over 1,000,000 a year *(1,000,000 = 20,000 x 50 weeks)*	***Salmonella***: 5 carcases once every 4 week for each species	
	3	Below 1,000,000 but over 150,000 a year *(150,000 = 3,000 x 50 weeks)*	***Salmonella***: not required	
	4	Below 150,000 a year (ex-low throughput)	***Salmonella***: not required	

Food category and criterion number	Microorganisms	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.1.6 Minced meat	Aerobic colony count[7]	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E. coli	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.7 Mechanically separated meat (MSM)	Aerobic colony count	5	2	$5x10^5$ cfu/g	$5x10^6$ cfu/g	ISO 4833	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
	E. coli	5	2	50 cfu/g	500 cfu/g	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials
2.1.8 Meat preparations	*E. coli*	5	2	500 cfu/g or cm^2	5000 cfu/g or cm^2	ISO 16649-1 or 2	End of the manufacturing process	Improvements in production hygiene and improvements in selection and/or origin of raw materials

Aerobic colony count: this criterion does not apply to minced meat produced at retail level when the shelf-life of the product is less then 24 hours.

E. coli is used here as an indicator of faecal contamination.

These criteria apply to mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in section V of Annex III of Regulation No 853/2004/EC of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

(continued…)

Sampling frequencies for minced meat, meat preparations and mechanically separated meat

The food business operators of slaughterhouses or establishments producing minced meat, meat preparations or mechanically separated meat shall take samples for microbiological analysis at least once a week. The day of sampling shall be changed each week to ensure that each day of the week is covered.

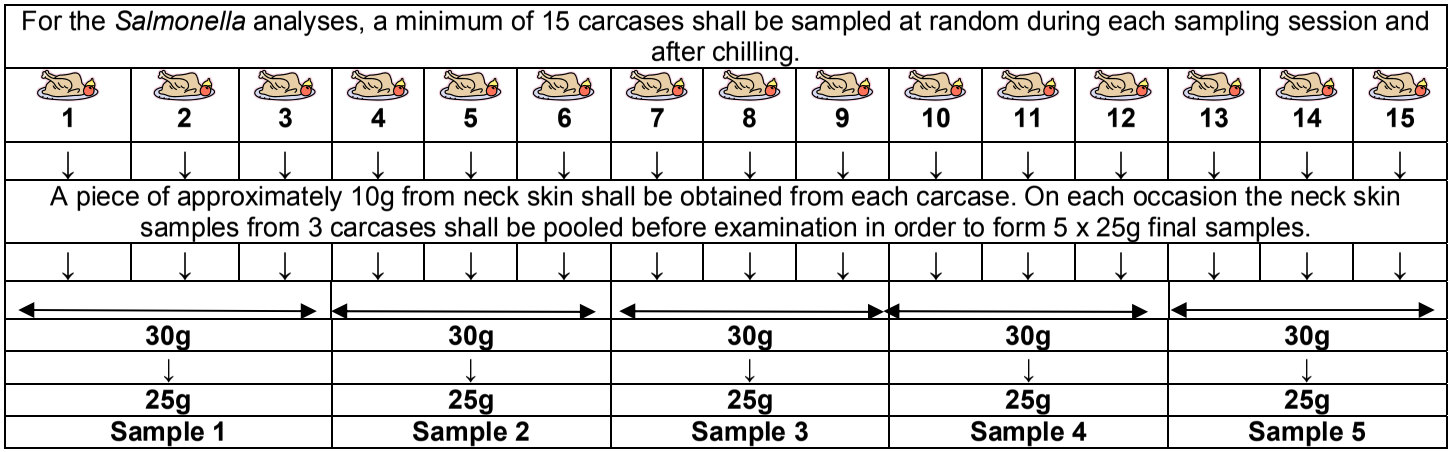
As regards the sampling of minced meat and meat preparations for *E. coli* and aerobic colony count analyses, the frequency may be reduced to fortnightly testing if satisfactory results are obtained for six consecutive weeks. If any subsequent results exceed M, then sampling frequency should return to weekly.

However, when justified on the basis of a risk analysis and consequently authorised by the competent authority, small slaughterhouses producing small quantities may be exempted from these sampling frequencies.

A representative sample of a batch cannot be obtained at retail level. Sampling should take place as early as possible in the production chain.

Interpretation

Figure 2: Sampling rules for poultry carcases



After each sampling session, the results of the last ten sampling sessions (50 results) are assessed, e.g. a moving window - after 10 weeks new results are produced. These results should then be used to determine whether the process hygiene criteria have been met.

(continued...)

Interpretation of the test results

Unlike the criteria for other product types the testing frequencies for carcases, minced meat and meat preparations are a statutory requirement for Food Business Operators producing these products.

The limits given refer to each sample unit tested. When testing carcases the testing is carried out on pooled samples and the limits refer to results from 50 samples.

The test results demonstrate the microbiological quality of the process tested.

Process Hygiene - Milk and dairy products

Food category and criterion number		Microorganisms	Sampling plan		Limit		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.2.1	Pasteurised milk and other pasteurised liquid dairy products	*Enterobacteriaceae*	5	2	<1 cfu/ml	5 cfu/ml	ISO 21528-1	End of the manufacturing process	Check on the efficiency of heat-treatment and prevention of recontamination as well as the quality of raw materials
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	*E. coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649- 1 or 2	At the time during the manufacturing process when the *E. coli* count is expected to be highest	Improvements in production hygiene and selection of raw materials
E. coli is used here as an indicator for the level of hygiene. For cheeses which are not able to support the growth of *E.coli*, the *E.coli* count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of *E.coli*, it is normally at the end of the ripening period.									

Note: 'Heat treatment' is pasteurisation or any lower heat treatment than pasteurisation. Pasteurisation is achieved by means of a treatment:

(i) involving a high temperature for a short time (at least 71.7°C for 15 seconds) or a low temperature for a long time (at least 63°C for 30 minutes) or any other time-temperature conditions to obtain equivalent effect;

(ii) sufficient to ensure that the products show a negative reaction to an alkaline phosphatase test immediately after heat treatment.

(continued…)

Process Hygiene - Milk and dairy products (continued)

Food category and criterion number		Microorganisms	Sampling plan		Limit		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.2.3	Cheeses made from raw milk	Coagulase-positive *staphylococci*	5	2	10^4 cfu/g	10^5 cfu/g	EN/ISO 6888-2	At the time during the manufacturing process when the number of *staphylococci* is expected to be highest	Improvements in production hygiene and selection of raw materials. If values greater than 10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
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	Coagulase-positive *staphylococci*	5	2	100 cfu/g	1000 cfu/g	EN/ISO 6888-1 or 2		
2.2.5	Unripened soft cheeses (fresh cheeses) made from milk or whey that has undergone pasteurisation or a stronger heat treatment	Coagulase-positive *staphylococci*	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values greater than 10^5 cfu/g are detected, the cheese batch has to be tested for staphylococcal enterotoxins.
Excluding cheeses where the manufacturer can demonstrate, to the satisfaction of the competent authorities, that the product does not pose a risk of staphylococcal enterotoxins.									

If an unsatisfactory coagulase-positive staphylococci *count is obtained and the product is sent for enterotoxin testing, it is advisable to hold the batch concerned (i.e. not release onto the market) until the enterotoxin results are obtained. If staphylococcal enterotoxin is present, the batch would then present an unacceptable risk to human health and must not be placed onto the market (see Food Safety Criterion 1.21).*

For cheeses which are not able to support the growth of S.aureus *e.g. hard cheese, the* S.aureus *count is usually the highest at the beginning of the ripening period, and for cheeses which are able to support the growth of* S.aureus*, e.g. soft cheeses, it is normally at the end of the ripening period.*

(continued...)

Process Hygiene - Milk and dairy products (continued)

Food category and criterion number		Microorganisms	Sampling plan		Limit		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	M	M			
2.2.6	Butter and cream made from raw milk or milk that has undergone a lower heat treatment than pasteurisation	*E. coli*	5	2	10 cfu/g	100 cfu/g	ISO 16649- 1 or 2	End of the manufacturing process	Improvements in production hygiene and selection of raw materials
E. coli is used here as an indicator for the level of hygiene.									
2.2.7	Milk powder and whey powder	*Enterobacteriaceae*	5	0	<10 cfu/g		ISO 21528- 1	End of the manufacturing process	Check on the efficiency of heat treatment and prevention of recontamination
		The criterion does not apply to products intended for further processing in the food industry.							
		Coagulase-positive *staphylococci*	5	2	10 cfu/g	100 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene. If values greater than 10^5 cfu/g are detected, the batch has to be tested for staphylococcal enterotoxins.
If an unsatisfactory coagulase-positive *staphylococci* count is obtained and the product is sent for enterotoxin testing, it is advisable to hold the batch concerned (i.e. not release onto the market) until the enterotoxin results are obtained. If staphylococcal enterotoxin is present, the batch would then present an unacceptable risk to human health and must not be placed onto the market (see Food Safety Criterion 1.21).									

(continued…)

Process Hygiene - Milk and dairy products (continued),

Infant formula and dried dietary foods for infants for special medical purposes

Food category and criterion number	Micro-organisms	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.2.8 Ice cream (only ice creams containing milk ingredients) and frozen dairy desserts	*Enterobacteriaceae*	5	2	10 cfu/g	100 cfu/g	ISO 21528- 2	End of the manufacturing process	Improvements in production hygiene
2.2.9 Dried infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age	*Enterobacteriaceae*	10	0	Absence in 10 g		ISO 21528- 1	End of the manufacturing process	Improvements in production hygiene to minimise contamination. If Enterobacteriaceae are detected in any of the sample units, the batch has to be tested for *E. sakazakii* and *Salmonella*

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

If Enterobacteriaceae *are detected in any of the sample units the batch must be tested for* E. sakazakii *and* Salmonella. *As required in Food Safety Criteria 1.22 and 1.23, if the results obtained exceed the criteria for* E. sakazakii *and* Salmonella *they are unsatisfactory and the affected product must be withdrawn from the market. The Competent Authority must also be notified.*

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Process Hygiene - Egg products

Food category and criterion number	Micro-organisms	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
		n	c	m	M			
2.3.1 Egg products	*Enterobacteriaceae*	5	2	10 cfu/g or ml	100 cfu/g or ml	ISO 21528-2	End of the manufacturing process	Checks on the efficiency of the heat treatment and prevention of recontamination

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Process Hygiene - Fishery products and shellfish

Food category and criterion number		Microorganisms	Sampling plan		Limit		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.4.1	Shelled and shucked products of cooked crustaceans and molluscan shellfish	*E. coli*	5	2	1 cfu/g	10 cfu/g	ISO TS 16649-3	End of the manufacturing process	Improvements in production hygiene
		Coagulase-positive *staphylococci*	5	2	100 cfu/g	1 000 cfu/g	EN/ISO 6888-1 or 2	End of the manufacturing process	Improvements in production hygiene

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.

Process Hygiene - Produce

Food category and criterion number		Microorganisms	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies	Action in case of unsatisfactory results
			n	c	m	M			
2.5.1	Pre-cut fruit and vegetables (ready-to-eat)	*E. coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials
2.5.2	Unpasteurised fruit and vegetable juices (ready-to-eat)	*E. coli*	5	2	100 cfu/g	1 000 cfu/g	ISO 16649-1 or 2	Manufacturing process	Improvements in production hygiene, selection of raw materials

Interpretation of the test results

The limits given refer to each sample unit tested.

The test results demonstrate the microbiological quality of the process tested.