

AUDIT
REPORT

Audit of Official Controls
related to Liquid Milk
Establishments –
Department of Agriculture,
Food and the Marine

FEBRUARY 2015



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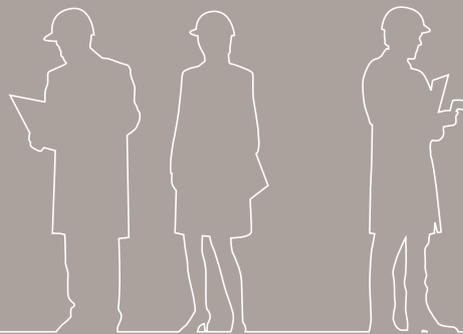


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1. GLOSSARY

CCP	Critical Control Point
DAFM	Department of Agriculture, Food and the Marine
FSAI	Food Safety Authority of Ireland
FSMS	Food Safety Management System
HACCP	Hazard Analysis Critical Control Point
Liquid Milk	Pasteurised drinking milk
SOP	Standard Operating Procedure
VPN	Veterinary Procedural Notice

2. EXECUTIVE SUMMARY

The Food Safety Authority of Ireland (FSAI) is responsible for the enforcement of all food legislation in Ireland, which is carried out through service contracts with official agencies. 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, the FSAI completed an audit of the Department of Agriculture, Food and the Marine's (DAFM) official controls related to liquid milk.

The audit involved the Veterinary Public Health Inspection Service at the establishment level, the District Veterinary Offices at the regional level and the Eradication of Animal Diseases Division at national level. The three District Veterinary Offices visited covered both the North and South Area Management Team regions of DAFM.

The project included an audit of three Veterinary Public Health Inspection Service regions where two liquid milk establishments were visited in each region. The three District Veterinary Offices selected were selected due to a likely expectation that certain herds in the locality would be supplying raw milk to the liquid milk establishments to be audited.

At the milk supply level, the FSAI audit focused on DAFM controls in relation to bovine Tuberculosis (bTB) as this was the main zoonotic disease of concern. Controls specifically around Brucellosis were not evaluated as there have been no recent cases and Ireland has attained an 'Officially Brucellosis Free' status since 2009.

During the audit of DAFM official controls, many positive elements of the system were observed in relation their organisation, planning and delivery. Correspondingly, certain aspects for improvement have also been identified, requiring a strengthening of the current system of official controls, and which are highlighted in this report.

A summary of the main audit findings are highlighted below:

- Regular enforcement action in the form of compliances notices were issued by DAFM to deal with non-compliances identified at liquid milk establishments
- A voluntary cessation of activities at one establishment as required by DAFM, took place in order to suspend unhygienic practices observed during the course of the FSAI audit
- DAFM audits of food business operators processing liquid milk in accordance with standard operating procedure SOP 17/2012 were still evolving at the time of the FSAI audit
- DAFM has carried out a significant amount of training in respect of rolling out a detailed audit system
- Comprehensive audits by DAFM were observed in many cases with good level of follow-up being carried out
- In some other cases, certain important deficiencies had not been highlighted during DAFM audits of liquid milk establishments
- The FSAI audit team observed that certain deficiencies detected during DAFM audits of establishments had also not been corrected in a number of cases by the food business operators
- DAFM checklists associated with SOP 17/2012 were in many cases, not appropriate or relevant for the liquid milk establishments to be audited and could not be considered as fully comprehensive or fit for purpose
- The lack of detailed and specific checklists for the performance of veterinary inspector audits in liquid milk establishments cannot ensure that a consistent and uniform approach for assessments is carried out
- Further work needs to be carried out by the Veterinary Public Health Inspection Service at central level in order to review procedures to be used for the performance of official controls. This is needed in order to ensure that the inspectors are clearly informed as to which procedures and requirements are relevant
- Obsolete procedures (in relation to liquid milk) should be clearly flagged or archived on the e-zone intranet system

- The new audit approach adopted by DAFM will also need to ensure that unannounced official controls are also carried out. This will need to be taken into account in any amendments to the current DAFM SOP 17/2012, where there may need to be an ad-hoc inspection component factored in, in order to be fully effective
- The audit team considers that Regional Superintending Veterinary Inspectors have an important role to play in terms of verifying the effectiveness of DAFM official controls at liquid milk establishments. Their role in this regard needs to be incorporated more fully into the auditing procedure SOP17/2012, where it is currently not captured
- A highly automated system for the performance of DAFM official controls in relation TB and Brucellosis disease eradication is in place, which is coordinated at central level by the Eradication of Animal Disease Division, and implemented regionally by the District Veterinary Offices
- The audit team observed that in one instance there was a lack of communication of six consecutive antibiotic non-compliant results for one herd owner in 2013. They were not conveyed by DAFM Veterinary Medicines Division at central level to the District Veterinary Office, who would have carried out an inspection as part of their follow-up had they been aware of these results. The herd owner was visited by the milk purchaser but was not delisted as an approved supplier
- When a positive bTB test is detected on farms supplying milk, the private veterinary practitioner is required to advise the herd owner verbally, to withhold milk from collection for liquid milk supply. The lack of the requirement to record this important communication as evidence that this advice has been given, is considered as a weakness in the current control system of controls. Because milk collections occur frequently on a daily basis, prompt and real time communications aimed at preventing supply, are considered as important steps in the interests of food safety, public health and animal health. Formal notifications by DAFM with herd owners in relation to restrictions on raw milk supply are retrospective to the private veterinary practitioner's verbal advice
- DAFM documented procedures do not currently describe how consignments of milk originating from outside ROI are verified as complying with the animal health requirements and raw milk criteria listed in Regulation (EC) No 853/2004; Annex III; Section IX
- This report makes a number of findings requiring corrective action which, in the view of the audit team, if implemented nationally, should enhance the effectiveness of the system of official controls for the supply of liquid milk for human consumption

3. INTRODUCTION

3.1. Audit Objective

The FSAI is responsible for the enforcement of food legislation in Ireland which is carried out through a series of 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. DAFM has entered into a service contract with the FSAI and is responsible for the enforcement of food legislation as it applies to liquid milk establishments. It is a requirement of the service contract and food legislation that 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. The objective of this audit was to verify the effectiveness and appropriateness of DAFM official controls related to liquid milk. This audit was carried out as part of the FSAI's audit programme for 2013/2014.

3.2. Audit Scope

The audit covered the organisation, planning, implementation and review of official controls in DAFM in relation to liquid milk, in order to confirm compliance with the requirements of the FSAI Service Contract, Regulation (EC) No 882/2004 and the Multi-Annual National Control Plan.

The audit of DAFM official controls involved the Veterinary Public Health Inspection Service but also included other relevant sections associated with controls in relation to liquid milk, e.g. the Eradication of Animal Disease Division, the Milk Hygiene Division and DAFM controls at District Veterinary Offices, in order to gain full oversight of the DAFM system of official controls in the liquid milk sector.

3.3. Audit Criteria and Reference Documents

- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998), as amended
- [Service Contract](#) between the FSAI and the Minister for Agriculture, Food and the Marine (Revision 4 – 08/01/2013)
- National Control Plan for Ireland 2012-2016
- [Regulation \(EC\) No 178/2002](#) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, as amended
- [Regulation \(EC\) No 852/2004](#) on the hygiene of foodstuffs, as amended
- [Regulation \(EC\) No 853/2004](#) laying down specific hygiene rules for food of animal origin, as amended
- [Regulation \(EC\) No 854/2004](#) laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, as amended
- [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
- [Regulation \(EC\) No 2073/2005](#) on microbiological criteria for foodstuffs, as amended
- European Communities (Food and Feed Hygiene) Regulations, 2009 ([S.I. No. 432 of 2009](#)), as amended
- Other relevant legislation detailed in the FSAI Service Contract
- Relevant guidance notes/codes of practice and trader notices
- Relevant FVO and DAFM internal audit reports
- DAFM Documented Procedures, business plans and relevant data supplied to the FSAI

3.4. Audit Methodology

This audit of official controls was undertaken using the FSAI Audit Procedure which is included in the FSAI Quality Management System. This and other procedures implement the FSAI audit obligations, defined in Schedule 5 of the Service Contract between the FSAI and DAFM, and are in accordance with the requirements of Regulation (EC) No 882/2004 (including Article 6.1 of Commission Decision 2006/677/EC) and also the FSAI Act.

An evaluation plan describing the audit process and approach (including the scope, objectives, criteria and the audit team) was sent to the Veterinary Public Health Inspection Service and the Eradication of Animal Disease Division before commencement of the on-site activities. As part of the desktop element of this audit, a review of relevant information held within the FSAI was also carried out ahead of on-site activities.

The audit included a review of the performance and delivery of official controls by DAFM at central, regional and local levels. The audit team evaluated whether official controls were being carried out in accordance with DAFM's own documented procedures which are used to implement the service contract requirements with the FSAI and related legislation.

The audit team also assessed the adequacy and performance of controls at the establishment level in relation to the implementation of good hygiene practices and principles of Hazard Analysis Critical Control Point (HACCP) as part of the food business operator's food safety management system.

On completion of the on-site visits to establishments, the audit findings relevant to each food business operator were verbally outlined by the FSAI audit team. The food business operator was informed that follow-up in relation to these would be carried out by the Veterinary Public Health Inspection Service and that the FSAI would communicate the audit findings in writing to DAFM following completion of the audit.

Following the audits conducted in each of the DAFM regions, a final closing meeting was also held at DAFM central level which included representatives from the Veterinary Public Health Inspection Service, the Eradication of Animal Disease and Milk Hygiene divisions of DAFM.

4 AUDIT FINDINGS

4.1 Audit Findings – Veterinary Public Health Inspection Service

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 performance of the official controls and lays down operational criteria for the competent authority.

Findings

DAFM has the responsibility for carrying out official controls in accordance with the requirements of the service contract with the FSAI, Regulation (EC) No 882/2004, Regulation (EC) No 854/2004 and DAFM's own business plans as part of service delivery.

The Veterinary Public Health Inspection Service is organised at central, regional and local levels and is responsible for the supervision of liquid milk establishments falling within the scope of the FSAI audit.

At central level, the Veterinary Public Health Inspection Service coordinates the activities of DAFM official controls through five veterinary public health regions. Each region comes under the responsibility of a Regional Superintending Veterinary Inspector. The five Veterinary Public Health Inspection Service regions are: East, North East, South East, South and West. Veterinary inspectors from the Veterinary Public Health Inspection Service are responsible for the supervision and performance of official controls at liquid milk establishments.

The Milk Hygiene Division within DAFM deals with administrative support to a number of different divisions responsible for food safety including the Veterinary Public Health Inspection Service and the Dairy Produce Inspectorate. The administrative assistance provided includes formal communications with the food business operators in the areas of registration and licensing, dissemination of relevant trade information, issuing of sampling results and notification of breaches of legislation.

In the three Veterinary Public Health Inspection Service regions audited, a structured and well organised approach for the performance of official controls at liquid milk establishments was in place and the audit team was satisfied that in general, sufficient numbers of DAFM staff had been provided to deliver official control requirements.

4.1.2 Registration/Approval of Establishments

Article 31 of Regulation (EC) No 882/2004 requires Member States to establish procedures for the registration/approval of food and feed business establishments, for reviewing compliance with conditions of approval and for the withdrawal of approvals.

Article 4 of Regulation (EC) No 853/2004 requires that establishments handling products of animal origin shall not operate unless the competent authority has approved them.

Findings

A list of approved liquid milk establishments and associated milk purchasing food business operations, i.e. food business operators dealing with collection and supply of raw milk from herd owners, was forwarded to the audit team by the Milk Hygiene Division of DAFM. This list is maintained on the DAFM website via the following link - [Milk & Dairy Establishments approved and/or registered under S.I. No. 432 of 2009](#).

In the Southern Veterinary Public Health Inspection Service region, seven liquid milk establishments were approved by DAFM at the time of the audit

Three establishments were not in operation in the Veterinary Public Health Inspection Service Southern region at the time of the audit:

- One establishment had ceased liquid milk production in January 2014 (a copy of the voluntary cessation was provided to the audit team)
- One establishment had also ceased liquid milk production (in 2013) however, continued with its cheese production and consequently, was supervised by the Dairy Produce Inspectorate and no longer came within the remit of Veterinary Public Health Inspection Service
- One establishment was not in operation at the time of the audit due to the seasonal nature of liquid milk production and was due to resume production in March 2014

In the Western/North Western Veterinary Public Health Inspection Service region, six liquid milk establishments were listed as approved by DAFM at the time of the audit.

- One establishment had ceased liquid milk production and an e-mail (dated 26th September 2013) indicating their voluntary cessation was provided.
- One establishment had closed and the revocation of approval letter (dated 13th May 2013) was provided to the audit team.

In the Eastern region, two liquid milk establishments were listed as approved by DAFM at the time of the audit.

The audit team confirmed that the DAFM register of approved establishments was being maintained by the Milk Hygiene Division and accurately reflected the list of food business operators assessed in the Veterinary Public Health Inspection Service regions audited.

In some cases, the approval for the liquid milk establishment also covered the collection and handling of raw liquid milk, i.e. where the establishment was responsible for both the purchasing and processing of the milk. In these cases, both activities were covered by the same approval number.

In other cases, the milk purchasers involved in the collection and handling of raw milk were an entirely separate entity and therefore, the purchasing and processing of the milk were covered by separate approval numbers. Liquid milk establishments are approved under Regulation 4 of S.I. No. 432 of 2009. Milk purchasers are registered under Regulation 3 and approved under Regulation 4 of S.I. No. 432 of 2009. Supervision of milk purchasing activities is carried out by the dairy produce inspectorate.

For a number of dairy establishments audited, due to the range of activities being carried out, they were supervised by both the Veterinary Public Health Inspection Service and dairy produce inspectorates. The Veterinary Public Health Inspection Service was responsible for supervision of liquid milk and dairy produce inspectorate for dairy products.

The audit team was advised by DAFM that all liquid milk establishments were authorised to 'heat treat' milk from herds restricted under the bovine TB or Brucellosis schemes. The Milk Hygiene Division regularly reviews the plant approval certificates and letters and updates them as necessary.

4.1.3 Coordination and Planning of Official Controls

Article 4.5 of Regulation (EC) No 882/2004, when within a competent authority, more than one unit carries out official controls, efficient and effective coordination and cooperation shall be ensured between the different units.

Findings

The audit team confirmed that there was a structured approach in place for the coordination and planning of Veterinary Public Health Inspection Service official controls between the DAFM central, regional and local levels. At a strategic level, the planning and delivery of Veterinary Public Health Inspection Service official controls at liquid milk establishments were outlined in the business plans (for 2012 and 2013) for the Veterinary Public Health Inspection Service division which were provided to the audit team.

Evidence was also provided in the form of agendas of meetings attended by official control staff at central, regional and local levels in relation to coordination of official control activities, their prioritisation and also for the review of performance delivery against the business plan requirements. Regular meetings were taking place between the central and regional levels and between the Regional Superintending Veterinary Inspectors as a group. In the Southern, Eastern and Western Veterinary Public Health Inspection Service regions, details of meetings between the Regional Superintending Veterinary Inspector and veterinary inspectors were provided.

In accordance with Article 4.5 of Regulation (EC) No 882/2004, when within a competent authority, more than one unit carries out official controls, efficient and effective coordination and cooperation shall be ensured between the different units. To support this requirement, evidence of communication was provided to the audit team by the Eradication of Animal Disease and Milk Hygiene divisions at central level, demonstrating their interaction regarding policy, administration and on-going support to the other DAFM divisions involved in liquid milk controls. The extent of communication and cooperation between the two DAFM inspectorates (dairy produce inspectorate and Veterinary Public Health Inspection Service) was not audited as the dairy produce inspectorate did not fall within the scope of the audit.

4.1.4 Prioritisation and Performance of Official Controls

Article 3 of Regulation (EC) No 882/2004 requires that official controls are to be carried out regularly, on a risk basis and with appropriate frequency.

Article 10 of Regulation 882/2004 requires tasks related to official controls shall, to be carried out using appropriate control methods and techniques such as monitoring, surveillance, verification, audit, inspection, sampling and analysis.

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.

Findings

The audit team confirmed that tasks relating to official controls at liquid milk establishments used a range of methods and techniques including audit, inspection, sampling and analysis. At local level, veterinary inspectors plan their frequency of official controls (for inspections/audits) in accordance with DAFM procedures (see Section 4.1.5 of this report).

Prioritisation and Frequency of Official Controls: Audits and Inspections

In 2012, and prior to the first audit being completed in 2013 as part of the new DAFM auditing approach, veterinary inspectors were planning their frequency of official controls for inspections in accordance with the DAFM SOP Milk 1 / 2006. A risk assessment was performed in order to determine the frequency of these visits to each establishment. The assessment criteria took into account the compliance history of the establishment, the response by plant management to corrective actions and legal notices, and also the adequacy of the plant food safety management system in place and the nature of the product in terms of its risk.

In 2012, inspection frequency for liquid milk establishments was typically carried out once every two months for routine inspections unless a higher frequency was required, based the risk assessment outlined above. The audit team saw evidence of this approach being applied in practice, where an increase in visit frequency to one per month for an establishment in the Veterinary Public Health Inspection Service Eastern region in 2012, was observed.

In another instance in the Eastern region in 2013, the audit team observed that the Veterinary Public Health Inspection Service veterinary inspector risk-assessed score had been incorrectly calculated for one establishment, and had not taken into account the results of enforcement action which should have resulted in an increase in visit frequency for this food business operator. Although not fully complying with DAFM procedures, the audit team was satisfied however, that between both the veterinary inspector and Regional Superintending Veterinary Inspector visits to this establishment, regular and active supervision of this particular food business operator was taking place at the time of the audit.

The audit team confirmed that in 2013, two veterinary inspector audits were in general, carried out at liquid milk establishments in accordance with SOP 17/2012 requirements. For establishments reviewed by the audit team, where a deviation had occurred from this target frequency to be achieved, this was attributable to food business operators not being in operation and consequently, audits were not applicable.

Prioritisation and Frequency of Official Controls: Sampling

The frequency of sampling at liquid milk establishments is decided by the Veterinary Public Health Inspection Service division at central level. At the time of the audit, the schedule had been issued from the Dairy Science Laboratories to the veterinary inspectors for each establishment.

The FSAI audit team reviewed the sampling schedules issued by the Dairy Science Laboratories for liquid milk establishments for a number of high, medium and lower throughput milk volume food business operations audited and also where enforcement action had been taken, e.g. Compliance Notices.

The audit team assessed whether higher throughput volumes and enforcement carried out resulted in increased sampling frequency and/or numbers to be taken as part of official controls to be performed. In general, no increase/decrease in the frequency of official controls and/or numbers of samples taken was observed. For liquid milk establishments, the frequency of official control sampling was monthly in 2012, once every two months in 2013 and moving to a quarterly sampling frequency for 2014. This was in line with Veterinary Public Health Inspection Service instructions.

The audit team verified that scheduling of sampling activities by veterinary inspectors at liquid milk establishments was required to take place in accordance with the sampling programme and regime decided by DAFM at central level. The sampling activities performed by the veterinary inspector in practice targeted the range of pasteurised liquid milk products produced at the establishment and also involved sampling from the liquid milk, filler heads. Evidence of sampling conducted for each of the three Veterinary Public Health Inspection Service regions visited was provided to the audit team. Although the Dairy Science Laboratories schedule the sampling at the primary frequency set out in SOP 1/2006 (Rev1 Nov 2012), the veterinary inspector may increase the level of sampling frequency in relation to issues identified at plant level.

Performance of Official Controls: Audits and Inspections

During 2012, DAFM official controls, i.e. audits and inspections, were in the process of changing over to a more 'audit focussed' system. The first full veterinary inspector audit conducted in 2013 was to mark the transition to full implementation of the new audit procedure SOP 17/2012, and routine inspections as per Milk SOP 1/2006 were expected to be discontinued.

Full food safety management system audits were in general, not conducted at liquid milk establishments during 2012. The audit team was informed however, by veterinary inspectors performing official controls, that verification of the effectiveness of the food safety management system was routinely being checked during inspections and sampling visits to the liquid milk establishments.

The FSAI audit team confirmed that veterinary inspector audits were being carried out at liquid milk establishments in 2013/2014 in accordance with SOP 17/2012 requirements. These audits were announced to the food business operator and where at least two weeks prior notice was given.

The FSAI audit team observed that, for many of the audits of liquid milk establishments reviewed, detailed assessments were performed. It was clear that in many cases, detailed preparations ahead of on-site assessments had also taken place which contributed to focused and thorough audits being conducted.

The audit team observed that the level of information recorded in contemporaneous notes and checklists was more detailed and more comprehensive for certain audits than for others. Variations in approach may however, have been due to the application of the new audit procedure which was still in the process of evolving at the time of the FSAI audit.

The audit team observed however, that:

- SOP 17/2012 did not detail following completion of audits, where the supporting audit documents used as part of veterinary inspector audits, should be retained and by whom. In one case, the contemporaneous notes and audit checklists were not available during the FSAI audit as the veterinary inspector had moved to another section of DAFM
- In another case, for one establishment veterinary inspector audit carried out in the Veterinary Public Health Inspection Service Eastern region, the *aide memoires* and contemporaneous notes completed during the audit had not been kept on file as per SOP 17/2012 requirements

In a number of instances, veterinary inspector audits had not detected some important deficiencies at liquid milk establishments and consequently, the audits for these establishments were not considered as being fully effective:

- For one establishment in the Southern region, the food business operator had not included cream in their food safety management system and consequently, their system of controls could not be considered as effective for this product. This had not been picked up during veterinary inspector audits of this establishment

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- For one establishment in the Eastern region, the critical limits for pasteurised milk were incorrectly being used for cream, which had also been identified during a DAFM audit of this establishment. However, this had not been included in the corrective action plan requiring remedial action to be taken and resulting in the finding not being corrected by the food business operator
- For another establishment in the Eastern region, the Flow Diversion Valve Verification could not be confirmed on the thermograph for the pasteurisation process, although it had been included in the food business operator's food safety management system as part of the verification of valve operation. This had not been picked up during veterinary inspector audits of this establishment
- Important deficiencies, both current and historic, were observed during the FSAI audit for one establishment in the Eastern region which required corrective action. The audit team acknowledges that appropriate and effective enforcement action was taken by DAFM to deal with certain unhygienic practices taking place on the day of the audit
- Packaging materials were being stored in curtain sided containers in the yard area for two establishments, i.e. for one food business operator in the Southern region and another in the Eastern region, which could not be considered as adequately pest proofed and suitable for this activity/operation

Performance of Official Controls: Sampling

Sampling activities in 2014 are required to be completed with the veterinary inspector as part of close-out of previous audits/inspections as per SOP 17/2012 Section 7.10.

In accordance with DAFM SOP 1/2006 (11/12) - Annex I, Section (B), part (c) Water sampling: '*Water samples are to be taken annually, one each for microbiological and chemical analysis*' which is also defined in Table 4 of Annex I of the procedure.

In the six liquid milk establishments visited, water samples were being taken to check for microbiological parameters in accordance with Milk SOP 1/2006 requirements, with the exception of one medium-sized liquid milk establishment in the Eastern region, which had been sampled in 2012 but not in 2013.

Chemical parameters for water are also required to be checked on an annual basis in accordance with Milk SOP 1/2006 requirements. The audit team observed that for four of the six liquid milk establishments audited, samples had been taken in 2012 and 2013 as per requirements. For one medium sized liquid milk establishment in the Veterinary Public Health Inspection Service Eastern region however, water sampling checking for chemical parameters had not been taken in 2012 and 2013. For a large liquid milk establishment in the Eastern region, a sample had been taken in 2012 but not 2013.

In the Veterinary Public Health Inspection Service Southern region, veterinary inspector audits were announced as required by SOP 17/2012. The audit team was informed however, that from a practical viewpoint, sampling activities also tended to be announced to the food business operator.

Consequently, because veterinary inspector sampling visits were required to also coincide with the follow-up inspections to be conducted, i.e. as per DAFM instructions from central level, the audit team was informed that it was proving difficult to carry out an unannounced element to official controls at liquid milk establishments. This could not be considered as fully meeting the requirements of Article 3 (2) of Regulation (EC) No 882/2004.¹

¹ DAFM response to finding: Prior arrangements are required for the success of an audit by ensuring that key management personnel and all necessary documentation (hard copy and electronic) are available on the day. However, SOP 17/2012 is being amended to provide for un-announced inspections.

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 and must keep these procedures up-to-date.

Article 4.4 of Regulation 882/2004 requires that competent authorities shall ensure the impartiality, quality and consistency of official controls at all levels.

Findings

DAFM carries out official controls in accordance with documented procedures which contain information and instructions to staff. The main procedures used by DAFM included a combination of Veterinary Procedural Notices (VPNs) and Standard Operating Procedures (SOPs), associated checklists and specific records and forms.

The computerised system for management of DAFM documented procedures is the 'e-zone' intranet and is used to provide access, control, updates to SOPs and VPNS.

Relevant procedures in use by Veterinary Public Health Inspection Service in liquid milk establishments:

- MILK 1/2006 Official Controls at Milk Pasteurising Plants ((11/12) Rev 01)
- SOP/017/2012 Audits of Food Business Operator Food Safety Management System (Date of Issue 9/11/2012)
- SOP 013/2011 Food and Drinking Milk Complaints Investigation & Reporting (Rev 01)
- VPN 4/2011 Verification by Veterinary Inspectors of compliance by Food Business Operators with Regulation 2073/2005 (as amended) on Microbiological Criteria for Foodstuffs in DAFF approved plants (Date: March 2011)
- VPN 5/2004 Self-monitoring Program for Residues by Primary Processing Plants (Date: 16th June 2004)

The Milk SOP1/2006 and SOP/017/2012 are the main procedures used for the performance of veterinary official controls at DAFM liquid milk establishments. The procedure itself provides a structured and clear approach for the on-site audit assessments to be carried out. However, SOP 17/2012 and associated checklists will need to be reviewed and updated in order to be fully effective. At the time of the FSAI audit, the transition between both DAFM procedures was still a work in progress. Although SOP 17/2012 was being used in practice, elements of the previous Milk SOP 1/2006 continued to be used. This was not in accordance with the planned changeover requirements specified in both procedures.

In the Veterinary Public Health Inspection Service regions visited, it was unclear as to what aspects of the previous Milk SOP1/2006 were obsolete or should still be retained and/or be used for the performance of official controls at liquid establishments as several aspects remained relevant but had not been incorporated into the new audit procedure and/or associated checklists.

The audit team observed variation in the use of certain forms and checklists, which related to Milk SOP 1/2006, and which had been replaced by SOP 17/2012. These were still being used in certain Veterinary Public Health Inspection Service regions audited whilst not in others and consequently, an inconsistent approach regarding their application was observed.

For example:

- The standalone check report form (SCR1) from Milk 1/2006 for milk pasteurising plants continued to be regularly used in all regions
- The HACCP Pre-requisite Form from Milk 1/2006 SOP was being used regularly for some regions and infrequency for others

During the audit of DAFM official controls at central level, it was unclear as to whether certain VPNs were still required to be used or remained relevant for the performance of official controls at liquid milk establishments. As a result, variations were observed by the audit team regarding their use at liquid milk establishments for 2012 and 2013, which was viewed as inconsistent.

For example:

- VPN 5/2004: *Self-monitoring Program for Residues by Primary Processing Plants* (16th June 2004) was being used routinely to assess food business operator controls in relation to self-monitoring for residues, for one establishment in the southern region for 2012 and 2013. In general however, it was not being used in other Veterinary Public Health Inspection Service regions
- Variation in the use of VPN 4/2011: *Verification by Veterinary Inspectors of compliance by Food Business Operators (FBOs) with Regulation 2073/2005 (as amended) on Microbiological Criteria for Foodstuffs in DAFF approved plants* (Date: March 2011) was seen with its use throughout the DAFM Veterinary Public Health Inspection Service regions. Variations ranged from frequent four times in 2012 and once in 2013 for one establishment in the Veterinary Public Health Inspection Service Southern region to less regular use, once in 2011 for one establishment in the Veterinary Public Health Inspection Service Western region.

The audit team concluded that clear direction will be required from DAFM at central level in order to determine the status of these procedures and ensure a consistent approach to their usage.

Checklists developed for audits required by SOP 17/2012 and to be used for assessing compliance and effectiveness of controls at liquid milk establishments are in many cases, more relevant and more specific to meat establishments, i.e.

- Veterinary Public Health Inspection Service Audit - HACCP Audit (Date 14/08/2012): Section 5.3 Hazard Analysis Assessment refers to meat temperature and maximum levels of preservatives. The Critical Control Points (CCPs) section lists only CCPs for carcass chilling and final carcass inspection. No CCPs relevant to milk are mentioned
- Veterinary Public Health Inspection Service Audit - Operational Hygiene Audit (Date 14/08/2012): The checklist refers to cutting plants, minced meat/meat preparations, mechanically separated meat/meat products. However, there is no mention of liquid milk establishments
- Veterinary Public Health Inspection Service Audit – Food Safety Management System Audit Plant & Equipment (Date 14/08/2012): Calibration of equipment doesn't cover in detail the specific checks for milk processing equipment including calibration of holding tube, flow diversion valve and temperature monitoring devices
- Veterinary Public Health Inspection Service Audit – Food Safety Management System Audit End Product Testing (Date 14/08/2012):

Within the scope of the checklist, a section for milk is referenced. However, no section dealing with milk exists

in the content. The checklist gives requirements for minced meat, meat preparations, meat products, ready-to-eat foods and mechanically separated meat.

In the context of milk, i.e. as a ready-to-eat food, criteria specific to liquid milk are also not covered in this section of the checklist.

The checklist only includes end-product testing and consequently, SOP 17/2012 does not include verification of the process hygiene criteria requirements of Regulation (EC) No 2073/2005. Currently, Veterinary Public Health Inspection Service veterinary inspectors generally do not carry out sampling for in-process hygiene criteria and consequently, Veterinary Public Health Inspection Service assessments are reliant on effective verifications to be carried out during audits of the establishment which are not defined or referenced in SOP 17/2012 or associated checklists.

It was also not entirely clear how this checklist, i.e. Food Safety Management System Audit End Product, cross-referenced with and/or relates to another Veterinary Public Health Inspection Service checklist, i.e. VPN 4/2011: *Verification by veterinary inspectors of compliance by FBOs with Regulation (EC) No 2073/2005 on Microbiological Criteria for foodstuffs* in DAFM approved plants, which was also being used by certain Veterinary Public Health Inspection Service veterinary inspectors at liquid milk establishments.

DAFM checklists associated with SOP 17/2012 are in many cases, not appropriate or relevant for liquid milk establishments to be audited and could not be considered fully comprehensive or fit for purpose. The lack of detailed and specific checklists for the performance of veterinary inspector audits in liquid milk establishments cannot ensure that a consistent and uniform approach for assessments is carried out.

4.1.6 Identification, Follow-up and Close-out 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 that 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.

Findings

In accordance with SOP 17/2012, following veterinary inspector audits, a corrective action plan is issued to the food business operator detailing the actions to be taken and the timeframes for delivery and is monitored for its completion. These procedures and process as observed by the FSAI audit team are generally effective in meeting the requirements of Regulation (EC) No 882/2004 and Regulation (EC) No 854/2004. In general, DAFM non-compliances were being followed up and closed out in most cases, subject to certain exceptions.

The audit team confirmed that regular enforcement action was being taken by DAFM when required, in order to deal with significant non-compliances detected at food establishments and these were appropriate and effective.

Complaints

In general, food complaints were being followed and closed out in accordance with DAFM SOP 13/2013 requirements.

The audit team selected a number of food complaints that had arisen in 2011, 2012 and 2013 and assessed whether DAFM's own procedures were being followed. The audit team confirmed that DAFM had adhered to its

SOP 13/2011, i.e. the Food and Drinking Milk Complaints SOP, in dealing with both complaints and that detailed records had been kept on file. These included details of the food business operator's investigation of the complaint itself and of the associated verification, follow-up and close-out by DAFM.

However, in the case of one complaint that had been investigated by the liquid milk establishment, both the FSAI and DAFM were provided with incorrect information by the food business operator. Following this discovery, DAFM issued an enforcement notice on the food business operator which was considered an appropriate means of dealing with this issue identified.

4.1.7 Verification and Review of Official Controls

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 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 corrective action is taken when needed and to update documentation as appropriate.

Findings

At a strategic level, target delivery and performance are specified in the DAFM Veterinary Public Health Inspection Service business plan which is assessed by central management on an annual basis and copies of the business plan for both 2012 and 2013 were provided to the audit team.

At an operational level, performance delivery links directly with the performance management system, where a role profile is completed by veterinary inspectors and is assessed by the Regional Superintending Veterinary Inspector. The audit team confirmed that for each veterinary inspector inspecting liquid milk establishments, role profiles were assessed by the Regional Superintending Veterinary Inspector following a review of performance delivery. Dates of these reviews were provided to the audit team.

The approach used by Regional Superintending Veterinary Inspectors to review the effectiveness of veterinary inspector official controls in relation to liquid milk establishments for 2012/2013 is as follows:

- Regional Superintending Veterinary Inspectors review veterinary inspector reports for audits of liquid milk establishments and propose amendments and changes as required
- The audit team was informed by the Regional Superintending Veterinary Inspectors that veterinary inspector controls were monitored via the quarterly ARM1 reports which are the veterinary inspector returns on official controls performed for each plant
- It was the Regional Superintending Veterinary Inspector's intention going forward, to attend a certain percentage of veterinary inspector audits conducted
- Throughout 2013, Regional Superintending Veterinary Inspectors attended a number of veterinary inspector audits either as an observer or as an audit team member

- Sampling plans were received by the Regional Superintending Veterinary Inspector from veterinary inspectors for liquid milk establishments for 2012 and 2013

For the period 2012 and 2013, Regional Superintending Veterinary Inspector activities were being planned and scheduled in accordance with an annual risk assessment. This was in order to determine the frequency of visits to each establishment and for the review of the delivery of official controls by DAFM staff. Although in most cases these were carried out, some exceptions were observed:

- The audit team observed that, generally Regional Superintending Veterinary Inspector visits were taking place at liquid milk establishments in accordance with the minimum risk-based frequency levels to be performed. In a number of cases, these had not been carried out for two liquid milk establishments in 2012/2013 in the Western region and also for one in the Eastern region in 2013

In the Southern Veterinary Public Health Inspection Service region, the audit team confirmed that all Regional Superintending Veterinary Inspector visits had taken place in accordance with the risk-assessed frequencies allocated to establishments in this region.

At the time of the audit, a copy of a proposed amendment to SOP 17/2012 was provided to the FSAI team where Regional Superintending Veterinary Inspectors were writing their oversight role into the procedure. This was considered as a useful and practical improvement to the current SOP subject to it being approved by DAFM at central level and will assist fulfilment of the requirements Article 8.3 of Regulation (EC) No 882/2004 if inserted into the procedure. The audit team's view is that Regional Superintending Veterinary Inspectors have an important role regarding both oversight and verification of the effectiveness of official controls conducted at liquid milk establishments and this amendment will reflect that role.

At national/central level, DAFM has developed a system of internal audits in line with Article 4.6 of Regulation (EC) No 882/2004 and the FSAI Service Contract. An audit of Veterinary Public Health Inspection Service official controls in liquid milk plants was carried out in 2011 and a follow-up corrective plan was provided which indicated that the findings raised had been closed out.

4.1.8 Reports to Food Business Operators

Article 9 of Regulation (EC) No 882/2004 requires that competent authorities 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 food business operator with a copy of the report on official controls carried out, at least in case of non-compliance.

Findings

In accordance with Section 7.8 of SOP 17/2012, copies of the veterinary inspector audits report and associated corrective action plan template are to be forwarded to the food business operator. In general, the audit team observed that reports were detailed and well documented and a corrective action plan was issued to the food business operator detailing the actions to be taken and the timeframes for delivery which is monitored for its completion.

Similarly, for inspections carried out at DAFM liquid milk establishments where non-compliances occur, a corrective action report is issued to the food business operator which details the corrective action to be carried out and the time frames for completion.

4.1.9 Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure 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 confirmed that in 2012/2013 for all Veterinary Public Health Inspection Service regions, specific training in auditing of food safety management systems had been carried out prior to the rolling out of the new procedure SOP 17/2012. In virtually all cases, the training had been attended by both veterinary inspectors and Regional Superintending Veterinary Inspectors in the Veterinary Public Health Inspection Service regions (including those supervising liquid milk establishments) and also by DAFM at central level.

In addition, the use of an audit team approach, the rotating audit team members and the attendance by Regional Superintending Veterinary Inspector at veterinary inspector audits to be conducted, allows for continued, practical, on-the-job training to be carried out.

4.1.10 Veterinary Public Health Inspection Service Official Controls performed in Liquid Milk Establishments

Article 4 of Regulation 854/2004 requires the competent authority to carry out official controls in order to verify food business operators' compliance with the requirements of Regulation 852/2004 and Regulation 853/2004.

As part of the audit of DAFM official controls, six liquid milk establishments were visited in order to confirm their compliance with legislation requirements. A report of the results of this on-site audit verification at these establishments has also been sent to DAFM. Although in many cases, the food business operator level of compliance was considered satisfactory and where effective food safety management systems were considered to be in place, in a number of other instances, important deficiencies were also observed. In these cases, corrective action has been requested to remedy non-compliances where they have occurred.

4.2 Audit Findings ~ DAFM Eradication of Animal Disease Division and District Veterinary Offices Controls relating to Liquid Milk

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

4.2.1 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.

Article 4(2)c The competent authorities shall ensure: that they have, or have access to, an adequate laboratory capacity for testing and a sufficient number of suitably qualified and experienced staff so that official controls and control duties can be carried out efficiently and effectively.

Findings

DAFM is the competent authority for the implementation of controls in the area of animal health, animal welfare and also for particular areas relating to public health and food safety. The Eradication of Animal Disease Division is responsible for developing and managing the Bovine TB and Brucellosis policy framework for national disease eradication programmes. These programmes are operational throughout Ireland and are managed through administrative areas each served by District Veterinary Offices.

Activities of District Veterinary Offices are co-ordinated in a regional structure, which come under the control of an Area Management Team. Ireland is divided into two Area Management Team regions, i.e. North and South. Each District Veterinary Office has a veterinary manager (superintending veterinary inspector), technical manager and includes a team of administrative staff, technical agricultural officers and veterinary inspectors.

The audit team visited DAFM Eradication of Animal Disease Division at central level and three District Veterinary Office divisions at regional level, as part of the audit of DAFM official controls directly applicable to liquid milk supply.

At the time of the audit, the service at regional level was undergoing a reorganisation process where activities were being coordinated through more centralised, regional offices. This will result in an overall reduction in the number of District Veterinary Offices. An IT system-based approach had been rolled out nationally and electronic documentation had also replaced paper-based records.

4.2.2 Coordination and Planning of Official Controls

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

The audit team confirmed that there was a structured and well organised approach in place for the coordination and planning of official controls.

The TB eradication programme is implemented by means of an automated and interlinked IT system of controls (the Animal Health Computer and the Animal Identification and Movement systems). This ensures that controls relevant to the eradication and control of TB are implemented nationally through each regional District Veterinary Office.

DAFM at central level, outlined its interpretation in relation to positive bovine Tuberculosis (bTB) results. In its view, a 'test positive animal' is an "animal showing...a positive reaction to the prophylactic tests..." and therefore, legal restrictions on the use of milk from a bTB test positive animal apply from the moment it is identified.

In such instances, these are considered as 'TB breakdowns' and DAFM controls to deal with these notifications at District Veterinary Office level are organised as part of the operation of the Animal Health Computer and Animal Identification and Movement automated IT systems. In addition, the Agriculture Field Inspection and Test system is used for scheduling and recording inspections. Official controls are carried out also using the procedures referenced in Section 4.2.4 of this report.

The FSAI audit team was primarily interested in milk production holdings which were the subject of a TB

breakdown, i.e. within the District Veterinary Offices selected for audit. This was to confirm that an adequate and robust system of officials was in place for overseeing the supply of liquid milk from production holdings preventing its supply to liquid milk establishments in accordance with the requirements of Regulation (EC) No 853/2004. Regulation (EC) No 853/2004; Annex III; Section IX; Chapter I. I. 4 requires that *“Raw milk and colostrum from any animal not complying with the appropriate requirements of points 1 to 3, and in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC, must not be used for human consumption.”*

In addition to responsibilities as part of the national disease eradication programme, the District Veterinary Office is also required to carry out official controls on holdings (inspections of herd owners which also include liquid milk suppliers) in relation to their controls of veterinary medicines used for livestock and in order to confirm that the correct withdrawal periods are respected.

The audit team observed in one instance however, because of a lack of internal communication within DAFM, several antibiotic non-compliant results for one herd owner in 2013 were not conveyed by DAFM's Veterinary Medicines Division at central level to the District Veterinary Office at regional level. The audit team was informed by the District Veterinary Office that had they been aware of these results, this would have triggered an on-farm follow-up inspection in order to assess the herd owner's control and usage of veterinary medicines where the withdrawal periods for these would have been checked. Consequently, no inspections were scheduled by the district veterinary office for this herd owner in 2013.²

The audit team's view is that this lack of communication was not in accordance with the requirements of Article 4(5) of the Regulation 882/2004 requirements, where efficient and effective coordination and cooperation shall be ensured between the different units of a competent authority where more than one unit carries out official controls (see Section 4.1.6 for more details).

4.2.3 Prioritisation and Performance of Official Controls

Findings

At District Veterinary Office level, both veterinary and technical agricultural officers carry out inspections in line with circulars/Standard Operating Procedures and/or manuals. The main areas of involvement for field staff are:

- Eradication schemes (TB and lesser extent Brucellosis) including holding registration, ruminant identification, dealers, marts
- International trade and to a lesser extent, contingency planning
- Veterinary medicines, animal welfare, Class B diseases and animal breeding
- Animal by-products
- Aquaculture inspections carried out by veterinary inspectors in Area Management Team divisions

Inspections were carried out by field staff at liquid milk holdings, i.e. farms, and these were managed using both the Agriculture Field Inspection and Test and the Animal Health Computer systems. DAFM outlined its approach to bTB positives and the official controls required at regional District Veterinary Office level.

The audit team was informed that when a herd producing milk for sale is restricted for TB, the District Veterinary Office contacts the keeper/herd owner by phone to establish the name of any milk purchaser(s). The procedure is outlined in Circular ER 11 of 2012. The procedure outlined in Circular ER 11 of 2012 however, does not require the District Veterinary Office to confirm that the keeper is already aware of the restrictions placed on the use of

² DAFM response to finding: DAFM's Veterinary Medicines Division has put in place a procedure under the Self-Monitoring Regime to report multiple positive results from the same herd owner to the Regional Office for follow-up action and/or targeting of the herd for inspection. Proposed completion Date: Complete (Q1 2014).

milk (1) from the TB reactor(s) or (2) from the rest of the herd. The responsibility for this communication has been delegated by DAFM in the first instance to the private veterinary practitioner as part of the important advice delivered to the herd owner, following a positive bTB test.

Formal communication by the District Veterinary Office with both the milk purchaser, i.e. the food business operator approved by DAFM for collection of raw milk, see Section 4.1.2 of this report, and the herd owner, is made via the following notification forms - ER122A, ER20 and ER22 (see Section 4.2.4 for details). These documents provide the first verifiable communication/notification by DAFM to the herd owner, that milk from 'reactor cows' should not be sent to liquid milk establishments.

Visits to milk production holdings as a result of 'TB breakdowns' are carried out in accordance with the requirements of DAFM Circular 06/09 (Ver. 6). These visits are required to take place within five days of receipt of the positive result and either a technical agricultural officer or veterinary inspector can be involved in performing inspections. Generally, visits do not take place for single reactors in accordance with ER 06/09 requirements. However, for two or greater reactors, inspections take place.

The audit team confirmed certain instances where ER 0/09 requirements were not strictly followed.

- In some cases, the audit team observed that inspections did not always take place within the five-day period, i.e. as per ER06/09 and instructions provided to the audit team from the District Veterinary Offices, in accordance with planned arrangements.³

DAFM communications and interventions although well organised and structured, are retrospective to the initial bTB positive test. They are triggered typically following the entry of the test data by the private veterinary practitioner on the Animal Health Computer system and following interpretation of the test results by the District Veterinary Office.

In some cases, the audit team observed delays between communications by the District Veterinary Office to the herd owner and the milk purchaser.^{4,5} These communications and also the advice given by the private veterinary practitioner to the herd owner in the event of 'TB breakdowns', i.e. to withhold milk from supply, are considered important elements of the DAFM system of official controls.

The DAFM procedure ER4 outlines the conditions and instructions for veterinary practitioners involved in testing and sampling under the Bovine Tuberculosis and Brucellosis Eradication Programme.

The lack of a requirement to record communication of important advice by the private veterinary practitioner to the herd owner to withhold milk from supply in the case of a positive bTB result, is considered as a weakness in the current system of controls. The audit team's view is that this should be strengthened in the interest of public health/food safety and in order to ensure that objectives of Regulation (EC) No 853/2004 and (EC) No 854/2004 are met.⁶

During contact between the District Veterinary Office and the herd owner (in relation to positive bTB test), the herd owner in these cases is asked by District Veterinary Office staff to provide details about establishments being

³ DAFM response to finding: It is unusual for visits not to take place but it can happen due to staffing/additional controls, average delay is 10%. Staff will be reminded again of the five day goal.

⁴ DAFM response to finding: An automatic email notification system is being implemented to notify the milk purchaser which will ensure timely notification.

⁵ DAFM response to finding: District Veterinary Offices will be reminded of the requirement to contact the herd owner in a timely manner once notification of a positive test is received from testing vet.

⁶ DAFM response to finding: It is proposed to amend the private veterinary practitioner notification of test results to include a tick box to allow the private veterinary practitioner indicate that they have advised the farmer to withhold milk from any reactor animals.

supplied with raw milk, i.e. from their farm where positive bTB animals have been identified.⁷ A log of calls to herd owners was only being kept in one of three District Veterinary Offices audited.

A register of all milk purchasers/processing establishments is maintained by DAFM's Milk Hygiene Division and is used by the District Veterinary Office to notify milk purchasers and milk processing establishments of positive bTB tests confirmed on farm, where the herd owner is a supplier of liquid milk. The register also includes DAFM inspectors to be contacted in these instances and is located on DAFM the e-zone system.

The audit team confirmed at liquid milk establishments that in general, communication by the herd owner with the milk purchaser, i.e. in accordance with DAFM Trader Notice DH2/2012, does not happen in practice.

The milk purchaser and liquid milk establishment are in general, informed about 'TB breakdowns', i.e. from farms supplying milk to them, via the ER122A notifications from the District Veterinary Office.⁸ The requirements of DAFM Trader Notice DH2/2012 are therefore, not being met in this regard.

4.2.4 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 and must keep these procedures up-to-date.

Findings

The Eradication of Animal Disease Division has developed a series of documented procedures which describe how official controls are carried out at District Veterinary Office level. The following procedures in relation to TB controls relating to liquid milk relevant to the audit are listed below:

- Circular ER 06/09 - Arrangements with regard to official controls applied by DAFM in respect of:
 - (A) Restriction of holdings arising from 'reactor disclosure'
 - (B) Protocol for visits to restricted holdings, management of at risk contiguous herds and quality control checks on TB eradication programme
 - (C) Reactor collection system
 - (D) Completion of specified disinfection requirements
 - (E) Animal trading premises
 - (F) Bovine farm premises registration, and
 - (G) At local authority supervised slaughter premises
- Circular ER 11/ 2012 – notifying milk purchaser of herd restriction and de-restriction
- ER 4: - Conditions and instructions for veterinary practitioners involved in testing and sampling under the Bovine Tuberculosis and Brucellosis Eradication Programme
- TN DH2/2012, i.e. for food business operators: Reminder re: obligations regarding the collection of raw milk from bovine dairy herds restricted due to TB and or Brucellosis
- Forms
- ER 122A/B – Form to notify milk purchaser of herd restriction/de-restriction
- ER20 – Notice of reactor animal(s) and inconclusive reactor(s) in a herd
- ER20B – Notice of inconclusive reactor animal(s) for restriction and isolation in a non-reactor herd

⁷ DAFM response to finding: District Veterinary Offices will be reminded to log calls made to farmers in relation to the restriction of their herd.

⁸ DAFM response to finding: Experience in the North West is that generally the farmer does phone the plant, and the plant records the call. This is built into the plant SOP. Did not see the FSAI point demonstrated at either North West region plants visited.

- ER20 D – (derogated) Notice of inconclusive reactor animal(s) for restriction and isolation in a non-reactor herd.
- ER 20F – Suspect TB lesion at slaughter
- ER22 – Notice declaring a holding a restricted holding
- ER 23 - Notification regarding restrictions on a holding

Subject to a number of exceptions, DAFM procedures and records were in general, sufficiently detailed and provided clear instructions to staff performing official controls.

ER4, Section F, i.e. Advice to Keepers: requires private veterinary practitioners carrying out bTB testing to advise keepers, i.e. herd owners, that:

- Milk from reactor/inconclusive animals may not be used for any purpose even if heat-treated
- Milk from healthy animals belonging to reactor herds may not be used for the manufacture of heat-treated milk or for the manufacture of milk-based products unless it is first heat-treated at an establishment authorised by the Department

The advice given to the keeper/herd owner is however, verbal and no written communication is required in the current DAFM procedure (ER No.4) in order to confirm that this requirement has actually been met.

At District Veterinary Office level, the audit team was informed that the Animal Health Computer system could easily be adapted to include confirmation that timely and verifiable advice had been provided to the herd owner in relation to:

- Public health risks to the herd owner and family from drinking raw milk
- Compliance with food law as laid down in Regulation (EC) No 853/2004
- Compliance with animal health rules

ER 06/09 does not detail when a restricted herd visit report should be completed.⁹

During the course of the audit, inconsistent terminology was identified between a number of DAFM forms. These were promptly corrected by DAFM at central level.

4.2.5 Identification, Follow-up and Close-out 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 that 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.

Findings

The audit team observed in one instance, a lack of communication of non-compliant results for five consecutive antibiotic positives detected, during a two month period in 2013. These were not conveyed by DAFM's Veterinary Medicines Division at central level to other relevant DAFM inspectorates.

⁹ A restricted herd visit report should be completed when the breakdown ends. ER06/09 to be amended to reflect same.

The audit team was informed by the District Veterinary Office that this would have triggered an inspection as part of official control verification to be performed by the District Veterinary Office. Consequently, no inspections were scheduled by the District Veterinary Office for this herd owner in 2013.

4.2.6 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 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 corrective action is taken when needed and to update documentation as appropriate.

Findings

The inspections for field staff are managed through the Agriculture Field Inspection and Test system and the Animal Health Computer system. The IT systems in place allow verification on performance of activities within the District Veterinary Office to be easily checked.

The audit team was informed that the Superintending Veterinary Inspector was involved in monitoring inspections performed by veterinary inspectors via the IT systems and also the completion of epidemiological and restricted herd visit reports.

Within the restricted herd visit report, there is a section for Superintending Veterinary Inspector sign off which in most cases for the reports reviewed, had been completed by the Superintending Veterinary Inspector.

At District Veterinary Office level, the audit team was informed that delays or outstanding tasks are clearly visible on the IT systems, allowing the Superintending Veterinary Inspector to monitor performance in relation to activities completed.

At national/central level, DAFM has developed a system of internal audits in line with Article 4.6 of Regulation (EC) No 882/2004 and the FSAI Service Contract which includes assessment of DAFM official controls performed at District Veterinary Office level.

4.2.7 Staff Performing Official Controls

Article 4 (2) of Regulation (EC) No 882/2004 requires the competent authority to ensure 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 confirmed that evidence of on-going DAFM training is captured via reports and returns sent to the FSAI (for both Eradication of Animal Disease Division and District Veterinary Office staff). Training of DAFM staff at both Eradication of Animal Disease Division and District Veterinary Office level, was not assessed by the audit team.

4.3 Review of Previous Food and Veterinary Office (FVO) Missions to Ireland

Certain findings/recommendations/corrective actions were selected from previous FVO Mission reports to Ireland as part of the verification of their closeout. These included:

- DG (SANCO) 2011-6017, in order to evaluate the follow-up action taken by the competent authorities with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products (2011)
- DG (SANCO) 2010-8408, in order to evaluate the animal health controls in place in relation to bovine tuberculosis (2010)

The audit team confirmed that numerous improvements have been put in place by DAFM to close out previous FVO recommendations and to implement corrective actions.

The audit team considers that the following additional improvements below would further assist close-out of previous FVO Recommendation 8 [DG (SANCO) 2011-6017]: *i.e. To ensure that the requirements of Chapter I, Section IX, Annex III to Regulation (EC) 853/2004 in relation to the use of raw milk from animals not complying with the requirements of points 1 to 3 of Chapter I, Section IX, Annex III to Regulation (EC) 853/2004, and, in particular, from any animals showing a positive reaction to the prophylactic test vis-à-vis TB, are met.*

Circular ER11 of 2012 (21 May 2012) Revised Policy, was issued by DAFM: “An FVO audit carried out in 2011 recommended that (i) DAFM procedures be amended to include controls to ensure that milk from reactor animals is prevented from entering the food chain”.

As part of the approach to preventing the supply referenced in circular ER 11/2012, the audit team’s view is that the private veterinary practitioner’s communication to the herd owner regarding advice given to them (that such milk withheld as per DAFM procedure ER No. 4) should be documented/recorded as confirmation that it has taken place. This would provide real-time evidence of communication aimed at preventing supply in the interests of public health/food safety and in order to assist compliance with the objectives of the Regulation.

5 AUDIT FINDINGS REQUIRING CORRECTIVE ACTION

Audit findings relating to DAFM official controls requiring corrective action to be taken, are listed in the corrective action plan associated with this report.

Audit findings identified during the course of the FSAI audit relating to the liquid milk establishments audited have been highlighted in a separate report dealing with these specific points. This report has also been sent to DAFM, where follow-up corrective action has been requested. At one establishment, a number of significant deficiencies were observed by the FSAI audit team during the audit. Prompt and appropriate enforcement action was taken by DAFM on the day of the audit to deal with these.

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



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