

AUDIT
REPORT

Audit of official controls
in DAFM supervised
infant formulae and follow-on
formulae establishments

Department of Agriculture,
Food and the Marine – Dairy
Produce Inspectorate

DECEMBER 2016 TO APRIL 2017

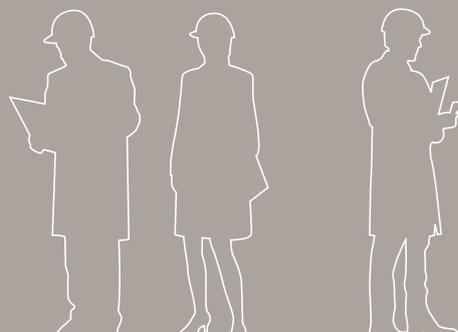


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1. GLOSSARY

AI	Agricultural Inspector
AAI	Assistant Agricultural Inspector
DCCD	Dairy Control and Certification Division
DAFM	Department of Agriculture, Food and the Marine
DAFM MHD	Department of Agriculture, Food and the Marine Milk Hygiene Division
DPI	Dairy Produce Inspectorate
FBOs	food business operator(s)
FSAI	Food Safety Authority of Ireland
HACCP	hazard analysis and critical control point
SOP(s)	standard operating procedure(s)

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) has completed an audit of the official controls performed by the Department of Agriculture, Food and the Marine (DAFM) Dairy Produce Inspectorate (DPI). The audit was undertaken as part of the planned programme of audits carried out by the FSAI to determine the level of compliance with Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and the service contract in place between the DAFM and the FSAI.

The first part of the audit involved an audit of paperwork associated with official controls, including the establishment's files and inspection reports. The second part involved audits of four infant formulae and follow-on formulae establishments and one milk base powder ingredient manufacturer.

Overall, the audit concluded that the official controls carried out by the DPI in infant formulae and follow-on formulae establishments are in compliance with the legislation and there is an organised approach to the identification and follow-up of non-compliances. Detailed food safety management systems had been put in place by the food business operator (FBO) at each of the establishments audited, in order to comply with the food safety requirements.

The establishments audited are large, complex food businesses with elaborate systems of controls in place that require specialist knowledge to interrogate and monitor. As such, the audit identified that further specialist training should be provided to inspectors in order to maintain the adequacy and effectiveness of controls. Considering the nature of the product produced and the vulnerable consumer population, the audit team recommends that the DAFM systems of official controls should be reviewed to request the FBO to inform the DAFM immediately of any issues which may affect the safety of the products manufactured, even where there is no explicit statutory requirement to do so.

In particular, the DAFM should review training and/or documented procedures in the following areas:

- The interrogation of sampling plans/results to determine compliance with Commission Regulation (EC) No 2073/2005
- The preventative maintenance and engineering programmes in place at these types of facilities.

FBOs may use other sampling and testing procedures if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. The audit team noted that industry uses alternative analytical methods for microbiological analysis which are validated against the reference methods given in Annex I of Regulation (EC) No 2073/2005. The competent authorities, including the FSAI and the DAFM, should put a procedure in place to enable competent authorities to assess the equivalence of alternative methods used by the food industry.

On-site verification was carried out at five establishments, including four manufacturers of infant formula (IF) and follow-on formula (FOF), and one milk base powder ingredient plant.

Non-compliances identified during DAFM inspections are recorded on a corrective action report. Such non-compliances are followed up by the Assistant Agricultural Inspector (AAI), and this was well-documented on visit records.

In the establishments audited, the audit team did not identify any significant non-compliances with food law. In one of these establishments, microbiological non-compliances in the product and in the production environment were identified by the FBO, and corrective actions were being implemented. No non-compliant product was placed on the market. Following a comprehensive investigation of the problem and the corrective actions taken by the FBO, in January 2017 a compliance notice was issued by the DAFM. Further corrective actions were requested by the audit team and these have been addressed by the FBO under the supervision of the DAFM.

3. INTRODUCTION

The 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. The DAFM has entered into a service contract with the FSAI and is responsible for the enforcement of food legislation as it applies to infant formulae and follow-on formulae establishments. It is a requirement of the service contract and food legislation that the DAFM ensures official controls are carried out regularly, on a risk basis, and with the 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 system of official controls is working effectively. This audit was carried out for the purpose of assessing the official controls implemented by the DAFM in infant formulae and follow-on formulae establishments. Compliance by the DAFM with relevant food legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant documented procedures, were assessed.

The audit was undertaken as part of the FSAI's audit programme for 2016. This report describes the audit objective, scope, methodology and the findings of the audit.

3.1 Audit objective

The objectives of this audit were to verify the delivery of official controls in infant formulae and follow-on formulae establishments. The audit focused on the organisation, planning, coordination, delivery and review of official controls related to the supervision of infant formulae and follow-on formulae establishments.

3.2 Audit scope

The FSAI audits of official controls involve verifying compliance by the DAFM with regard to relevant legislation, adherence to the FSAI service contract, and the official agencies' documented procedures (see section 3.3 for the full range of audit criteria referred to as part of the audit).

The scope of the audit covered the implementation of official controls in infant formulae and follow-on formulae establishments.

3.3 Audit criteria and reference document

The audit criteria referred to during the audit included the following non-exhaustive list:

Principal audit criteria

- 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
- The FSAI DAFM Service Contract (including the FSAI Act 1998, as amended)
- Regulation No 852/2004 on the hygiene of foodstuffs, as amended
- Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs, as amended
- Commission Directive 2006/141 EC on infant formulae and follow-on formulae.

Secondary criteria

- 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
- The National Control Plan for Ireland 2012–2016
- Service plans and data supplied to the FSAI
- Documented procedures
- Guidance notes/Codes of Practice
- Other relevant legislation detailed in the FSAI Service Contract.

3.4 Audit methodology

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System, namely the FSAI Audit Procedure. These procedures outline the FSAI audit obligations, defined in schedule 5 of the service contract between the FSAI and the DAFM, and in accordance with the requirements of Regulation (EC) No 882/2004 (including Annex Section 6.1 of Commission Decision 2006/677/EC) and also the FSAI Act 1998, as amended.

An evaluation plan describing the audit process and approach (including the scope, objectives, criteria and the audit team) was sent to the DAFM DPI ahead of the on-site activities. The evaluation plan also included a proposed audit itinerary with approximate timeframes for the completion of the audit. Following the issuing of the evaluation plan, the audit team also requested from the official agency the main procedure(s) used for the performance of official control duties at infant formulae and follow-on formulae establishments.

The audit included a review of the performance and delivery of official controls by the official agency at both DAFM central and regional levels. The audit team (AT) reviewed information and activities relevant to the supervision and performance of official controls at the establishment level; they also reviewed regional results of official control audits and inspections carried out, sampling activities and analyses, as well as enforcement action(s) conducted.

The audit team evaluated whether the official controls were being carried out in accordance with the DAFM's own documented procedures which are used to implement the requirements of the service contract in place between the DAFM and the FSAI.

As part of the audit of FBOs, the audit team assessed the performance of the controls put in place at establishments in relation to the adequacy, effectiveness and implementation of the FBO's food safety management system and sampling programmes, and whether these were in compliance with food law.

On completion of the visits to the establishments, the audit findings relevant to the FBO were presented by the FSAI audit team. The FBO was informed that follow-up in relation to these findings would be carried out by the DAFM and that the FSAI would communicate the audit findings to the DAFM following completion of the audit. Following completion of all site audits, a final closing meeting was also held with DAFM staff at central level; at this meeting, findings were discussed, in order to allow follow-up in relation to any issues identified. In addition, preliminary findings were issued separately for each establishment.

4. AUDIT FINDINGS

4.1 Official controls performed in accordance with Regulation (EC) No 882/2004

4.1.1 Organisation and structure of official controls

Article 4 of Regulation (EC) No 882/2004 requires Member States to designate the competent authorities responsible for the purposes of the official controls set out in the Regulation. It also lays down operational criteria for the competent authorities.

Findings

The DPI is part of the DAFM Agricultural Inspectorate and is responsible for carrying out official controls in milk processing establishments, including infant formulae and follow-on formulae establishments. The DPI operates on a regional structure, with each region reporting to a Senior Inspector. In each region, an Agricultural Inspector (AI) manages the activities of Assistant Agricultural Inspectors (AAIs) who are responsible for the day-to-day implementation of official controls in dairy establishments. Other staff, Technical Agricultural Officers (TAOs), Senior Dairy Produce Officers (SDPOs) and Dairy Produce Officers (DPOs) carry out ancillary functions such as sampling, market support scheme controls, etc. In addition to the planned official control activities, the Inspectorate also carries out reactive/unplanned controls. Authorisations to carry out official control activities under food legislation are in place for all Dairy Control and Certification Division (DCCD) staff.

4.1.2 Coordination and planning of official controls¹

Article 4(3) of Regulation (EC) No 882/2004 provides for efficient and effective coordination and cooperation between competent authorities. Article 4(5) of the Regulation requires that, when within a competent authority more than one unit is competent to carry out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

In terms of planning and coordination of official controls, the audit team confirmed that there is a structured and well-organised approach for the prioritisation, planning, coordination and delivery of official controls between DAFM central and regional levels. Each year, the Senior Inspector in consultation with the regions produces a business plan, which reflects the requirements of the Inspectorate's documented procedures for official control activities. Regional official control activities are planned and scheduled in accordance with the requirements of SOP 24, where an annual risk assessment is carried out in order to determine the frequency of visits to each establishment. In addition to agreeing targets and planning, official controls sampling plans are drawn up locally in conjunction with the regional AI, as per SOP 1. The audit team noted that AIs in all regions are monitoring how official activities are carried out via SOP 16.

Communication between national management and the regions in relation to the development and roll-out of SOPs and updates on official control activities is provided. There is regular communication between the AI and the AAI, and this was demonstrated during discussion by the AIs' familiarity with non-compliances and FBO files.

¹**Recital 15** The competent authorities should ensure that, where different control units are involved in carrying out official controls, appropriate coordination procedures are in place and are effectively implemented.

Recital 16 The competent authorities should also ensure that, where the competence to carry out official controls has been delegated from the central level to a regional or local level, there is effective and efficient coordination between the central level and that regional or local level.

4.1.3 Registration of establishments

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration of food and feed business establishments. Article 6 (2) of Regulation (EC) No 852/2004 requires every food business operator to notify the appropriate competent authority with a view to the registration of each establishment.

Findings

All premises audited were registered as required by Regulation 852/2004.

4.1.4 Prioritisation of official controls and risk categorisation

Article 3 of Regulation (EC) No 882/2004 requires that official controls are carried out regularly, on a risk basis and with appropriate frequency. In doing so, account must be taken of identified risks that may influence food safety, past records of FBOs, the reliability of own checks and any additional information on non-compliance.

Findings

Risk-based priorities for official controls are planned/scheduled in order to meet the requirements of SOP 24 in the case of inspections where an annual risk assessment is carried out to determine the frequency of visits to each establishment. In addition, planned sampling official controls are drawn up locally by the AAI in conjunction with the regional AI, as per SOP 1, and with the official microbiological and chemical analysis laboratories. In addition, SOP 27 details how official controls are organised in relation to the composition and labelling of infant formula (IF) and follow-on formula (FOF).

A risk assessment² had been carried out in all infant formulae and follow-on formulae establishments to determine the nature and frequency of official controls to be performed. Records of the risk assessments carried out were available on the establishment files maintained by the AI or AAI.

Depending on the process and structures of the establishment, the number of risk assessments per site varied across regions. Table 1 shows the maximum risk score per site, which determines the inspection frequency. Mainly due to the nature of the products produced and the size of the establishments, all sites received the maximum risk rating. The number of planned official controls (inspections and audits) carried out was well in excess of the frequency laid down in the risk assessment in all establishments. In addition, the Inspectorate carried out extensive on-site inspections for other official reasons and for follow-up inspections. In general, all of the inspections were recorded on AFIT (the DAFM database), as required. Checklists A, B and D were completed during 2015 and 2016.

² Risk scoring SOP 24 (**Low risk assigned**: Where the overall risk weighting is less than 50, at least one planned control per two calendar years. **Medium risk assigned**: Where the overall risk weighting is greater than or equal to 50 and less than or equal to 70, at least one planned control per calendar year. **High risk assigned**: Where the overall risk weighting is greater than 70, at least two planned controls per calendar year.

Table 1: Risk rating of infant formulae establishments

	Risk rating
Establishment 1 2015	105
Establishment 1 2016	90
Establishment 2 2015	85
Establishment 2 2016	85
Establishment 3 2015	85
Establishment 3 2016	90
Establishment 4 2015	80
Establishment 4 2016	80
Establishment 5 2015	95
Establishment 5 2016	95

***Source:** CR4s (Compliance Report 4) for all regions, 2015 and 2016

4.1.5 Documented procedures

Article 8 of Regulation (EC) No 882/2004 requires that competent authorities carry out their official controls in accordance with documented procedures containing information and instructions for staff; in addition, competent authorities must keep these procedures up to date.

Findings

The DPI has developed a comprehensive series of SOPs which describe how official controls are carried out. SOPs are developed by the AI with responsibility for internal controls in conjunction with regional AIs and other staff. Special memoranda are also issued to staff in the event of issues arising following meetings, etc.

The main official control tasks performed by AAIs at IF and FOF establishments include inspections under SOP 24 and sampling under SOP 1. SOP 16 has been established to provide a supervisory system for the AI and the AAI in the region to assess the effectiveness of official controls and to enhance the system of oversight and supervision at regional and national level. SOP 27 stipulates instructions for the Inspectorate relating to the composition and labelling of IF and FOF. Types of official controls covered by the SOP include: inspection of label; audit of the FBO's own controls; sampling for compositional analysis; sampling for contaminants and reactive controls. A number of observations were made by the audit team in relation to the SOPs.

There are no detailed instructions included in the SOPs for the Inspectorate on the interrogation or review of the following:

- Sampling plans/results to determine compliance with Commission Regulation (EC) No 2073/2005
- Maintenance and engineering process which are critical to product safety, e.g. reviewing crack tests in driers

FBOs may use other sampling and testing procedures if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. The audit team noted that industry uses alternative analytical methods for microbiological analysis which are validated against the reference methods given in Annex I of Regulation (EC) No 2073/2005. The competent authorities, including the FSAI and the DAFM, should put a procedure in place to enable competent authorities to assess the equivalence of alternative methods used by the food industry.

FBOs are audited for hygiene and hazard analysis and critical control point (HACCP) requirements under Commission Regulation (EC) No 852/2004 and microbiological criteria Commission Regulation (EC) No 2073/2005. In terms of compositional criteria, Article 12 of Regulation (EC) No 178/2002 allows for third countries to establish their own criteria, and where no national standards are established, the Codex standard applies. The DAFM controls on composition criteria are based on these principles. National standards apply to some countries (USA/Canada/China/Australia), whereas other countries apply the Codex standard. Although the inspectors review the relevant standards and rules that apply to each business as part of the annual risk assessment, the documented procedures do not require the inspector to document the rules that are relevant to each establishment at the time of the risk assessment and/or the inspection.

SOP 24: Implementation of official control procedures relating to Food Hygiene Regulations

The audit team verified that inspections are planned and are generally performed in accordance with SOP 24, as required. The audit team noted that, in general, verification of the FBO's own checks, and monitoring of critical control points (CCPs) was being carried out above the required frequency by the DPI.

SOP 1: Official control sampling and reporting procedures

Planned sampling controls for each establishment are drawn up by the local AAI in conjunction with the Regional AI. Three testing laboratories are used by the Inspectorate depending on which region the FBO is located in.

SOP 27: Official control procedures relating to the composition and labelling of IF and FOF

SOP 27 details instructions for the Inspectorate relating to the composition and labelling of IF and FOF. The SOP details that the control plan will be agreed nationally at a meeting with the Senior Inspector. Types of official controls covered by the SOP include: inspection of label; audit of the FBO's own controls; sampling for compositional analysis; sampling for contaminants and reactive controls

Audits of labels were carried out, and samples for compositional and contaminants analysis were taken. At the time of the audit the reporting of audits and inspections was inconsistent across the regions (see Table 2). This has been reviewed by the DAFM centrally, and new instructions have been issued to clarify definitions.

Table 2: SOP 27 Official controls, 2015 and 2016

Establishment 1	Establishment 2	Establishment 3 (base powder establishment – not all the controls relevant)	Establishment 4	Establishment 5
0 Inspections were recorded under this SOP	30 Inspections (including 30 label checks)		26 Inspections (label checks)	0 Inspections were recorded under this SOP
6 audits (5 label checks and 1 FBO own control audit) were completed.	2 audits of FBO's own controls		2 audits (FBO's own control audit)	6 audits (4 label checks and 2 FBO's own controls)
26 samples (including 12 labels and 14 compositional) were completed.	47 samples (including 14 contaminants, 30 compositional analysis, 3 follow-up) were completed	8 samples (including 7 contaminants, 1 prohibited substance)	67 samples (including 15 contaminants, 16 labels and 26 compositional)	61 samples (including 24 contaminants, 20 labels and 35 compositional) were completed

Source: Quarterly Summary of Official Controls 2015 and 2016, SOP 27

SOP 16: National supervisory system for staff performing official controls

This SOP has been established to provide a supervisory system for the AI and the AAI in the region to enhance the system of oversight and supervision at regional and national level. The SOP provides for:

- A desktop review of official controls, i.e. file review by the AI
- Accompanied on-the-spot supervisory checks by the AI
- Reporting arrangements regarding supervision at central level. Each year the regional AI must complete a plan which details the expected controls that will be carried out under this SOP. The form titled Planned Supervisory Controls (PSC) should be used for this purpose. The form titled Reporting Supervisory Controls (RSCs) must be completed on a quarterly basis; this outlines the actual controls carried out under this SOP. Targets are monitored nationally.
- Joint AAI controls.

Evidence that reviews, joint inspections and audits were carried out by the DAFM at all establishments audited and reporting to central level was in compliance with the SOP.

4.1.6 Identification, follow-up and closeout of non-compliances

Article 54 of Regulation (EC) No 882/2004 requires that when the competent authority identifies non-compliance, it shall ensure that the operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the operator's past record with regard to non-compliance.

Article 8.3 (b) of Regulation (EC) No 882/2004 requires that competent authorities shall have procedures in place to ensure that corrective action is taken when needed and that the documentation referred to in paragraph 1 is updated as appropriate.

Findings

Non-compliances identified during manufacturer's inspections are recorded on a corrective action report and are followed up by the AAI; this was well-documented in the records examined. On-site verification was carried out at five establishments. In the establishments audited, the audit team did not identify any significant non-compliances with food law. In one establishment, in June 2016, microbiological non-compliances in the product and production environment were identified by the FBO and corrective actions were being implemented. No non-compliant product was placed on the market. An official control audit prior to the FSAI audit reviewed the micro controls and the food safety management system implemented by the FBO, and microbiological non-compliances were not documented in the inspection report although the DAFM was following up the inspection with a targeted review of elements of the food safety management system. Further information was requested by the DAFM Inspectorate in January 2017 on the microbiological issues in the plant. Following a comprehensive investigation in January 2017, a compliance notice was issued by the DAFM; further corrective actions were requested by the audit team and these have been addressed by the FBO under the supervision of the DAFM.

4.1.7 Reports to food business operators and announcing inspections

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities to draw up reports on the official controls carried out, including a description of the purpose of official controls, the methods applied, the results obtained and any action to be taken by the business operator concerned. The competent authority shall provide the FBO with a copy of the report on official controls carried out, at least in case of non-compliance.

Article 3 (2) of Regulation (EC) No 882/2004 requires official controls to be carried out without prior warning, except in cases such as audits where prior notification of the feed or food business operator is necessary. Official controls may also be carried out on an ad hoc basis.

DPI SOP 24 Section 3 details that inspections shall be unannounced, whereas audits should be prearranged with the FBO.

Findings

Copies of inspection reports were available for all establishments audited. In the files audited, the FBOs received a report after all inspections, both announced and unannounced.

4.1.8 Verification and review of official controls and procedures

Article 4(4) of Regulation (EC) No 882/2004 requires the competent authorities to ensure the impartiality, consistency and quality of official controls at all levels and to guarantee the effectiveness and appropriateness of official controls.

Article 4(6) of the Regulation requires the competent authorities to carry out internal audits or to have external audits carried out. These must be subject to independent scrutiny and carried out in a transparent manner.

Article 8(3) states that the competent authorities must have procedures in place to verify the effectiveness of official controls and to ensure that corrective action is taken when needed and that documentation is updated as appropriate.

Findings

At regional and national Inspectorate meetings official controls are discussed and reviewed by the Senior Inspector, AIs and AAls. Compliance with SOPs, and in particular with SOP 16, facilitates review of the effectiveness of official controls at local level and national level. The controls stipulated were conducted in the five establishments.

Considering the nature of the product produced and the vulnerable consumer population, the audit team recommends that the DAFM systems of official controls should be reviewed to request the FBO to inform the DAFM immediately of any issues which may affect the safety of the products manufactured, even where there is no explicit statutory requirement to do so.

Extensive official controls are carried out under SOP 27 in terms of audit, inspections of labels, sampling and analysis. In addition, labeling inspections are carried out centrally by the FSAI. With the exception of a small number of sample non-compliances, no non-compliances have been identified by the DAFM as a result of all of these official controls in 2015 and 2016.

4.1.9 Staff performing official controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure that staff performing official controls are suitably qualified and experienced staff, that appropriate and properly maintained facilities and equipment are available, and that staff performing controls are free of any conflict of interest.

Article 6 of Regulation (EC) No 882/2004 requires the competent authorities to ensure that staff receive appropriate training and are kept up to date in their competencies.

Findings

The audit team noted that the Senior Inspector forwards an annual training needs request to each of the regions, and responses are then collated and forwarded to the DAFM training unit for the development of an annual training plan. Training is organised nationally and rolled out to the regions. Training records are maintained for each member of staff centrally. The AI has a coordinating role in relation to oversight of AAI and technical staff work, which is generally organised at central level. The audit team noted that DPI staff interviewed during the audit were knowledgeable about national and EU legislation requirements and also about DPI SOPs.

The audit team noted that thermal processing training was organised for the Inspectorate in 2016 and staff attended numerous dairy industry conferences/seminars in 2015 and 2016. Specific training is required in relation to the interrogation of sampling plans/results and the interpretation of equivalent testing methods used by industry to determine compliance with Commission Regulation (EC) No 2073/2005 and the preventative maintenance and engineering programmes in place at these types of facilities.

4.2 Official controls performed in food establishments

As part of the audit of food business operations the audit team assessed the performance of the controls put in place at the establishments audited in relation to the implementation of good hygiene practices and HACCP principles as part of the FBO's food safety management system and whether these were being adequately maintained and were effective.

The audit team confirmed that in general the appropriate checks on structure, HACCP, sampling programmes, etc. were being carried out by the AAls in accordance with the requirements of Regulations and the SOPs.

An assessment was made under (a) Structure, maintenance and operational hygiene; (b) Food safety management system; and (c) Sampling and testing.

Findings

Structure, maintenance and operational hygiene

Article 4(2) of Regulation (EC) No 852/2004 requires FBOs to comply with general hygiene requirements as set out in Annex II of the Regulation. These provisions relate to cleaning and maintenance, layout, design, construction and size of food premises.

The general hygiene requirements relating to the design/layout, structure, equipment/maintenance and facilities were generally met. In one establishment, some issues pertaining to cleaning and maintenance of equipment had been identified by the FBO prior to the audit and are being addressed under the supervision of the DAFM.

Food safety management system

Article 5 of Regulation (EC) No 852/2004 requires FBOs to put in place, implement and maintain a permanent procedure or procedures based on HACCP principles. Regulation (EC) No 852/2004 allows the HACCP-based procedures to be implemented with flexibility, so as to ensure that they can be applied in all situations.

A documented food safety management system based on HACCP principles (including procedures and records) was in place in all of the establishments audited. Regular official control inspections were taking place in all establishments.

Sampling and testing: Commission Regulation (EC) No 2073/2005

Sampling programmes were in place in all of the establishments audited and there was a high level of compliance with the Regulation. FBOs may use other sampling and testing procedures if they can demonstrate to the satisfaction of the competent authority that these procedures provide at least equivalent guarantees. The audit team noted that industry uses alternative analytical methods for microbiological analysis which are validated against the reference methods given in Annex I of Commission Regulation (EC) No 2073/2005. The competent authorities, including the FSAI and the DAFM, should put a procedure in place to enable competent authorities to assess the equivalence of alternative methods used by the food industry.

Sampling and testing: Commission Directive 2006/141

Extensive chemical and compositional sampling is carried out to verify compliance with Commission Directive 2006/141. When product is exported to third markets, compositional criteria for that market are applied.

5. CONCLUSIONS

The audit team confirmed that there was a well-organised and structured approach for the prioritisation, planning, coordination and delivery of official controls between DAFM central and regional levels within the DPI.

Due to the scale of these establishments, it was not possible for the audit team to review all activities on a single day. The audit team noted that detailed food safety management systems had been put in place at each of the establishments audited in order to comply with all of the food safety regulatory requirements. The establishments audited are large, complex food businesses with elaborate systems of controls in place that require specialist knowledge to interrogate and monitor. Therefore, further specialist training should be provided to inspectors, and a review of documented procedures to address the findings of this audit is recommended in order to maintain the adequacy and effectiveness of controls.

6. AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

The findings identified during this audit should be disseminated nationally in order to ensure that the corrective actions and opportunities for improvement identified are implemented across all regions.

Audit findings requiring corrective action are listed in the corrective action plan.



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