MICROBIOLOGICAL TESTING & INTERPRETATION GUIDANCE

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MICROBIOLOGICAL TESTING AND INTERPRETATION GUIDANCE

Background

This document provides

1. General guidance to chilled food manufacturers, their customers and enforcement authorities on the purpose and interpretation of microbiological testing, both environmental samples and of food ingredients and food products themselves

2. Clarification as to the role of microbiological testing and interpretation of microbiological results to assist in implementing requirements of the European Union (EU) Microbiological Criteria Regulation (MCR) 2005 within HACCP.

The MCR define microbiological food safety in the EU from 1 January 2006. The MCR relate to the EU general hygiene regulations (852/2004/EC) that are also due to come into effect on that date, and to the General Food Law (GFL) Regulation (178/2002/EC), which came into force on 1 January 2005.

The MCR stipulate a certain level of sampling for official control purposes and by the Food Business Operator (FBO) for minced meat products. Otherwise sampling is to be determined by the FBO on a HACCP and hygiene control procedure basis, as set out in recital 23, Article 4.2 and Article 5.1 of the Regulation.

'Guidance on the Practical Implementation of the EC Regulation on Microbiological Criteria for Foodstuffs' is available from CFA: www.chilledfood.org/content/guidance,asp

CONTENTS

MICROBIOLOGICAL TESTING & INTERPRETATION

1. Introduction

It is of key importance to be aware that the safety of food is neither guaranteed nor controlled by microbiological testing.

Chilled foods

- Are not homogeneous, many are multicomponent
- May not be heat processed
- That are heat processed could have significant post process handling
- May be ready to eat, ready to reheat or ready to cook
- Are generally short shelf life

These factors all contribute to the variable microbiological population both within and between products within a batch. Therefore conclusions are difficult to draw from isolated results and the overlying trend must be considered.

Due to the short life of chilled products testing results will often not be available within the shelf life. Therefore positive release testing cannot be done for short life chilled products. It is important to note that positive release is neither the intent nor a requirement of the Microbiological Criteria Regulation. In addition it is not commercially viable to test sufficient products for positive release in order to have statistically reliable results.

Microbiological testing must be used to validate and monitor processes, verify CCPs identified through HACCP, and provide for due diligence. Indeed, the criteria are not obligatory where a food business is confident of its HACCP systems. Microbiological testing of end products should not be relied upon for anything other than for due diligence purposes.

It should be noted that the MCR does not require any specific sampling frequency other than for minced meat, meat preparations and mechanically separated meat.

2. Definitions

Batch

This is defined in Article 2 (e) 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.

In practice, 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.

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.

Microbiological criteria are essentially of three types:

- Standard
- Guideline
- Specification

These terms were defined by CODEX in 1981 and revised in 1993 to cover the working definitions below:

Standard – This is a microbiological criterion contained in a law or regulation where compliance is mandatory. As well as being an offence, products not complying with the standards are rejected as unfit for intended use. Current and proposed EU standards are summarised later in this document.

Guideline – This is a criterion applied at any stage of food processing which indicates the microbiological condition of the sample. Significant deviations from the norm may indicate the need for attention before control is lost. Investigative action is required to identify and rectify the cause. The Public Health Laboratory Service (now the Health Protection Agency) has published Guidelines on ready to eat foods to aid food examiners and enforcement officers.

Specification - This is a criterion applied to a purchase agreement and may include pathogens, toxins, spoilage or indicator organisms. Non-conforming products require investigation to determine the cause.

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.

Official control

“Official control” means any form of control that the competent authority or the European Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules.

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.

Reference Method

This refers to the method in the annex, which is normally 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 hurdles or inhibiting factors that may be used.

Terms Used in the Criteria Tables

The following definitions apply to the tables:

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

3. Why Do Microbiological Testing?

Recital 5 of the MCR states that:

"The safety of foodstuffs is mainly ensured by a preventive approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. It is therefore appropriate to set microbiological criteria defining the acceptability of the processes, and also food safety microbiological criteria setting a limit above which a foodstuff should be considered unacceptably contaminated with micro-organisms for which the criteria are set."

For Food Business Operators (FBOs) to ensure that microbiological criteria are met, every preceding point in the chain needs to be monitored. However, owing to seasonality for example, monitoring needs to be regular and planned to allow trends to be identified and acted upon appropriately.

Article 5.3 of the MCR states that

"The number of sample units of the sampling plans set out in Annex I may be reduced, if the food business operator can demonstrate by historical documentation, that he has effective HACCP-based procedures."

Given this, the number of samples outlined in the MCR applies when sampling is carried out for official control (enforcement) purposes only, i.e. "*to specifically assess the acceptability of a certain batch of foodstuffs or a process*" (Article 5.4). Otherwise, it is for the FBO to determine the frequency of sampling, based on HACCP.

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 HACCP can be found in the 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 is often used to verify that the overall process is in control.

When deciding the frequency of microbiological tests 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.

Table 1: Testing level vs. confidence in HACCP systems

Confidence in HACCP systems	Testing Level
High ↓ Low	Low ↑ High

3.1 Validation of a Process

Testing pre- and post-process can be used to establish process performance standards for future monitoring. This is primarily undertaken during new product and/or new process development, installation of new equipment and process engineering

3.2 Microbiological Verification/Monitoring

The efficacy of the process rather than the microbiological quality of the individual product should be verified to ensure the critical control points (CCPs) are adequately controlled. This would not usually be final product testing, but should include work in progress and in process checks.

Variation from the established trends should be investigated and acted upon. See Section 9.

3.3 Due Diligence

Due Diligence testing is carried out to provide evidence to be able to demonstrate that all that is reasonably possible is being done to ensure that the food that is being produced is as safe as possible. Due Diligence comprises verifying that CCPs are under control and checking final product on a scheduled basis (see Table 1 and preceding section). However, owing to the short life of chilled products microbiological testing of them is retrospective and therefore of very limited value except for historical data and trend analysis purposes.

Testing final product for indicator organisms has limited use. However, periodic testing for the pathogens which the CCPs control should be carried out on final product, or at the point at which no further contamination could take place.

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 MCR and the specific requirements of Annex I of the Regulation do not apply.

Date of production testing can be used to generate trend data and give an indication of process control efficacy.

End of life testing can be used to establish that relevant microbiological criteria (e.g. *Listeria monocytogenes* in ready-to-eat foods supporting the growth of *Listeria monocytogenes*) are not exceeded at the end of the given shelf life under expected storage conditions.

Appropriate action to be taken in the event of a positive result should be clearly defined before testing is carried out (see Section 8 – Effective communication of results).

4. Monitoring Points

Points to be monitored may include

- growing to harvest
- raw materials
- components, work in progress and processing
- the process environment
- water
- people (personal hygiene)
- final product

4.1 Growing to harvest

Microbiological monitoring must be considered for the whole of the food chain. For example, for produce the following areas should be included

- water used for irrigation / cooling / storage / make up of pesticides
- soil
- packhouse (as for processing sites)
- harvesting equipment
- people (return to work / hand hygiene)

For further information see CFA's Microbiological Guidance for Produce Suppliers to Chilled Food Manufacturers (see Section 10).

For meat products consider sampling points at slaughter, evisceration and cutting in addition to water sampling at wash points to help prevent spread and multiplication of pathogens.

This approach may also be extended to feed mills, hatcheries and farms throughout the supply chain.

4.1.1 Where and when to sample

Identification of the points at which to sample, and the frequency of sampling is determined by the FBO on the basis of HACCP (see Section 3).

4.1.2 How to sample

This is defined by the type of material being sampled, e.g. water. See Appendix 1.

If samples are not taken in their final packaging then aseptic techniques must be used.

4.2 Raw Materials

Raw materials should be approved for use via supplier approval and monitoring

Raw material is material as delivered to the processing site. Testing will therefore monitor supplier controls and could include for example processed materials, such as cooked meat, in a sandwich factory.

Specifications agreed must be appropriate to the material and process it has received.

Positive release by manufacturers has very limited use as it can only be applied to long life materials, e.g. frozen, dried, canned. If positive release is used, product must not be used prior to receipt of an acceptable result or an acceptable confirmation certificate.

Testing will only provide confirmation of trends since to sample a statistically significant portion of the product to provide assurance of the quality of the whole of the consignment will rarely be commercially viable.

Positive release must not be relied on in chilled food manufacture unless there is a sound statistical basis for the sampling.

4.2.1 Where and When to sample

Sampling of raw material by the FBO for positive release is carried out on receipt only where the raw material has a sufficiently long shelf life to make testing viable.

Sampling of raw material for monitoring purposes is carried out on receipt or when the material is in pre-use storage. This would generally be for indicator organisms (see Table 2). Product may be used prior to receipt of results in this instance.

The frequency of sampling is determined by risk assessment.

4.2.2 How to sample

This is defined by the type of material being sampled. See Appendix 1.

If samples are not taken in their final packaging then aseptic techniques must be used.

4.3 Components, work in progress and processing

4.3.1 Components and work in progress

Components and work in progress are raw materials or intermediate products that have received some handling/processing on site.

Testing is carried out to monitor the effect of this handling/processing by testing for appropriate indicator organisms (see Table 2). Individual results should not be acted upon, but should be trended. Adverse trends should be actioned accordingly (see Sections 7-10).

Trends for produce may only be seen year on year, and vary through season and changes of Country of Origin.

4.3.2 Processing

Processing may include thawing, washing, cutting, blanching, cooking, cooling, depositing, mixing, fermentation and curing. Processes can be monitored by testing samples taken at each stage and trending the effect of each process on appropriate indicator organisms (see Table 2).

4.3.3 Where and When to sample

There should be a programme of regular monitoring for appropriate indicator organisms of the key process and handling procedures, determined by on the basis of HACCP (see Section 3).

4.3.4 How to sample

This is defined by the type of material being sampled. See Appendix 1.

If samples are not taken in their final packaging then aseptic techniques must be used.

4.4 Process Environment

Environmental testing is used to verify the efficiency of cleaning and disinfection.

4.4.1 Where and When to Sample

Environmental monitoring should be done after cleaning and disinfection immediately before start-up of production or following production cleaning. Any surfaces that are not visibly clean at this point must be re-cleaned before swabbing (swab results do not add any value in such cases).

During commissioning and/or maintenance of plant, equipment or processes (including cleaning and disinfection systems) environmental sampling of key areas is an appropriate means of confirming that the cleaning and disinfection methods are effective.

The food business operator should decide on the points to be swabbed, selecting items that are particularly difficult to clean and/or have been shown to cause problems in the past. During commissioning, a large number of items may be tested, the number being reduced once confidence in cleaning methods is established.

It is good practice to allow for a certain amount of random sampling, rotate sample points and lines tested as well as the shift, time and day of sampling. Swabbing plans should be reviewed periodically to ensure that all equipment is captured by the plan and represents the trends being found.

4.4.2 How to Sample

See Appendix 1 and CFA's "Best Practice Guidelines for the Production of Chilled Food". Sampling should involve both product contact and non-contact surfaces after cleaning and disinfection and may use microbiological samples such as swabs, contact plates, rinses and/or non-microbiological indicator systems such as ATP swabs. Consider using sponges for sampling larger areas.

- **Rapid Hygiene Monitoring:** ATP swabbing and similar rapid hygiene monitoring systems give a result that can be interpreted before start-up. ATP results do not relate directly to microbial levels, but are an excellent indicator of hygiene. As such testing is relatively expensive, it is best used to monitor specific CCPs, e.g. food contact critical equipment such as slicing blades, and to train hygiene staff in cleaning. Manufacturers of systems will advise on the setting of standards.

- **Microbiological Testing:** The results of environmental microbiological tests are not available soon enough to be used for real time hygiene monitoring, but can be used to verify cleaning and disinfection, to evaluate trends and can also be used for investigation purposes. Investigation results should not be used to monitor trends. Any additional sampling points highlighted in the investigation need to be included in the routine sampling plan.

Air sampling: Settle plates have limited use, but there may be certain circumstances where microbiological air quality needs to be verified. For example in the spiral chilling of bakery products yeast and mould issues are of particular importance. Air samplers, which allow a set volume of air to be sampled, are also available.

4.5 Water

Water companies can provide results of microbiological and chemical testing after treatment.

Chilled food manufacturers should notify their water company of their activities, and request inclusion on priority alert lists.

A plan of the factory's water system must be drawn up and the point of entry of the mains to the site clearly identified.

For further information see CFA's "Water Quality Management Guidelines".

4.5.1 Where and When to sample

The point at which water is supplied to the site should be monitored, with sample points identified throughout the site appropriate to risk assessment, taking into account usage, length of pipework and presence of deadlegs, for example,

There should be a programme of regular monitoring, determined by risk assessment and water usage.

4.5.2 How to sample

See Appendix 1.

4.6 People

People are significant sources of microbiological contamination, both directly (personal hygiene and health) and through their actions (cross contamination).

Personal hygiene and health is controlled by pre-employment and return to work questionnaires and hand washing and changing procedures.

4.6.1 Where and When to sample

The random swabbing of hands/gloves should take place for staff directly handling food, after hand washing and/or on line. A rota should be used with the aim that all shifts of food handling staff are covered.

All personnel working in food factories should be screened by using a medical questionnaire. Some testing may be required where concerns are raised.

After periods of absence through sickness a return to work questionnaire should be completed and reviewed. Some testing may be required where concerns are raised.

See return to work and pre employment screening in CFA's "Best Practice Guidelines for the Production of Chilled Food".

4.7 Final Product

This testing should only be carried out for Due Diligence purposes (see Section 3.3).

Table 3 sets out suggested pathogen testing usage.

Annex I of the MCR sets out food safety criteria. The sampling levels referred to in the MCR relate to sampling to be carried out within a formal sampling plan and for official control purposes only.

As stated earlier, the number of samples to be taken is determined primarily on the basis of HACCP (see Section 3). Compositing of samples across comparable batches of products is appropriate, i.e. identifiable products obtained from a given process under practically identical circumstances and produced in a given place with one defined production period.

Whether or not a product is ready-to-eat is for the producer or manufacturer of the food to decide, as stated in recital 21.

The criteria in Annex I of the MCR require, in relation to RTE products, that if *Listeria monocytogenes* (Lm) is present before the product has left the immediate control of the FBO which has produced it then the FBO needs to be able to prove (e.g. through historical data or modelling) that levels will remain at no more than 100 cfu/g during the shelf life. The product shelf life should be set accordingly and following the general approach set out in Annex II of the MCR.

Products therefore need to be tested at an appropriate point to demonstrate that this level will not be exceeded within the shelf life.

It should be noted that pH controlled products may be most appropriately sampled at the beginning of life whereas those where pH control is not present may be best tested at the end of life.

With regard to Lm criteria for RTE products in the MCR it should be noted that products with shelf lives of less than 5 days are assumed within the Regulation not to support the growth of Lm and therefore the criterion of less than 100 cfu/g applies to them.

Regarding the Salmonella criterion for minced meat, meat preparations and mechanically separated meat, one product type per factory per week is required to be sampled by the FBO.

Mathematical predictive modelling of microbial growth, shelf-life testing and challenge testing of foods with target organisms are useful tools for gauging how specific microorganisms will behave in the conditions being experienced by the final product. These tools and their uses will be discussed later in this document (see Section 8).

4.7.1 How to sample

Samples should be taken in their final packaging after the full process.

See Appendix 1.

5. Microorganisms for consideration

Annex I, Chapter 1 of the MCR sets out food safety criteria, non-compliance with which requires notification by the FBO to the authorities (in the UK the Local Authority and Food Standards Agency), in accordance with Article 19 of the General Food Law 178/2002/EC. The prime focus of Annex I, Chapter 1 is on Salmonella and Lm. The aim in relation to uncooked RTE products is to minimise risk, however no CCP yet exists for many of these products.

It is partially for this reason that the MCR allows for FBOs to provide proof that Lm, if present in a RTE product when placing on the market it will not grow to more than 100 cfu/g.

Compliance with the MCR with respect to behaviour of microorganisms in foods should initially be based on historical final product testing data. Predictive mathematical modelling can be used to theoretically indicate if compliance can be met, but any prediction has to be validated. Challenge testing is neither required by the MCR nor is it intended as a primary action, instead historical final product testing data and the use of predictive models are the key information for proving compliance. It should be noted that RTE products with shelf lives of less than 5 days are excluded from the scope of the MCR in relation to Lm.

5.1 Indicator organisms

A range of indicator organisms can be tested for and is dependent on the foodstuff in question. Table 2 below is for guidance only and shows appropriate usage of various indicator organisms or microbiological monitoring. The table relates to tests required and not to specifications as different standards* will apply, e.g. cooked vs uncooked.

Uncooked food ingredients that are to be cooked prior to consumption (e.g. raw meat, fish, produce) should be monitored for appropriate indicator organisms for quality purposes only.

See Section 7 regarding interpretation and action required.

Table 2: Usage of Indicator Organisms

Indicator Organism	Cooked food/ingredients (raw materials, work in progress)	RTE produce (uncooked)	Uncooked protein (not RTE)	Uncooked RTE protein (e.g. cold smoked salmon, salami)	Environmental Swabs (High Care/Risk Areas)♥	Water (process & cleaning)
Enterobacteriaceae	Yes♣	No	No	Yes♣	Yes	No
Coliforms	No	Yes♣	No	No	No	Yes (per 100 ml)
E coli	Yes♣	Yes	Yes – Meat	Yes♣	No	Yes (per 100 ml)
TVC	Yes Not where live starters are used (e.g. cheese)	No	No	Not where live starters are used (e.g. salami)	Yes	Yes
Pseudomonas	No	No	Yes – Fish	No	No	No
Yeasts	No	No	No	No	No	No
Lactic Acid Bacteria	No	No	No♦	Not where live starters are used (e.g. salami)♦	No	No
Listeria spp	Yes (where there is post process handling)	Yes	No	Yes	Yes♠	No

Key:

♣ Different standards apply to uncooked and cooked (more stringent for cooked)

♠ Speciation is required if isolated

♥ Low Risk Areas (see CFA "Best Practice Guidelines for the Production of Chilled Food") should be monitored appropriate to the process. *Listeria* monitoring may not be appropriate

♦ If lactic acid bacteria are known to cause spoilage in a particular product it may be worthwhile testing for them

5.2 Pathogens

Pathogens of potential concern include:

- VTEC*
- *Campylobacter* (see detail in Table 3)
- *S.aureus*≅
- *B.cereus* (see detail in Table 3)
- *Salmonella* spp
- *Listeria monocytogenes*
- Viruses*
- Protozoa*
- *C.botulinum**≅
- *C.perfringens**.

* **Testing for these organisms in final product is unlikely to deliver meaningful reductions in the associated risk for consumers and is therefore not necessary**. However, HACCP and the reduction of possible faecal contamination along the whole food chain and microbiological risk assessment during product development will have a greater effect upon reducing public health risk by these organisms.

≅ Consideration must also be given to the toxins formed by these organisms. It should be noted that the EC's Scientific Committee for Veterinary Measures relating to Public Health (SCVPH) issued an opinion on verotoxigenic *E. coli* (VTEC) in foodstuffs on 21-22 January 2003,

concluding that applying an end product microbiological standard for VTEC O157 is unlikely to deliver meaningful reductions in the associated risk for the consumers. However, microbiological guidelines aimed at reducing the faecal contamination along the food chain can contribute to a reduction in public health risks including VTEC.

Table 3 below is for guidance only.

Table 3: Testing for Pathogens

Pathogen	Final Product	Hand swabs
VTEC	No	No
Campylobacter spp	Relevant foods only (e.g. poultry)	No
Salmonella spp	Yes	No
Listeria monocytogenes	Yes (RTE)	No
B cereus	Relevant foods only (e.g. cereal-, rice-based products)	No
S aureus	Yes	Yes
Viruses	No	No
Protozoa	No	No
Cl botulinum	No	No
Cl perfringens **(anaerobic sulphite reducers)**	Yes (cooked foods)	No

Consult Appendix 3 (pathogen growth and survival data) to determine whether it is valid to test specific products on the basis of their formulation/processing.

6. Microbiological Specifications

Specifications should be clearly defined for raw materials and final products.

For final products criteria are set out in HPA Guidelines (UK), IFST's "Development and Use of Microbiological Criteria for Foods" (1999) and the European MCR. The latter set out food safety criteria (Annex I, Chapter 1 of the Regulation), which would trigger notification/withdrawal if exceeded.

Terminology must be clear. Terms such as maximum, unacceptable, unsatisfactory should be avoided.

Instead the following are recommended:

- Target
- Report – does not indicate that there is a safety or quality issue, but is agreed to be reported to the customer
- Action

In addition, the action that can be taken at each of these points needs to be clearly stated, for example can the food be reprocessed or should it be withdrawn from sale.

7. Interpretation of data

An adverse trend is when levels are frequently at or near the Report level or when a significant increase over the level normally observed is seen.

Adverse trends must be identified, investigated and actioned accordingly (see Section 10 - Troubleshooting). Documentation of the actions taken must be kept and corrective actions must be verified as being effective. See Table 4 for an indication of monitoring points and action required.

Table 4: Monitoring Points and Actions

Monitoring point	Action
Growing to harvest	React to adverse trends. Notify the supplier of any adverse trends.
Raw materials	Reject against agreed specification if on positive release. If not on positive release notify the supplier of any adverse trends.
Components, WIP, processing	Effectively address the cause of the adverse trend.
Process Environment	Effectively address the cause of the adverse trend.
Water	Effectively address the cause of the adverse trends or report to water company if issue is related to water as supplied
People	*S aureus* on hand swabs – persistent carriers should not handle open food
Final product (ready-to-eat food not intended for infants or for special medical purposes)	If in breach of Annex I, Chapter 1 of the MCR notify Local Authority and FSA and recall. If there is evidence that Lm will not exceed 100 cfu/g during shelf life internal action must be taken but notification is not required.

8. Effective communication of results

Action should only be taken on confirmed results unless there is a written agreement to the contrary with the customer.

If an external laboratory is used, a written agreement must be in place covering communication of findings to the manufacturer and to any agreed third party.

For further detail see Table 5 (Findings, Laboratory Action and Communication of Results).

Table 5: Findings, Laboratory Action and Communication of Results

Finding	Action by Laboratory	Communication
Suspect colony or presumptive	Confirmatory test according to the internal methodology or as agreed with the external laboratory	From the laboratory to the manufacturer, in line with written agreement. The manufacturer to advise the customer of the findings.
Counts exceeding the Report level	Carry out additional testing as agreed with the manufacturer or customer	Advise customer of exceedance, in line with written agreement
Presence of Lm	Carry out enumeration	The laboratory to advise the manufacturer, in line with written agreement.
Counts exceeding the food safety criteria set out in the MCR (Annex I, Chapter 1)	Carry out additional testing as agreed with the manufacturer or customer	**Retailer own label product**: Manufacturer to advise brand owner of exceedance. Brand owner to advise Competent Authorities of exceedance. **Branded product**: Brand owner to advise Competent Authorities of exceedance.
Counts exceeding the process hygiene criteria set out in the MCR (Annex I, Chapter 2)	Carry out additional testing as agreed with the manufacturer or customer	The laboratory to advise the manufacturer, in line with written agreement. Manufacturer to investigate and take effective corrective action.

See the Food Standards Agency website for the incident form for food and feed withdrawals and recalls: www.food.gov.uk/foodindustry/foodfeedform.htm

9. Shelf life

Food businesses should be able to demonstrate to the satisfaction of the competent authorities that their products, when properly handled and stored during distribution, retail and by consumers, meet the food safety criteria throughout the shelf life. To this end the food businesses may need to conduct studies to investigate the compliance during shelf life.

As stated in the European Commission's Impact Assessment (para 7.3.1.2 of SANCO /869/2005)

"there is no need to conduct durability studies for all production lines of ready-to-eat foods, as in many cases the proper shelf-life of the product can be determined without expensive durability studies. It should be pointed out also that for ready-to-eat-products promoting the growth of Listeria and having a shelf-life less than 5 days there is no need to carry out durability studies."

The MCR sets out in Article 3.2 and Annex II the recommended approach to shelf life assessment.

The emphasis is on standard shelf life assessment testing, taking into account the storage and processing conditions and available scientific literature and research data regarding the growth and survival characteristics of the microorganisms of concern. Historical data is therefore of particular value. See Section 5.

Secondary tools such as pathogen modelling (see Section 9.1) and challenge testing (see Section 9.2) may also be used, but there are practical restrictions as to their applicability.

The shelf life of chilled products is not just limited by microorganisms. Often enzymatic, physical or chemical changes or a combination of these limit shelf life. Spoilage of chilled products can often be detected earlier by visual and other organoleptic means rather than by testing.

HACCP, with the assistance of Microbiological Risk Assessment is used to control safety during product development, at which point the whole of the supply chain is considered and pathogens which are not generally tested for (e.g. VTEC) controlled. Pathogen testing and challenge testing as

part of shelf life is therefore of little relevance in a well-designed product made under controlled conditions.

See CCFRA Guideline 46 (2004) "Evaluation of Product Shelf-life for Chilled Foods" for further details.

9.1 Historical Data

Historical data provides the best indication of the behaviour of an organism in a particular foodstuff. When present, *Listeria monocytogenes* 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, i.e. as is the case in predictive models and challenge testing.

Data on the levels of *Listeria monocytogenes* present at the beginning and at the end of shelf life can be used to assess its potential for growth.

For example, if *Listeria monocytogenes* was detected in a (ready-to-eat) cooked meat product at the beginning of shelf life at a level of <10 cfu per g, and end of life data on a representative sample from the same batch showed levels remained no more than 100 cfu/g, then the data helps demonstrate that from a *Listeria monocytogenes* perspective that the product remains within the food safety criteria set out in the MCR over its shelf life. Under such circumstances, a low level (<10 cfu/g) detection during shelf life will not need to be withdrawn.

This approach is 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 monocytogenes* should be absent in the foodstuff; 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.

Manufacturers should therefore construct a database for *Listeria monocytogenes* consisting of appropriate samples taken at the beginning and end of life for each ready-to-eat product.

9.2 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 monocytogenes* management/monitoring plan, and the establishment of a safe shelf life using the studies detailed here.

9.3 Use of pathogen and spoilage microorganism predictive modelling systems

Modelling systems are of significant value is assessing the growth of pathogens and spoilage organisms. However, it is important when using predictive models to be aware of their limitations. For example:

- The models (e.g. Growth Predictor) were often developed in artificial media rather than in foods. Although many of the models have been validated in foods, these foods may be different from one that you are producing.
- The models are fail-safe, i.e. they will predict growth to be faster that it will be in a food.

- Models also assume the worst case scenario regarding pathogen presence in the final product, i.e. they assume that a pathogen or spoilage organism is present. In reality, this is controlled by the use of GMP/GHP and HACCP.

Since most chilled products are not homogeneous. It is important to understand the source data of the model being used, i.e. whether the organism was grown in broth or real food. In addition, processed foods often contain stressed cells, which need to be taken into account.

9.4 Challenge testing

A company having implemented GMP, HACCP and supporting systems and following the shelf life assessment approach set out in Annex II of the MCR is not expected to have to carry out *Listeria monocytogenes* challenge testing.

Challenge testing involves inoculation of a product with relevant microorganisms and/or storage under a range of controlled environmental conditions in order to assess the risk of food poisoning or to establish product stability.

Microbiological challenge testing is a laboratory simulation of what can happen to a product during distribution and handling. Challenge testing is neither quick nor simple, nor reflects neither actual contamination levels nor the physical state of organisms which may be expected to be present. Challenge testing is therefore usually only resorted to if other methods of assessing safety/stability of the product are thought to be inadequate.

The safety/stability of a product should instead be satisfactorily addressed during new product development.

10. Manufacturers' and brand owners' obligations

10.1 Exceedance of MCR Annex I, Chapter 1 Criterion (Food Safety)

In the case of a food safety issue arising, timely action must be taken to protect consumer safety. Actions required relate to Article 19 of 178/2002/EC and include:

1. In the case of own label product manufacture, immediate liaison with the brand owner.

2. Brand owner i.e. food manufacturer or retailer in the case of retailer own label products to notify Local Authority and FSA and recall final product.

   The extent of the problem must be made clear.

   For example:

   - Restricted to a particular batch/size/distribution area
   - Reassure that all other batches/sizes/products are safe
   - Number of packages involved
   - Speed and efficiency of recall
   - Cause of fault being investigated

3. Remedial actions in the supply chain should involve the consideration of:-

   i) What to do to re-establish control and prevent reoccurrence of the hazard (see internal action in Section 10.2)
   ii) What to do with product and raw material held in stock or in the supply chain that might be out of specification
   iii) When the action taken should be completed, i.e. the timescale for the action
   iv) Who has responsibility for the action

10.2 Presence of Lm in RTE product at no more than 100 cfu/g; Exceedance of MCR Chapter 2 Criterion (Process Hygiene); Adverse Monitoring Trends

If there is evidence that Lm will not exceed 100 cfu/g during shelf life notification is not required.

Internal action is required on exceedances of process criteria in Annex I, Chapter 2 of the MCR and on discovery of adverse monitoring trends.

Internal action will include:

- Traceability of the sample
- Review micro testing results
- Investigate common influences
- Monitoring at key points to establish the source of contamination or the breakdown of the process, e.g. equipment and external influences such as water quality issues
- Take corrective action
- Verify that the corrective action has been successful. This may include increased sampling

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APPENDIX 1

SWABBING & SAMPLING - KEY POINTS

Swabbing

- Use swabs appropriate to the size of the surface being tested, sterile sponges can also be used for larger areas.
- Use an appropriate medium or neutraliser for transportation to the laboratory
- If swabbing after cleaning, ensure that a deactivation agent has been applied beforehand i.e. swabs must be pre treated with deactivating agent prior to swabbing. Deactivation agents are available from most laboratories.
- Swabs should be tested within 24 hours of swabbing.

Product Sampling

- Where plastic sample bags are used they must be sterile and should be sufficiently robust not to tear
- Samples must be taken using aseptic techniques
- The bag must be labelled and secured with a tamperproof seal
- The sample should be labelled (date and time of sampling, location) to enable it to be traced
- Samples taken during normal working hours should be delivered to a holding fridge where the temperature is monitored and maintained at 2-6°C
- If the sample is taken outside of office hours, it should be delivered to the laboratory in a cool box/mobile refrigerator pre-cooled to 2-6°C as soon as practicable
- Samples must not be frozen before submission to a laboratory
- Final product samples should be taken in pack at the end of the process

Water Sampling

- As the aim is to determine the quality of water at the point of use, it is not recommended to run the water prior to sampling
- Appropriate clean, new, sterile containers must be used
- A minimum of a 500 ml sample should be taken
- The sample should be labelled (date and time of sampling, location) to enable it to be traced
- Samples should be taken to the laboratory with the minimum delay
- If there is a delay in testing the sample of more than 6 hours, it is good practice to maintain the sample at 0-5°C
- Choose your sample point with care. Samples should be taken from the end of the water delivery system to best reflect water quality.
- When taking samples of chlorinated water, the chlorine must be neutralised with sodium thiosulphate.
- If the aim is to assess the quality of the water supplied at the cartilage then the tap does need to be run before use and sampling done in accordance with the recommendations of 'The Microbiology of Drinking Water 2002' (see Bibliography)
- Note that for irrigation water results may be erroneous if samples are taken from the surface of the water, owing to UV effects.

NOTE:
Great care must be taken during sampling to ensure that samples are not contaminated by the procedure.

APPENDIX 2

LABORATORIES

Selection of a laboratory

The selection and performance of a microbiological testing laboratory is key to assuring that accurate data are generated.

Concerns include not only false positive results, but also false negatives, which may give an unwarranted sense of security.

Consideration must be given to the following in the selection of a microbiological testing laboratory:

- Accreditation by an appropriate approved body to ISO 17025 e.g. UKAS
- Schedule of accreditation must list the methods required
- Methods must be appropriate and validated for the sample type
- Contracts must be drawn up with the laboratory to include
    - out of hours contacts
    - methods
    - reporting systems
    - maintenance of the chill chain
    - sample and culture retention
    - visit requirements
    - confidentiality
    - insurance
- Initial visits are recommended to assess on site expertise, key contacts, capacity, work patterns and weekend and Bank Holiday cover. Follow up visits at regular intervals (announced and unannounced) should also be done.
- Laboratory operating hours and sample collection must match the business needs (e.g. 7 day week including Bank Holidays?)

Sampling for microbiological testing

Samples must be representative of the full process and taken at the appropriate stage, e.g. for final product after blast chill and in final packaging. Samples must be stored according to recommended storage temperature at all stages from sample collection to analysis. An additional sample should be placed in with a batch of samples for temperature checking upon receipt at the lab.

Samples must be labelled to ensure full traceability – this would normally include sample description, date and time of sampling as a minimum.

Samples must be sent in leak proof containers and appropriate transport used to ensure no cross contamination occurs.

There must be disciplined procedures in place to prevent cross contamination from transport to analysis according to microbial risk, e.g. cooked components, raw RTE, raw ready to cook.

If samples are not taken in their final packaging then aseptic techniques must be used.

Sample handling at the laboratory

Any anomalies associated with the samples must be recorded, i.e. damaged or leaking packaging. Sampling and testing queries must be resolved promptly between the laboratory and the client.

The laboratory must have disciplined segregation procedures in place to prevent cross contamination from transport, sample receipt, storage (e.g. chillers), preparation (including equipment) and analysis, according on the basis of microbial risk, e.g. cooked components, raw RTE, raw ready to cook, different client samples and reference cultures.

Reporting of results

It should be agreed in writing between the laboratory and the client at what stage results need to be reported. Specifications/limits need to be agreed to enable out of specification results to be identified.

Care must be taken to clearly discriminate between suspect, presumptive and confirmed results, and define which results require direct reporting by telephone to the client and which require immediate action by the laboratory and/or client (see Table 5).

APPENDIX 3

KEY PATHOGENIC MICROORGANISMS: COMMONLY ACCEPTED GROWTH BOUNDARIES AND HEAT RESISTANCE CHARACTERISTICS OF PATHOGENIC MICROORGANISMS[1]

	Growth Criteria		Heat Resistance (mins)				
Microorganism[2]	**Min Temp (°C)***	**Min pH***	**Min a_W***	**Aerobic / Anaerobic**[3]	**D 70 °C**	**D 90 °C**	**D 121 °C**
B. cereus	4[4]	4.5[5]	0.93**[1]	Facultative	-	10	-
Campylobacter jejuni	32	4.9	0.99	Microaerophilic	0.0001	-	-
Cl. Botulinum Mesophilic/proteolytic	10-12[1]	4.6	0.93	Anaerobic	-		0.21
Cl. Botulinum Psychrotrophic/non-proteolytic	3.3	5.0	0.97 (5% NaCl)	Anaerobic	-	1.5	-
Cl. perfringens	12[1]	5.5-5.8[1]	0.935[1]	Anaerobic	-	-	0.15
E. coli	7-8	4.4	0.95	Facultative	0.001	-	-
‡*E. coli* O157:H7	6.5	4.5	0.95	Facultative	0.3		
L. monocytogenes	-0.4[1]	4.3	0.92	Facultative	0.3	-	-
Salmonella	6	4.0	0.94	Facultative	0.001-0.01	-	-
Staphylococcus aureus[6]	***5.2[7]	4.5	****0.86	Facultative	0.1	-	
V. cholerae	10	5.0	0.97	Facultative	0.3	-	-
V. parahaemolyticus	5	4.8	0.94	Facultative	0.001	-	-
Y. enterocolitica	-1.3[1]	4.2	0.96	Facultative	0.01	-	-

Notes

* Under otherwise optimal conditions. Growth criteria will vary according to strain, temperature, type of acid, solute and other factors and will normally be higher in foods. However, variabilities in measurement, etc., must be allowed for - a margin of error must be incorporated.

** *B cereus* Aw of 0.91 in egg fried rice has been claimed

*** Toxin not produced below 10°C

**** *S. aureus* low growth limit a_w of 0.83 justified in non-food systems. 0.86 generally recognised minimum in food. However, toxin production range is Aw 0.87-0.99

‡ Definitive information not yet available

[1] *Microorganisms in Foods. Vol. 5. Microbiological Specifications of Food Pathogens*. (1995), ICMSF, Blackie Academic & Professional; *ACMSF Report on Verocytoxin-Producing* Escherichia coli (1995), HMSO, ISBN 0-11-321909-1.

[2] Growth boundaries given under otherwise optimal conditions, Growth criteria will vary according to strain, temperature, and type of acid, solute and other factors, and will normally be higher in foods. However, variability in measurement, etc., must be allowed for – a margin of error must be incorporated.

[3] It is important to note that even aerobically processed foods may present a risk of growth of anaerobic organisms since they may have an anaerobic internal environment.

[4] No emetic toxin formation at temperature below 10°C

[5] Evidence for this limit provided by LL Prokopova (1970) Multiplication and toxigenicity of *Bacillus cereus* contained in food products stored under different thermal conditions. Voprosy Pitaniia, **29**, 56-61 (in Russian, English summary) and M Raevuori and C Genigeorgis (1975). Effect of pH and sodium chloride on growth of *Bacillus cereus* in laboratory media and certain foods. Applied Microbiology, **29**, 68-73.

[6] Limits for enterotoxin production, not growth

[7] Most serotypes fail to grow at <7ºC

Some degree of survival will usually occur under conditions not allowing growth (survival time will depend on the particular growth-limiting condition, composition of the food, and packaging and storage conditions).

It is important to note that even aerobically processed foods may present a risk of growth of anaerobic organisms since they may have an anaerobic internal environment.

Viruses and parasites (e.g. Cyclospora, Giardia, Cryptosporidium) may be present in raw materials but require a host to multiply. Most are killed by normal pasteurisation treatments.

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APPENDIX 4

CFA MISSION, STRATEGY AND MEMBERSHIP

CFA's mission is to promote and defend the reputation of the chilled food industry through the development and communication of standards of excellence in the production and distribution of chilled food.

CFA's strategy

- Is to promote its standards to regulatory bodies, policymakers and other stakeholders
- CFA Members promote CFA standards throughout their supply base
- CFA catalyses action on issues broader than the chilled food sector alone

CFA membership is open to chilled food manufacturers and chilled component/raw material suppliers who commit to meet CFA *Guidelines* standards and are UKAS audit accredited to a minimum of BRC Foundation Level or the International Food Standard.

For current membership, see CFA's website: www.chilledfood.org