



General Guidance for Food Business Operators

**EC Regulation No. 2073/2005
on Microbiological Criteria for Foodstuffs**

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¹ Annex I of Regulation 2073/2005 sets down detailed sampling plans for each of the microbiological criteria included; and Annex II of 2073/2005 sets down specific requirements for shelf-life studies.

INTRODUCTION

1. The aim of this guidance note is to help UK food business operators gain a general understanding of the requirements of new European legislation on microbiological criteria for foodstuffs. This guidance should be read in conjunction with EC Regulation 2073/2005.
2. Legislation on microbiological criteria for foodstuffs changes from 11 January 2006. Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs (hereafter referred to as Regulation 2073/2005) was published in the Official Journal of the European Communities on 22 December 2005.
3. The revised legislation supports new EU food hygiene rules that apply to all UK food businesses from 1 January 2006. Details of all the relevant EU regulations and associated national legislation are given in Appendix A of this guidance note. The EU Regulation applies directly but national regulations are needed to provide the enforcement powers for the EU regulations. A breach of Article 7 (1) (Unsatisfactory results) of Regulation 2073/2005 constitutes an offence under the Food Hygiene No 2 Regulations 2005.
4. This note is not legally binding and it should therefore be read together with the EU and national legislation listed in Appendix A of this guidance note. Additional sources of advice and information (including Agency guidance on the new food hygiene legislation) that can help you comply with the law are detailed in Appendix B of this guidance note.
5. While this note represents the considered view of the Agency, only the courts can give a definitive view of the law.

PART 1: SUMMARY FOR SMALL BUSINESSES

1. Up to the end of 2005 there were numerous pieces of legislation covering the hygiene of specific commodities and many of these included microbiological criteria. From 1 January 2006 a new package of food hygiene rules has replaced these pieces of legislation. The existing microbiological criteria were reviewed to produce a new Regulation (Regulation 2073/2005) which supports that package. Many of the existing criteria remain unchanged, but some no longer exist and criteria have been established in new areas where this is necessary e.g. pre-cut fruit and vegetables, infant formula, *Salmonella* on some meat carcasses and *Listeria monocytogenes* in some ready to eat products.
2. The Regulation applies to all food business operators involved in the processing, manufacturing, handling and distribution of food, including retailers and caterers. Most primary producers are at present not directly affected, as specific microbiological criteria have not been set for primary products, other than sprouted seeds and live bivalve molluscs, echinoderms, tunicates and gastropods. However, primary producers may be affected indirectly if their customers require changes to specifications, as a result of developments in their food safety management procedures (e.g. improvements in production hygiene and selection of raw materials). Food business operators must ensure that foodstuffs comply with the relevant microbiological criteria and to comply with the regulation fully, they must also take the required action if a product is found to fail any of the criteria.
3. Two types of microbiological criteria are to be introduced:
 - **food safety criteria** which should be used to assess the safety of a product or batch of foodstuffs. These apply throughout the shelf-life and if they are not met, the food business operator will not be able to place the food on the market or will need to remove it from the market. In some cases a product recall may be required. The food safety management procedures should also be reviewed to ensure the products are likely to comply in the future.
 - **process hygiene criteria** which help show that the production processes are working properly. These apply throughout every stage of manufacturing and handling. If a process criterion is exceeded this should lead to a review of current procedures to improve product hygiene. In two cases, further testing may be required. These are when Enterobacteriaceae in infant formula or coagulase positive staphylococci in dairy products are found.
4. The Regulation does not specify minimum requirements for testing (except for carcasses, minced meat, meat preparations and mechanically separated meat, where harmonised minimum sampling frequencies are specified). Nor does it require food business operators to carry out routine microbiological testing or to wait for the results of any testing carried out

before the food is placed on the market. The criteria should be used to ensure that the food safety management procedures are functioning correctly.

5. Food business operators must consider in what circumstances it is appropriate to use microbiological testing to demonstrate compliance with the criteria, but (with the exceptions given in the above paragraph) are not required to carry out testing in every case. For example, where food safety management procedures based on Hazard Analysis Critical Control Point (HACCP) principles and good hygiene practice are in place routine monitoring of physical parameters (such as monitoring time/temperature profiles, pH, level of preservative and water activity) may provide adequate assurance that the criteria are being met. Evidence that the business is following guidance from the Food Standards Agency, Local Authorities or industry guides to good practice can also help demonstrate compliance e.g. adoption of schemes such as “Safer Food Better Business” and equivalent Agency schemes. If required, further advice can be obtained from your local authority or the Agency website (<http://www.food.gov.uk/foodindustry/hygiene/sfbb/>)
6. Where testing is appropriate, with the exceptions listed in paragraph 4 above, the Regulation allows food business operators to use their food safety management procedures to establish an appropriate sampling regime. The level of sampling required will depend on considerations such as the food safety management procedures in place, the risk associated with the product, and the nature and size of the business.
7. Enforcement officers must ensure that food business operators are complying with the Regulation. In the UK this will be either Local Authorities or the Port Health Authority. Food business operators will be required to provide evidence that the necessary food safety management procedures are in place to ensure all relevant criteria are met. Enforcement officers will not routinely carry out testing to support their assessment of the evidence but there may be instances where they wish to do so, for example, if they identify a particular problem or where they are carrying out surveys.
8. Food safety criteria apply to trade between Member States and can be applied by enforcers to check imports from countries outside of the EU.

PART 2: OVERVIEW

1 Purpose

1.1 Regulation 2073/2005 modernises and harmonises existing microbiological criteria contained in numerous commodity-based EC directives to ensure they are consistent, based on up-to-date scientific risk assessment and relevant to consumer health protection. It also includes several new criteria that apply to certain food groups and micro-organisms not previously included in Community legislation (for example criteria for pre-cut fruit and vegetables, powdered infant formulae, *Salmonella* on meat carcasses and *Listeria monocytogenes* in certain ready-to-eat food products).

1.2 The Regulation establishes two types of criterion and requires that food business operators take corrective action when these criteria are not met. These two types are:

- **food safety criteria** which should be used to assess the safety of a product or batch of foodstuffs; and
- **process hygiene criteria** which should be used to ensure the production processes are operating properly.

1.3 The corrective actions required differ for each type of criterion:

- **Failure to meet food safety criteria.** If a food safety criterion is not met, this usually means the food business operator will not be able to place the foodstuff on the market or will need to remove the food from the market (as provided in Regulation 178/2002 laying down general food safety requirements) and take steps to ensure future production meets the criterion. In certain circumstances, a recall of the food may be required.
- **Failure to meet food hygiene criteria.** If a process hygiene criterion is not met the product can be placed on the market, but the food business operator must review the production processes and improve process hygiene to ensure future production will meet the criteria.

The action taken in either case should be included in the food safety management procedures (see [2.3] below), which should also include relevant actions specified in Annex I (chapter 2) of the Regulation. In both cases, enforcement authorities will require sufficient evidence that the food business operator has taken the appropriate corrective action.

2 Scope – who is affected?

2.1 Regulation 2073/2005 and associated national legislation applies to all food business operators involved in the processing, manufacturing, handling and distribution of food, including retailers and caterers.

2.2 Most primary producers are not directly affected, as specific microbiological criteria have not been set for primary products, other than sprouted seeds and live bivalve molluscs, echinoderms, tunicates and gastropods. However, primary producers may be affected indirectly if their customers require changes to specifications, as a result of developments in their food safety management procedures (e.g. improvements in production hygiene and selection of raw materials).

2.3 The new legislation on microbiological criteria for foodstuffs complements the preventive approach to food safety established by the new food hygiene legislation. Article 4(3) and (4) of Regulation 852/2004 provides the legal basis for the Microbiological Criteria Regulation. The food hygiene legislation requires all food businesses (other than those undertaking primary production activities) to have food safety management procedures based on HACCP principles, and specifies the general requirements for all food business operators. Food business operators should apply the criteria within these food safety management systems.

2.4 In accordance with EU Regulation 882/2004 on Official feed and food controls, the relevant competent authority (e.g. local food authority) is required to verify compliance with the rules and criteria laid down in the microbiological criteria Regulation.

2.5 Certain activities, such as occasional preparation of food by individuals or groups for sale at charitable events, would not necessarily come within the scope of the definition of food businesses. Such activities would however still be subject to the general legal requirements relating to placing unsafe food on the market contained in the Food Safety Act 1990 and the UK General Food Regulations 2004. More guidance on this can be found in the Food Standards Agency guidance on the requirements of the food hygiene legislation, details at www.food.gov.uk.

3 Compliance

3.1 The safety of food is neither guaranteed nor controlled by microbiological testing. **The new legislation on microbiological criteria for foodstuffs does not impose a general requirement for increased end product microbiological testing or positive release.**

3.2 Microbiological criteria should be considered an integral part of a food business's food safety management procedures. The criteria are intended to assist with validating and verifying food safety management procedures. They may also help with assessing the acceptability of foodstuffs and their manufacturing, handling and distribution processes.

3.3 The degree to which businesses will be affected will depend on the procedures that the food business operator currently has in place. In many cases current practices may be sufficient to demonstrate compliance with the Regulation, as it is not intended that there should be increased emphasis on microbiological testing where food safety management procedures based on

HACCP principles and good hygiene practices are in place and appropriate verification is carried out. Furthermore, this Regulation is not expected to lead to any practical changes for any food commodity where microbiological criteria are not included.

3.4. Many businesses will already have established food safety management procedures and supporting sampling and testing regimes. Also many food businesses may also currently test products in accordance with specifications from customers, or as part of industry specific guidelines and standards. They may also seek additional certification, such as that provided by the British Retail Consortium (BRC), Natures Choice, Assured Food Standards, Linking Environment and Farming (LEAF) etc. The need to comply with the microbiological criteria Regulation is not expected to lead to a significant change in these current working practices.

3.5 The new legislation on microbiological criteria allows flexibility for the food business to decide what should be done to demonstrate compliance and, where testing is carried out, the sampling and testing plan should be proportionate to the risk and to the nature and size of the business.

3.6 For all commodities (except for carcasses, minced meat, meat preparations and mechanically separated meat) the Regulation allows food businesses to decide for themselves what frequency of sampling and testing is appropriate, according to the specific local risk. Food business operators may not need to test, or may plan infrequent testing if they can provide evidence to show that food safety management procedures are in place and functioning correctly, and/or they are following guidance from the FSA, local authorities or industry guides to good practice.

3.7 Where microbiological testing is considered appropriate, the Regulation allows a number of flexibilities in terms of sampling and testing frequency. For example, food businesses that carry out regular microbiological testing will not need to test every batch against the microbiological criteria to demonstrate compliance. Food businesses may also satisfy the criteria through their own controls and develop procedures that use alternative indicators, such as time/temperature profiles, which demonstrate that the same end result is achieved. Other ways to demonstrate compliance with the criteria could include operation of good hygiene practices demonstrating, for example, procedures to monitor that food is being cooked thoroughly, to ensure the cold chain is maintained, to ensure raw foods are stored separately from cooked foods and to ensure that an effective cleaning system is in operation.

3.8 To assist small businesses in complying with Regulation 852/2004 on the hygiene of foodstuffs the Agency is running a series of initiatives throughout the UK. These schemes are initially targeted at the catering sector and are intended to help catering businesses implement effective food safety management procedures and demonstrate compliance with the food hygiene legislation. Operation of such schemes can also help catering businesses to demonstrate compliance with microbiological criteria without the need for microbiological testing. These include:

- “Safer Food, Better Business” (SFBB) in England;
- “Cooksafe” in Scotland;
- “Safe Catering” in Northern Ireland which has been established over a number of years in the catering sector; and
- In Wales, several local authorities have developed their own guidance packs over the years and FSA Wales has encouraged sharing of these packs throughout Welsh local authorities. A guidance pack written in English/Welsh; English/Bengali; English/Chinese and English/Turkish is available from Welsh local authorities.

Source references for these Agency initiatives are included at Appendix B of this guidance.

3.9 These schemes have been developed to allow catering businesses to manage food safety and protect consumers through the operation of simple and practical guidance, whilst at the same time avoiding unnecessary burdens. The Agency plans to develop SFBB further and adapt the scheme for different business sectors during 2006. Details can be found on the Agency’s web site at www.food.gov/catering.

3.10 Food business operators responsible for the production of raw minced meat, meat preparations and meat products intended to be cooked before consumption must comply with the specific requirement to label products sold at retail with cooking information. This is because there are several countries in the EU where these types of meat may be consumed raw or with minimal cooking. Where this type of product is made from poultry meat this requirement applies until 31 December 2009.

3.11 The Regulation includes a transitional derogation from the 11 January 2006 until 31 December 2009 for the criteria for *Salmonella* for raw minced meat, meat preparations, and meat products intended to be eaten cooked. Under the derogation, products complying with a less stringent criterion than that required for intra-community trade would be allowed to be placed on the national market of the producing country. To take advantage of this derogation, manufacturers will need to comply with the requirement to clearly label all such products with a special mark (indicating it is marketed under the derogation) as well as clear information that the product requires cooking. Certain details, such as the design of the special mark, are still being discussed with relevant stakeholders and, in due course, further information will be provided in the Draft Guide To Food Safety and Other Regulations for the Meat Industry (<http://www.food.gov.uk/foodindustry/meat>). The Agency intends to notify the Commission that the UK wishes to operate the derogation and provide it with details of the special mark, once the design of this mark has been finalised.

3.12 Comprehensive guidance on the application of microbiological criteria in the Meat Industry is provided in the Draft Guide to Food Safety and Other Regulations for the Meat Industry, which may be found at

<http://www.food.gov.uk/foodindustry/meat> and on sampling and testing at <http://www.ukmeat.org>

4 Enforcement

4.1 The enforcement authorities (e.g. local food authorities) in each Member State will be responsible for ensuring food business operators are complying with the microbiological criteria throughout the food production and distribution chain.

4.2 In practice it is expected that this will be achieved through the audit of businesses' food safety management procedures. Food business operators will therefore need to provide enforcement officials with supporting evidence that the criteria are being met. On occasion the enforcement officer may wish to take samples to support the audit of the food safety criteria but this will not always be the case.

4.3 To comply fully with the Regulation if any of the criteria are exceeded food business operators must carry out the corrective actions outlined in the relevant Annex of the Regulation, together with those specified as part of their food safety management procedures.

4.4 The Agency is intending to provide guidance to enforcers through an updated version of the statutory Code of Practice and accompanying Practice Guidance. The European Commission is also developing guidelines to cover the sampling and testing of food against the microbiological criteria for official control purposes. The Commission has not provided a timetable for the production of the guidelines, but discussions with Member States are continuing and these are not expected to be finalised before Spring 2006. The Agency will continue to seek views and comments from stakeholders as the guidelines are developed.

PART 3: GUIDANCE ON ANNEXES I AND II OF REGULATION 2073/2005

Annex I: Microbiological Criteria for Foodstuffs:

General requirements

Food business operators must (with notable exceptions) decide the appropriate level of microbiological testing for products within their procedures based on HACCP principles and the general requirements of the hygiene regulations, to validate and verify these procedures are functioning correctly. In general the Regulation does not specify a minimum level of testing that must be carried out and therefore if there is sufficient supportive evidence testing may in some cases be required only infrequently or not at all. The exceptions to this are food business operators of slaughterhouses or establishments producing minced meat, meat preparations or mechanically recovered meat where the sampling frequency for testing is specified (at least once per week). It may be possible for food business operators to use routine monitoring of physical parameters associated with procedures based on HACCP principles (e.g. critical control points (CCPs)) and the general requirements of the hygiene regulations to help demonstrate compliance with the criteria, rather than testing.

Where testing is appropriate, sampling frequency should be based on risk, taking account of instructions for use of the foodstuff (e.g. ready-to-eat, intended to be eaten after cooking or other processing). Where weekly sampling frequencies are specified for carcasses, minced meat, meat preparations and mechanically recovered meat, they do not apply to small slaughterhouses and establishments producing minced meat and meat preparations in small quantities. The description of small and the frequencies that do apply are given in the Draft Guide to Food Safety and Other Regulations for the Meat Industry at <http://www.food.gov.uk/foodindustry/meat> and <http://www.ukmeat.org>

Sampling plans and analytical methods set down in Annex I of the Regulation provide the minimum level to be observed when specifically assessing the acceptability of foodstuffs or a process. However, food business operators may reduce the number of sample units in sampling plans from that specified in Annex I of the Regulations based on risk as long as they are able to provide evidence to support the proposed sampling plan and satisfy the competent authority that effective procedures based on HACCP principles and GHP are in place.

Other sampling or testing procedures may be used if it can be demonstrated that they provide at least equivalent guarantees. This may include alternative sampling sites or trend analyses.

In the case of process hygiene criteria the Regulation allows Food business operators to demonstrate compliance with the by testing against alternative micro-organisms/limits and for non-microbiological analytes.

Alternative methods must be validated against the reference methods or else validated against an internationally recognised protocol and authorised for use by the competent authority. Proprietary methods (e.g. a rapid method available as a commercial kit) must be validated against the reference method and certified by a third party in accordance with EN/ISO standard 16140.

Food businesses manufacturing ready-to-eat foods which could pose a risk to public health through the presence or growth of *Listeria monocytogenes*, should monitor the processing areas and equipment for *Listeria monocytogenes* as a part of their sampling plans.

Food businesses manufacturing dried infant formula and dried dietary foods for special medical purposes intended for infants below 6 months should sample the processing environment for Enterobacteriaceae as a part of their sampling plans.

Chapter 1, Food Safety Criteria and Chapter 2, Process Hygiene Criteria

Chapters 1 and 2 of Annex 1 of the Regulation set out detailed sampling plans and corrective actions for the microbiological criteria set down in this Regulation. Most criteria require no further explanation and so are not covered in this guidance.

Guidance in the form of decision trees is included in this section for criteria covering:

- (i) *Listeria monocytogenes* in ready to eat foods;
- (ii) coagulase-positive staphylococci and staphylococcal enterotoxins in dairy products; and
- (iii) *Salmonella*, *Enterobacter sakazakii* and Enterobacteriaceae in infant formulae and dried dietary foods for special medical purposes intended for infants below 6 months of age.

Detailed guidance on criteria for meat and processed meat and sampling is provided in the Draft Guide to Food Safety and Other Regulations for the Meat Industry: <http://www.food.gov.uk/foodindustry/meat> and at: <http://www.ukmeat.org>

Annex II: Shelf-life studies for ready to eat foods able to support the growth of *Listeria monocytogenes*

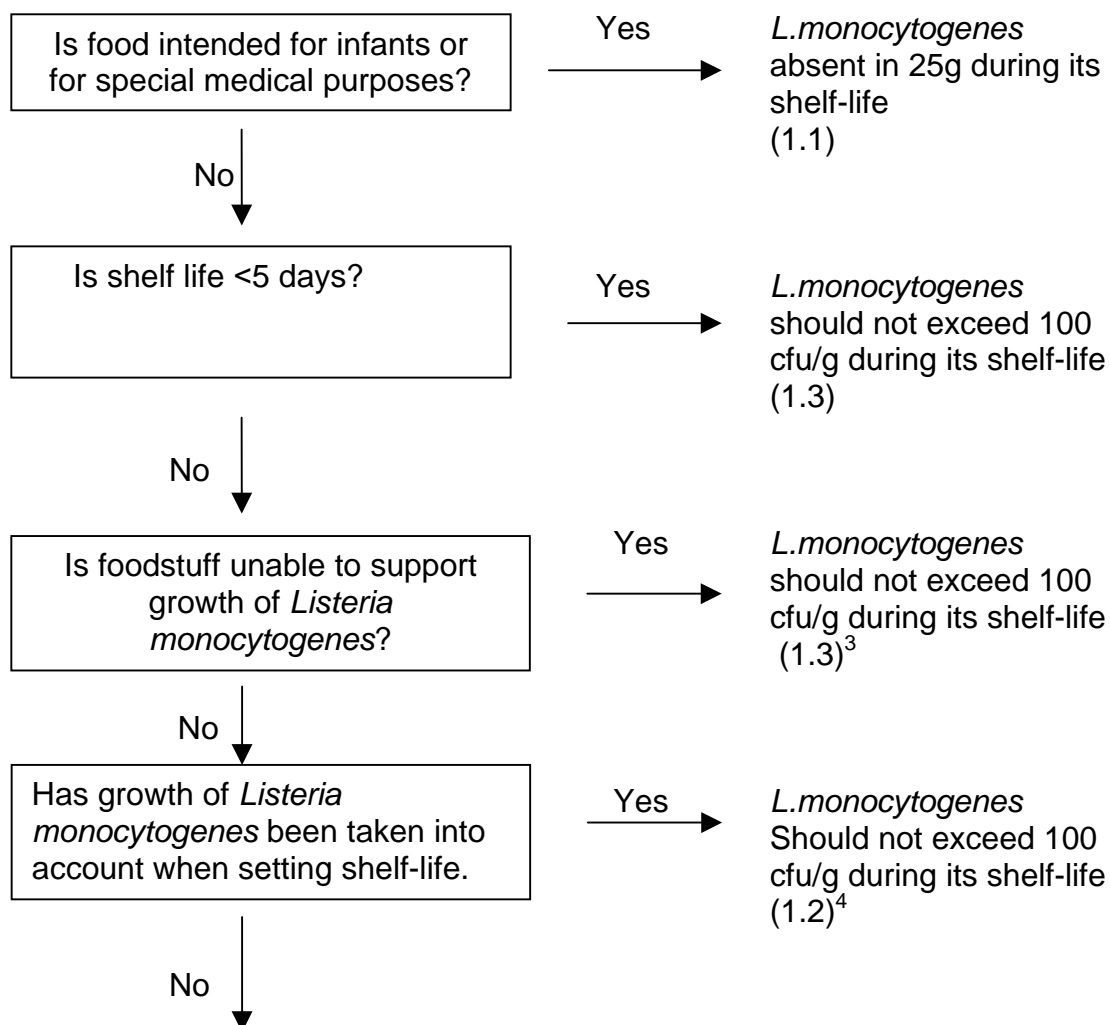
All manufacturers of ready-to-eat products should consider whether these products are able to support the growth of *Listeria monocytogenes*. This annex gives some guidance on the types of studies that could be used to determine whether *Listeria monocytogenes* would grow in a product and the ways in which businesses may demonstrate compliance with the criteria.

For example, will *Listeria monocytogenes* grow in the product during storage, or do the physico-chemical properties of the product prevent such growth e.g. the pH, salt levels, water activity? Is it possible to control growth and ensure food safety, e.g. by monitoring water activity or by modifying the level of preservatives?

Food business operators are allowed to use available data contained in the literature to demonstrate compliance for equivalent or similar products.

Where necessary food business operators may use models, challenge tests or any other type of study appropriate for showing the behaviour of micro-organisms of concern, which includes relevant historical product data.

Decision tree 1: Which *Listeria monocytogenes* criteria should I be using for ready to eat foods?²



Absence in 25g before food leaves immediate control of food business operator who has produced it (1.2)

² Regular testing not useful for the following ready to eat foods:

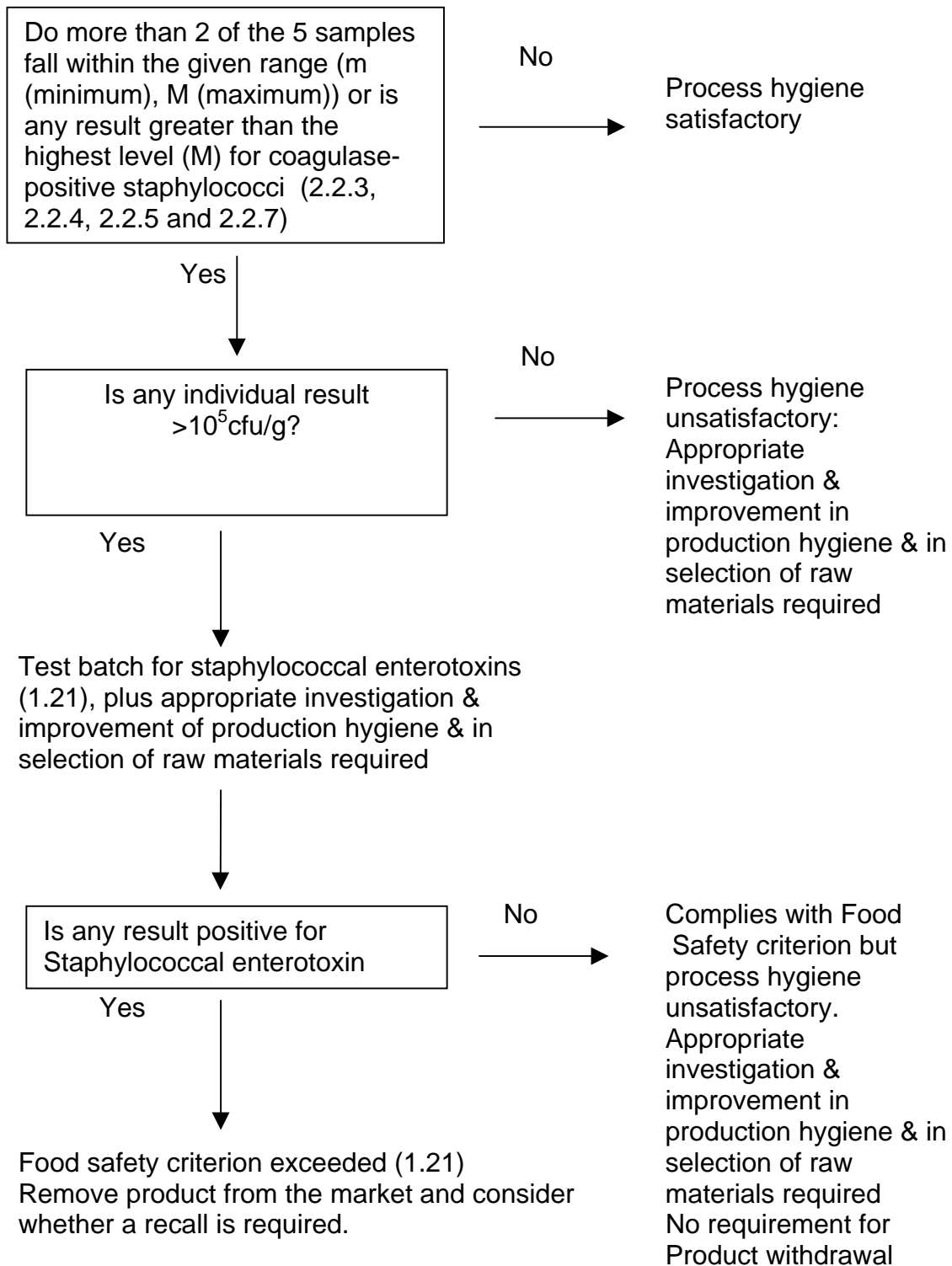
- foods processed sufficiently to eliminate *Listeria monocytogenes* when recontamination not possible e.g. foods heat-treated in final packaging
- fresh uncut and unprocessed fruit and vegetables (excluding sprouted seeds)
- bread, biscuits, breakfast cereals and similar products
- bottled or packaged waters, soft drinks, beer, cider, wine, spirits and similar products
- sugar, honey and confectionery, including cocoa and chocolate products
- live bivalve molluscs

³ Includes products with:

- pH less than or equal to 4.4
- Water activity a_w less than or equal to 0.92
- pH less than or equal to 5.0 and a_w less than or equal to 0.94

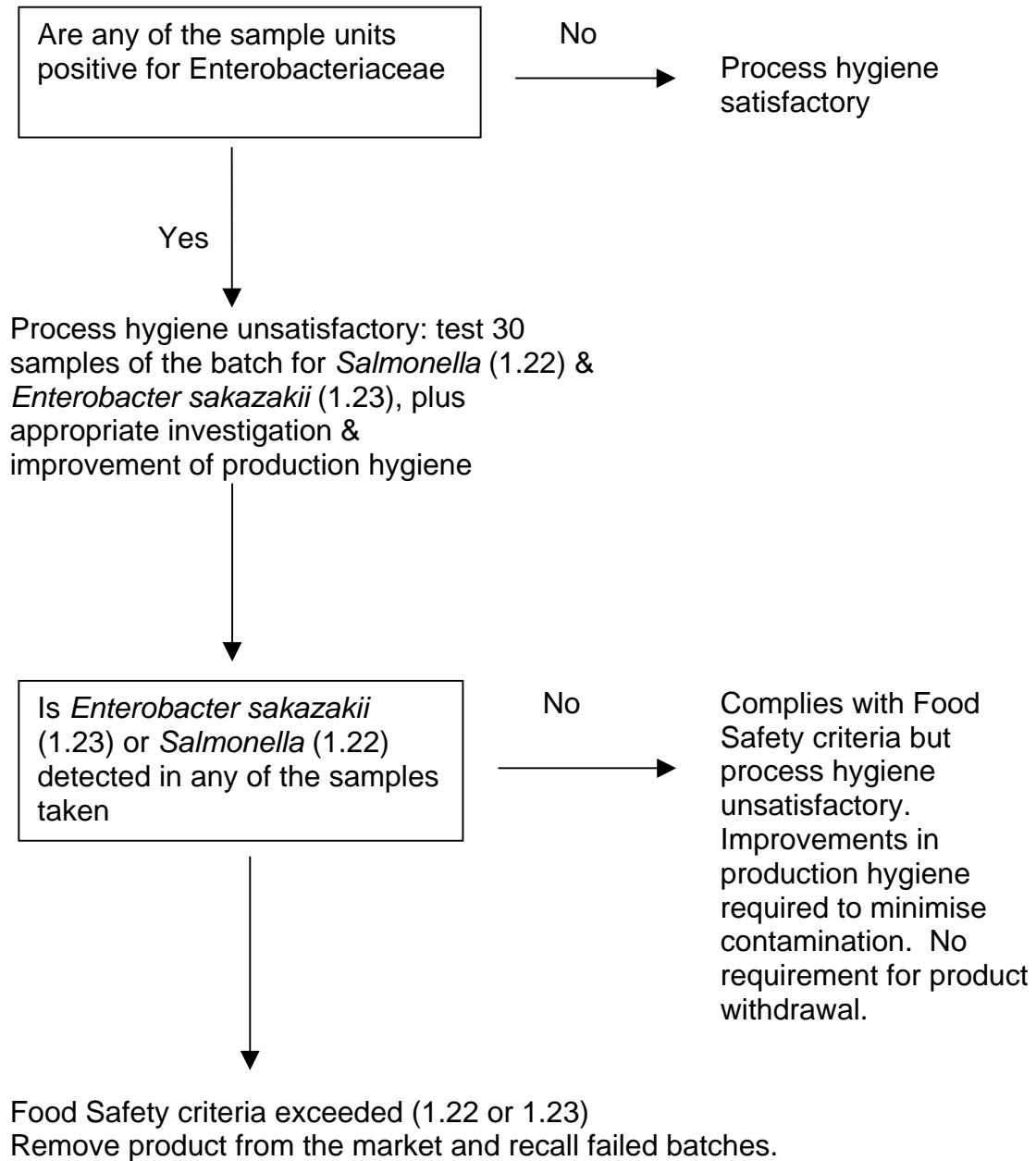
⁴ if shelf life studies show 100cfu/g is likely to be exceeded before the end of the shelf life, options include reviewing shelf life, reviewing food safety management procedures, of ensuring absence in 25g before the food leaves the immediate control of food business operator.

Decision tree 2: What should I do if I find Coagulase positive-staphylococci and Staphylococcal enterotoxins in dairy products?⁵



⁵ A 2-tiered approach is to be used for staphylococcal enterotoxins. Batches only need to be tested against this food safety criterion if a result of > 100,000 cfu/g is initially obtained for any of the sample units when testing against the coagulase-positive staphylococci process hygiene criterion.

Decision tree 3: What do I do if I find Enterobacteriaceae, *Salmonella* or *Enterobacter sakazakii* in dried infant formulae and dried infant foods?



PART 4: SUMMARY GUIDE TO THE REGULATION

European Commission Regulation on Microbiological Criteria for Foodstuffs: Selected Recitals, Articles and Annexes	What it means/Guidance
Recital 1	<ul style="list-style-type: none"> • Background Information.
Recital 2	<ul style="list-style-type: none"> • Microbiological food safety objectives.
Recital 3	<ul style="list-style-type: none"> • General responsibilities of food business operators and reasons for introducing microbiological criteria.
Recital 4	<ul style="list-style-type: none"> • Use of microbiological criteria.
Recital 5	<ul style="list-style-type: none"> • Emphasis on prevention in controlling food safety hazards and use of criteria to support procedures based on HACCP principles and GHP.
Recital 6	<ul style="list-style-type: none"> • Legal basis and obligations on food business operators.
Recital 7	<ul style="list-style-type: none"> • Requirements for competent authorities.
Recitals 8 to 18	<ul style="list-style-type: none"> • Framework within which microbiological criteria set down and basis for the criteria introduced.
Recital 18	<ul style="list-style-type: none"> • Notes that harmonised criteria will replace National criteria.
Recital 19 – 20	<ul style="list-style-type: none"> • Revision and incorporation of certain criteria contained in repealed Decisions and Directives.
Recital 21	<ul style="list-style-type: none"> • Labelling requirements (instructions for use) and obligation for these to be reflected in frequency of testing.
Recital 22	<ul style="list-style-type: none"> • Sampling and testing of the processing environment.
Recital 23	<ul style="list-style-type: none"> • Flexibility for setting sampling and testing frequency, food safety management procedures based on HACCP principles and GHP but allows for frequency to be set at Community level, where necessary.
Recital 24	<ul style="list-style-type: none"> • Use of reference methods for testing and flexibility for use of alternative methods and indicators.
Recital 25	<ul style="list-style-type: none"> • Requirement for trend analysis.
Recital 26	<ul style="list-style-type: none"> • Provision for review and revision of criteria.
Recital 27	<ul style="list-style-type: none"> • Intention to introduce criteria for pathogenic viruses and <i>Vibrio parahaemolyticus</i> in live bivalve molluscs, once reliable test methods are developed.
Recital 28	<ul style="list-style-type: none"> • Criteria for meat and processed meat should take account of improvements in <i>Salmonella</i> prevalence brought about by national control programmes.
Recital 29	<ul style="list-style-type: none"> • Transitional derogation allowed for certain food safety criteria (i.e. <i>Salmonella</i> in minced meat, meat preparations

	and meat products intended to be eaten cooked).
Recital 30	<ul style="list-style-type: none"> • Regulation adopted by the Standing Committee on the Food Chain and Animal Health.
Article 1 Subject-matter and scope	<ul style="list-style-type: none"> • Sets out the legal basis and responsibilities of food business operators and the competent authority. • Primary producers, manufacturers, processors, distributors, retailers and caterers are all affected. • Fresh produce growers are not directly affected (except for producers of sprouted seeds for which specific criteria have been set). However, in practice, improvements to production hygiene may still be required, as a consequence of customers' food safety management procedures. This may, for example, include taking measures to ensure that source materials are uncontaminated, fields are not affected by contaminated run-off or manure spreading, field boundaries are stock-proof, water used for irrigation is of acceptable microbiological quality, harvesting equipment is cleaned properly, and that field workers and packers observe good hygiene practices and maintain standards of personal hygiene.
Article 2 Definitions	<ul style="list-style-type: none"> • Defines a list of the terms used in the Regulation. These definitions cross-refer to relevant definitions given in current Community legislation where appropriate.
Article 3 General requirements	<ul style="list-style-type: none"> • Indicates that food business operators need to take steps within their procedures based on HACCP principles and GHP to ensure compliance with the criteria (e.g. controls on raw materials, hygiene, temperature and shelf-life). Routine monitoring of physical parameters associated with such procedures (e.g. Critical Control Points) is allowed to demonstrate compliance with the criteria in Annex 1. • Process hygiene criteria apply throughout the entire process of supply, handling and processing of raw materials. • Food safety criteria apply to foodstuffs throughout their shelf-life under normal conditions. • Where relevant, manufacturers must carry out studies to show that foodstuffs comply with criteria throughout the shelf-life, in particular to take account of the growth of <i>Listeria monocytogenes</i>. Food businesses are allowed to collaborate when conducting such studies, e.g. trades associations may commission general studies, and guidance may be produced in industry guides.
Article 4 Testing against criteria	<ul style="list-style-type: none"> • Requires food business operators to conduct testing as appropriate against microbiological criteria as part of validation and verification of procedures based on HACCP and GHP. • Flexibility is allowed so that sampling frequencies may be set within procedures based on HACCP principles and GHP, according to risk and the nature and size of the business (except for carcasses, minced meat, meat preparations and mechanically separated meat, where specified sampling frequencies are set at Community level).
Article 5 Specific rules for testing and sampling	<ul style="list-style-type: none"> • Specifies that the sampling plans and reference methods in Annex 1 should be used as reference methods. • Requires food business operators to carry out sampling and testing of the processing environment for <i>Listeria monocytogenes</i> in relation to manufacture of ready-to-eat foods to which the Listeria criteria apply and <i>Enterobacteriaceae</i> in relation to manufacture of dried infant formulae intended for infants below 6 months/dried foods for special medical purposes. • Food business operators are allowed to reduce the number of sample units if they can show historical

	<p>documentation that their procedures based on HACCP principles and GHP are effective.</p> <ul style="list-style-type: none"> • If testing is specifically to assess acceptability of a certain batch of foodstuffs or a process – for example when the origin of raw materials is not known or when a problem has arisen – then the sampling plans in Annex 1 must be followed as a minimum requirement. • Allows other sampling and testing procedures to be set within procedures based on HACCP principles and GHP (including alternative sampling sites and trend analysis). Additionally, alternative micro-organisms or other non-microbiological analytes may be used when testing against process hygiene criteria. • Alternative methods must be appropriately validated and authorised by the competent authority as specified.
Article 6 Labelling requirements	<ul style="list-style-type: none"> • Labelling of minced meat, meat preparations and meat products of all species intended to be eaten cooked must include cooking instructions for the consumer. For poultry, such instructions will no longer be required from 01.01.10.
Article 7 Unsatisfactory results	<ul style="list-style-type: none"> • Corrective actions required in the event of an unsatisfactory result must be documented within procedures based on HACCP principles and GHP. • Food business operators are obliged to investigate the cause of any unsatisfactory results to prevent reoccurrence. • If food safety criteria are not met, food business operators must withdraw the product or batch as appropriate from the market and inform the competent authority in accordance with Article 19 of Regulation 178/2002. The competent authority may, in addition, require recall of product from the market. • Products not yet on the market may be further processed to eliminate the hazard (except at retail level), providing there would be no risk to public or animal health and such action forms part of approved procedures based on HACCP principles and GHP. • Batches of mechanically recovered meat which fail to meet the food safety criteria for <i>Salmonella</i> may only be used to manufacture heat-treated meat products in establishments approved under Regulation 853/2004. • If process hygiene criteria are not met, food business operators must carry out corrective actions which include those laid down in Annex 1, Chapter 2.
Article 8 Transitional Derogation	<ul style="list-style-type: none"> • Until 31.12.09, minced meat, meat preparations, and meat products intended to be eaten cooked are allowed to be placed on the national market of the producing member state where no more than 1 out of 5 samples test positive for <i>Salmonella</i>. • Member States must notify the Commission and other Member States if they wish to take up this derogation. • Such products must be clearly labelled with a special mark indicating it is marketed under the derogation and therefore intended only for the domestic market of the producing member state, and with clear instructions for cooking.
Article 9 Analyses of trends	<ul style="list-style-type: none"> • Food business operators should monitor results and take action if there is a trend towards unsatisfactory results. In practice it is likely to be part of the procedures based on HACCP principles and GHP.
Article 10 Review	<ul style="list-style-type: none"> • Allows the Regulation to be reviewed over time as knowledge and conditions change.

Article 11 Repeal	<ul style="list-style-type: none">• Repeals Decision 93/51/EEC on the microbiological criteria applicable to production of cooked crustaceans and molluscan shellfish
Article 12 Date(s) of entry into force and application	<ul style="list-style-type: none">• Applies to all UK food businesses from 11 January 2006.

Appendices

Appendix A: European Commission Microbiological Criteria for Foodstuffs Regulation and Other Associated Legislation

1. The EU Regulations are:

- Commission Regulation No. 2073/2005 on microbiological criteria for foodstuffs, was subject to public written consultation on 12 September 2005, details of which can be found at: <http://www.food.gov.uk/foodindustry/Consultations/ukwideconsults/microcriteria2005> . This measure was adopted at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) on 20 July 2005.
- Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs;
- Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin; and
- Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.⁶

They were published in the Official Journal of the European Union of 30 April 2004, L139. Corrected versions were published in the Official Journal Of the European Union of 25 June 2004, L226. Copies are obtainable from the European Commission website: <http://europa.eu.int/eur-lex/lex/en/index.htm>.

2. In addition, a number of more detailed measures, including implementing and transitional measures have been adopted. These are:

- Commission Regulation (EC) No1688/2005 implementing Regulation (EC) No. 853/2004 of the European Parliament and of the Council as regards special guarantees concerning salmonella for consignments to Finland and Sweden of certain meat and eggs;
- Commission Regulation (EC) No. 2073/2005 on microbiological criteria for foodstuffs;
- Commission Regulation (EC) No. 2074/2005 laying down implementing measures for certain products under Regulation (EC) No. 853/2004, for the organisation of official controls under Regulations (EC) Nos. 854/2004 and 882/2004, derogating from Regulation (EC) No. 852/2004 and amending Regulations (EC) Nos. 853/2004 and

⁶ This has been amended by Regulation (EC) 882/2004 of the European Parliament and of the Council on official controls to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

854/2004;

- Commission Regulation (EC) No. 2075/2005 laying down specific rules on official controls for *Trichinella* in meat; and
- Commission Regulation (EC) No. 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No. 853/2004, (EC) Nos. 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) Nos. 853/2004 and 854/2004.

This legislation was published in the Official Journal of the European Union of 22 December 2005, L338.

Copies in pdf format can be accessed from the Food Standards Agency's web site at:

www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/

or from the Stationery Office. The telephone number of the Customer Service is 0870 600 5522 and ask for 'agencies'.

3. This legislation is applied in the UK by:

- The Food Hygiene (England) Regulations 2005 (SI 2005/2059)
- The Food Hygiene (Scotland) Regulations 2005 (SSI 2005/505)
- The Food Hygiene (Wales) Regulations 2005 [Awaiting publication]
- The Food Hygiene (Northern Ireland) Regulations 2005 (SR 2005/356)

Copies are obtainable from the Office of Public Sector information. You can access these from the website at: www.opsi.gov.uk

Appendix B: Sources of advice and information

Draft Guide to Food Safety and Other Regulations for the Meat Industry

<http://www.food.gov.uk/foodindustry/meat>.

Safer food, better business toolkit for enforcement officers in England

<http://www.food.gov.uk/foodindustry/hygiene/implementstrategy/enforcertoolkit/>

CookSafe. Food Safety Assurance System. FSA Scotland

<http://www.food.gov.uk/foodindustry/hygiene/cooksafe/>

Safe Catering. FSA Northern Ireland for further information please contact Esther Chartres on 02890 417737 or by eMail at

esther.chartres@foodstandards.gsi.gov.uk

For more information about guidance materials in Wales please contact the Environmental Health Department of your local county borough council or Keith Blake at FSA Wales – email: keith.blake@foodstandards.gsi.gov.uk or telephone 029 2067 8902

FSA guidance on the requirements of the food hygiene legislation is available at <http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/fhlguidance/>.

In addition there are a number of independent documents which provide guidance on the regulations or acceptable microbiological standards for foods (these documents are not legally binding), for example:

- BRC/CFA Guidance on the Practical Implementation of the EC Regulation on Microbiological Criteria for Foodstuffs (<http://www.chilledfood.org/content/guidance.asp>)
- The Public Health Laboratory Service (PHLS) Guidelines for the Microbiological Quality of Some Ready-to-eat Food Sampled at the Point of Sale (www.hpa.org.uk)
- The Institute of Food Science and Technology UK's (IFST) Development and Use of Microbiological Criteria for Foods ISBN 0 905367 16 2 (www.ifst.org).