

AUDIT  
REPORT

Audit of official controls  
carried out by the Local  
Authority Veterinary Service  
(Regulation 2073/2005) –  
Kerry County Council

APRIL 2019

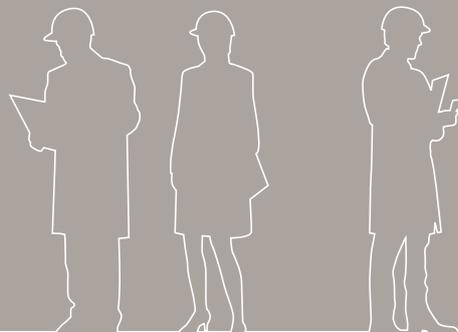


# AUDIT REPORT

## Audit of official controls carried out by the Local Authority Veterinary Service (Regulation 2073/2005) – Kerry County Council

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In accordance with Schedule 5 of the FSAI  
Service Contract, it is the responsibility of the  
official agency to close out all audit findings.



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## **1. GLOSSARY**

|       |  |
|-------|--|
| FSAI  | Food Safety Authority of Ireland           |
| HACCP | Hazard analysis and critical control point |

## 2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland, which is carried out through service contracts with official agencies. Kerry County Council is responsible for official controls in low-throughput food businesses that produce products of animal origin within its functional area. As part of its legal mandate, the FSAI is required to verify that the system of official controls is working effectively.

This audit was carried out to assess the effectiveness and appropriateness of official controls conducted by Kerry County Council in respect of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. A secondary objective was to verify selected food business operators' compliance with the requirements of this Regulation.

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs sets legal microbiological criteria for a range of foods. These criteria are used to assess the acceptability of a batch of food or a food process. Food business operators are required to perform microbiological testing when they are validating or verifying the correct functioning of their procedures based on hazard analysis and critical control point (HACCP) principles and good hygiene practice. The frequency of sampling may be adapted to the nature and size of the food business, provided that the safety and integrity of foodstuffs will not be endangered. The Regulation allows for the exemption of small slaughterhouses and meat establishments from the sampling frequencies set out in Annex I of the Regulation when such an exemption is justified on the basis of risk analysis and is consequently authorised by the competent authority.

The Cross-Agency Hygiene Package Implementation Working Group provided a guidance document, *Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in low-throughput premises*, which includes guidance on the reduced sampling frequencies to be applied in low-throughput slaughterhouses and small meat manufacturing premises. In order to determine whether reduced sampling applies, a risk analysis is carried out, the result of which is then combined with the premises' overall throughput to indicate the minimum sampling requirement. Following assessment of risk and throughput, there are three main categories of sampling frequency that may be applied:

- An approach involving absence of sampling
- A reduced sampling frequency
- Sampling frequency as per Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Kerry County Council conducted official control sampling broadly in line with the sampling programme which is agreed between the Cork County Council Veterinary Food Safety Laboratory, the local authorities and the FSAI. In some instances, deviations from the plan were made due to changes in the food business operators' scheduled activities and the non-availability of product. Additional sampling was conducted in response to unsatisfactory results.

*Listeria monocytogenes* has been detected through official control sampling in ready-to-eat products in three premises supervised by Kerry County Council since 2015. In each case, the results were communicated to the food business operator, including a clear explanation of the results, direction as to the corrective actions required, and information relating to the follow-up actions that were being instigated by the County Veterinary Officer. On each occasion, the County Veterinary Officer conducted thorough investigations, which included sampling of additional product and environmental monitoring as appropriate.

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Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs and associated guidance requires that if a food business operator is to use a reduced frequency of sampling, it must be on the basis of a risk analysis and consequently must have been authorised by the competent authority. In Kerry, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency. The County Veterinary Officer had conducted assessments in relation to the 30 approved establishments under the supervision of Kerry County Council (Figure 1). The templates provided in the Cross-Agency Hygiene Package Implementation Working Group guidance document, *Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in low throughput premises*, had been used to guide the assessment of risk and overall throughput, and detailed records of the assessment were maintained on the establishments' files.

One of the 30 approved establishments was not subject to the requirements of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs due to the fact that the activities being undertaken or the products being produced did not fall within the Regulation's remit. The remaining 29 approved establishments within Kerry County Council's functional area were subject to assessment to determine the manner in which Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs would be applied. Following assessment of risk and plant throughput, an approach involving absence of sampling has been applied with regard to 25 food businesses. The 25 food businesses for which the assessment determined that an approach involving absence of sampling was appropriate were not notified that they do not need to conduct sampling. The outcome of the assessment of risk and throughput in three of the remaining establishments was that testing was required at a reduced sampling frequency. The remaining business was conducting product testing and environmental monitoring for *Listeria monocytogenes*, for which there is no set sampling frequency.

On-site verification was carried out for two of the food business operations in order to assess their compliance with the requirements of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs and to verify the effectiveness of official controls in this regard. The first establishment selected was a slaughter and cutting plant which was conducting testing at a reduced sampling frequency. The second establishment selected produced a range of both ready-to-eat and non-ready-to-eat products, and so was conducting product testing and environmental monitoring for *Listeria monocytogenes*. Both food business operators had identified all relevant criteria as they applied to their businesses. During file review, it was noted that the food business operators' own testing programmes and results were being reviewed during official control inspections. One of the food business operators had detected *Listeria monocytogenes* as part of his testing regimes. The food business operator had notified the County Veterinary Officer and had participated in extensive follow-up, which included additional testing and amendments to his production processes in order to provide additional controls in relation to *Listeria monocytogenes*.

Trend analysis was not being carried out for results of one food business operator's own testing for aerobic colony count and Enterobacteriaceae, as testing had only commenced some months prior to the audit. However, trend analysis was undertaken for the official control sample results prior to commencement of the food business operator's own testing programme. This involved the use of detailed graphs, with the limits indicated on the graphs for ease of reading. The food business operator intended to use this format of graph to trend the results of his own testing as well. The other food business operator was conducting product testing for *Listeria monocytogenes*, and so was not conducting trend analysis using a graph, as interpretation of the results of *Listeria monocytogenes* testing relates to detection or non-detection. Both food business operators were observing best practice in relation to using an accredited laboratory; however, at the time of the audit, neither food business operator had confirmed with their laboratory that the testing methods used were either those stipulated in the legislation or a validated alternative method. The labelling of products which are intended to be eaten cooked, with the instruction to cook thoroughly, was not applicable to the two food businesses selected for on-site verification. The food business operator producing ready-to-eat products was applying a criterion of absence in 25 g in relation to *Listeria monocytogenes* and so had not conducted shelf life challenge testing for *Listeria monocytogenes*.

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The audit team confirmed that official controls as they relate to Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs were being implemented. The two food businesses for which on-site verification was conducted were aware of their responsibilities under the Regulation. During on-site verification, the first food business operator demonstrated a good understanding of the Regulation as it applied to his business. The second food business operator, although not present at the on-site verification, also demonstrated that he had a good understanding of the requirements of the legislation. This was evidenced by the fact that he had developed an extensive microbiological testing programme, associated procedures and operational controls which included corrective actions in the case of unsatisfactory results. The communications related to Commission Regulation (EC) No 2073/2005 that the County Veterinary Officer had provided to the food businesses were detailed and provided clear information and guidance to the food business operators.

### 3. INTRODUCTION

Microbiological criteria are used to assess the acceptability of a batch of food or a food process. When a particular food is tested for a particular microorganism (toxin or metabolite), the results can indicate whether:

- The food is safe to eat or not
- The food is of acceptable quality or not
- The hygiene standards in the food establishment are satisfactory or unsatisfactory.

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs sets legal microbiological criteria for a range of foods. Article 4 of the Regulation requires that food business operators shall perform microbiological testing when they are validating or verifying the correct functioning of their procedures based on hazard analysis and critical control point (HACCP) principles and good hygiene practice. The frequency of sampling may be adapted to the nature and size of the food business, provided that the safety and integrity of foodstuffs will not be endangered. Additionally, the Regulation allows for exemption of small slaughterhouses and meat establishments from the frequencies set out in Annex I of the Regulation when such an exemption is justified on the basis of risk analysis and is consequently authorised by the competent authority.

The Cross-Agency Hygiene Package Implementation Working Group provided a guidance document, *Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in low-throughput premises*, which includes guidance on the reduced sampling frequencies to be applied in low-throughput slaughterhouses and small meat manufacturing premises. To determine if reduced sampling applies, a risk analysis is carried out, the result of which is then combined with the premises' overall throughput (livestock units per annum for slaughterhouses and overall throughput in tonnes per week for minced meat and meat preparation plants) to indicate the minimum sampling requirement.

The guidance recommends inclusion of the following aspects as part of the risk analysis:<sup>1</sup>

- Operational hygiene at the premises
- Sanitation of the premises and equipment
- Hygiene of raw materials, e.g. the cleanliness of the animals supplied to the establishment
- Results of previous microbiological or other hygiene checks, e.g. rapid tests
- Compliance history
- Design and maintenance of premises and equipment
- Training, experience and competency of personnel
- Potential of temperature abuse within the distribution chain
- Risk categorisation of customer
- Interoperational variation
- Throughput of the premises
- Compliance with HACCP-based procedures.

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<sup>1</sup> The list is not exhaustive and alternative criteria may be included at the discretion of the Official Veterinarian.

Following assessment of risk and throughput, there are three main categories of sampling frequency which may be applied:

1. An approach involving absence of sampling
2. A reduced sampling frequency
3. A sampling frequency as per Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

### **3.1. Audit objective**

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activity that the official agencies perform as agents of the FSAI. Kerry County Council is one of the agencies that has entered into a service contract with the FSAI and is responsible for the enforcement of food legislation as it applies to low-throughput slaughterhouses, meat plants and cold stores in the county. The food legislation and the Service Contract require Kerry County Council to ensure that official controls are carried out regularly, on a risk basis and at an appropriate frequency.

As part of its legal mandate, and in accordance with Schedule 5 of the Service Contract, the FSAI is required to verify that the systems of official controls put in place by the official agencies are working effectively. The audit covered the organisation, planning, implementation and review of official controls within Kerry County Council in respect of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, and also verified the selected food business operators' compliance with food law. On-site verification of compliance with food law at two approved establishments was assessed as part of this audit. This audit was undertaken as part of the FSAI's audit programme for 2017.

This report describes the audit's objective, scope, methodology and findings.

### **3.2. Audit scope**

This audit was carried out for the purpose of assessing the effectiveness and appropriateness of official controls conducted by Kerry County Council in respect of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. A secondary objective was to verify selected food business operators' compliance with the Regulation.

### **3.3. Audit criteria and reference documents**

The principal audit criteria were:

- [Commission Regulation \(EC\) No 2073/2005 on microbiological criteria for foodstuffs, as amended](#)
- [Regulation \(EC\) No 882/2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules, as amended](#)
- [European Communities \(Food and Feed Hygiene\) Regulations 2009 \(S.I. No. 432 of 2009\), as amended](#)
- [Guidance Note No. 27, Guidance Note on the Enforcement of Commission Regulation \(EC\) No 2073/2005 on Microbiological Criteria for Foodstuffs \(including checklist\)](#)

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- [Cross-Agency Hygiene Package Implementation Working Group, Recommendation No. 5 Version 1: Implementation of Commission Regulation \(EC\) No 2073/2005 on microbiological criteria for foodstuffs in low-throughput premises](#)
- [EU \(2008\) Guidance Document on official controls, under Regulation \(EC\) No 882/2004, concerning microbiological sampling and testing of foodstuffs](#)
- [Guidelines on sampling the food processing area and equipment for the detection of \*Listeria monocytogenes\*](#)
- [The Control and Management of \*Listeria monocytogenes\* Contamination of Food \(FSAI 2005\)](#)
- [EU \(2008\) Guidance Document on \*Listeria monocytogenes\* shelf-life studies for ready-to-eat foods, under Regulation \(EC\) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs](#)
- [EU \(2014\) EURL \*Lm\* Technical Guidance Document for conducting shelf-life studies on \*Listeria monocytogenes\* in ready-to-eat foods.](#)

The secondary audit criteria were:

- [Food Safety Authority of Ireland Act, 1998 \(Number 29 of 1998\), as amended](#)
- [Service Contract between the Food Safety Authority of Ireland and Kerry County Council](#)
- [Regulation \(EC\) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended](#)
- [Regulation \(EC\) No 852/2004 on the hygiene of foodstuffs, as amended](#)
- [Regulation \(EC\) No 853/2004 laying down specific hygiene rules for food of animal origin, as amended](#)
- [Regulation \(EC\) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended](#)
- The National Control Plan for Ireland for the period from 1st January 2012 to 31st December 2016
- Service plans and data supplied to the FSAI
- Documented procedures
- [Guidance Note No. 18, Validation of Product Shelf-life \(Revision 3\)](#)
- [Guidance Note No. 20, Industrial Processing of Heat-Chill Foods](#)
- Other relevant legislation detailed in the FSAI Service Contract.

### **3.4. Audit methodology**

This audit of official controls was undertaken using the audit procedures documented in the FSAI's Business Management System. These procedures describe the FSAI's audit obligations defined in Schedule 5 of the Service Contract between the FSAI and Kerry County Council, and in accordance with the requirements of Regulation (EC) No 882/2004, Commission Decision 2006/677/EC, and Section 48(9) of the Food Safety Authority of Ireland Act, 1998, as amended.

As part of the preparation for this audit, a review of relevant information and data held within the FSAI relating to official controls relevant to Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs carried out by Kerry County Council was conducted. Following this review, Kerry County Council completed a pre-audit questionnaire in respect of information regarding the establishments under its supervision.

An evaluation plan describing the audit process and approach – including the scope, objectives, criteria and audit team – was then sent to Kerry County Council. The audit commenced with an opening meeting followed by an audit to assess how Kerry County Council delivers its obligations under the Service Contract, as relevant to Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, and to assess how it adheres to documented procedures and guidance documents.

The audit team assessed the adequacy and performance of the controls put in place by food business operators in relation to Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in order to determine if they were effective and in compliance with food law. On completion of the on-site visits to two establishments, the FSAI audit team outlined the audit findings relevant to each food business. The food business operator was informed that the FSAI would communicate the audit findings to the County Veterinary Officer for follow-up. Following completion of the establishments' audits, a final closing meeting was held with the County Veterinary Officer, during which the preliminary findings were discussed.

## **4. AUDIT FINDINGS**

### **4.1. Official controls performed in respect of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs**

Kerry County Council has been designated a competent authority for the purpose of carrying out official controls to ensure verification of compliance with food law in the food business operations under its supervision. This responsibility is discharged on behalf of the FSAI through the Service Contract. At the time of this audit, there was one full-time County Veterinary Officer who organises and conducts official controls in food business operations supervised by the local authority. There are 30 approved establishments under the supervision of Kerry County Council.

#### **4.1.1. Official control sampling**

**Section 2.2.3 of the FSAI's Service Contract with Kerry County Council relates to the provision of additional services, which include requirements related to official control sampling from food businesses.**

**Article 1 of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs requires that the competent authority shall verify compliance with the rules and criteria laid down in this Regulation in accordance with Regulation (EC) No 882/2004 without prejudice to its right to undertake further sampling and analyses for the purpose of detecting and measuring other microorganisms, their toxins or metabolites, either as a verification of processes for food suspected of being unsafe or in the context of a risk analysis.**

Microbiological sampling from food businesses in the local authorities is undertaken as part of the official control microbiological sampling programme. Testing of official control samples is undertaken by the Cork County Council Veterinary Food Safety Laboratory, which provides microbiological analysis of foodstuffs and other samples of relevance to food safety, for example water, animal tissues and environmental samples.

As part of the Service Contract between the FSAI and Cork County Council, microbiological testing is carried out in accordance with Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. Sample types tested in the laboratory include cooked meats, meat products, raw meat, poultry, milk, potable water and carcase/environmental swabs.

Food and environmental samples are currently tested for the following (depending on the sample):

- Aerobic colony counts
- *Salmonella* spp.
- *Listeria monocytogenes*

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- *E. coli*
- *Campylobacter* spp.
- Shiga toxin-producing *E. coli* (STEC), also referred to as verocytotoxigenic *E. coli* (VTEC).

The sampling programme is agreed between the laboratory, the local authorities and the FSAI. As part of the sampling programme, each local authority conducts official control sampling in specified establishments on specified dates. The County Veterinary Officer in Kerry is responsible for conducting the official control sampling within his/her functional area.

Kerry County Council conducted official control sampling broadly in line with the sampling programme. In some instances, deviations from the plan were made due to changes in the scheduled food business operator's activities or the non-availability of product. Additional sampling was conducted in response to unsatisfactory results.

#### **4.1.2. Results of official control testing**

**Section 2.2.3 of the FSAI's Service Contract with Kerry County Council relates to the provision of additional services and requires that the official agency shall aim to ensure the appropriate follow-up of noncompliant samples.**

The results of the testing conducted as part of official controls were assessed during the audit. As part of the communication of official control test results to food business operators, the County Veterinary Officer outlines the results, including clear guidance in relation to any action that is required on the part of the food business operator.

There was an unsatisfactory process hygiene criteria result for aerobic colony count for an official control sample of beef mince in 2017. The County Veterinary Officer wrote to the food business operator to outline the unsatisfactory result, to provide guidance in relation to the result, and to require that the food business operator conduct his own sampling in order to monitor the situation.

*Listeria monocytogenes* has been detected through official control sampling in ready-to-eat products in three premises supervised by Kerry County Council since 2015. In each case, the results were communicated to the food business operator, including a clear explanation of the results, direction as to the corrective actions that were required, and information relating to the follow-up actions that were being instigated by the County Veterinary Officer. On each occasion, the County Veterinary Officer conducted thorough investigations, which included sampling of additional product and environmental monitoring, as appropriate. In one of the premises, *Listeria monocytogenes* was detected in two ready-to-eat products, as well as in an environmental swab from a drain in 2015. This food business operator has since implemented an extensive own-checks testing regime and has, on the advice of the County Veterinary Officer, amended production protocols to provide additional control.

It was confirmed that the non-destructive (i.e. sponge) swabbing method was used for the ovine carcass swab and sampling of carcasses for other animal species both by the County Veterinary Officer and the food businesses in the county. Footnote 4 to Table 2.1 of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs states that the limits (i.e. m and M)<sup>2</sup> do not apply to the non-destructive sampling method. There is currently no guidance on appropriate limits for m and M in local authorities' guidance or in FSAI Guidance Note

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<sup>2</sup> For a microbiological criterion in Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs:

- c = the number of sample units giving values between m and M
- n = the number of units comprising the sample.

No. 27. The non-destructive method is known to be less sensitive than the destructive method, which means that lower limits for m and M would be more appropriate.

Results of official control testing of carcass swabs conducted from 2015 to the time of this audit were reviewed, and it was noted that the County Veterinary Officer had categorised three process hygiene criteria results as unsatisfactory and 15 process hygiene criteria results as falling into the acceptable range. The County Veterinary Officer communicated the results and followed up with the food business operators in order to ensure that improvements were made in relation to process hygiene in the businesses.

During the on-site verification which took place in two establishments, the records of the official control testing which had been carried out were provided to the food business operators. The food business operator that was present during the audit of his establishment also confirmed that the County Veterinary Officer had discussed the results with him and had indicated what action was required.

#### ***4.1.3. Assessment of food businesses with regard to compliance with Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs***

**Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs allows for exemption of small slaughterhouses and meat establishments from the sampling frequencies set out in Annex I of the Regulation when such an exemption is justified on the basis of risk analysis and is consequently authorised by the competent authority.**

The Cross-Agency Hygiene Package Implementation Working Group provided guidance to facilitate the implementation of reduced sampling frequencies in low-throughput premises such as those supervised by Kerry County Council. As part of this guidance, templates for conducting risk analysis are provided. The result of the risk analysis is then combined with the premises' overall throughput<sup>3</sup> to indicate the minimum sampling requirement (Tables 1 and 2).

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<sup>3</sup> Premises' overall throughput is determined based on livestock units per annum for slaughterhouses and overall throughput in tonnes per week for minced meat and meat preparation plants.

**Table 1: Sampling requirements for slaughterhouses based on risk analysis**

| Risk analysis score | Overall throughput (livestock units per annum) | Minimum sampling requirement*  |
|---------------------|--|--|
| ≤1,000              | <750   | An approach involving absence of process hygiene sampling may be applied |
|                     | 750–1,500                                      | 5 carcass samples in most frequently slaughtered species every 4 months  |
|                     | 1,501–5,000                                    | 5 carcass samples per species every month                                |
| >1,000              | <750   | 5 carcass samples in most frequently slaughtered species every 2 months  |
|                     | 750–1,500                                      | 5 carcass samples in most frequently slaughtered species every month     |
|                     | 1,501–5,000                                    | 5 carcass samples per species every 2 weeks                              |
| N/A                 | >5,000   | Sampling frequency as per Commission Regulation (EC) No 2073/2005        |

\*Note: Aerobic colony count, Enterobacteriaceae and *Salmonella*

Microbiological criteria, including index organisms for each species, are as defined in Commission Regulation (EC) No 2073/2005.

**Table 2: Sampling requirements for small meat manufacturing establishments based on risk analysis**

| Risk analysis score | Overall throughput (tonnes per week)                   |   | Minimum sampling requirement                                      |
|---------------------|--|---|---|
|                     | Minced meat plants and minced meat preparation plants* | Meat preparation plants other than minced meat preparation plants |   |
| ≤900                | 0–0.5  | 0–0.5   | An approach involving absence of sampling may be applied          |
|                     | >0.5–3   | >0.5–5  | 5 samples (1 sampling session) every 2 months                     |
| >900                | 0–0.5  | 0–0.5   | 5 samples (1 sampling session) every 2 months                     |
|                     | >0.5–3   | >0.5–5  | 5 samples (1 sampling session) every month                        |
| N/A                 | >3   | >5  | Sampling frequency as per Commission Regulation (EC) No 2073/2005 |

\*Minced meat of any species that is incorporated into a meat preparation brings a connotation of risk closer to that of minced meat than to that of non-minced meat preparations. Differing microbiological criteria are stipulated for minced meat and meat preparations in Commission Regulation (EC) No 2073/2005. The above approach aligns the frequency of sampling sessions in these two types of plants.

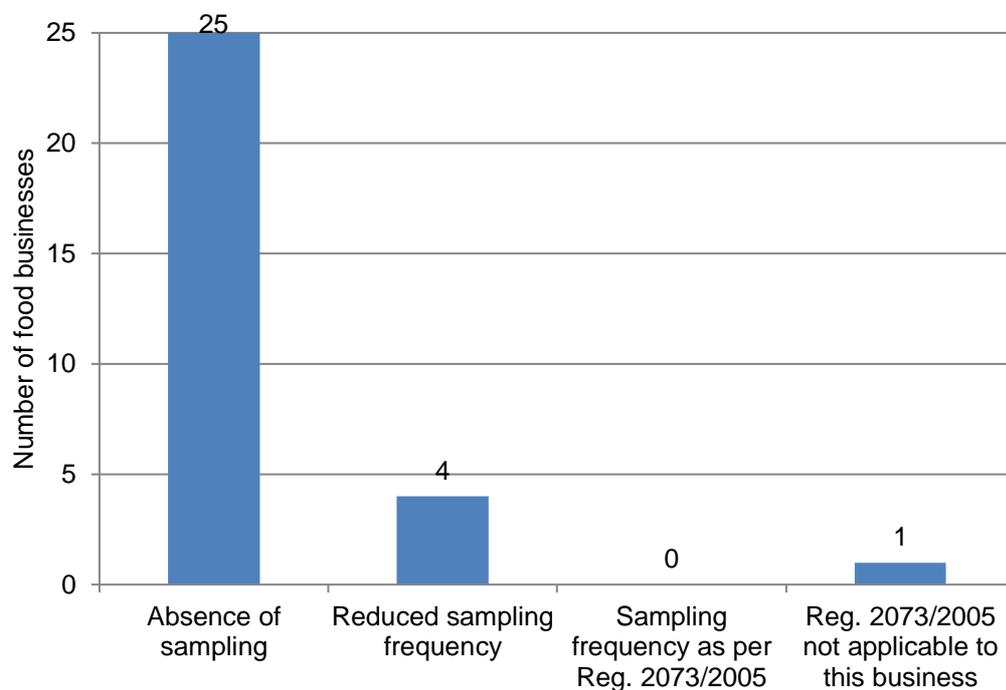
Following assessment of risk and throughput, there are three main categories of sampling frequency which may be applied in low-throughput establishments:

1. An approach involving absence of sampling
2. A reduced sampling frequency
3. A sampling frequency as per Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs and associated guidance requires that if a reduced frequency of sampling is to be used, it must be on the basis of a risk analysis and consequently must be authorised by the competent authority. In Kerry, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency.

The County Veterinary Officer had conducted assessments in relation to the 30 approved establishments under the supervision of Kerry County Council, the results of which are outlined in Figure 1. The templates provided in the Cross-Agency Hygiene Package Implementation Working Group guidance document, *Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in low-throughput premises*, had been used to guide the assessment of risk and overall throughput, and detailed records of the assessment were maintained on the establishments' files.

Figure 1: Categories of sampling frequency



One of the 30 approved establishments was not subject to the requirements of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs due to the fact that the activities being undertaken or products produced did not fall within the remit of the Regulation.

The remaining 29 approved establishments within the Kerry County Council's functional area had been subject to assessment to determine the manner in which Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs would be applied. Following assessment of risk and plant throughput, an approach involving absence of sampling has been applied with regard to 25 food businesses. The 25 food businesses for which the assessment determined that an approach involving absence of sampling was appropriate were not notified that they do not need to conduct sampling. The outcome of the assessment of risk and throughput for three of the remaining establishments was that testing was required at a reduced sampling frequency. One business was conducting product testing and environmental monitoring for *Listeria monocytogenes*, for which there is no set sample frequency. Notification regarding the outcome of the assessment was made to the four food business operators and the notification letters outlined in detail the products to be tested, the frequency, and what test parameters were required, as appropriate. Records of the results of the assessment were maintained on all establishments' files.

The County Veterinary Officer indicated that the decision regarding the frequency of sampling and any exemptions granted is kept under review during official controls and any amendments are mainly linked to changes in the throughput figures of establishments. The County Veterinary Officer reviews the risk analysis every 12 to 18 months, or more frequently should a significant change occur in the business.

During file review, the audit team verified the risk analysis conducted in relation to five establishments using the information regarding the approved activities and the overall throughput of the establishments.

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#### **4.1.4. Review of food business operators' own testing as part of official controls**

Four food businesses were conducting their own testing at the reduced sampling frequency which the County Veterinary Officer had communicated to them. A record of the reduced frequency applied had been maintained in the establishments' files and is outlined in Table 3.

Food business operators manufacturing ready-to-eat foods which may pose a *Listeria monocytogenes* risk for public health shall sample the processing areas and equipment for *Listeria monocytogenes* as part of their sampling scheme. One of the food business operators was conducting product testing and environmental monitoring for *Listeria monocytogenes*.

One food business operator was notified verbally that microbiological testing was required to be carried out, following the assessment of risk and throughput undertaken by the County Veterinary Officer in 2016. However, testing only commenced in the summer of 2017 following a written notification to the food business operator. In the interim period, the food business operator was reviewing and trending the official control test results provided by the County Veterinary Officer.

During file review, it was noted that the food business operators' own testing programmes and results were being reviewed during official control inspections. Inspection reports included notes to the food business operators to conduct testing, when the testing was due and had not yet been carried out. Records of inspections also contained notes relating to the fact that microbiological analysis of product and the environment had been assessed as part of the inspection and found to be satisfactory.

**Table 3: Sampling frequencies for those food businesses conducting testing**

| Food business operator | Ready-to-eat foods                      | Environmental monitoring  | Minced meat  | Meat preparations  | Carcase samples   | Fresh poultry meat   |
|------------------------|---|---|--|--|---|--|
|                        | <i>Listeria monocytogenes</i>           | <i>Listeria monocytogenes</i>   | <i>Salmonella</i> , aerobic colony count, <i>E. coli</i> | <i>Salmonella</i> , <i>E. coli</i>                         | Aerobic colony count, Enterobacteriaceae, <i>Salmonella</i>                 | <i>Salmonella</i> Typhimurium, <i>Salmonella</i> Enteritidis |
| 1                      | 5 samples (1 sampling event) every week | Swabbing from 1 location every 2 weeks (rotating through food contact and non-contact surfaces) | Not applicable   | An approach involving absence of sampling had been applied | Not applicable  | Not applicable   |
| 2                      | Not applicable                          | Not applicable  | Not applicable   | Not applicable   | 5 carcase samples in the most frequently slaughtered species every 4 months | Not applicable   |
| 3                      | Not applicable                          | Not applicable  | Not applicable   | Not applicable   | 5 carcase samples in the most frequently slaughtered species every 2 months | Not applicable   |
| 4                      | Not applicable                          | Not applicable  | 5 samples (1 sampling event) every 2 months              | Not applicable   | Not applicable  | Not applicable   |

#### 4.1.5. Identification, follow-up and closeout of unsatisfactory test results as part of official controls

Article 7 of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs regarding unsatisfactory results requires that:

1. When the results of testing against the criteria set out in Annex I are unsatisfactory, the food business operators shall take the measures laid down in paragraphs 2 to 4 of this Article, together with other corrective actions defined in their HACCP-based procedures and other actions necessary to protect the health of consumers.

In addition, they shall take measures to find the cause of the unsatisfactory results, in order to prevent the recurrence of the unacceptable microbiological contamination. Those measures may include modifications to the HACCP-based procedures or other food hygiene control measures in place.
2. When testing against the food safety criteria set out in Chapter 1 of Annex I provides unsatisfactory results, the product or batch of foodstuffs shall be withdrawn or recalled in accordance with Article 19 of Regulation (EC) No 178/2002. However, products placed on the market which are not yet at retail level and which do not fulfil the food safety criteria may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

The food business operator may use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and has been authorised by the competent authority.
3. A batch of mechanically separated meat (MSM) produced with the techniques referred to in Chapter III, paragraph 3, in Section V of Annex III to Regulation (EC) No 853/2004, with unsatisfactory results in respect of the *Salmonella* criterion, may be used in the food chain only to manufacture heat-treated meat products in establishments approved in accordance with Regulation (EC) No 853/2004.
4. In the event of unsatisfactory results as regards process hygiene criteria, the actions laid down in Annex I, Chapter 2 shall be taken.

In the first establishment in which on-site verification was carried out, there had been no unsatisfactory results from the sampling programme undertaken as part of the food business operator's own checks. Where there were results which were not satisfactory (but which were in the acceptable range, i.e. a borderline level between satisfactory and unsatisfactory) from official control testing relating to process hygiene criteria, the food business operator had been notified. The notifications provided included details of the test results along with advice on the corrective actions to be taken by the food business operator.

In the second establishment in which on-site verification was carried out, there had been unsatisfactory results from the sampling programme undertaken as part of the food business operator's own checks. These had related to detection of *Listeria monocytogenes* in product. An extensive investigation was conducted by the County Veterinary Officer, which included sampling of additional product and environmental swabs, as appropriate. This food business operator has implemented an extensive own-checks testing regime and has, on the advice of the County Veterinary Officer, amended production protocols in order to provide additional control.

## 4.2. Food business operator findings

On-site verification was carried out in two food business operations to assess their compliance with the requirements of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs and to verify the effectiveness of official controls in this regard. The first establishment selected was a slaughter and cutting

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plant which was conducting testing at a reduced sampling frequency. The second establishment selected produced a range of ready-to-eat and non-ready-to-eat products and so was conducting product testing and environmental monitoring for *Listeria monocytogenes*. The food business operator for the second establishment was not available to the audit team at the time of the on-site verification.

Food business operators that produce, manufacture or package food for which criteria are set in the Regulation must:

1. Identify the criteria in the Regulation that are relevant to the food they manufacture, package or produce
2. Test (where appropriate) the food they produce, manufacture or package to check that it complies with the relevant criteria
3. Take the appropriate action if test results are unsatisfactory
4. Analyse trends in their test results
5. Conduct environmental monitoring, as appropriate
6. Label products with the instruction to cook thoroughly, if they manufacture or pack minced meat and meat preparations (made from species other than poultry) which are intended to be eaten cooked
7. Demonstrate that the food complies with the relevant criteria throughout its shelf life.

During on-site verification, the audit team confirmed that the audited food business operators were conducting microbiological testing and assessed whether or not they had identified all relevant criteria as they applied to their businesses. Both food businesses had identified the correct criteria and were conducting testing.

One of the food business operators had detected *Listeria monocytogenes* as part of its testing regimes. The food business operator had notified the County Veterinary Officer and had participated in extensive follow-up, which included additional testing and amendments to his production processes to provide additional controls in relation to *Listeria monocytogenes*.

Trend analysis was not being carried out for results of one food business operator's own testing for aerobic colony count and Enterobacteriaceae, as testing had only commenced some months prior to the audit. However, trending was undertaken for the official control sample results prior to commencement of the food business operator's own testing programme. This involved the use of detailed graphs with the limits indicated on the graphs for ease of reading. The food business operator intended to use this format of graph to trend the results of his own testing as well. The other food business operator was conducting product testing for *Listeria monocytogenes*, and so was not conducting trend analysis using a graph, as interpretation of the results of *Listeria monocytogenes* testing relates to detection or non-detection.

Both food business operators were observing best practice in relation to using an accredited laboratory; however, at the time of the audit, neither food business operator had confirmed with its laboratory that the testing methods used were either those stipulated in the legislation or a validated alternative method.

The labelling of products which are intended to be eaten cooked, with the instruction to cook thoroughly, was not applicable to the two food businesses selected for on-site verification.

The food business operator producing ready-to-eat products was applying a criterion of absence in 25 g in relation to *Listeria monocytogenes* and so had not conducted shelf life challenge testing for *Listeria monocytogenes*.

Findings relating to the noncompliance with food law identified during this part of the audit were communicated verbally to the food business operator or the County Veterinary Officer at a closing meeting upon conclusion of the audit in each establishment. Closeout of these findings will be monitored by the County Veterinary Officer during subsequent official control inspections.

## **5. CONCLUSIONS**

Kerry County Council supervises 30 active approved establishments under its Service Contract with the FSAI. The audit team confirmed that official controls as they relate to Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs were being implemented. The two food businesses for which on-site verification was conducted were aware of their responsibilities under the Regulation. During on-site verification, the first food business operator demonstrated a good understanding of the Regulation as it applied to his business. The second food business operator, although not present at the on-site verification, also demonstrated that he had a good understanding of the requirements of the legislation. This was evidenced by the fact that he had developed an extensive microbiological testing programme, and associated procedures and operational controls which included corrective actions in the case of unsatisfactory results. The communications related to Commission Regulation (EC) No 2073/2005 that the County Veterinary Officer had provided to the food businesses were detailed and provided clear information and guidance to the food business operators.

## **6. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION**

Audit findings requiring corrective action are listed in the Corrective Action Plan. Corrective actions in response to the findings of this report are required to ensure the effectiveness of official controls and to enhance food business operators' compliance with the Regulation. The findings identified during this audit should be disseminated to all food businesses within Kerry County Council's functional area in order to ensure that the identified opportunities for improvement are implemented across all businesses.

The Corrective Action Plan can be found by visiting [https://www.fsai.ie/enforcement\\_audit/audit/reports.html](https://www.fsai.ie/enforcement_audit/audit/reports.html)





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