

AUDIT
REPORT

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

APRIL 2019

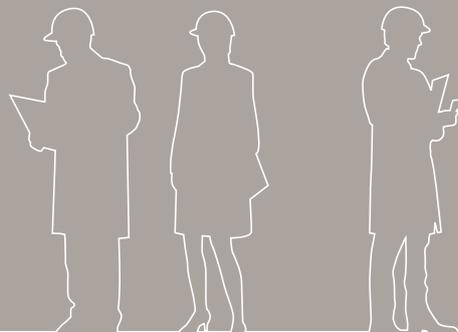


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In accordance with Schedule 5 of the FSAI
Service Contract, it is the responsibility of the
official agency to close out all audit findings.



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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. Limerick City and 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 Limerick City and 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 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 to indicate the minimum sampling requirement. Following assessment of risk and throughput, there are three main categories of sampling frequency which 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.

Limerick City and County Council conducted official control sampling in line with the sampling programme which is agreed between the Cork County Council Veterinary Food Safety Laboratory, the local authorities and the FSAI.

Listeria monocytogenes was detected in an environmental swab taken from a drain in the high-care area of a cooked meats plant in 2016 as part of the official control sampling. The results were communicated to the food business operator and corrective action was taken. There were two unsatisfactory process hygiene criteria results for aerobic colony count in the official control samples of minced meat (bovine and ovine) taken from another food business in February 2017. The County Veterinary Officer communicated the results and followed up with the food business operator. Follow-up testing was conducted in both of these incidents, and the results of both additional environmental monitoring and product tests were satisfactory.

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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 sampling frequency, it must be on the basis of a risk analysis and consequently authorised by the competent authority. In Limerick, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency. The County Veterinary Officer had conducted assessments in relation to the 18 approved establishments under the supervision of Limerick City and County Council. 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.

Five of the 18 approved establishments were 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 remit of the Regulation. The 13 remaining approved establishments within the Limerick City and County Council's functional area were assessed to determine the manner in which Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs would be applied. An approach involving absence of sampling has been applied to six of the food businesses. In six of the seven remaining establishments, testing was required at a reduced sampling frequency, and the remaining business was conducting product testing and environmental monitoring for *Listeria monocytogenes*.

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 conducting testing at a reduced sampling frequency. The second establishment was conducting product testing and environmental monitoring for *Listeria monocytogenes*, for which there is no set sampling frequency. Both food business operators had identified all the relevant criteria that 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. Neither food business operator had identified any unsatisfactory results as part of their own testing regimes. One of the food business operators was carrying out trend analysis on the results of testing for aerobic colony count and Enterobacteriaceae, and the graphs had been colour coded to aid interpretation of the results. In the other food business, since the testing related to *Listeria monocytogenes*, trend analysis using a graph was not carried out, as interpretation of the results related to detection or non-detection. Environmental swabbing for *Listeria monocytogenes* was being carried out during processing across a number of designated sites, which included food contact and non-contact surfaces. Both food business operators had conducted shelf-life testing on their products and had maintained records of these tests. The food business operator producing raw product had labelled it for consumers to indicate that thorough cooking was required. Both food business operators were observing best practice in relation to using an accredited laboratory, and both had confirmed with their laboratory that the testing methods used were those stipulated in Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs or that a validated alternative method was used.

Limerick City and County Council supervises 18 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 effectively. The two food businesses in which on-site verification was conducted were aware of their responsibilities under the Regulation. During on-site verification, both food business operators demonstrated a good understanding of the Regulation as it applied to their businesses. This was evidenced by the fact that both food business operators had identified and were conducting testing under the Regulation as required and, where relevant, they were conducting trend analysis and had documented procedures and corrective actions in place in case of unsatisfactory results. The communications related to the Regulation 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 the inclusion of the following aspects as part of the risk analysis:¹

- Operational hygiene at the premises
- Sanitation of the premises and equipment
- Hygiene of raw materials, e.g. 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.

¹ 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. 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. Limerick City and 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. Food legislation and the Service Contract require Limerick City and 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. This audit covered the organisation, planning, implementation and review of official controls within Limerick City and County Council in respect of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs and also verified selected food business operators' compliance with food law. On-site verification of compliance in 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 Limerick City and 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 \(including checklist\)](#)
- [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 Limerick City and 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 2017
- 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 Limerick City and 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.

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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 was conducted. Following this review, Limerick City and 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 Limerick City and County Council. The audit commenced with an opening meeting followed by an audit to assess how Limerick City and County Council delivers its obligations under the Service Contract as relevant to Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, as well as 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 to determine if the controls were effective and in compliance with food law. On completion of the on-site visits to the establishments, the FSAI audit team outlined the audit findings relevant to each food business operator. Each 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 and the Clerical 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

Limerick City and 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. There is one full-time County Veterinary Officer who organises and conducts official controls in food business operations supervised by the local authority. There are 18 approved establishments and two registered cold stores under the supervision of Limerick City and County Council.

4.1.1. Official control sampling

Section 2.2.3 of the FSAI's Service Contract with Limerick City and County Council relates to the provision of additional services and includes 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.

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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 count
- *Salmonella* spp.
- *Listeria monocytogenes*
- *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 Limerick is responsible for conducting the official control sampling within his/her functional area.

Limerick City and County Council conducted official control sampling in line with the sampling programme.

4.1.2. Results of official control testing

Section 2.2.3 of the FSAI's Service Contract with Limerick City and 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 as part of the audit. As part of the communication of official control test results to the food business operators, the County Veterinary Officer outlines the results, including an explanation of the status of the results (satisfactory, acceptable, or unsatisfactory) as well as clear guidance in relation to any action that is required. Trend analysis, which the County Veterinary Officer conducts on official control test results, is also provided to the food business operators.

Listeria monocytogenes was detected in an environmental swab taken from a drain in the high-care area of a cooked meats plant in 2016, and these results were communicated to the food business operator. The County Veterinary Officer had also sampled cooked product at the same time as the environmental swab was taken. *Listeria monocytogenes* was not detected in the various products also sampled on that date. Limerick City and County Council and the food business operator conducted additional environmental monitoring in the high-care area, as well as additional product testing. *Listeria monocytogenes* was not detected as part of this follow-up testing.

There were two unsatisfactory process hygiene criteria results for aerobic colony count from official control samples of minced meat (bovine and ovine) in February 2017. The County Veterinary Officer communicated the results and followed up with the food business operator. Following the County Veterinary Officer's advice, the food business operator agreed to cease mincing at his establishment in light of these results. This establishment also cuts poultry meat, and the food business operator has been requested to conduct his own testing on the cut

poultry product even though the quantities produced are within the limit which would allow an approach involving absence of sampling. Once a history of test results is built up, the County Veterinary Officer will review the requirement for testing.

It was confirmed that the non-destructive (i.e. sponge) swabbing method was used for the sampling of carcasses both by the County Veterinary Officer and the food businesses in which on-site verification was carried out.

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)² do not apply to the non-destructive method. There is currently no guidance on appropriate limits for m and M in local authorities' guidance or in FSAI Guidance Note No. 27. The non-destructive method is known to be less sensitive than the destructive method. This means that lower limits for m and M would be more appropriate.

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. Both food business operators also confirmed that the County Veterinary Officer had discussed the results with them and indicated what action they were required to take in the case of unsatisfactory results and where *Listeria monocytogenes* was detected in the processing environment.

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 Limerick City and 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 throughput³ to indicate the minimum sampling requirement (Tables 1 and 2).

² 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.

³ 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 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.

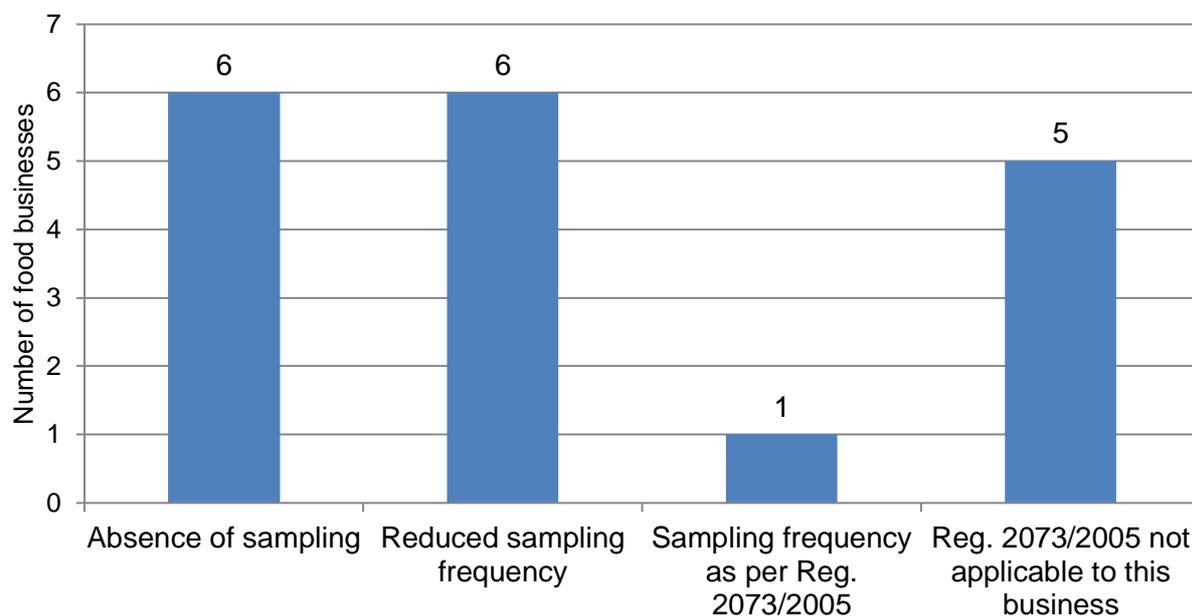
Following assessment of risk and throughput, there are three main categories of sampling frequency which may be applied in low-throughput establishments:

1. An approach involving absence of sampling
2. A reduced sampling frequency
3. 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 authorised by the competent authority. In Limerick, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency.

The County Veterinary Officer had conducted assessments in relation to the 18 approved establishments under the supervision of Limerick City and 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



Five of the 18 approved establishments were 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 remit of the Regulation.

The 13 remaining approved establishments within the Limerick City and County Council's functional area were assessed 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 six of the food businesses, and the County Veterinary Officer notified these food businesses that they do not need to conduct sampling. The outcome of the assessment of risk and throughput for six of the remaining seven 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.

The seven food businesses for which testing was required were notified of the outcome of the assessment and were provided with an outline of the minimum sampling requirements, where appropriate. Records of the results of the assessment were maintained on the establishments' files and the reduced sampling frequency was communicated to the food business operators.

The County Veterinary Officer indicated that he kept the decision regarding the frequency of sampling under review during official controls, and evidence of this was recorded in the establishments' files. The County Veterinary Officer had conducted formal reassessments of the throughput figures relating to two establishments due to changes in the nature of their activities and calculation of the throughput of the businesses. The details of the formal reassessments were maintained in the establishments' files.

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

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

Seven food businesses were conducting their own testing; of those seven businesses, six were conducting testing at a reduced sampling frequency which the County Veterinary Officer had communicated to them. A record of the reduced frequency which was 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 environmental monitoring in their high-care area as part of their sampling programme.

The two food businesses for which on-site verification was carried out were complying with the designated sampling frequency that the County Veterinary Officer had determined and communicated to them. During file review, it was noted that the food business operators' own testing programmes and results were being reviewed during inspections. Inspection reports included notes to the food business operators to conduct testing, when testing was due and when testing 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 was found to be satisfactory.

Table 3: Sampling frequencies for those food businesses conducting testing⁴

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	Not applicable	Not applicable	Not applicable	Not applicable	5 carcase samples in the most frequently slaughtered species every 4 months	Not applicable
2	5 samples (1 sampling event) every 2 weeks	Swabbing from 4/5 locations every 2 weeks	Not applicable	Not applicable	Not applicable	Not applicable
3	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	5 samples (1 sampling event) every 2 months
4	Not applicable	Not applicable	5 samples (1 sampling event) every 2 months	Not applicable	Not applicable	Not applicable
5	Not applicable	Not applicable	5 samples (1 sampling event) every 4 months	5 samples (1 sampling event) every 4 months	Not applicable	Not applicable
6	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable	5 samples (1 sampling event) every 3 months
7	Not applicable	Not applicable	Not applicable	5 samples (1 sampling event) every 3 months	Not applicable	Not applicable

⁴ Some of the food businesses also carried out microbiological testing in addition to the requirements of Commission Regulation (EC) No 2073/2005 as part of their compliance with their food safety management system or at the request of customers. This additional testing is not reflected in the above table.

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 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 with regard to process hygiene criteria, the actions laid down in Annex I, Chapter 2 shall be taken.

In the two establishments in which on-site verification was carried out, there had been no unsatisfactory results from the sampling programmes undertaken as part of the food business operators' 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, and where *Listeria monocytogenes* had been detected in the processing environment, the food business operators had been notified of these results. The notifications provided to the food business operators included details of the results of the tests and provided advice on the corrective actions to be taken by the food business operators.

When notified of the detection of *Listeria monocytogenes* in the processing environment (in a drain), the food business operator carried out enhanced cleaning and disinfection of the high-care area. Limerick City and County Council and the food business operator conducted additional environmental monitoring in the high-care area, as well as additional product testing, following the actions outlined above. *Listeria monocytogenes* was not detected as part of this additional testing.

In the case of the process hygiene result which was not satisfactory (but which was in the acceptable range), the food business operator spoke to staff regarding process hygiene and end-of-line checks for clean carcasses.

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 slaughterhouse and cutting plant which also produced minced meat and meat preparations; this food business operator was conducting testing at a reduced sampling frequency. The second establishment that was selected produced cooked meat products and was conducting product testing and environmental monitoring for *Listeria monocytogenes*, for which there is no set sampling frequency.

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 relevant criteria throughout its shelf life.

During on-site verification, the audit team verified that the audited food business operators were conducting microbiological testing and had identified all relevant criteria in the Regulation as they applied to their businesses. Both food business operators had detailed, documented procedures regarding their microbiological testing plans and actions to be taken in case of unsatisfactory results. Neither food business operator had identified any unsatisfactory results as part of their own testing regimes.

One food business operator was conducting product testing and environmental monitoring for *Listeria monocytogenes* and so was not conducting trend analysis using a graph, as interpretation of the results related to detection or non-detection. The other food business for which on-site verification was conducted was carrying out trend analysis of the results of testing for aerobic colony count and Enterobacteriaceae, and had colour coded the graphs to aid interpretation of the results.

Environmental testing for *Listeria monocytogenes* was being carried out in one of the businesses, with swabbing being conducted during processing (as recommended by European Union (EU) guidance) across a number of designated sites, which included food contact and non-contact surfaces.

Both food business operators had conducted shelf-life testing on their products and had maintained records of these tests. The food business operator producing raw product had labelled it for consumers to indicate that thorough cooking was required.

Both food business operators were observing best practice in relation to using an accredited laboratory, and both had confirmed with their laboratory that the testing methods used were those stipulated in Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs or that the laboratory was using a validated alternative method.

5. CONCLUSIONS

Limerick City and County Council supervises 18 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 effectively. The two food businesses for which on-site verification was conducted were aware of their responsibilities under the Regulation. During on-site verification, both food business operators demonstrated a good understanding of the Regulation as it applied to their business. This was evidenced by the fact that both food business operators had identified and were conducting testing under the Regulation as required, and that, where relevant, they were conducting trend analysis and had documented procedures and corrective actions in place in 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

No audit findings requiring corrective action were identified as part of this audit.



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