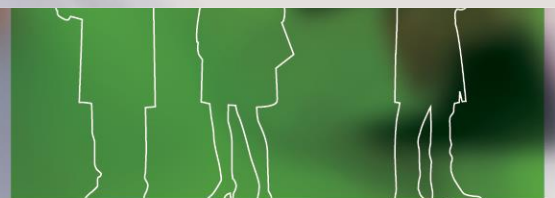


AUDIT REPORT

Audit of Official
Controls in the Dairy
Production Chain

Dairy Controls &
Certification Division
of the Department of
Agriculture, Food and
the Marine

December 2023



Contents

1.	GLOSSARY	3
2.	EXECUTIVE SUMMARY	5
3.	INTRODUCTION	7
3.1	Audit objective	7
3.2	Audit scope	7
3.3.	Audit criteria and reference documents	8
3.4.	Audit methodology	9
4.	AUDIT FINDINGS	9
4.1	SERVICE CONTRACT	9
4.2	GENERAL OBLIGATIONS CONCERNING THE COMPETENT AUTHORITIES AND THE ORGANIC CONTROL AUTHORITIES	10
4.3	INTERNAL AUDIT	15
4.4	GENERAL RULES OF OFFICIAL CONTROLS	16
4.5	OPERATORS, PROCESSES, AND ACTIVITIES SUBJECT TO OFFICIAL CONTROLS	22
4.6	DOCUMENTED CONTROL PROCEDURES	25
4.7	WRITTEN RECORDS OF OFFICIAL CONTROLS	28
4.8	METHODS AND TECHNIQUES FOR OFFICIAL CONTROLS	29
4.9	OBLIGATIONS OF OPERATORS	29
4.10	RELATION WITH REGULATION (EC) NO 852/2004 AND (EC) NO 853/2004 REGARDING APPROVAL OF FOOD BUSINESS ESTABLISHMENTS	30
5.	FOOD BUSINESS OPERATOR FINDINGS	31
6.	CONCLUSIONS	34
7.	FINDINGS REQUIRING CORRECTIVE ACTION	36

1. Glossary

ABP	Animal By-Product
AFIT	Agriculture Field Inspection Testing
APPR	Approval / Registration Form
BTSF	Better Training for Safer Food
CN	Compliance Notice Form
CR1	Compliance Report Form
CR4	Risk Rating Form
DCCD	Dairy Controls and Certification Division
DAFM	Department of Agriculture Food and the Marine
EU	European Union
FBO	Food Business Operator
FSAI	Food Safety Authority of Ireland
FSMS	Food Safety Management System
HACCP	Hazard Analysis Critical Control Point

Audit of Official Controls in the Dairy Production Chain

DECEMBER 2023

HQDPI	Headquarters Dairy Produce Inspector
IAU	Internal Audit Unit
LDPI	Local Dairy Produce Inspector
LNA	Learning Needs Analysis
MHD	Milk Hygiene Division
OCR	Official Control Regulation 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended.
PMDS	Performance Management & Development System
RDPI	Regional Dairy Produce Inspector
SOP	Standard Operating Procedure
SP1	Annual Sampling Plan Form

2. Executive summary

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland. This is carried out through service contracts with official agencies. As part of its legal mandate, the FSAI is required to verify that the system of official controls is working effectively. For the purposes of assessing the delivery of official controls in the official agencies, the FSAI conducts an annual programme of audits.

The FSAI completed an audit of official controls performed by the Dairy Controls and Certification Division (DCCD) of the Department of Agriculture Food and the Marine (DAFM) in the dairy production chain across five out of the six regions of the DCCD. The audit covered the organisation, planning, implementation, and review of official controls within the DCCD at national and regional levels to confirm compliance with official control regulations, food law, service contract requirements and with procedures documented by the DCCD.

The scope of the audit included the structure and organisation of official controls carried out by the DCCD relating to establishments within the dairy production chain during 2021 and the relevant period of 2022. It also assessed whether the DCCD were complying with the criteria against which the audit was carried out. The scope also included an assessment of compliance with relevant food law in selected food business operators within the dairy production chain.

There is a structured and organised system of official controls in place for the supervision of food businesses within the dairy production chain. Those involved in official controls are suitably qualified and trained to perform this work. Regional Dairy Produce Inspectors (RDPIs) and Local Dairy Produce Inspectors (LDPIs) are duly authorised to perform official controls and the necessary legislation to enforce same is in place.

Records of official controls are maintained and a copy of same is issued to food business operators. Documented procedures for carrying out official controls have been established in a series of documented standard operation procedures (SOP's) and checklists, all of which are made available to staff through the DCCDs E-Doc systems. Procedures are in place for those who wish to apply to the competent authority, DAFM Milk Hygiene Division for approval / registration. All establishments once approved / registered are issued with a unique approval / registration number which is then managed and maintained by the Milk Hygiene Division.

Findings relating to the performance, suitability and effectiveness of official controls as required by the OCR were identified during the component of the audit conducted in regional areas. These audit findings have identified opportunities to further strengthen elements of the DCCDs official controls systems and processes. The audit team assessed compliance with relevant food law in 11 food business operations within the dairy production chain.

During the audit of food business operators, non-compliances with food law were identified which resulted in the issuing of compliance notices by the DCCD. In addition, product deemed to be unfit for human consumption by the DCCD was disposed of, as category 2 Animal By-Product (ABP) by the relevant food business. Where non-compliances with food law were established during on-site FBO audits, they were verbally notified to the food business operator at a closing meeting in agreement with the DCCD. All non-compliances have been followed up during subsequent official controls by the DCCD.

It is important to note, that during 2021 Ireland was still in the middle of a global pandemic. The audit team acknowledge the level of official controls completed, despite the challenges faced by the DCCD while working through a global pandemic and the impact that COVID-19 has had on the delivery of planned official controls.

3. Introduction

This audit was part of the planned programme of audits of official controls, undertaken by the FSAI in 2022. The opening meeting and initial audit of DCCD's structures and processes took place at a national level, while the proceeding audits consisted of a more in-depth review of structures and processes at a regional level. All audits were conducted face-to-face and on-site. The DCCD is divided into 6 regional areas, the North region, South-East region, South region, Mid-West region, South-West region and the Dublin region. In each region, a Regional Dairy Produce Inspector (RDPI) manages the activities of the Local Dairy Produce Inspectors (LDPI) who are responsible for the day-to-day implementation of official controls in dairy establishments. All six RDPIs report into the Senior Inspector. Five regional areas and a total of 11 food business operators were audited as part of this audit program. A closing meeting was held virtually between the FSAI and the DCCD.

The audit was carried out using documentation contained in the FSAI business management system i.e., the Audit Charter and FSAI Audit procedure. The FSAI team were at all times accompanied throughout the audit by representatives from the DCCD.

3.1 Audit objective

The overall objective of the audit was to evaluate official controls carried out by the DCCD of the Department of Agriculture Food and the Marine (DAFM) in the dairy production chain. The primary objective was to assess the suitability and effectiveness of official controls carried out by the DCCD in food business operations that come under their supervision. The secondary objective was to assess the compliance of selected establishments with food law which related to their food business operation.

3.2 Audit scope

The scope of the audit included the structure and organisation of official controls carried out by the DCCD relating to establishments within the dairy production chain during 2021 and the relevant period of 2022. The scope of the audit was focused on food products and food business establishments under the remit and supervision of the DCCD with a particular emphasis on (but not limited to) cheese products.

The scope also included an assessment of a selected number of food business operators' compliance with food law with a particular emphasis on traceability and on the provision of food information. It also assessed

whether authorised officers from the DCCD were complying with the audit criteria against which the audit was carried out.

The scope included:

- Legislation applicable to official controls.
- Procedures documented to ensure that these controls are carried out uniformly and to a consistently high standard.
- Inspections, sampling plans and reports of same.
- Relevant Guidance Notes.
- Food business operators' food safety management systems and related records.

3.3. Audit criteria and reference documents

[Food Safety Authority of Ireland Act 1998](#) (S.I. No 29 of 1998), as amended.

[Regulation 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority, as amended.

[Regulation 2017/625](#) on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended.

[Regulation 852/2004](#) on the hygiene of foodstuffs, as amended.

[Regulation 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended.

[S.I. No. 747 of 2007](#) European Communities (General Food Law) Regulations 2007

[S.I. No. 369 of 2006](#) European Communities (Hygiene of Foodstuffs) Regulation 2006

[S.I. No. 22 of 2020](#) European Union (Food and Feed Hygiene) Regulations 2020

[Regulation \(EU\) No. 1169/2011](#) on the provision of food information to consumers, as amended.

[S.I. No. 556/2014](#) European Union (Provision of food information to consumers).

[Regulation \(EC\) 2073/2005](#) on microbiological criteria for foodstuffs

[S.I. No. 474 of 2012](#) European Union (Microbiological Criteria for Foodstuffs) regulations 2012

Operational Plans & data supplied to FSAI.

Documented Procedures and protocols

Guidance Notes / Codes of Practice.

Other relevant legislation listed in Schedule 1 of DAFM Service Contract

3.4. Audit methodology

This audit was undertaken using documented procedures which are included in the FSAI Business Management System, namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI's audit obligations as set out in Section 48 (9) of the Food Safety Authority of Ireland Act 1998, as amended. They are also in accordance with the requirements of the EU Commission guidance document on the implementation of the provisions for the conduct of audits under Article 6 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

To prepare, the audit team used information maintained in FSAI which was supplemented by that contained in the pre-audit questionnaire completed by the DCCD. The audit commenced with a face-to-face opening meeting and included a high-level overview and assessment of the DCCD structures and processes. This was followed by visits to five regional offices during which the audit team assessed compliance with the requirements of Regulation (EU) 2017/625 and other relevant legislation. This aspect of the audit consisted of two components. The first involved an assessment of official controls performed by inspectors within the regional areas and the outcomes associated with same. The second component consisted of an audit of selected establishments to verify the performance of official controls and to assess compliance with food law.

4. Audit findings

4.1 Service contract

Section 48 of the FSAI Act 1998 makes provision to allow the Authority for the purposes of carrying out its functions enter a service contract with official agencies. For this audit the service contract is between the Authority and the Department of Agriculture, Food and the Marine

Schedule 2, section 5.1 of the contract details how conformance with its requirements is monitored through liaison and review meetings. Such meetings shall be held according with an annual schedule developed by the Authority, in consultation with DAFM.

Preamble 5a of the service contract sets out the requirement for DAFM to ensure compliance with food legislation. The service contract states that such compliance with food legislation is completed by means of inspection, approval, licensing and/or registration of premises and equipment, including premises or equipment used in connection with the manufacture, processing, disposal, transport, and storage of food.

Schedule 4, section 1.1 of the contract provides the general requirements for data collection and reporting to the FSAI. It states that the Official Agency will collect, and store information generated from food control activities specified in schedule 2 and electronically transmit such information to the FSAI.

Findings

To verify that the DCCD was adhering to the terms set out in preamble 5a and schedule 4, section 1.1, the audit team reviewed information and records submitted by the DCCD for 2021 and the relevant period of 2022. The minutes of the liaison meetings for this period were also reviewed. The audit team confirmed that the liaison meetings were taking place as per the schedule within the service contract and found that the minutes were detailed and contained information on the performance of all aspects of official controls on establishments within the dairy production chain.

The audit team verified that for the purposes of ensuring compliance with food legislation, the DCCD carry out official controls on a risk basis in accordance with official control regulations and the service contract. The DCCD have implemented a suite of documented standard operating procedures and checklists to support the completion of official controls including sampling and inspection.

The DCCD submit an annual report as required by section 48(8) of the FSAI Act and in addition to this, a quarterly report is also submitted to the FSAI. The audit team verified that the annual and quarterly reports for 2021 were submitted to the FSAI as part of the service contract requirements.

4.2 General obligations concerning the competent authorities and the organic control authorities

Article 5 of Regulation 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, as amended, requires competent authorities to have procedures and/or arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities. Competent authorities shall also have the legal powers to perform official controls and other official activities and to take the action provided for within the Regulation. It is also a requirement that staff receive appropriate training for their area of competence.

Findings

The audit team confirmed that the DCCD has procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities in accordance with Article 5 of the OCR. The audit team verified that there is a suite of standard operating procedures (SOPs), aide-memoires and checklists in place which are utilised to ensure the effectiveness and appropriateness of official controls applied, for example: SOP 24 "Official Control Procedure", SOP 1 "Food Safety Sampling", SOP 29 "FIC" (Food Information to Consumers) and SOP 26 "Water Sampling". The audit team were made

aware that several of these SOPs were in the process of being reviewed and updated at the time of the audit.

The audit team verified that there are arrangements in place to ensure that all DCCD staff performing official control activities are impartial and free from any conflict of interest. On an annual basis, each member of staff must make a conflict-of-interest return. A conflict-of-interest declaration form is completed by all staff and submitted to the heads of division for sign off before being submitted to the Human Resources People Support and Development (HRPS&D) division. Office Notice 2/2021 provides details to all staff regarding the completion of conflict-of-interest returns. A sample of conflict-of-interest declaration forms were reviewed by the audit team during the course of the audit which demonstrated compliance with this requirement.

During the on-site component of the audit, the FSAI team verified that authorised officers performing official controls have been issued with warrants or other documents to enforce legal powers. These are contained in Statutory Instruments which allow them to perform official controls and other official activities as set out in the OCR. S.I. No. 22 of 2020 European Union (Food and Feed Hygiene) Regulations 2020 was confirmed as the principal legislation in place providing legal powers to perform official controls and other official activities. The Milk Hygiene Division (MHD) Standard Operating Procedure (SOP) 9 “Authorisation Cards” Rev 11.7.19 details the process regarding the appointment of authorised officers and the issuing of authorisation cards. The MHD is responsible for submitting letters to the Minister for Agriculture seeking authorisation for relevant persons and for the issuing of authorisation cards. The audit team reviewed the signed and sealed letter by the Minister for Agriculture which demonstrated the authorisation of all relevant RDPIs and LDPIs within each region audited. An authorisation card as stated in the MHD SOP 9 “is required by the officer for carrying out functions if he/she has cause to suspect that for example: food is present on the premises, food has been processed, stored, or otherwise dealt with on a premises or where a premises is subject to approval and/or registration”.

The number of suitably trained staff required to perform official controls is dependent on the size of each DCCD region and the number of FBOs under the remit of the DCCD within that region. When a resource is required, a business case is made to DAFM to request additional staff. The DCCD have established a dedicated training officer for the implementation of the divisions’ training needs and to ensure that authorised officers performing official controls receive appropriate training and keep up-to-date in their area of competence. On-the-job training is provided to all staff. In addition to this, a Learning Needs Analysis (LNA) is conducted at the start of the year in each region to identify specific training needs for the division. Identified training needs are coordinated by the training officer who collates the information and submits it to the senior inspector for consideration. The LNA is submitted to DAFM’s training unit for final appraisal. Training requests can also be submitted directly to the training officer and/or training needs can be identified through the individuals’ PMDS reviews (Performance Management & Development System). Formal training

courses are also available to all staff through DAFM's shared "one learning" system. Divisional training needs are discussed at regular management meetings, staff meetings and annual business plan meetings. The training officer notifies staff of any relevant courses organised by organisations such as the FSAI, Teagasc and University College Cork. Staff are also encouraged to attend the Better Training for Safer Food (BTSF) courses as appropriate.

A sample of training logs maintained by the LDPIs, and training records were reviewed by the audit team within several of the regions audited. For the most part, the audit team confirmed through the training records evaluated that staff carrying out official controls have received training on documented procedures for the performance of official controls, however, in some cases, documented evidence of training completed against certain SOPs could not be demonstrated. It was explained by the DCCD that while there was no formal documented evidence of SOP training for certain inspectors, training on new and revised SOPs was provided to all staff including newly employed staff.

The Learning Needs Analysis (LNA) and PMDS were presented to the audit team as a representation of the DCCD's training program. It was established by the audit team that while the LNA and PMDS identifies specific training and/or additional training needs, it does not fully ensure that staff performing official controls receive in full the training referred to in points (a), (b) and (c) of Article 5(4). Despite this, the audit team confirmed that those involved in the performance of official controls could demonstrate an in-depth knowledge of the documented control procedures and processes. On an annual basis a training return is completed by each individual and submitted to DCCD headquarters. This provides information regarding all training completed by staff within that relevant year. The annual training return for 2021 was demonstrated to the audit team during the course of the audit.

From a review of training material provided, the audit team noted that there was no documented training SOPs in place establishing the process to ensure that staff performing official controls receive appropriate training and keep up-to-date in their area of competence. It was acknowledged by the audit team that there was a draft training SOP in the process of being developed and reviewed for implementation by the DCCD during the time of the audit¹.

Following the completion of on-site audits within two particular FBO's (one small scale and one very small scale), the audit team found that the application of official controls was not effective and the assessment of compliance against food law was not adequate. Compliance notices under S.I. No. 22 of 2020 European Union (Food and Feed Hygiene) Regulations 2020 were issued to both FBO's by the DCCD following these audits. From a review of one of the compliance notices issued to a very small scale FBO, the audit team

¹ Subsequent to the audit, a training SOP was issued to all staff on the 15/02/2023 by the DCCD.

found that the level of enforcement action was not appropriate or in proportion with the severity of the non-compliances identified. It was acknowledged by the audit team that all non-compliances have been followed up by the DCCD subsequent to the audit and evidence of remedial actions have been provided to the audit team.

Within one region, it was noted that following an increase of official controls, a series of non-compliance with food law had been identified by the DCCD with one FBO between 2021 and 2022. Following these official controls, compliance notices were issued under S.I. 22 of 2020 European Union (Food and Feed Hygiene) Regulations 2020 by the DCCD. At the time of the audit, four compliance notices remained in place. A “working group on downgrade product” was established by the DCCD in 2022 to review the controls in place within the dairy industry, regarding downgraded dairy products. As a result of official controls carried out by DCCD staff on downgraded cheese, a RASFF alert was raised regarding the unauthorised placing on the market of cheese unfit for human consumption which originated from this FBO subjected to increased official controls.

A detailed overview of official controls performed, enforcement actions taken and the increased level of engagement between the DCCD and the FBO in question was provided to the FSAI audit team. It was the opinion of the audit team that every effort was made by the DCCD to ensure that the FBO was fully engaged and working towards compliance. Based on the information provided to the FSAI team, this FBO was selected for audit. Significant non-compliance with food law was identified during this audit resulting in 4.46T of cheese being deemed unfit for human consumption and disposed of as Category 2 Animal By-Product (ABP) under the supervision of the DCCD. As an output from this audit, the FBO was requested to review all stock on hand within the establishment. This resulted in approximately 42T of product being disposed of as Category 2 ABP under the supervision of the DCCD. Subsequent audits conducted in another region by the FSAI audit team identified an additional quantity of product being stored and or consolidated for this same FBO, these products were also deemed to be unfit for human consumption and were disposed of as Category 2 ABP under the supervision of the DCCD.

The official controls carried out regarding the FBO in question were found to be effective in the identification of non-compliance. However, it was noted that the actions taken to address the identified non-compliances did not prevent further occurrences as required by Article 138 (1) b of the OCR.

Audit findings from the completion of 11 FBO audits by the FSAI team resulted in enforcement action being taken by the DCCD on four FBOs and the continuation of pre-existing enforcement actions on a fifth FBO. All non-compliances have been followed up by the DCCD after the audit and evidence of remedial actions have been provided to the audit team. Table 1 summarises the enforcement actions taken and the reasons for same.

Table 1: Summary of enforcement actions taken by the DCCD

Enforcement Order Type		Food Business Type	Scale	Key Reasons	
FBO 1	Compliance Notice	1 x CN2 ² 1 x CN3 ³	Temperature Controlled store	Large	<ul style="list-style-type: none"> Inadequate backward traceability. Inadequate control of flying insects.
FBO 2	Compliance Notice	1 x CN2 1 x CN3	Cheese Processing Plant	Large	<ul style="list-style-type: none"> Inadequate controls regarding the identification, assessment, and control of downgraded blocks of cheese intended for human consumption. Cleaning.
FBO 3	Compliance Notice	1 x CN3	Cheese Processing Plant	Small – Medium	<ul style="list-style-type: none"> Inadequate backward traceability. Inadequate control of flying insects. Infrastructure. Cleaning.
FBO 4	Compliance Notice	1 x CN3	Cheese Processing Plant	Small	<ul style="list-style-type: none"> Inadequate traceability. Inadequate labelling. Absence of HACCP / FSMS. Absence of FBO food safety testing. Absence of shelf-life validation.
FBO 5	Compliance Notice	Continuation of pre-existing CN's	Cheese Processing Plant	Large	<ul style="list-style-type: none"> Findings contributing to the continuation of pre-existing compliance actions

² CN (Compliance Notice) 2 shall be issued to the FBO for Category 2 non-compliance(s). Category 2 = any non-compliance which poses a potential risk to public health.

³ CN (Compliance Notice) 3 shall be issued to the FBO for Category 3 non-compliance(s). Category 3 = any non-compliance other than the above where the conditions, requirements and principles of the Regulations are not met.

					<p>identified by the DCCD.</p> <ul style="list-style-type: none"> • 4.46T of cheese disposed of as Category 2 ABP. • Inadequate supplier controls. • Inadequate product intake controls. • Inadequate controls regarding the management of products unfit for human consumption.
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4.3 Internal audit

Article 6 of the OCR requires the competent authorities to carry out internal audits or have audits carried out on themselves. It also requires the competent authorities to take appropriate measures considering the results of those audits. Such internal audits shall be subject to independent scrutiny and shall be carried out in a transparent manner.

Findings

The audit team verified that there is an established DAFM internal audit function which carries out internal audits as required by Article 6 (1) of the OCR. The DCCD is audited as part of this by the DAFM Internal Audit Unit (IAU). Audits are undertaken using documented procedures namely the “Internal Audit Charter for Technical Audits conducted by the Internal Audit Unit of the Department Of Agriculture, Food and the Marine”.

The objective of the IAU is to verify the DCCD’s compliance with official legislation and to verify the effectiveness and suitability of planned arrangements. It was confirmed that the IAU has established an audit universe and applies a risk universe assessment for food audit planning and prioritisation, after which a five-year audit program is developed. A review of the audit universe and five-year audit plan took place in 2021. The most recent dairy audit was completed in February 2020 and appropriate measures in the form of a Corrective Action Plan (CAP) were put in place by the DCCD to address shortcomings identified. The close out of corrective action plans are monitored by the IAU on a quarterly basis until all appropriate measures are put in place. The IAU had intended on carrying out an internal audit of the DCCD in 2022, however, due to the FSAI’s planned audit of official controls in the dairy production chain and to optimise auditing time and resources, it was temporarily postponed.

The IAU provides the FSAI with updates on internal audit programs and on the completion of corrective action plans as specified in schedule 4 of the service contract. Updates regarding the work of the IAU are discussed during routine scheduled Technical Internal Audit Group (TIAG) liaison meetings with the FSAI. The audit team confirmed that liaison meetings were taking place as per the schedule agreed with the Authority and found that the minutes were detailed and contained updates regarding the work of the IAU. The audit team also verified that independent scrutiny of the internal audit process and function is completed routinely.

4.4 General rules of official controls

Article 9 of the OCR requires competent authorities to perform official controls on all operators regularly, on a risk basis and with appropriate frequency. Official controls shall be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out. Article 9 of the OCR also requires official controls to be carried out to identify possible intentional violations perpetrated through fraudulent or deceptive practices.

Findings

The audit team verified that official controls are carried out by the DCCD on a risk basis and in accordance with the OCR and the service contract. The following planned official controls and related official control procedures were reviewed as part of this audit:

- SOP 24 - Official Control Procedure (Inspections and Audits)
- SOP 01 - Food Safety Sampling
- SOP 10 - Food Chemical Sampling
- SOP 26 - Water Sampling
- SOP 29 - FIC (Food Information to Consumers) Assessment

Table 2 details the information collated and collected by the audit team regarding the percentage of planned official controls completed in 2021. This takes into consideration all establishments under the remit and supervision of the DCCD. It is important to note that during 2021, Ireland was still in the middle of a global pandemic. The audit team acknowledge the level of official controls completed, despite the challenges faced by the DCCD while working through a global pandemic and the impact that COVID-19 has had on the delivery of planned official controls.

Table 2 Summary of planned official controls completed

	Official Control	Period	% Completed
1	SOP 01 (Food Safety Sampling)	2021	94%
2	SOP 10 (Food Chemistry Sampling)	2021	90%
3	SOP 24 (Audit/Inspection)	2021	89%
4	SOP 26 (Water Sampling)	2021	92%
5	SOP 29 (FIC)	2020 – 2021	40%

SOP 24 Official Control Procedure – Audit and Inspections:

SOP 24 Rev 6 “Official Control Procedure” outlines the requirements regarding the development of official control plans and the risk-based approach to determine the frequency of official controls. There are two main types of official controls performed by the DCCD under SOP 24 i.e., planned official controls and reactive official controls. A planned official control as per SOP 24 “involves carrying out an official control at an establishment or a production unit within the establishment using auditing and inspection techniques”. Reactive official controls as per SOP 24 are “Follow-up controls, controls in relation to official complaints, controls in relation to registration and/or approval requests, controls in relation to other official requests/notifications”. Reactive official controls do not form part of the official control plan.

In establishing the frequency of planned official controls, each establishment is risk assessed annually at the start of the calendar year, by applying the risk rating scheme in Appendix V of SOP 24. The frequency of a planned official control is risk based taking into consideration several parameters, namely, the type of product, the type of process, the throughput, the level of compliance with previous official controls and confidence in the reliability of FBO’s own controls. Each parameter is individually scored to establish an overall risk score / weighting.

Appendix V of SOP 24 states the following:

- “*Low Risk Assigned*: Where the overall risk weighting is less than 50, at least 1 planned control per 2 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 1 planned control per calendar year”.*
- *“High Risk Assigned: Where the overall risk weighting is greater than 70, at least 2 planned controls per calendar year”.*

The audit team noted that while Appendix V of SOP 24 prescribes the risk rating scheme to be applied to establishments such as manufacturers of milk products, processers of milk products, milk purchasers and storage establishments, it does not specify how the risk rating scheme is to be applied to traders⁴ of milk products under the supervision of the DCCD. It was noted by the audit team that the trading activities of one large multi-site manufacturer was not registered / approved by the DCCD and was therefore not subjected to official controls. It was acknowledged by the audit team that the DCCD had engaged with this FBO regarding the registration / approval of the FBOs trading activity at the time of the audit. It was the opinion of the audit team that this type of trading activity may not be limited to this one multi-site manufacturer, however, this was being reviewed and followed up by the DCCD subsequent to the audit.

The risk rating and official control program is documented on an annual basis on form CR4 (Risk rating form). An electronic copy of the completed form CR4 is sent to DCCD Headquarters at the start of the calendar year and is uploaded to the DCCDs Agriculture Field Inspection Testing (AFIT) system. AFIT is the IT system used to plan, record, and report official controls. The audit team reviewed the risk rating and official control program developed for 2021 and 2022. The AFIT system containing the official control plans and reports was also demonstrated to the audit team within several of the regions visited. On numerous occasions non-compliance was noted regarding the risk-based official control plans reviewed and the DCCDs adherence with SOP 24. Table 3 collates the information collected by the audit team regarding the assessment of the risk-based official control programs for 2021 and 2022.

Table 3 Assessment of risk based official control plans for 2021 and 2022

	Detail	Outcome
1	In establishing the frequency of planned official controls for 2021, a small percentage of establishments were not risk assessed.	<ul style="list-style-type: none"> • Not all establishments under the remit and supervision of the DCCD were risk assessed in 2021 as per SOP 24 & Appendix V. • The 2021 official control plan was not up-to-date and did not identify all establishments requiring planned official controls. • There were eight missed official controls in 2021.

⁴ Trader in this context refers to an agent or broker (non-manufacturing traders) who buy, sell, or facilitate the trade of products, provide a critical link in the movement and trade of products as well as being responsible for maintaining an effective chain of traceability.

<p>2</p>	<p>In establishing the frequency of planned official controls for 2021 and 2022, three storage and distribution establishments were not risk assessed for the re-packaging of cheese.</p>	<ul style="list-style-type: none"> • Not all storage and distribution establishments under the remit and supervision of the DCCD were risk assessed or approved for the re-packaging of cheese in 2021 and 2022 as per SOP 24 & Appendix V. (The activity of cheese re-packaging has ceased in all three storage & distribution establishments since September 2022.) • The 2021 & 2022 official control plan was not up-to-date and did not identify all establishments requiring planned official controls (Regarding the handling and re-packaging of cheese). • There were three missed official controls⁵ in 2021 (Regarding the handling and re-packaging of cheese). • Three official controls (regarding the handling and re-packaging of cheese) were not identified in the 2022 official control plan.
<p>3</p>	<p>The frequency of planned official controls was not in line with the overall risk rating assigned to two establishments in 2021.</p>	<ul style="list-style-type: none"> • The interpretation of the frequency of planned official controls was not in line with the overall risk rating as per SOP 24 & Appendix V. • The 2021 official control plan and risk assessment were not aligned in respect of these two FBOs (No official controls were missed).
<p>4</p>	<p>Inaccurate risk scores were assigned to certain parameters contributing to the overall risk rating of several establishments in the 2021 and 2022 risk assessment.</p>	<ul style="list-style-type: none"> • Risk scores assigned to certain parameters were not accurate and in line with SOP 24 & Appendix V. • This resulted in a change to the overall risk rating of 3 establishments (no official controls were missed).
<p>5</p>	<p>In establishing the frequency of planned official controls, for 2021 and 2022, two multi-facility establishments did not</p>	<ul style="list-style-type: none"> • Two multi-facility establishments were not risk assessed in line with SOP 24 between 2021 and 2022.

⁵ Planned official controls were not performed to address the requirements concerning the re-packaging of cheese, however, it was acknowledged by the audit team that planned official controls including hygiene inspections in line with “Checklist C – Storage Facilities” had been carried out in these establishments.

receive a separate risk rating for each production unit.	
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It is recognised that the number of missed planned official controls identified by the audit team in 2021 represents a small percentage of the total number of official controls performed during that period. Nevertheless, it is a requirement under Article 9 (1) of the OCR and within the DCCDs own internal procedure SOP 24 to ensure that official controls are performed on all operators regularly, on a risk basis and with the appropriate frequency.

SOP 24, Rev 6, Section 2.3.1 states that “The risk rating and official control program for the approved and/or registered establishments shall be reviewed, agreed and documented on an annual basis in consultation with the Regional Inspector”. Due to the findings outlined in table 3, the audit team concluded that the review of the risk rating and official control program carried out in 2021 was not fully effective in ensuring that the full program of official controls are performed on all operators regularly, on a risk basis and with the appropriate frequency. It was noted by the audit team that there was no re-prioritisation of planned official controls which had not been completed in 2021, in the 2022 official control plan. There is also no documented process to ensure that planned official controls are not missed on a consecutive basis concerning the same establishment.

It was stated by the DCCD that many of the findings highlighted in relation to the 2021 risk rating and official control program, may have been attributed to changes in ways of working brought about by the introduction of the DCCDs “E-Docs” system in 2021.

It was acknowledged by the audit team that on an annual basis the DCCD performs a greater number of reactive official controls than planned official controls. In 2021 there were 241 planned controls (audits / inspections) performed, while in the same year there were 537 reactive controls (follow-up controls, controls in relation to official complaints, controls in relation to registration and/or approval requests, controls in relation to other official requests/notifications) performed. In relation to the 11 missed planned official controls identified in table 3, reactive official controls were performed in four out of the 11 establishments concerned. These reactive controls consisted of loading checks and the issuing of health certifications.

SOP 29 – FIC Official Controls

Documented risk-based controls covering food information to consumers at all stages of production and placing on the market are performed by the DCCD. This is to ensure that the official control system meets the main requirements of EU and National legislation relating to FIC (Food Information to Consumers). SOP 29, Rev 2, “FIC”, section 1.7 states, “A control is carried out for each FBO at a minimum once every 2 years”. The planned two-year period of 2020 – 2021 was reviewed as part of the audit. It was noted by the audit team, that while one out of the six regions of the DCCD completed 95% of the planned FIC controls for their

area, only 40% of the total required FIC controls were completed across the DCCD as a whole. SOP 29 was in the process of being updated to version 3 during the audit and was issued by the DCCD in August 2022. SOP 29 version 3 significantly changed the risk-based approach for the completion of official controls relating to FIC and establishes a more comprehensive and robust procedure. In establishing the risk rating and frequency of planned official controls, each establishment is now risk assessed annually at the start of the calendar year by applying a specific risk rating scheme outlined in Annex 1 of SOP 29.

SOP 01 – Food Safety Sampling Official Controls

Risk based food safety sampling controls are drawn up using form SP1 (Annual Sampling Plan) annually for each establishment. SOP 01 Revision 15 “Food Safety Sampling” details the process for official control sampling and reporting. Food safety criteria sampling and process hygiene criteria sampling (in line with Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs) are the two main types of planned official sampling completed. Other planned sampling includes targeted salmonella monitoring, pasteurisation testing, samples to determine the effectiveness of UHT/Sterilisation process, antibacterial substances testing and raw milk for direct human consumption testing. In addition to planned sampling, the DCCD also carries out reactive sampling which may include product sampling, environmental monitoring, or hygiene monitoring. The risk-based plan for food safety sampling was reviewed by the audit team and was found to be robust and in line with SOP 01 Revision 15. However, within one region audited, it was noted by the audit team that one very small-scale establishment did not receive the required frequency of food safety and process hygiene sampling controls as outlined in the DCCD’s 2021 annual sampling plan. It was explained by the DCCD, that due to Covid-19 and reduced production, the DCCD halved the sampling frequency for this FBO. During an on-site inspection of the same establishment, it was identified by the FSAI audit team that this FBO had not performed any product testing as appropriate in line with Regulation (EC) 2073/2005 and was relying on official control sampling to verify compliance with relevant food safety requirements.

Article 9(2) of the OCR requires official controls to be carried out to identify possible intentional violations perpetrated through fraudulent or deceptive practices. The DCCD participate and contribute to various working groups such as the Food Safety and Authenticity Working Group and the Downgraded Products Working Group to identify possible intentional violations of the rules referred to in Article 1(2), perpetrated through fraudulent or deceptive practices. The various inspection checklists and sampling / monitoring programs which are completed during routine official controls are also deemed to form part of the DCCD’s controls in identifying possible fraudulent and deceptive practices within the dairy production chain.

The DCCD confirmed that where possible official controls are performed without prior notice in conjunction with Article 9(4) of the OCR. SOP 24, Rev 6, section 3 states that “inspections shall be unannounced,

whereas audits may be prearranged with the FBO.” The audit team noted that in many cases there was no written or electronic confirmation maintained regarding the announced / unannounced nature of official control inspections and or the justification for the provision of prior notice. While there is currently no specific requirement within the OCR for this to be documented, verification of compliance with article 9(4) which states “official controls shall be performed without prior notice, except where such notice is necessary and duly justified for the official control to be carried out” cannot be determined from the current inspection reports reviewed. Confirmation of whether official controls are announced or unannounced is in some cases recorded on CR1 reports, however, the audit team also found that in some cases it was based on the ability of the inspecting officer to recall such from memory.

4.5 Operators, processes, and activities subject to official controls

Article 10 of the OCR requires that to the extent necessary to ascertain compliance with the rules referred to in Article 1(2) of the Regulation, competent authorities shall perform official controls on animals and goods at any stage of production, processing, distribution, and use. The competent authority shall also draw up and keep up to date a list of operators.

Findings

The audit team verified that the DCCD has in place a system of official controls relating to establishments which collect, handle or process raw milk, dairy products, and composite products. This system of official controls provides for an assessment of compliance with relevant legislation through inspection / auditing and sampling / monitoring programs. The audit team verified that there is a suite of documented SOPs in place which outline the processes and steps to be taken when performing such official controls. These SOPs are further supplemented by specific records such as inspection checklists and dedicated forms which are utilised to document official controls performed and their outcomes.

Within one establishment audited, it was noted that as well as the standard production and sale of premium blocks of cheese, non-premium blocks of cheese were being consolidated for sale. Non-premium blocks of cheese typically consist of products which have been graded and sampled by the manufacturer and/or product which has fallen outside the limits of agreed customer specifications for certain physio-chemical or microbiological criteria. These products are still deemed compliant with relevant food safety legislation by the manufacturer and suitable to be placed on the market. From a review of non-premium product within the establishment and within their external sub-contracted storage facility, the audit team noted that non-

premium blocks of cheese also included mouldy blocks, leakers⁶, damaged blocks, and exposed blocks of cheese.

The audit team raised concerns regarding the suitability of such non-premium products and how food business operators ensure that these products comply with relevant food law and are suitable to be placed on the market. The establishment in question did not assess the extent of the mouldy blocks, leakers, damaged blocks, and exposed blocks of cheese which it placed on the market. The establishment's food safety management system and associated records did not take these products into consideration and as such there was no assessment of the hazards associated with same. It was also noted by the audit team that such products were not subject to official controls as required by Article 10 of the OCR.

From a review of storage and distribution establishments under the supervision of the DCCD within each region visited, the audit team identified that there were six cold store establishments carrying out additional activities regarding the handling and re-packaging⁷ of cheese products. It was noted that three of these establishments were not formally approved by the DCCD to carry out the re-packaging of cheese and as a result, were not subject to all relevant routine official controls. It was acknowledged by the audit team that between Aug / Sept 2022 all cold store establishments not approved for the re-packaging of cheese had ceased this activity with immediate effect. In relation to cold store establishments who were approved for this activity, the audit team found that official controls applied were effective and appropriate.

All FBOs who collect, handle, or process milk must apply to the competent authority for registration. All applications for registration are made to the Milk Hygiene Division (MHD) of DAFM. On receipt of communication from the MHD, the DCCD carries out the relevant on-site official controls to determine whether the FBO meets the relevant requirements of food law. Where the on-site control is deemed to be satisfactory regarding registration / approval, form CR1 (Compliance Report) and Form APPR (Approval / Registration Form) is issued to the MHD proposing registration / approval. The MHD is responsible for maintaining a database of approved and / or registered establishments under the supervision of the DCCD. The MHD publishes a register of approved food business operators on the DAFM website as required by Regulation (EC) 853/2004. There is no requirement to publish a register of registered food business operators. MHD SOP No 17, (suspension / revocation procedure) issued 21/10/2015, section 3.1 states that the register is "updated when a new FBO is approved, when an FBO ceases to operate or when an FBO is instructed to cease operations". It is the responsibility of the DCCD to notify the MHD if an FBO has ceased trading and if suspension or revocation of a registration and / or approval is necessary.

⁶ Leaking vacuum on sealed cheese blocks.

⁷ Re-Packaging of cheese = the removal of the food contact pouch and the placing of the cheese block into a new food contact pouch. This may also involve the removal of visual surface mould prior to placing the cheese block into the new pouch.

From a review of the register of approved / registered establishments and the suspension / revocation process within each region visited, the audit team noted the following:

- Several establishments whose registration had been proposed for suspension / revocation by the DCCD, remained registered and on the list of registered food businesses for significant periods of time.
- Several establishments who had ceased trading / operations did not have their approval / registration proposed for revocation by the DCCD and as a result remained approved / registered and on the register of approved / registered establishments for significant periods of time.
- The register of approved / registered establishments was not maintained up to date and in line with MHD SOP 17 and in compliance with Article 10 of the OCR.

Concerns were raised by the audit team regarding the prolonged periods of time in which establishments remained approved / registered, despite having either ceased trading / operations or having its approval / registration proposed for suspension or revocation. While there was no evidence of any FBO continuing to operate without the appropriate approval / registration, concerns were raised by the audit team regarding the possible risk of such establishments re-commencing trade / operations or in other cases continuing to operate despite having their approval / registration proposed for suspension / revocation and not being subjected to official controls. It was acknowledged by the audit team that the DCCD in conjunction with the MHD immediately actioned and remedied all findings regarding the register of approved / registered establishments subsequent to the on-site component of the audit. It was explained by the DCCD that in early 2022 the MHD have since allocated additional resources to improve the management and control of suspensions and revocations. Communications from the DCCD are now sent to a centralised email within the MHD to ensure improved oversight and a timely turnaround of submitted suspensions and revocations. Table 4 summarises a sample of the information collated and collected by the audit team from a review of the register of approved / registered establishments.

Table 4: Summary of findings from assessment of approved / registered list of establishments.

	Suspended / Revoked / Ceased trading	DCCD proposed suspension / revocation to MHD	MHD Action of proposal	Outcome
FBO 1	Revoked	May 2021	Aug 2022	<ul style="list-style-type: none"> • Remained registered for circa 15 months. • List of registered FBOs not up to date.
FBO 2	Suspended	2019	Aug 2022	<ul style="list-style-type: none"> • Remained registered for circa 2+yrs.

				<ul style="list-style-type: none"> List of registered FBOs not up to date.
FBO 3	Suspended	2019	Aug 2022	<ul style="list-style-type: none"> Remained registered for circa 2+yrs. List of registered FBOs not up to date.
FBO 4	Ceased Operations 2021 – Revocation required	No proposal of suspension / revocation issued to the MHD at the time of the audit	No proposal received to action or notify FBO at the time of the audit	<ul style="list-style-type: none"> List of approved FBOs not up to date. Proposal letter of revocation issued by the DCCD and acted upon by MHD subsequent to the audit.
FBO 5	Ceased Operations 2020 - Revocation required	No proposal of suspension / revocation issued to the MHD at the time of the audit	No proposal received to action or notify FBO at the time of the audit	<ul style="list-style-type: none"> Remained registered for circa 2 yrs. List of registered FBOs not up to date. Proposal letter of revocation issued by the DCCD and acted upon by MHD subsequent to the audit.
FBO 6	Ceased Operations 2020 - Revocation required	No proposal of suspension / revocation issued to the MHD at the time of the audit	No proposal received to action or notify FBO at the time of the audit	<ul style="list-style-type: none"> Remained registered for circa 2 yrs. List of registered FBOs not up to date. Proposal letter of revocation issued by the DCCD and acted upon by MHD subsequent to the audit.
FBO 7	Ceased Operations 2019 – Revocation required	Jul 2022	Aug 2022	<ul style="list-style-type: none"> Remained registered for circa 3 yrs. List of registered FBOs not up to date.
FBO 8	Suspended	Feb 2022	Feb 2022	<ul style="list-style-type: none"> FBO remained on the list of approved premises until May 2022. List of approved FBOs not up to date.

4.6 Documented control procedures

Article 12 of the OCR requires competent authorities to perform official controls in accordance with documented procedures. They shall cover the subject areas for official controls, contain instructions for staff performing such official controls, take corrective action where shortcomings are identified and be updated as appropriate. Competent authorities shall have control verification procedures (arrangements put in place and

actions performed by the competent authorities for the purpose of ensuring that official controls and other official activities are consistent and effective).

Findings

The DCCD have developed a suite of documented SOPs which outline the processes and steps to be taken when carrying out official controls. These SOPs are further supplemented by specific records such as inspection checklists and dedicated forms which are utilised to document official controls performed and their outcomes. The audit team verified that all SOPs, checklists, and forms were available to all staff through the DCCD's "E-Doc" document management system. SOPs are developed at a central level in conjunction with RDPIs and other staff. Special memoranda are also used to communicate updates, amendments, and temporary changes in ways of working to staff. The audit team confirmed that all SOPs have been documented with an aim to support the completion of official controls and to ensure the effectiveness and appropriateness of those official controls. The main SOPs reviewed by the audit team included:

- SOP 01 - Food Safety Sampling
- SOP 10 - Food Chemistry Sampling
- SOP 16 - Supervisory
- SOP 17 - Suspension / Revocation (Milk Hygiene Division Procedure)
- SOP 24 - Official Control Procedure
- SOP 26 - Water Sampling
- SOP 29 - FIC

All SOPs reviewed had document controls evident in the form of an SOP number, issue date, revision number, and were authorised by the Senior Inspector of the DCCD. Despite this, it was noted that there was no formal document control procedure in place detailing the methods by which documentation is (for example) created, stored, approved, updated, published, archived, and disposed of. The audit team acknowledged that the DCCD were reviewing document control and were in the process of developing a draft procedure for same at the time of the audit. While there was no evidence of the use of incorrect versions of SOPs or forms during the audit, the audit team did note that several documents and records appended to certain SOPs did not contain any evidence of document control. For example, documents and records appended to SOP 24 (Appendix III - X) and SOP 01 (Annex 2,3,5,6,7).

The audit team confirmed that in general, official controls were being performed in accordance with documented procedures and acknowledged that there were several SOPs in the process of being developed, modified, and updated during the course of the audit. However, there were instances identified during the audit where the requirements of certain SOPs were not being adhered to in full, such as the following:

- SOP 26 “Water Sampling” Rev 3 section 2.1 states, “All areas of a food business operator’s establishment should be sampled over time” and that “The objective of sampling is to determine the microbiological quality of the water at the point of use”. From a review of one FBO file it was noted that water had only been sampled from a sampling point within a pilot plant twice yearly for the period of 2021 & 2022.
- SOP 24 “Official Control Procedure” Rev 6 section 3.4 states, “For Category 2 non-compliance(s), Form CN 2 shall be issued to the FBO directing them to take action(s) as specified under Regulation 16 (3) (a-i) * of SI 22 of 2020 and allowing a reasonable time limit for the Notice to be complied with, up to a maximum of 7 days.” From one FBO file reviewed, it was noted that time frames of between two and four weeks were specified on certain CN 2 forms for the completion of Category 2 Non-compliances. This does not adhere to the time frame specified in SOP 24, which is 7 days for a Category 2 Non-compliance.

The audit team confirmed that control verification procedures were in place to ensure that official controls performed by the DCCD are effective, appropriate, and consistent. SOP 16 “National Supervisory System for Staff Performing Official Food Safety Controls” Rev 3 sets out the supervisory system to evaluate the effectiveness and appropriateness of official controls at a regional and national level.

At a national level, the following is completed:

- RDPI meetings are held periodically where the suitability and implementation of official controls are reviewed.
- Data from official control reports is analysed.
- Recommendations and findings from internal and external audits are reviewed and implemented, if deemed necessary.
- Routine liaison meetings are held with the FSAI which include discussions regarding the implementation of official controls.
- DAFM internal audits.

At a regional level, the following is completed:

- RDPI accompanied on the spot planned controls.
- RDPI desk-based documentary checks.
- Joint inspections with LDPIs.

A plan of supervisory controls is drawn up by the RDPI for each region on an annual basis. At the end of the year a report of all supervisory controls completed is also drawn up by each RDPI. Both the plan and report of supervisory checks are submitted to the Senior Inspector annually. Within two regions visited, the plan and report for 2021 was reviewed by the audit team. No shortcomings were identified in any of the supervisory records reviewed. The audit team found that supervisory checks carried out within each region

were comprehensive and robust. It was noted by the audit team that SOP 16 does not detail the steps to be taken should shortcomings be identified by the RDPI during the completion of supervisory checks. There is also no section on the supervisory check record to capture corrective action in response to any potential shortcomings identified by the RDPI.

4.7 Written records of official controls

Article 13 of the OCR requires that competent authorities shall draw up written or electronic records of every official control that they perform, and they shall contain a description of the purpose of the official controls, the control methods applied, the outcome of the official controls; and where appropriate, action that the competent authorities require the operator concerned to take as a result of their official controls. The operator shall be promptly informed in writing by the competent authorities of any case of non-compliance identified through the official controls.

Findings

The audit team verified that a combination of written and electronic records was in place for the completion of official controls. All records / checklists are appended to the relevant SOPs and are available to all staff through the “E-Doc” system. The schedule for official controls is drawn up annually from CR4 and then populated on to AFIT. AFIT is then used to plan, record, and report official controls. The requirements to be fulfilled during the completion of an official control inspection / audit are set out in the relevant checklists. After completing the relevant checklist, the LDPI then uploads their findings to AFIT only recording by exception the non-compliances raised. All compliance reports and compliance notices are populated from AFIT, all of which was demonstrated to the audit team within several of the regions visited.

The audit team verified that a description of the purpose of the official control, the control method, the outcome of the official control and where relevant the actions required by the DCCD were being captured on official control records. The audit team verified that procedures relating to written records were being adhered to and correspondence pertaining to official control outcomes had been issued by the LDPI to the FBO in all cases reviewed. The audit team also verified that records of official controls were available on file within each FBO audited.

The audit team noted that in some cases the LDPIs carrying out official control inspections did not always use the defined checklists prescribed within SOP 24 “Official Control Procedure” Rev 6. In such cases personalised records documenting the official control inspection were being completed based on the LDPIs experience and knowledge of the checklists. Within one region visited, the audit team could not verify from a review of the LDPIs personal records that all sections of the relevant checklist had been completed during an official control inspection.

4.8 Methods and techniques for official controls

Article 14 of the OCR specifies the methods and techniques to be used during official controls and may include the examination of the controls that operators have put in place and of the results obtained, inspection of equipment, cleaning and maintenance products and processes, traceability, labelling, and controls on the hygiene conditions in the operators' premises.

Findings

SOP 24 "Official Control Procedure" Rev 6, section 2.1 states that official control methods consist of an "inspection of the infrastructure, hygiene, equipment, facilities, labelling and handling of ingredients and final products and prerequisite programmes". The requirements for which are set out in the relevant sections of Checklist A, B, C and D. Official control methods also include an audit of prerequisite programmes and HACCP, the requirements of which are set out in the relevant sections of Checklist B, C and D.

These checklists require the authorised officers to determine compliance with all relevant aspects of food law enforced through (but not limited to) Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004 and SI. No. 22 of 2020 European Union (Food and Feed Hygiene) Regulations 2020.

There are four checklists in total, checklists A, B, C and D. During the completion of a planned official control, HACCP checklist D is completed every time and subsequent planned controls must ensure that at a minimum, all three sections of checklist A & B are completed within a three-year cycle. Checklist C is a dedicated inspection / audit checklist for storage facilities. From several FBO files reviewed, the audit team confirmed that the relevant checklist was utilised and that at a minimum all relevant sections and checklists were completed within the three-year cycle. The audit team found that in general, the methods and techniques utilised by LDPIs during official controls were robust and were designed to incorporate all the relevant criteria outlined in Article 14 of the OCR.

4.9 Obligations of operators

Article 15 of the OCR requires competent authorities to the extent that this is necessary for the performance of official controls or of other official activities that operators shall, where required by the competent authorities, give staff of the competent authorities' access to premises and other places under their control, access to computerised information management systems, their documents, and any other relevant information.

Findings

The audit team were satisfied that during official controls conducted by authorised officers, that food business operators provided access to all areas of the food business and that the relevant information requested was provided by means of hard copy or electronic records. The FSAI team during the on-site verification part of the audit were given full access to all relevant areas of the premises and were provided with full access to the food businesses food safety management systems and associated records.

4.10 Relation with Regulation (EC) No 852/2004 and (EC) No 853/2004 regarding approval of food business establishments

Article 148 of the OCR states that Competent authorities shall establish procedures for food business operators to follow when applying for the approval of their establishments. Upon receipt of an application for approval from a food business operator, the competent authority shall make an on-site visit and the competent authority shall approve an establishment for the activities concerned only if the food business operator has demonstrated that it complies with the relevant requirements of food law. The competent authority may grant conditional approval if it appears that the establishment meets all the infrastructure and equipment requirements. The competent authority shall grant full approval only if it appears from a new official control that the establishment meets the relevant requirements of food law. The competent authority may prolong the conditional approval; however, conditional approval shall not exceed a total of six months.

Findings

The MHD and the DCCD work in conjunction to register and or approve food business operators involved in the production of milk and milk-based products. The MHD carries out the administrative functions regarding the registration and / or approval of food businesses, while the DCCD performs the various official controls to verify that the relevant requirements of food law are being complied with.

SOP 24 "Official control procedure" Rev 6 details the process for the registration and approval of a food business. The FBO must apply to the MHD for registration / approval. On receipt of the application from the MHD, the DCCD carry out an on-site official control to assess whether the establishment meets the relevant requirements of food law. Following an on-site official control(s) at a new establishment, conditional approval is proposed if the establishment meets all the hygienic infrastructural and equipment requirements. Where on-site controls are deemed to be satisfactory, the DCCD issue form CR1 and form APPR proposing conditional approval with a timescale of three months to the MHD. If clear progress is being made within the three months but the establishment has not yet met all the requirements for approval, then conditional approval may be prolonged, but the total period of conditional approval must not exceed six months. Once

approved by the DCCD, establishments are then issued with a unique registration / approval number and are then added to the list of registered / approved establishments by the MHD.

The audit team found that in general the process and controls regarding the management of conditional approval and the extension of conditional approval was comprehensive and robust. Examples of the registration process, granting of conditional approval and the extension of conditional approval were demonstrated to the audit team within several of the regions visited. On one occasion where an extension to a conditional approval was proposed by the DCCD to the MHD, it was noted that no updated conditional approval certificate with the extended timescale was issued to the FBO by the MHD. On a separate occasion it was identified by the audit team that one FBO remained in a status of conditional approval for approximately 11 months between Oct 2021 and Sept 2022 before the suspension of conditional approval letter was issued. It was acknowledged however, that this small producer was not in production for several months during this period. The audit team were advised that the DCCD and MHD have plans to improve the oversight of all three-month and six-month conditional approvals. The MHD are also in the process of introducing a system which will monitor the issuing and expiry of all conditional approvals in conjunction with the DCCD.

As referenced within section 4.5 of this report, the audit team identified six cold store establishments conducting additional activities regarding the handling and re-packaging of cheese products. It was noted by the audit team that three of these establishments were not formally approved by the DCCD to conduct the re-packaging of cheese and as a result, planned official controls to address the requirements concerning the re-packaging of cheese were not performed. However, it was acknowledged by the audit team that planned official controls including hygiene inspections in line with “Checklist C – Storage Facilities” had been carried out in these establishments.

5. Food Business Operator Findings

As part of the FSAI audit process, five out of six DCCD regional areas were audited i.e., the North region, South-East region, South region, Mid-West region, South-West region. A total of 11 food business operators were audited to assess compliance with relevant food law. A range of food businesses were selected for on-site audit taking into consideration the various types of operations and activities carried out. The size and complexity of establishments audited ranged from very small-scale operations to large commercial food businesses.

Non-compliance with food law was found within one small scale and one very small scale FBO inspected, which resulted in compliance notices under S.I. No. 22 of 2020 European Union (Food and Feed Hygiene)

Regulations 2020 being issued by the DCCD to both food businesses in question. The audit team noted that within one very small scale FBO there was no food safety management system and associated records in place and available on the day of the audit. The FBO could partially demonstrate one step forward traceability but could not demonstrate one step back traceability as required by Regulation (EC) No. 178/2002 and the provision of food information to consumers as required by Regulation (EU) No. 1169/2011 was inadequate.

Within the other FBO's inspected, the audit team noted partial compliance with traceability requirements, food safety management system requirements and the provision of food information to consumers as required by relevant legislation. It is a requirement that food businesses have in place a food safety management system and associated records commensurate with the nature and extent of the operation and can identify and document information on products "one step forward and one step back" in the food chain. It is also a requirement that food businesses provide all relevant information in accordance with Regulation (EU) No. 1169/2011 on the provision of food information to consumers, as amended.

Significant non-compliance with food law was also identified within one large scale FBO inspected, which resulted in a significant quantity of cheese being deemed unfit for human consumption and disposed of as Category 2 ABP and the continuation of pre-existing compliance notices issued by the DCCD prior to the audit.

Where non-compliances with food law were established during FBO audits, they were verbally notified to the food business operator at a closing meeting in agreement with the DCCD. It was acknowledged by the audit team that FBO non-compliances have been followed up in all food businesses during subsequent official controls by the DCCD. Evidence of follow-up has been provided to the audit team.

5.1 Traceability – FBO audit findings

Non-compliance contrary to Regulation (EC) 178/2002 Article 18 was observed within six out of the eleven establishments audited. All non-compliances have been followed up during subsequent official controls by the DCCD.

Table 5: Summary of FBO audit findings contrary to Regulation (EC) 178/2002 Article 18

No.	Food Business Type	Findings
FBO 1	Cheese Processing Plant	<ul style="list-style-type: none"> Partial one step forward traceability, unable to demonstrate one step back traceability. No traceability procedure

FBO 2	Cheese Processing Plant	<ul style="list-style-type: none"> Partial one step forward traceability. Unable to demonstrate forward traceability for all finished products sold. Partial one step back traceability. Unable to demonstrate backward traceability on all raw material. Several procured finished products in storage with no traceability details available.
FBO 3	Dairy Processing Plant	<ul style="list-style-type: none"> No traceability details provided for on two pallets of product (1 x raw material and 1 x work in progress product)
FBO 4	Temperature Controlled Store	<ul style="list-style-type: none"> One step back traceability could not be established for three boxes of downgraded cheese. Lack of traceability details on dispatch docket.
FBO 5	Temperature Controlled Store	<ul style="list-style-type: none"> No traceability or health mark details on four mega bins of cheese curd in storage. No label, traceability, or health mark details on five blocks of re-packaged cheese in storage.
FBO 6	Dairy Processing Plant	<ul style="list-style-type: none"> Several bags of dry raw materials had no traceability details evident.

5.2 Provision of food information – FBO audit findings

Non-compliance contrary to Regulation (EU) No. 1169/2011 on the provision of food information to consumers was observed within five out of the eleven establishments audited. All non-compliances have been followed up during subsequent official controls by the DCCD.

Table 6: Summary of FBO audit findings contrary to Regulation (EU) No. 1169/2011 on the provision of food information to consumers

No	Food Business Type	Findings
FBO 1	Cheese Processing Plant	<ul style="list-style-type: none"> Several blocks of cheese (produced on site) in storage had no labels present. (Product is further cut for sale at market) Several blocks of cheese (Procured externally) in storage had no labels present. (Product is further cut for sale at market)

FBO 2	Cheese Processing Plant	<ul style="list-style-type: none"> Not all mandatory information was being provided for business-to-business customer or final consumer. For example, allergen information, “RAW milk cheese” statement, storage instructions, name, and address of business.
FBO 3	Dairy Processing Plant	<ul style="list-style-type: none"> Several bags of raw material product in storage had no labels evident.
FBO 4	Temperature Controlled Store	<ul style="list-style-type: none"> Several blocks of re-packaged cheese (which was deboxed⁸) had no labels evident.

6. Conclusions

There is a structured and organised system of official controls in place for the supervision of food businesses within the dairy production chain. Those involved in official controls are suitably qualified and trained to perform this work. RDPIs and LDPIs are duly authorised to perform official controls and the necessary legislation to enforce same is in place.

The DCCD have procedures and arrangements in place to ensure the effectiveness and appropriateness of official controls and other official activities in accordance with Article 5 of the OCR. Whilst in the main, official controls carried out were effective and appropriate, there were however, specific instances identified at two small scale FBO's whereby the application of official controls was not effective, the assessment of compliance against food law was not adequate and the level of enforcement action taken thereafter was not appropriate or in proportion with the severity of the non-compliances identified. Five out of eleven on-site FBO audits carried out by the FSAI resulted in compliance notices being issued by the DCCD and / or the continuation of pre-existing compliance notices.

There is an established internal audit function within DAFM which carries out internal audits as required by Article 6 (1) of the OCR. Such internal audits include an assessment of the effectiveness and suitability of the DCCDs planned arrangements as required by the OCR. Official controls are carried out by the DCCD on a risk basis and in accordance with the OCR and the service contract. However, non-compliance was noted regarding the 2021 risk-based official control program. This resulted in a small percentage of establishments not being risk assessed and several missed official controls. The audit team concluded that the review of the

⁸ Deboxed cheese – Cheese which has been removed from its cardboard box.

risk rating and official control program carried out in 2021 was not effective in ensuring that official controls are performed on all operators regularly, on a risk basis and with the appropriate frequency.

Official controls are carried out on goods at relevant stages of the food chain under the remit of the DCCD and the outcome of official controls are recorded and maintained on AFIT. It was identified by the audit team that certain activities were not subject to official controls as required by Article 10 of the OCR. A register of approved / registered establishments is in place and is maintained by the MHD in conjunction with the DCCD, however, it was identified by the audit team that the register was not maintained up-to-date and in compliance with Article 10 of the OCR.

There is a comprehensive suspension / revocation process applied by the DCCD in conjunction with the MHD for food business operators who have ceased production. In general, the suspension / revocation process applied was found to function well, however, there were instances identified by the audit team where the process was not effective. In such instances, several establishments whose registration had been proposed for suspension / revocation by the DCCD remained registered and several establishments who had ceased trading / operations did not have their approval / registration proposed for suspension / revocation by the DCCD. There was no evidence of any such FBO continuing to operate without the appropriate approval / registration.

Records of official controls are maintained as required and in all cases reviewed, the audit team found that the operator was promptly informed in writing as to the outcome of official controls performed. Standard operating procedures for carrying out official controls have been documented in the form of SOPs. DCCD procedures have been developed at national level and made available to all regions via the DCCDs E-Doc system. There were instances identified during the audit where the requirements of certain procedures were not being adhered to in full. The audit team confirmed that control verification procedures were in place to ensure that official controls performed by the DCCD are effective, appropriate and consistent. The audit team found that supervisory checks conducted within each region were comprehensive and in line with the DCCDs control verification procedure.

The MHD and the DCCD work in conjunction to register and or approve food business operators involved in the production of milk and milk-based products. The MHD carries out the administrative functions regarding the registration and / or approval of food businesses, while the DCCD performs the various official controls to verify that the relevant requirements of food law are being complied with. Comprehensive documented procedures have been established by the DCCD and MHD to manage same. The audit team found that in general the process and controls regarding the management of conditional approval and the extension of conditional approval was comprehensive and robust. There were, however, instances identified during the audit where the requirements of Article 148 of the OCR were not complied with in full.

Audit findings have identified opportunities to further strengthen elements of the DCCD official controls systems and processes. Where non-compliances with food law were established during on-site FBO audits,

they were verbally notified to the food business operator at a closing meeting in agreement with the DCCD. It was acknowledged by the audit team that FBO non-compliances have been followed up in all food businesses during subsequent official controls by the DCCD. Evidence of follow-up has been provided to the audit team.

7. Findings Requiring Corrective Action

1. Ensure official controls performed are effective, appropriate and where non-compliances are established, verify that:
 - i. Actions taken to address identified non-compliance prevent further occurrences of such non-compliance.
 - ii. The level of enforcement action is appropriate and proportionate with the severity of the non-compliance identified.

2. Ensure all relevant documented procedures and records are developed, in place, kept up-to-date and are adhered to.
 - i. There is no document control procedure in place detailing the methods by which documentation is (for example) created, stored, approved, updated, published, archived, and disposed of. Several documents and records appended to various SOPs did not contain any evidence of document control.
 - ii. There is no documented training procedure in place establishing the process to ensure that staff performing official controls receive appropriate training and keep up-to-date in their area of competence. The training program presented does not fully ensure that staff performing official controls receive in full the training referred to in points (a), (b) and (c) of Article 5(4). In addition, documented evidence of training completed against certain SOPs could not be demonstrated in all cases.
 - iii. Appendix V of SOP 24 does not specify how the risk rating scheme is to be applied to traders of milk products under the supervision of the DCCD.
 - iv. SOP 24 "Official control procedure" Rev 6 section 3.4 states, "For Category 2 non-compliance(s), Form CN 2 states a reasonable time limit for the notice to be complied with, up to a maximum of 7 days." From one FBO file reviewed, it was noted that time frames of between two and four weeks were specified on the CN 2 forms for the completion of a Category 2 Non-

compliance. This does not adhere to the time frame specified in SOP 24 which is 7 days for a Category 2 Non-compliance.

- v. SOP 26 "Water Sampling" Rev 3 section 2.1 states, "All areas of a food business operator's establishment should be sampled over time" and that "The objective of sampling is to determine the microbiological quality of the water at the point of use". From a review of one FBO file it was noted that water had only been sampled from a sampling point within a pilot plant twice yearly for the period of 2021 and 2022.
 - vi. SOP 01 "Food Safety Sampling" Rev 15 Part I states "Planned sampling controls should be drawn up taking into account the risk assessed according to the classification of risks with reference to Annex 4". From one FBO file reviewed, it was noted that Food Safety and Process Hygiene sampling controls were not being completed in line with the frequency established within SP1 (Annual Sampling Plan) 2021.
 - vii. Ensure that the register for approved / registered establishments is maintained up-to-date in line with Article 10 of the OCR. Ensure that the process adopted for the management of suspensions / revocations is effective. Ensure that the management of conditional approval and the extension of conditional approval meets the requirements of Article 148 of the OCR.
3. Ensure that official controls are performed on all operators regularly on a risk basis and with appropriate frequencies as required by Article 9 (1) of the OCR.
 4. Ensure that all relevant food business operators and / or activities performed by food business operators are approved / registered (Where required) by the DCCD and in compliance with Article 148 of the OCR, Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004 and are subject to the required official controls.
 5. Ensure that all non-compliances with food law identified during on-site FBO audits by the FSAI team are closed out.



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