

AUDIT
REPORT

Audit of Official Controls
in Non Liquid Milk
Processing Plants –
Department of Agriculture,
Food and the Marine

FEBRUARY 2013



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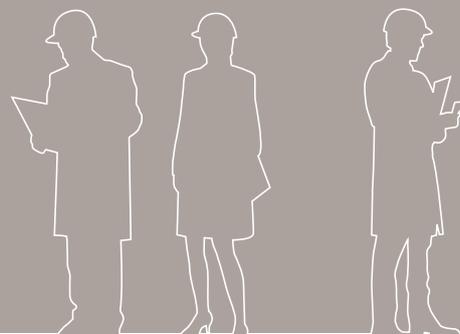


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1. GLOSSARY

AAI	Assistant Agricultural Inspector
AI	Agricultural Inspector
DAFM	Department of Agriculture, Food and the Marine
DPI	Dairy Produce Inspectorate
DPO	Dairy Produce Officer
DSL	Dairy Science Laboratory
DVO	District Veterinary Office
FSAI	Food Safety Authority of Ireland
MANCP	National Control Plan for Ireland
MHD	Milk Hygiene Division
PMDS	Performance Management and Development System
RAI	Regional Agricultural Inspector
SCC	Somatic Cell Count
SI	Senior Inspector
SOP	Standard Operating Procedure
QMS	Quality Management System
TAO	Technical Agricultural Officers
TBC	Total Bacterial Count

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. The Dairy Produce Inspectorate (DPI) is part of the overall Department of Agriculture, Food & the Marine (DAFM) Agricultural Inspectorate and is responsible for carrying out official controls in non-liquid milk processing establishments. For the purposes of assessing the delivery of official controls in this sector, the DPI was audited against the requirements of Regulation (EC) No 882/2004. In addition to the enforcement of food law, the DPI is also responsible for market controls work. However, in all regions visited, the audit team was informed that this work has at times in the past taken priority over food safety work.

The DPI has in place, a procedure for the approval of food business operators. All 50 medium to large scale food business operators covered by the scope of this audit have been approved. The frequency of official controls is established by applying a risk rating to each food business operator on an annual basis. Controls are in general spread out over the 12 month period but in one region visited, official controls were targeted towards the end of the year.

The DPI has developed a comprehensive series of documented procedures which describe how official controls are carried out. However, no time guidelines have been set during which all sections of checklists appended to the procedure are to be completed and there is no uniform method across all regions for tracking progress towards the completion of all sections. Also, it is a requirement that Regional Agricultural Inspectors (RAIs) should ensure effectiveness and appropriateness of official controls, it is unclear how this is achieved.

The DPI is routinely advised by the District Veterinary Office (DVO) of any breakdown in animal health status where milk is being supplied for the manufacture of raw milk products but for pasteurised milk products the DPI is not routinely advised of such breakdowns. The DPI verifies the efficacy of pasteurisation and the food business operator's own checks by taking official control samples on a quarterly basis as required by Standard Operating Procedure 1 (SOP 1). In one region, only two official control samples are taken.

Milk tankers are tested on arrival for temperature and antibiotics by food business operators. Milk which tested positive for antibiotic residues did not enter the food chain. Effective temperature/time combinations were being applied by all food business operators visited to achieve pasteurisation. To verify the efficacy of pasteurisation, all food business operators were carrying out daily Alkaline Phosphatase (ALP) tests. However, food business operators in one region were using a method not capable of detecting ALP down to the 350mU/L (milliunits of enzyme activity per litre) limit set in current legislation (Regulation (EC) No 2074/2005) and one was not monitoring the temperature of incoming raw milk.

Records reviewed for supplier Somatic Cell Count (SCC) results satisfied legislative requirements relating to test frequency, the calculation of geometric means and follow-up action. However, where suppliers have high SCCs, a seasonal supplier is unlikely to suffer any major restriction of supply due to interrupted supply (takes three months of supply in new year to establish a geometric mean), the permitted recovery period after new geometric mean established and the application of the seasonal correction factors in late autumn/early winter.

3. INTRODUCTION

The FSAI is responsible for the enforcement of all food legislation in Ireland. The FSAI carries out this enforcement function through service contracts with official agencies. These service contracts outline an agreed level and standard of food safety activities the official agencies perform as agents of the FSAI. DAFM has entered into a service contract with the FSAI. The DPI of the Department is responsible for the implementation and enforcement of national and EU legislation as it applies to dairy product establishments under their supervision. It is a requirement of the service contract that DAFM shall ensure that official controls are effective, risk-based and carried out with appropriate frequency.

As part of its legal mandate, and in accordance with Schedule Five of the service contract, the FSAI is required to verify that the system of official controls operated by DAFM is working effectively and is fit for purpose. The objective of this audit was to assess the organisation and implementation of official controls in medium/large scale non-liquid milk processing plants. Compliance by the DPI with regard to relevant food legislation, adherence to the terms and requirements of the FSAI service contract, as well as conformance with relevant documented procedures, was assessed.

4. AUDIT OBJECTIVE

The objective of this audit was to assess the organisation and implementation of official controls at a central level and how these controls were carried out in three DPI operational regions. The audit focused on the structures put in place to allow official control activities verify compliance with food law. It also assessed how the responsibilities of the Milk Hygiene Division (MHD) are conducted regarding the approval of milk processors as required by Regulation (EC) No 853/2004.

5. AUDIT SCOPE

During the audit, the audit team assessed the processes in place for the administration of approvals by MHD and how the DPI conducted controls in three of its operational regions. The scope of the audit was the implementation of official controls by the DPI in medium/large scale food business operators producing > 100 tonnes per annum of dairy products. The audit also verified that selected food business operators were subjected to official controls by the DPI and determined their level of compliance with relevant food law, in particular, raw milk intake/acceptance criteria and heat treatment requirements.

6. AUDIT CRITERIA AND REFERENCE DOCUMENTS

During the audit, the audit team assessed compliance with the audit criteria, which included:

- [Food Safety Authority of Ireland Act, 1998](#) (S.I. No. 29 of 1998), as amended
- [Service Contract](#) between the FSAI & the Department of Agriculture, Food and the Marine
- National Control Plan for Ireland 2007-2011 (MANCP)
- Documented Procedures for the Dairy Produce Inspectorate
- Documented Procedures for the Milk Hygiene Division
- [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 2074/2005](#) laying down implementing measures for certain products under Regulation (EC) No.853/2004 and for the organisation of official controls under Regulation (EC) No 854/2004
- [S.I. No. 432/2009](#): European Communities (Food and Feed Hygiene) Regulations, 2009, as amended
- Guidance Notes/Codes of Practice and other relevant other relevant legislation detailed in the FSAI Service Contract with the Department of Agriculture, Food and the Marine

7. AUDIT METHODOLOGY

This audit of official controls was undertaken using documented procedures which are included in the FSAI Quality Management System (QMS), namely the FSAI Audit Procedure and Charter. These procedures implement the FSAI audit obligations, defined in Schedule Five of the service contract between the FSAI and DAFM, and are in accordance with the requirements of Regulation 882/2004 (including Art. 6.1 of Commission Decision 677/2006) and the FSAI Act.

An evaluation plan was developed for each of the audits, which provided a detailed overview of the on-site activity including audit scope, objectives, criteria and reference documents.

The on-site activity took place during the second half of 2011. The first day commenced with an opening meeting to explain the objective of the audit, the audit methodology and how the audit findings would be reported. This part of the audit involved a review of the information provided as part of the pre-audit questionnaire. Depending on the location visited, this was followed by a detailed examination of documented procedures and food business operator files. In the regions, the food business operator's to be visited were then selected. The audit concluded with a closing meeting at which the audit team verbally delivered their findings.

8. OFFICIAL CONTROLS PERFORMED IN ACCORDANCE WITH REGULATION (EC) NO 882/2004

9. ORGANISATION OF OFFICIAL CONTROLS

The DPI is part of the overall DAFM agricultural inspectorate and is responsible for carrying out official controls in non-liquid milk processing establishments (including those with limited production capacity) collection centres and storage premises. Official controls include monitoring, auditing, inspection and surveillance activities in these establishments. The food safety/food control services are carried out in accordance with the service contract between DAFM and the FSAI.

The DPI operates on a regional structure, with each of four regions reporting to a Senior Inspector (SI). A Regional Agricultural Inspector (RAI) manages the activities of authorised officers responsible for the implementation of official controls in his/her operational area. At the time of the audit, one of the RAI posts was vacant. The management of official control activities for the vacant region was being shared by two of the other RAIs. Two additional Agricultural Inspector's (AI's) report to the SI, with responsibility for internal controls and certification respectively. In two of the regions visited the RAI was supported by 4 Assistant Agricultural Inspector's (AAI's), 2 TAO's and 1 DPO. In the third region, staff reporting to the RAI consisted of two fulltime and one part-time AAI's, 2 TAO's and 1 DPO.

In addition to the planned official control activities, the DPI also carries out reactive/unplanned controls. The audit team was informed that at the time of the audit in one region the approximate ratio of planned to reactive controls was 50:50. In another region, significant resources were being dedicated to a particular on-farm investigation with potential food safety implications. It is unclear how this reactive/unplanned work is captured for the FSAI or Multi Annual Control Plan (MANCP) returns.¹

In addition to the enforcement of food law, the DPI is also responsible for market controls work. In all regions visited, the audit team was informed that this work has at times in the past taken priority over food safety work. The audit team noted that targets for food safety controls were not met in either 2009 or 2010.

¹ DAFM advised that reactive/unplanned work is now included in the MANCP returns based on a template designed by the Department MANCP Board group and is now harmonised with the FSAI returns

10. APPROVAL

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.

The DAFM MHD has a documented procedure, SOP 15, in place to process approval and registration of food business operators. A list of registered and approved establishments under the supervision of the DPI is available on the DAFM website. During the audit at central level the audit team reviewed 16 food business operator files to verify the approval process. In all 16 files reviewed, approval had been granted in accordance with the requirements of Regulation (EC) No 853/2004. On a number of these files, the scope of activities on the application for approval was different to the certificate issued.

The DPI also has in place a procedure for the approval of food business operators. This is documented in Section 2.6 of SOP 24 Rev 3. In the three regions visited, all 50 medium to large scale food business operators covered by the scope of this audit have been approved.

A review of sample food business operator files in each of the three regions visited confirmed that when an approval application was submitted under Regulation (EC) No 853/2004, appropriate official controls were carried out before the approval certificate was issued.

A total of 50 food business operations classified as medium to large scale are supervised by the DPI in the regions audited. One region had 28 such food business operators while the other two supervised 11 each.

11. COORDINATION AND PLANNING OF OFFICIAL CONTROLS

12. RISK CATEGORISATION AND FREQUENCY OF OFFICIAL CONTROLS

Article 3.1 of Regulation (EC) No. 882/2004 requires that official controls are carried out regularly on a risk basis and at appropriate intervals.

To establish the frequency of official controls, the DPI applies a risk rating to each food business operator it supervises in accordance with SOP 24 Rev 3. This is completed on an annual basis by the AAIs in consultation with their RAI and remains in place for the year in question unless outcomes of official controls require its review. The results of the risk rating process are documented on form CR4 which is appended to SOP 24. The audit team was provided, when requested, with the CR4s for 2011 for the 50 food business operators relevant to the scope of this audit.

The audit team was informed that the policy in one region visited was to target official controls towards the end of the year as opposed to an even spread or matching milk supply patterns. This is not in keeping with the risk-based approach advocated in Regulation (EC) No 882/2004.

13. IMPLEMENTATION OF OFFICIAL CONTROLS

Article 3.2 of Regulation (EC) No. 882/2004 requires competent authorities to carry out official controls without prior warning except in cases such as audits.

SOP 24 describes in detail official control procedures relating to the implementation of the European Communities Food Hygiene Regulations (S.I. No. 432/2009) at establishments (other than primary production), which handle or process raw milk, dairy products and composite products. The SOP subdivides official controls into (i) inspection and (ii) audit and incorporates checklists for each of these activities (control checklists A-D). The SOP states that inspections are to be unannounced, whereas audits may be pre-arranged with the food business operator. The audit team was informed that in all three regions visited, audits are generally announced and usually follow an initial unannounced inspection. Reports of official controls reviewed by the audit team verified this practice.

SOP 24 does not set time guidelines during which all sections of checklists A, B and D² (these set out all aspects to be inspected/audited) are to be completed. Also there is no formalised method for tracking progress towards the completion of all sections. The audit team noted variation in the stated timeframe within the regions for completion of all sections of the checklist.

14. CONSISTENCY OF OFFICIAL CONTROLS

Article 4.4 of Regulation (EC) No 882/2004 requires that competent authorities shall ensure the impartiality, quality and consistency of official controls at all levels.

Official controls relating to the implementation of the European Community (Food & Feed) Hygiene Regulations, 2009 (S.I. No. 432/2009) which implement the requirements of Regulation (EC) No 882/2004 are carried out by the DPI in accordance with documented procedures. The audit team verified that up-to-date versions of these were available to the AAls.

RAIs in the regions agree the annual risk rating of food business operators with the AAls and this determines the frequency of planned controls. The audit team verified the completion of the risk rating applied for 2011. The RAI also receives copies of compliance reports and notices (forms CR1 and CN1) issued by the AAls and in particular discusses issues with the relevant AAI prior to the issue of a compliance notice. The RAI, when requested, will accompany AAls during routine official controls if and when a problematic situation arises and is routinely involved prior to the serving of a compliance notice.

There is no formalised procedure for tracking the completion of all sections of the SOP 24 checklists although in two of the regions visited, a localised system had been developed.

² Checklist C is used for off -site storage facilities, which were not visited as part of this audit

15. STAFF PERFORMING OFFICIAL CONTROLS

Article 6 of Regulation (EC) No. 882/2004 requires staff performing official controls to have appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner.

On an annual basis, through the Performance Management and Development System (PMDS), training needs for the DPI are identified. These training needs are then forwarded to the DAFM central training unit. Additional training comprises updates at regional meetings, attendance at relevant technical conferences and participation in specialised technical training, e.g. a recent course on pasteurisation.

The audit team verified that the staff in the regions visited are adequately qualified and are included in the ongoing training outlined. Liaison and joint visits with the RAI also constitute an important aspect of ongoing training and personal development for staff performing official controls.

16. DOCUMENTED PROCEDURES

Article 8.1 of Regulation (EC) No 882/2004 states that competent authorities shall carry out official controls in accordance with documented procedures.

The DPI has developed a comprehensive series of documented procedures in the form of SOPs which describe how official controls are carried out. These SOPs are now authorised by the SI. Documented procedures are developed by the AI with responsibility for internal controls, in conjunction with RAIs and other DPI staff. The SOP's relevant to this audit include:

- SOP 24 Rev 3 Official Control procedures relating to the implementation of the European Communities Food Hygiene Regulations at establishments (other than primary production), which collect, handle or process raw milk, dairy products and composite products
- SOP OPS 001 Rev 13 Official control (sampling & reporting) procedures relating to the implementation of the European Communities Food Hygiene Regulations at establishments (other than primary production), which handle or process raw milk, dairy products and composite products
- SOP 12 Rev 4 Monitoring of milk testing regime
- SOP 13 Rev 6 Official sampling arrangements of raw milk for residue testing drawn up under Council Directive 96/23/EC as amended and Protocol for dealing with official non compliant results
- SOP 23 Rev 2 Official Control procedures relating to the implementation of the European Communities Food Hygiene Regulations at Milk Production Holdings and own checks undertaken by Milk Purchasers
- SOP 26 Rev 1 Potable Water - Sampling, testing, and reporting of results for Microbiological analysis at processing premises

The SOPs are available to all DPIs on the DAFM 'G drive'. The audit team verified the availability of SOPs on the day of the audit and these were found to be at the correct revision level. The audit team noted that there are no equivalent documented procedures for the performance of the role of the RAI apart from that contained in the role profile. While section 5 of SOP 24 requires that RAI's should ensure effectiveness and appropriateness, it is unclear how this is achieved.

In addition, the MHD has in place documented procedures to describe critical aspects of the divisions work. For the scope of this audit, the audit team referenced SOP 15 regarding the approval process.

17. LEGAL POWERS AND PROCEDURES

Article 8.2 of Regulation (EC) No. 882/2004 requires member states to ensure that they have legal procedures in place in order to ensure that staffs of the competent authorities have access to premises and documentation kept by feed and food business operators so as to be able to accomplish their tasks properly.

The European Community (Food & Feed Hygiene) Regulations (S.I. No. 432 of 2009) provides authorised officers with the legal powers to carry out official controls as required by Regulation (EC) No 882/2004. Authorised officers are issued with warrants under this SI. The audit team verified during the audit at central level and during those in the regions that the staff involved in official controls carried valid warrant cards.

18. REPORTING

Article 9 of Regulation (EC) No. 882/2004 requires a competent authority to draw up reports on official controls that it has carried out.

SOP 24 Rev 3 requires the DPI to provide a copy of the CR1 (Compliance Report Form) to the food business operator following every official control visit, irrespective of whether non-compliances are detected.

The audit team were informed that the AAIs audited issue a report for every official control covered by SOP 24 and this was verified during the review of selected food business operator files in the regions. During the audit at central level however, it was noted by the audit team that compliance report forms (CR1s) were not present in a number of establishment files.

19. FOLLOW UP AND CLOSE OUT OF NON-COMPLIANCES

Article 54 of Regulation (EC) No 882/2004 states: When the competent authority identifies non-compliance, it shall take action to 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.

SOP 24 Rev 3 sets down the classification of non compliances (Section 3.2 of SOP 24) and the actions to take in the event of non compliances (3.3, 3.4, 3.5 of SOP 24). The categories assigned to non-compliances are as follows:

- (a) Category 1 – any non-compliance which poses an immediate risk to public health
- (b) Category 2 – any non-compliance which poses a potential risk to public health
- (c) Category 3 – any non-compliance other than the above where the conditions, requirements and principles of the Regulations are not met

Data provided to the audit team for 2010 in respect of the medium/large scale premises covered by the scope of this audit indicated that no Category 1 non-compliances were detected. Category 2 non-compliances were identified in food business operations in 2 regions. There was significant variation in the number of Category 3 non-compliances identified for the period concerned. The region with the most food business operations identified 175 while the regions with lower numbers of premises identified 47 and 1 respectively.

SOP 1 provides details of how to action a non-compliance following official control food safety sampling. SOP 25 sets down the procedures to be followed by the milk hygiene division when a food safety hazard is identified. Summary data for 2010 indicated that in the three regions audited, one food safety hazard notification was issued in respect of the target food business operators.

20. COMPLIANCE WITH REGULATION (EC) NO 854/2004

Article 4 of Regulation (EC) No. 854/2004 requires the competent authority to carry out official controls to verify food business operators' compliance with the requirements of Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004.

The audit team verified during the review of food business operator files that official controls in this regard are carried out by the DPI in each of the three regions visited.

21. MONITORING OF PROCESSOR CONTROLS OVER RAW MILK

SOPs 23 and 12 describe the role of DPI staff regarding the auditing of milk purchasers own monitoring and control systems (own checks). The records for official controls carried out in this area are documented on Form DH2.

Annex IV of Regulation 854 requires competent authorities to monitor the checks carried out by the food business operator with regard to raw milk at intake under Annex III of Regulation 853.

It is the responsibility of the food business operator to inform the competent authority on a monthly basis of the number of suppliers exceeding Somatic Cell Count (SCC), Total Bacterial Count (TBC) and antibiotic criteria. The audit team verified that AAIs in the regions visited receive monthly communications of supplier results for SCC and TBC by post or email. Numbers of dairy suppliers prohibited for exceeding SCC and TBC criteria are supplied directly to MHD and these are relayed to the DPI. One AAI informed the audit team that he does not routinely receive this information.

In the regions visited, the dairy processors inform the local inspector of antibiotic rejections and this information is held at local level. This food business operator information helps inform the risk basis for on-farm controls of suppliers especially with respect to sampling for antibiotics.

Direct DPI monitoring of food business operator laboratory performance consists of the submission of SCC standard samples (to check food business operator equipment for accuracy and repeatability) and observation of the on-site rapid test procedures for antibiotics.

The audit team was advised that the DSL organises proficiency tests for SCC in laboratories used by purchasers/processors to ensure the validity of the results and that some private processor laboratories also use standard samples from Teagasc, Moorepark to calibrate their equipment.³ In addition, the competent authority has organised a ring trial for the determination of somatic cells in raw milk through the Max Rubner-Institut in Kiel, Germany.

At the time of the audit, the DSL had commenced proficiency testing for total bacterial counts.

³ DAFM has advised the FSAI that the use of Teagasc Moorepark samples to calibrate private laboratory samples has now ceased.

22. COMPLIANCE WITH REGULATION (EC) NO. 853/2004

23. HEAT TREATMENT

Annex III, Section 9, Chapter 2.2 of Regulation (EC) No 853/2004 specifies requirements for heat treatment of dairy and colostrum-based products.

Official controls regarding heat treatment are documented in SOP 24. The Inspection Control Checklist Part A and the Audit Control Checklist Parts B & D, which are appended to this SOP, are used by the DPI during official controls in this area.

The audit team verified that the AAIs in all regions audited routinely apply a comprehensive set of checks to verify the correct functioning of heat treatment equipment. These include documentary and visual checks in the plant as well as checking the results of certification/calibration tests for the critical components/aspects of the pasteurisation process including temperature probe accuracy, holding times and plate integrity checks. To verify the efficacy of pasteurisation and the food business operator's own checks for this, AAIs are required to sample milk on a quarterly basis and these samples are submitted to the DSL for Alkaline Phosphatase (ALP) testing. In one region, the audit team was informed that AAIs only take two annual official control samples for ALP testing whereas SOP 1 requires that quarterly samples be taken.

24. ANIMAL HEALTH

Annex III, Section 9, Chapter 1.1 of Regulation (EC) No. 853/2004 sets out health requirements for animals for raw milk production in particular with respect to tuberculosis and brucellosis. Specifically Chapter 1.1.4 prohibits the use of milk from animals testing positive for TB or brucellosis.

Paragraph 2.4.1(ii) of SOP 24 documents the procedures to be followed by the DPI following official notification of a breakdown in animal health status.

Currently, the District Veterinary Office (DVO) has total responsibility for the control of raw milk from TB reactors. The audit team verified that the DPI in the regions are routinely advised by the DVO of any breakdown in animal health status where milk is being supplied for the manufacture of raw milk products. The audit team noted that in the case of milk used for pasteurised milk products, the DPI is not routinely advised of such breakdowns. This eliminates the opportunity for the DPI to follow up on such herds during official controls on intake or milk purchasers.

25. FOOD BUSINESS OPERATOR CONTROLS PERFORMED IN ACCORDANCE WITH REGULATIONS 178/2002, 852/2004 & 853/2004 AND STATUTORY INSTRUMENT 432/2009

26. INTRODUCTION

A total of five food business operator establishments were visited and the audit activity comprised of discussions with key personnel together with examination of relevant documents.

Three of the food business operators visited were part of a bigger group where the controls over raw milk for SCCs and TBCs and for direct on-farm sampling for antibiotics were carried out by a dedicated unit operating from the group headquarters location. In these instances, controls relevant to the scope of this audit were limited to the testing of tankers for antibiotics, monitoring of raw milk temperature at intake and those relating to pasteurisation. For the other food business operators, all controls for raw milk acceptance criteria (SCC, TBC and antibiotics) were being applied on site.

27. ANTIBIOTICS

The audit team noted that in all five food business operators every tanker is tested using rapid tests covering the beta-lactam group of antibiotics whereas one food business operator also used the Delvo SP test (which covers a broader spectrum of antibiotics) as well as additional specific tests for tetracycline, chloramphenicol and zinc bacitracin. One of the food business operators also tests milk silos on a monthly basis using the Delvo SP test but this is of limited value due to the dilution effect.

The rapid screening tests will detect most of the actives that are likely to be present and where combined with the Delvo SP comprehensive detection is achieved.⁴ The food business operators typically used the Delvo SP test for testing milk samples taken directly on farms (i.e. not those taken by the proportional sampler on the tanker).

At four of the food business operator sites visited, the audit team examined records relating to the disposal of milk from tankers that had tested positive for antibiotics and were satisfied that this milk had not entered the food chain.

28. MILK INTAKE TEMPERATURE

In the case of four of the food business operators visited, temperature probes monitor the raw milk at unloading and milk with a temperature of greater than 10°C being regarded as a non-conforming. At the time of the audit, one of the food business operators was not routinely monitoring the temperature of raw milk at intake. Records reviewed for the food business operator's monitoring on a daily basis indicated that temperatures at intake had not exceeded the 10°C threshold. The audit team noted that whilst four of the food business operators regard incoming milk with a temperature above the threshold as non-conforming product such milk would not be automatically rejected. Also, the audit team was informed that one food business operator visited does not have the facility to cool raw milk after intake.

⁴ DAFM, in conjunction with the FSAI, will carry out a study to determine whether the current regime of antibiotic monitoring is adequate.

29. HEAT TREATMENT

The audit team verified that effective temperature/time combinations were being applied by all food business operators visited. To verify the efficacy of pasteurisation all food business operators were carrying out daily tests for ALP. The food business operators in one region were relying on the Aschaffenburg and Mullen (A&M) test tube method for ALP determination although this method is not capable of detecting ALP down to the 350mU/L limit set in current legislation (Regulation (EC) No 2074/2005).

To help ensure the correct functioning of the pasteurisation equipment, food business operators were found to be carrying out a comprehensive set of checks for key aspects including plate integrity, holding tube times and temperature and pressure probe accuracy. In four of the food business operator establishments these checks were being carried out by external contractors and in the other food business operator by their own technical staff. The audit team reviewed documented results of these checks at all food business operator sites and these were found to be satisfactory.

30. SCC AND TBC CONTROLS

At two of the food business operator sites visited, tests and controls were being applied in respect of SCC and TBC and the on-site activity included visits to the milk quality laboratories as well as reviews of the overall control system for the processor group. For the enumeration of these quality characteristics, modern high throughput equipment employing the principle of flow cytometry was being used.

The audit team viewed records for supplier results and was satisfied that legislative requirements relating to test frequency, the calculation of geometric means and follow-up action were being met. At one food business operator, it was noted that the number of tests carried out for SCC was far in excess of legislative requirements in order to facilitate compliance for a small number of suppliers. It was also noted that where seasonal suppliers have high SCCs they are unlikely to suffer any major restriction of supply. This is due to a number of factors including interrupted supply patterns, the permitted recovery period and the application of the seasonal correction factors in late autumn/early winter.

31. CONCLUSIONS

DAFM through the DPI, has put in place, a system for the organisation and implementation of official controls in medium/large scale non-liquid milk processing plants under the Departments supervision. In addition to the enforcement of food law, the DPI is also responsible for market controls work. However, in all regions visited, the audit team was informed that this work has at times in the past taken priority over food safety work. Official control staff are adequately qualified and are included in ongoing training.

The DPI has in place a procedure for the approval of food business operators. In the three regions visited all 50 medium to large scale food business operators covered by the scope of this audit have been approved. The frequency of official controls is established by applying a risk rating to each food business operator on an annual basis. Controls are in general spread out over the twelve month period but in one region visited official controls were targeted towards the end of the year.

The DPI has developed a comprehensive series of documented procedures which describe how official controls are carried out. SOP 24 describes in detail official control procedures relating to the implementation of the European Communities Food Hygiene Regulations (S.I. No. 432/2009) at establishments which handle or process

raw milk, dairy products and composite products. However, the SOP does not set time guidelines during which all sections of checklists appended to the procedure A, B and D (these set out all aspects to be inspected/audited) are to be completed and there is no uniform method across all regions for tracking progress towards the completion of all sections. Also, it is a requirement of the SOP that RAIs should ensure effectiveness and appropriateness, it is unclear how this is achieved.

The DSL organises proficiency tests for SCC in laboratories used by purchasers/processors to ensure the validity of the results. At the time of the audit, the DSL had commenced proficiency testing for total bacterial counts.

The DPI is routinely advised by the DVO of any breakdown in animal health status where milk is being supplied for the manufacture of raw milk products but for pasteurised milk products the DPI is not routinely advised of such breakdowns.

As part of the system of verification of the efficacy of pasteurisation and the food business operator's own checks, the DPI takes official control samples (for ALP) on a quarterly basis as required by SOP 1. In one region, only two official control samples are taken.

Milk tankers are tested on arrival for temperature and antibiotics by food business operators. At the time of the audit, one of the food business operators was not routinely monitoring the temperature of raw milk at intake. The audit team verified that milk which tested positive for antibiotic residues did not enter the food chain. Appropriate temperature/time combinations were being applied by all food business operators visited to achieve effective pasteurisation. To verify the efficacy of pasteurisation all food business operators were carrying out daily ALP tests. The food business operators in one region were using a method not capable of detecting ALP down to the 350mU/L limit set in current legislation (Regulation (EC) No 2074/2005).

Records reviewed for supplier SCC results satisfied legislative requirements relating to test frequency, the calculation of geometric means and follow-up action. However, where suppliers have high SCCs a seasonal supplier is unlikely to suffer any major restriction of supply due to interrupted supply (takes 3 months of supply in new year to establish a geometric mean), the permitted recovery period after new geometric mean established and the application of the seasonal correction factors in late autumn/early winter.

RECOMMENDATIONS

- 6.1 DAFM should ensure that in future market support controls must not take absolute priority over food safety controls.
- 6.2 SOP 24 should set out time guidelines over which all sections of the appended checklists should be completed.
- 6.3 The process by which RAIs verify the effectiveness and appropriateness of official controls requires clarification.
- 6.4 The DPI should require all food business operators (as part of their HACCP based controls) to employ ALP tests capable of detection to the limit set out in Regulation (EC) No 2074/2005.
- 6.5 In keeping with the risk-based approach advocated in Regulation (EC) No 882/2004, official controls in all regions should be applied throughout the year and weighted towards peak milk production.



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