

AUDIT
REPORT

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

APRIL 2019

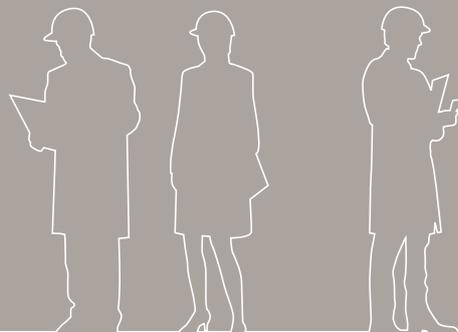


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In accordance with Schedule 5 of the FSAI
Service Contract, it is the responsibility of the
official agency to close out all audit findings.



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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. Clare 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 Clare 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 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.

Clare 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. Where there were deviations from the sampling programme, due to limited availability of samples, these were agreed with the laboratory.

There have been no detections of *Listeria monocytogenes* as part of the official control testing conducted by Clare County Council. 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 five process hygiene criteria results as unsatisfactory and three process hygiene criteria results as falling into the acceptable category. The County Veterinary Officer communicated the results to the food business operators and followed up to ensure that improvements were made in relation to process hygiene in the businesses.

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 must be authorised by the competent authority. In Clare, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency. The County Veterinary Officer had conducted assessments in relation to the 10 approved establishments under the supervision of Clare County Council. The

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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. Detailed records of the assessment were maintained on the establishments' files.

Two of the 10 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 activities being undertaken or the products being produced did not fall within the remit of the Regulation. The remaining eight approved establishments within the Clare County Council 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 five food businesses. These food businesses were notified by the County Veterinary Officer that they do not need to conduct sampling. The outcome of the assessment of risk and throughput in the remaining three establishments was that testing was required at a reduced sampling frequency. One of the three businesses was also conducting product testing 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 and the second establishment was conducting product testing for *Listeria monocytogenes*. During on-site verification, the audit team verified that the food business operators audited were conducting microbiological testing, and assessed whether or not they had identified all criteria relevant to their businesses. The small food business operator that was slicing cooked meat was conducting product testing for *Listeria monocytogenes*; however, they had not yet commenced environmental monitoring for *Listeria monocytogenes*. The food business operator had planned to conduct environmental monitoring in the months after the audit. Neither food business operator had obtained any unsatisfactory results as part of their testing regimes. One food business operator was not conducting trend analysis for results of own testing for aerobic colony count and Enterobacteriaceae, although the food business operator was calculating the mean of the log for each batch of results received. The County Veterinary Officer conducts trend analysis on food business operator test results as well as on official control results, and these are provided to the food business operator. In the other food business, as the testing related to *Listeria monocytogenes*, trending using a graph was not carried out, as interpretation of results related to detection or non-detection. The food business operator slicing cooked meats 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*. Both food business operators were observing best practice in relation to using an accredited laboratory, but they had not confirmed with their laboratory that the test methods used were those stipulated in the legislation or a validated alternative method.

Clare County Council supervises 10 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 in which on-site verification was conducted were generally aware of their responsibilities under Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. However, deficiencies were identified during on-site verification, which indicated a lack of understanding of certain aspects of the Regulation. Additional guidance is required for these food businesses in order to ensure that they are fully compliant with the requirements of the Regulation.

3. INTRODUCTION

Microbiological criteria are used to assess the acceptability 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 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 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 and small meat manufacturing premises in a document entitled *Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in low-throughput 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 (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. 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 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. Clare 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 Clare 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 Clare County Council in respect of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs and also to verify selected food business operators' compliance with food law. On-site verification of compliance with food law 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 purposes of assessing the effectiveness and appropriateness of official controls conducted by Clare 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 Clare 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 Quality Management System. These procedures describe the FSAI's audit obligations, defined in Schedule 5 of the Service Contract between the FSAI and Clare 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 Clare County Council was conducted. Following this review, Clare 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 Clare County Council. The audit commenced with an opening meeting followed by an audit to assess how Clare 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 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 operator. The food business operators were 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 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

Clare 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 10 approved establishments under the supervision of Clare County Council.

4.1.1. Official control sampling

Section 2.2.3 of the FSAI's Service Contract with Clare County Council relates to the provision of additional services, which 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.

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.

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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 Clare is responsible for conducting the official control sampling within his/her functional area.

Clare County Council conducted official control sampling broadly in line with the sampling programme. In one instance, due to the small volume of ready-to-eat (RTE) products being produced by a food business assigned to the sampling plan, the County Veterinary Officer in Clare agreed with the laboratory that it would be more appropriate to take five RTE and 20 non-RTE samples from this particular establishment.

4.1.2. Results of official control testing

Section 2.2.3 of the FSAI's Service Contract with Clare County Council relates to the provision of additional services and requires that the official agency shall aim to ensure the appropriate follow-up of non-compliant 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 the calculation of the mean of the log for process hygiene results for Enterobacteriaceae and aerobic colony count during official control inspections. Trend analysis, which the County Veterinary Officer conducts on official controls as well as food business operator test results, is also provided to the food business operators.

There have been no detections of *Listeria monocytogenes* as part of the official control testing conducted by Clare County Council.

It was confirmed that the non-destructive (i.e. sponge) swabbing method was used for ovine carcase swabs and the sampling of carcasses of other animal species by both 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)² 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 No. 27. The non-destructive method is known to be less sensitive than the destructive method, which means that the 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 five process hygiene criteria results as unsatisfactory and three process hygiene criteria results as falling into the acceptable category. The County Veterinary Officer communicated these results to the relevant food business operators and followed up 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. Both food business operators also confirmed that the County Veterinary Officer had discussed the results with them and had indicated what action was required by them.

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 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 Clare 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 assessment 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 assessment 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.

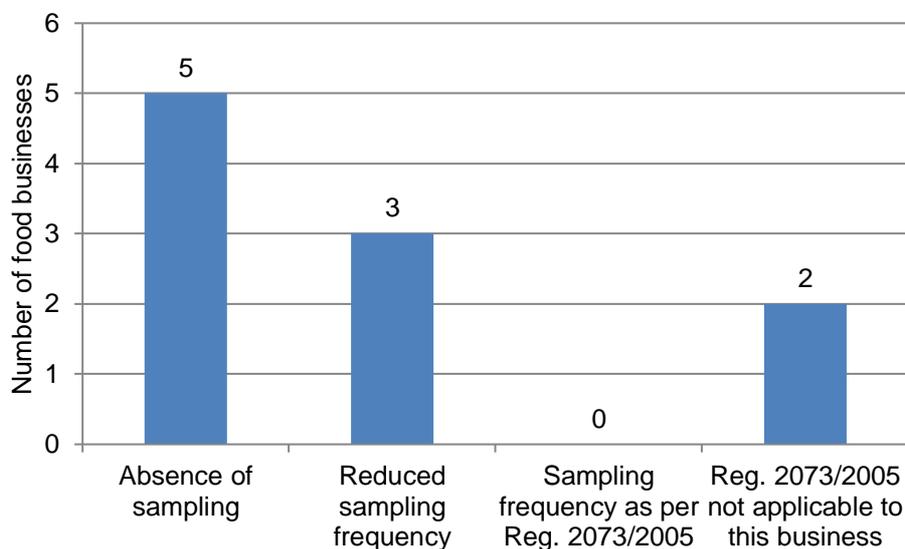
Following assessment of risk and throughput, there are three main categories of sampling frequency which may be applied in low-throughput establishments:

1. An approach involving absence of sampling
2. A reduced sampling frequency
3. 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 Clare, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency.

The County Veterinary Officer had conducted assessments in relation to the 10 approved establishments under the supervision of Clare 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



Two of the 10 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 activities being undertaken or the products being produced did not fall within the remit of the Regulation.

The remaining eight approved establishments within the Clare County Council 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 five food businesses. These food businesses were notified by the County Veterinary Officer that they do not need to conduct sampling. The outcome of the assessment of risk and throughput in the remaining three establishments was that testing was required at a reduced sampling frequency. One of the three businesses was also conducting product testing for *Listeria monocytogenes*. These three businesses were notified regarding 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 had been communicated to the food business operators.

The County Veterinary Officer indicated that the decision regarding the frequency of sampling and any exemptions granted would be kept under review during official controls, and evidence of this was noted in the establishments' files. The County Veterinary Officer re-evaluates the risk analysis on an annual basis, 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 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

Three food businesses were conducting their own testing at a reduced sampling frequency which had been communicated to them by the County Veterinary Officer. A record of the reduced frequency which was applied had been maintained in the establishments' files.

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Food business operators manufacturing ready-to-eat foods which may pose a *Listeria monocytogenes* risk to 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 for *Listeria monocytogenes*; however, it had not conducted environmental monitoring in its high-care area as part of its sampling programme at the time of this audit. The food business operator indicated that environmental monitoring was planned to be carried out in the months following the audit.

One of the food business operations in which on-site verification was carried out was not complying with the designated sampling frequency, as had been determined and communicated by the County Veterinary Officer. In this regard, the County Veterinary Officer had issued a non-compliance and corrective action report to the food business operator in December 2015, requiring that testing recommence at the designated frequency, which did in turn happen. In May 2017, it was noted that the microbiological testing had again deviated from the designated frequency. The County Veterinary Officer wrote to the food business operator reiterating the required sampling frequency and indicated that sanctions would be imposed in case of continued non-compliance. The food business operator recommenced sampling at the designated frequency.

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 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 equipment 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>	<i>Salmonella</i> , aerobic colony count, Enterobacteriaceae	<i>Salmonella</i> Typhimurium, <i>Salmonella</i> Enteritidis
1	Not applicable	Not applicable	Not applicable	Not applicable	5 carcase samples per species every month	Not applicable
2	5 samples (1 sampling event) every 6 months	Not conducted at the time of this audit	Not applicable	Not applicable	Not applicable	Not applicable
3	Not applicable	Not applicable	Not applicable	Not applicable	5 carcase samples per species every month	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 own 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 as regards 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, these results had been notified to the food business operators. 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 operator. Furthermore, 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 slaughter and cutting plant, which also produced minced meat. This food business operator was conducting testing at a reduced sampling frequency. One of the activities being carried out in the second establishment selected was the slicing of cooked meat.

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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 verified 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. The small food business operator that was slicing cooked meat was conducting product testing for *Listeria monocytogenes*; however, they had not yet commenced environmental monitoring for *Listeria monocytogenes*. The food business operator had planned to conduct environmental monitoring in the months after the audit.⁵

Neither food business operator had obtained any unsatisfactory results as part of their testing regimes.

One food business operator was not conducting trend analysis for results of own testing for aerobic colony count and Enterobacteriaceae, although the mean of the log was being calculated for each batch of results received. The County Veterinary Officer conducts trend analysis on food business operator test results as well as on official control results, and these are provided to the food business operator. 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 results related to detection or non-detection.

Both food business operators were observing best practice in relation to using an accredited laboratory; however, neither could confirm that the laboratory was using the testing methods stipulated in Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, or a validated alternative method.⁶

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 slicing cooked meats 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*.

⁵ Clare County Council note that because this aspect of the business did not continue, such sampling became irrelevant.

⁶ Clare County Council point out when the food business operators signed contracts with the laboratories, they ensured that the laboratories were accredited. They assumed that if the laboratory was accredited that the testing methodology stipulated in the Regulation was being followed.

Findings relating to the non-compliance with food law identified during this part of the audit were communicated verbally to the food business operator or their representative 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

Clare County Council supervises 10 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 generally aware of their responsibilities under Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. However, deficiencies were identified during on-site verification which indicated a lack of understanding of certain aspects of the Regulation; for example, one food business had not commenced environmental monitoring for *Listeria monocytogenes*, although it was conducting product testing.⁷ The County Veterinary Officer communicated the results of official control testing to the relevant food business operators, and followed up to ensure that improvements were made in relation to process hygiene in the businesses. Additional guidance is required for these food businesses in order to ensure that they are fully compliant with the requirements of the Regulation.

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 in order 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 Clare 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

⁷ Clare County Council points out that this was a new business slicing very small amounts of cooked ham, sporadically. The taking of environmental swabs would have commenced had the operation stayed in business. The results of environmental swabs taken by the County Veterinary Officer were communicated to the food business operator.



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