

AUDIT REPORT

Audit of official controls carried out by the Local Authority Veterinary Service (Commission Regulation (EC) No 2073/2005) – Roscommon County Council

APRIL 2019

AUDIT REPORT

Audit of official controls carried out by the Local Authority Veterinary Service (Commission Regulation (EC) No 2073/2005) – Roscommon County Council

APRIL 2019

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

APRIL 2019

CONTENTS

1.	GLOSS	ARY			
2.	EXECU	TIVE SUMMARY			
3.	INTRO	UCTION			
	3.1.	Audit objective			
	3.2.	Audit scope6			
	3.3.	Audit criteria and reference documents			
	3.4.	Audit methodology			
4.	AUDIT	FINDINGS			
	4.1.	Official controls performed in respect of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs			
		4.1.1. Official control sampling			
		4.1.2. Results of official control testing			
		 4.1.3. Assessment of food businesses with regard to compliance with Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs10 			
		4.1.4. Review of food business operators' own testing as part of official controls			
		4.1.5. Identification, follow-up and closeout of unsatisfactory test results as part of official controls			
	4.2.	Food business operator findings16			
5.	CONCL	USIONS17			
6.	AUDIT	INDINGS REQUIRING CORRECTIVE ACTION			

APRIL 2019

1. GLOSSARY

FSAI	Food Safety Authority of Ireland
HACCP	hazard analysis and critical control point

APRIL 2019

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. Roscommon 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 Roscommon 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 Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs.

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 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 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.

Roscommon 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. It was not possible to obtain samples from two of the food businesses, as one establishment closed before sampling was due to take place and the other establishment's days and times of operation precluded the samples from reaching the laboratory within the time requirements for testing. *Listeria monocytogenes* was detected in environmental swabs taken from a drain in the high-care area of a cooked meats plant in 2015 and 2016 as part of the official control sampling. The results were communicated to the food business operator and corrective action was taken. There was also an unsatisfactory process hygiene criteria result for Enterobacteriaceae in an official control sample from an ovine carcase swab in 2017. Again, the result was communicated to the food business operator and follow-up actions were taken.

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 Roscommon, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency. The County Veterinary Officer had conducted assessments in relation to the 14 approved establishments under the supervision of Roscommon 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*

APRIL 2019

in low-throughput premises, had been used to guide the assessment of risk and overall throughput, and records of the assessment were maintained on the establishments' files.

Three of the 14 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. One approved establishment had not been operational for one year at the time of this audit. The 10 remaining approved establishments within the Roscommon County Council's functional area were subject to assessment. An approach involving absence of sampling has been applied with regard to seven food businesses. In the remaining three food businesses, the outcome of the assessment was that testing was required at a reduced sampling frequency; the three food businesses were notified regarding the outcome of the assessment and were provided with an outline of the minimum sampling requirements. The outcomes of the assessments regarding minimum sampling frequency were kept under review during official controls, and evidence of this was noted in the establishments' files.

As part of this audit, on-site verification was conducted for two of the food businesses which were conducting testing at a reduced sampling frequency. The two food business operators were complying with the designated sampling frequency which had been determined and communicated 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. Neither food business operator had identified any unsatisfactory results as part of their own testing regimes. One food business operator was not conducting trend analysis of the results of the testing being carried out; the other food business operator had carried out some trend analysis, but in a collective manner, whereby the results of all testing were graphed together. This methodology made it difficult to identify trends towards unsatisfactory results for individual tests. Environmental testing for *Listeria monocytogenes* was being carried out at one of the business operators had conducted shelf life testing on their products and both had labelled raw products for consumers to indicate that they required thorough cooking. 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.

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, neither food business operator could confirm that the laboratory they were using was using the testing methods stipulated in the Regulation. Additional guidance from the County Veterinary Officer is required for these food businesses in order to ensure that they are fully compliant with the requirements of the Regulation and to strengthen the related official controls.

APRIL 2019

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 a guidance document, *Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in lowthroughput premises*, which includes guidance on the reduced sampling frequencies to be applied in lowthroughput 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. 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.

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

APRIL 2019

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. Roscommon 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 Roscommon 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 Roscommon 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 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 Roscommon 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.

APRIL 2019

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
- <u>Guidance Note No. 27, Guidance Note on the Enforcement of Commission Regulation (EC) No</u>
 <u>2073/2005 on Microbiological Criteria for Foodstuffs (including checklist)</u>
- <u>Cross-Agency Hygiene Package Implementation Working Group, Recommendation No. 5 Version 1:</u> Implementation of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs in <u>low-throughput premises</u>
- <u>EU (2008) Guidance Document on official controls, under Regulation (EC) No 882/2004, concerning</u> microbiological sampling and testing of foodstuffs
- <u>Guidelines on sampling the food processing area and equipment for the detection of *Listeria* <u>monocytogenes</u>
 </u>
- The Control and Management of Listeria monocytogenes Contamination of Food (FSAI 2005)
- <u>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</u>
- <u>EU (2014) EURL Lm Technical Guidance Document for conducting shelf-life studies on Listeria</u> <u>monocytogenes in ready-to-eat foods</u>.

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 Roscommon County Council
- <u>Regulation (EC) No 178/2002 laying down the general principles and requirements of food law,</u> establishing the European Food Safety Authority and laying down procedures in matters of food safety, as <u>amended</u>
- 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
- <u>Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on</u> 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 Roscommon 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.

APRIL 2019

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 Roscommon County Council was conducted. Following this review, Roscommon 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 Roscommon County Council. The audit commenced with an opening meeting followed by an audit to assess how Roscommon 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 the 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, the Director of Services 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

Roscommon 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 14 approved establishments under the supervision of Roscommon County Council.

4.1.1. Official control sampling

Section 2.2.3 of the FSAI's Service Contract with Roscommon 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 their 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.

APRIL 2019

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

In general, Roscommon County Council conducted official control sampling in line with the sampling programme. One of the establishments which had been selected for sampling had closed prior to the sampling date. Another premises was included in the sampling plan in 2015 and 2016, but it was not possible to obtain samples from this establishment, as the days and times of operation precluded the samples from reaching the laboratory within the time requirements for testing. This establishment was not included in the sampling plan for 2017.

4.1.2. Results of official control testing

Section 2.2.3 of the FSAI's Service Contract with Roscommon 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 as part of the audit. There were no unsatisfactory results in relation to the food safety criteria for official control tests conducted.

Listeria monocytogenes was detected in an environmental swab taken from a drain in the high-care area of a cooked meats plant in 2015 and 2016, and the results were communicated to the food business operator. On both occasions, 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 cooked product during either sampling event. Following communication of the results, the food business operator sampled the product, and the test results were satisfactory on both occasions.

There was an unsatisfactory process hygiene criteria result for Enterobacteriaceae for an official control sample from an ovine carcase swab in 2017. The County Veterinary Officer communicated the result verbally to the food business operator. The food business operator indicated that he spoke to staff regarding process hygiene and end-of-line checks for clean carcases. It was confirmed that the non-destructive (i.e. sponge) swabbing method was used for the ovine carcase swab and for the sampling of carcases of other animal species both by the County Veterinary Officer and by the food businesses in the county.

APRIL 2019

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 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 had been 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 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 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 Roscommon 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.

APRIL 2019

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

Table 1: Sampling requirements for slaughterhouses based on risk analysis

*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 establishmentsbased on risk analysis

Risk		throughput s per week)		
assessment score	Minced meat plants and minced meat preparation plants*	Meat preparation plants other than minced meat preparation plants	Minimum sampling requirement	
≤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.

APRIL 2019

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
- 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 Roscommon, the County Veterinary Officer conducts the risk analysis to determine the sampling frequency.

The County Veterinary Officer had conducted assessments in relation to the 14 approved establishments under the supervision of Roscommon 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 records of the assessment were maintained on the establishments' files.

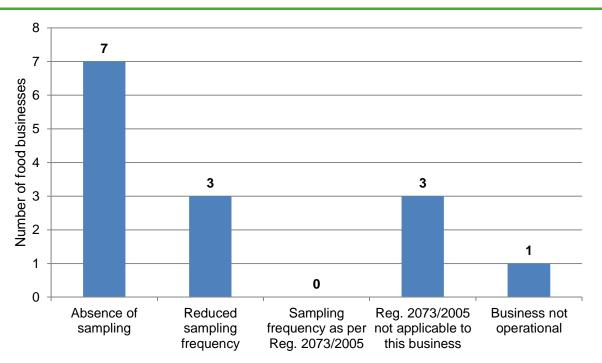


Figure 1: Categories of sampling frequency

APRIL 2019

Three of the 14 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. One approved establishment had not been operational for one year at the time of this audit.

The remaining 10 approved establishments within the Roscommon 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 seven food businesses; however, the seven 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 the three remaining establishments was that testing was required at a reduced sampling frequency. These three food businesses were notified regarding the outcome of the assessment and were provided with an outline of the minimum sampling requirements. 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 compliance with the requirements of Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs under review during official controls, and evidence of this was noted in the establishments' files. There was one food business in which the overall throughput was increasing, and the County Veterinary Officer conducted a reassessment of the risk and overall throughput in July 2016. Although throughput had increased, the food business stayed within the same category with regard to the minimum sampling requirements.

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.

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

Three food businesses were conducting their own testing at the reduced sampling frequency which the County Veterinary Officer had communicated to them, as outlined in Table 3. A record of the reduced frequency which was applied had been noted on the bottom of the risk analysis record in each of the three establishments' files.

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 business operations in which on-site verification was carried out were complying with the designated sampling frequency that had been determined and communicated 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 inspections. Inspection reports included notes to the food business operators to conduct testing, when the 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 equipment had been assessed as part of the inspection and was found to be satisfactory.

Food business operator	Ready-to-eat foods	Environmental monitoring	Minced meat	Meat preparations	Carcase samples
	Listeria monocytogenes	Listeria monocytogenes	<i>Salmonella</i> , aerobic colony count, <i>E. coli</i>	Salmonella, E. coli	<i>Salmonella,</i> aerobic colony count, Enterobacteriaceae
1	5 samples (1 sampling event) every 6 months	Swabbing 3 times per year	Not applicable	5 samples (1 sampling event) every 2 months	Not applicable
2	Not applicable	Not applicable	5 samples (1 sampling event) every 2 months	5 samples (1 sampling event) every 2 months	5 carcase samples from the most frequently slaughtered species every 4 months
3	Not applicable	Not applicable	Not applicable	Not applicable	5 carcase samples from the most frequently slaughtered species every 4 months

Table 3: Sampling frequencies for those food businesses conducting testing

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 unsatisfactory results 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 and actions were taken.

When notified of the detection of *Listeria monocytogenes* in the processing environment (on one food contact surface and on two non-contact surfaces), the food business operator reviewed and subsequently changed the cleaning products in use, instigated enhanced cleaning and disinfection of the high-care area, and conducted daily drain cleaning and disinfection, including on days when the high-care area was not in use. The food business operator also 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 unsatisfactory process hygiene result, the food business operator spoke to staff regarding process hygiene and end-of-line checks for clean carcases.

APRIL 2019

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 audit selected two establishments which were conducting testing at a reduced sampling frequency. One of the food businesses was a small meat manufacturing premises producing meat preparations, raw meat products and cooked meat products. The other food business was a slaughterhouse and cutting plant which also produced minced meat and meat preparations.

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 had identified all relevant criteria as they applied to their businesses. Neither food business operator had identified any unsatisfactory results as part of their own testing regimes.

One food business operator was not conducting trend analysis of the results of the testing being carried out, whereas the other had carried out some trend analysis, but in a collective manner, whereby results of all testing were graphed together. This methodology made it difficult to identify trends towards unsatisfactory results for individual tests.

One of the businesses was carrying out environmental testing for *Listeria monocytogenes*; however, the swabbing was being conducted post cleaning rather than during processing.

Both food business operators had conducted shelf life testing on their products and both had labelled raw products to indicate to consumers that the products required thorough cooking.

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.

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.

APRIL 2019

5. CONCLUSIONS

Roscommon County Council supervises 13 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, neither food business operator could confirm that the laboratory they were using was using the testing methods stipulated in Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs. Additional guidance from the County Veterinary Officer is required for these food businesses in order to ensure that they are fully compliant with the requirements of the Regulation and to strengthen the related official controls.

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 Roscommon 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



www.fsai.ie



Food Safety Authority of Ireland The Exchange, George's Dock, IFSC, Dublin 1, D01 P2V6

T +353 1 817 1300 E info@fsai.ie

in Join us on LinkedIn

Follow us on Twitter @FSAlinfo

f Say hi on Facebook

www.fsai.ie