



Audit Programme Summary Report

An Assessment of Local Authority Delivery of Official Controls on Milk and Dairy Products in England, Wales and Scotland 2014/2015

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Foreword

Audits of local authority (LA) feed and food law enforcement functions are part of the Food Standards Agency's arrangements to improve the consistency and effectiveness of enforcement. These arrangements recognise that the enforcement of UK feed and food law relating to feed and food safety, hygiene, composition, labelling, imported food and feeding stuffs is largely the responsibility of local authorities. These local authority regulatory functions are principally delivered through Environmental Health and Trading Standards Services. The Agency's website contains enforcement activity data for all UK local authorities and can be found at: www.food.gov.uk/enforcement/auditandmonitoring

Agency audits assess LAs' conformance against the Feed and Food Law Enforcement Standard ('the Standard'), the Feed Law Code of Practice and relevant official enforcement guidance. 'The Standard' was published by the Agency as part of the Framework Agreement on Official Feed and Food Controls by Local Authorities and is available on the Agency's website at: www.food.gov.uk/enforcement/enforcementwork/frameagree. It should be acknowledged that there will be considerable diversity in the way and manner in which local authorities may provide their feed and food enforcement services reflecting local needs and priorities.

The main aim of the audit scheme is to maintain and improve consumer protection and confidence by ensuring that local authorities are providing an effective feed and food law enforcement service. The scheme also provides the opportunity to identify and disseminate good practice and to provide information to inform Agency policy on food safety, standards and feeding stuffs. Parallel local authority audit schemes are implemented and managed by the Agency's offices in all the devolved countries comprising the UK.

The power to set standards, monitor and audit feed and food law enforcement authorities was conferred on the Food Standards Agency by the Food Standards Act 1999 and the Official Feed and Food Control (England) Regulations 2009, along with parallel Regulations for the devolved countries. The Agency's audits of LAs are undertaken under section 12(4) of the Act. Regulation (EC) No. 882/2004 on official controls performed to ensure the verification of compliance with feed and food law includes a requirement for competent authorities to carry out internal audits, or to have external audits carried out. The purpose of these audits is to verify whether official controls relating to feed and food law are implemented effectively. To fulfil this requirement, the Food Standards Agency, as the central competent authority for feed and food law in the UK has established external audit arrangements. In developing these, the Agency has taken account of the European Commission guidance on how such audits should be conducted.¹

¹ Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No. 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules (2006/677/EC)

Further information on the Agency's LA audit scheme, including questions and answers on the operation of the scheme and details of good practice identified during audits, is available on the Agency's website at:

www.food.gov.uk/enforcement/auditandmonitoring

Table of Contents

1.0	Background	5
1.1	Reason for the Audit	5
1.2	Overview of the Dairy Industry.....	5
1.3	Enforcement Responsibilities.....	6
1.4	Scope and Key Objectives of the Audit Programme	6
1.5	Audit Methodology and Design	7
2.0	Executive Summary	8
3.0	Summary of Findings	9
3.1	FBO checks on raw milk quality with particular regard to somatic cell counts and antibiotic residues.	10
3.2	Ensuring HACCP- based procedures in dairy processing establishments are effective	11
3.3	Microbiological Criteria for foodstuffs – Regulation (EC) No 2073/2005	12
3.4	Animal by-products in dairy establishments	13
3.5	Traceability	14
3.6	Deficiencies noted in relation to the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004	15
4.0	Relevant Sections of the ‘Standard’ in the Framework Agreement Delivery Issues	16
4.1	Organisation and Management - Service Planning	16
4.2	Officer Authorisation and Training	16
4.3	Identifying Relevant Businesses - Food Premises Databases	17
4.4	Inspections / Interventions.....	17
4.5	Reality Checks	19
4.6	Documented Procedures at Competent Authorities	19
4.7	Enforcement.....	20
4.8	Incidents/Reporting of OTF notifications	21
4.9	Internal Monitoring.....	21
5.0	Overall Conclusions	22
6.0	Other delivery issues raised by LAs	23
7.0	Recommendations	24
	Annex 1 - FSA Enforcement Letters to LAs	26
	Annex 2 - Audit Methodology and Design	27
	Annex 3 - Local Authorities Audited by Type	28
	Annex 4 - Summary Report Circulation	29
	Annex 5 - Glossary	30

1.0 Background

1.1 Reason for the Audit

1.1.1 This programme of focused audits was specifically developed in response to recommendations made by the Food and Veterinary Office (FVO) during an audit of control systems related to safety of milk and dairy products in the UK, as part of its routine audit programme. The FVO auditors concluded that the UK had in place an adequate general framework for official controls and that the procedures in place for carrying out and documenting official controls were well established. However deficiencies were noted in the implementation of controls in some instances and highlighted areas of concern where improvements were needed. The FVO made seven recommendations to the FSA as the Central Competent Authority (CCA). An enforcement letter Ref: ENF/E/13011/² (England) and ENF/W/14/007 (Wales) was sent to local authorities (LA) providing an update on the outcome of the FVO audit. The letters summarised the recommendations and additional concerns raised by the FVO auditors and where relevant the action to be taken by the LA (see Annex 1). The aim of the focussed audit programme was to provide an overall picture of the level of assurance concerning LA delivery of official controls in approved dairy establishments, with particular emphasis on the actions highlighted in the enforcement letters and to identify any improvements that needed to be addressed by the Agency and LAs. This work was in line with the FSA's strategy for 2010 – 2015 ensuring that food produced or sold in the UK is safe to eat and business compliance is effectively supported with a focus on effective; risk based and proportionate regulation and enforcement.

1.2 Overview of the Dairy Industry

- 1.2.1 As of 31 March 2015 the total number of registered dairy producers in England and Wales was 8094 and 1783 respectively. The figures for Scotland for the year ending 31 March 2014 were 1076 dairy cattle herds, two sheep and three goat milking herds. The industry has introduced the Red Tractor Farm Assurance Dairy Scheme which sets out standards to ensure that on assured dairy farms the milk is produced in a safe and hygienic manner. Those dairy farms in England, Wales and Northern Ireland which comply with the scheme have had the frequency of inspection by the FSA reduced from once every two years to once every 10 years. In Scotland they are still inspected at the minimum frequencies set out in the Food Law Code of Practice (FLCoP).
- 1.2.2 Milk is collected from farms by milk hauliers and the milk collection vehicles are typically operated by hauliers contracted by milk purchasers but some are operated by milk purchasers themselves. A milk purchaser is an organisation that holds a contract with a farmer to purchase the milk produced from that farm and can be a farmer co-operative, private dairy company or a public limited company (PLC). The milk bought from farmers will either be processed

² The incorrect year was referenced on the England letter it should have been EN//E/14/011

by the purchaser or sold onto other organisations for processing. Organisations that process milk can again be a co-operative, private dairy company or a PLC. Almost half of the milk purchased by UK dairy companies and co-operatives is processed into liquid milk. Other key dairy products are cheese, powders, condensed milk, butter and cream. (Source: The White Paper 2013 a guide to the UK dairy industry Dairy UK)

1.3 Enforcement Responsibilities

- 1.3.1 In England and Wales LAs are responsible for approving and enforcing relevant regulations in approved dairy establishments. The supervision and inspection of milk production holdings are dealt with by the FSA Dairy Hygiene Inspectors (DHIs). The DHIs are also responsible for sampling of raw cow's milk sold for human consumption. Food business operators (FBOs) whose operations are both as a milk production holding and a processing establishment are registered with the FSA as a production holding and approved by the LA as a dairy establishment for processing activities. LAs are also responsible for enforcement of relevant regulations and sampling, relating to raw milk from species other than cows. In Scotland the LAs are responsible for all aspects from point of milking through all stages of processing up to the point of sale to the final consumer.
- 1.3.2 The Department of Environment, Food and Rural Affairs (DEFRA) working with Animal and Plant Health Agency (APHA) is responsible for carrying out official tests for tuberculosis (TB) and brucellosis where appropriate. When a dairy herd loses the Officially Tuberculosis Free status (OTF) the APHA send a copy of the herd restriction notice (TB2) to the LA and will advise the LA when the OTF status has been regained (TB10). The TB restriction notice is issued on the herd owner and effectively suspends the OTF status of dairy herds. On receipt of the notification the LA should ensure that milk from the herd is no longer used for raw milk based products and if used subjected to appropriate heat treatment. Milk from individual reactor animals within a herd may not be used for human consumption. The LA should notify the FSA incidents team following their enquiries if milk from reactor animals or milk from non-reactor animals without appropriate heat treatment has entered the food chain.

1.4 Scope and Key Objectives of the Audit Programme

- 1.4.1 The programme comprised of audits of LAs in England, Wales and Scotland focusing on LA food law enforcement service arrangements for delivery of official controls on milk and dairy products. This included cows, buffalo, sheep, and goats milk products.
- 1.4.2 The programme involved audit assessments at local authorities and on site verification visits at approved dairy establishments. A total of 15 LAs were visited as part of the programme 10 in England, 2 in Wales and 3 in Scotland.

- 1.4.3 The programme took place between October 2014 and February 2015 at a range of selected LAs based upon the authority type, and geographical location. Particular emphasis was given to LAs that had a reasonable mix and variety of approved dairy establishments.
- 1.4.4 The audit examined LA delivery of official controls particularly in relation to relevant sections of Regulation (EC) No 882/2004, (EC) No 852/2004, (EC) No 854/2004, Regulation (EC) 1069/2009, Regulation (EC) 2073/2005, Article 18 of Regulation (EC) No. 178/2002 and Council Directive 98/83/EC at establishments producing and processing milk and dairy products against the relevant sections and/or sub-sections of the 'Standard' in Chapter 2 of the Framework Agreement. Audit checks included assessment of:
- **Service planning and delivery.**
 - **Provision and adequacy of officer training and the authorisation of officers.**
 - **Implementation and effectiveness of control activities, including inspection/interventions, food inspection and sampling and enforcement related to traceability.**
 - **Maintenance and management of appropriate records in relation to official controls at FBOs including the food premises database.**
 - **Internal service monitoring arrangements.**
 - **Liaison arrangements between LAs and other agencies responsible for dairy controls.**
- 1.4.5 The programme sought to gain assurance that LAs were effectively implementing controls in approved milk and dairy establishments in accordance with relevant legislation, with particular reference to the key recommendations and concerns raised by the FVO audit, and to disseminate good practice related to food control in this area.

1.5 Audit Methodology and Design

- 1.5.1 Details of the audit methodology, design, and the evaluation and assessment framework used during the audits are set out in Annex 2.

2.0 Executive Summary

2.1 Introduction

2.1.1 This report highlights the key findings and conclusions drawn from the audit of 15 LAs undertaken in England, Wales and Scotland in 2014/15. The audit was requested by the Agency's Hygiene Delivery Branch to gain assurance that LAs were effectively implementing official controls in approved dairy establishments and to identify areas for improvement. Particular focus was given to the enforcement letters Ref: ENF/E/13/011 (England) and ENF/W/14/007 (Wales) sent to LA's updating them of the outcome of the FVO audit and drawing attention to actions LAs should bear in mind when carrying out interventions.

2.2 Key Findings (with reference when appropriate to recommendations made to the FSA and LAs in Section 7.0).

2.2.1 Most of the LAs audited were undertaking planned interventions at the required frequency in their approved dairy establishments and officers were appropriately authorised to undertake the activity. Whilst there was some evidence of appropriate delivery of official controls, this was variable. Auditors were not provided with adequate assurance that all of the key controls required to be undertaken by FBOs identified in the enforcement letters, had been consistently assessed by all LAs during their interventions to verify FBO compliance. This report makes eleven recommendations, five for the FSA and six for LAs to help address the issues found and contains examples of good practice found during the audits. The following key findings were identified;

- The action taken by LAs in response to the enforcement letters was variable (LA recommendation no 5). The format of enforcement letters issued by the FSA should be reviewed to ensure the actions required and their priority are made clear to LAs (FSA recommendation no 5).
- Whilst in general officers had received some relevant training relating to approved dairy establishments, a need for further refresher training and guidance to support officers in their delivery of official controls and assessment of FBO compliance was identified (FSA recommendations no's 1- 2 and LA recommendation no 2).
- Whilst most LAs were carrying out inspections using sector specific aide memoires they did not always contain relevant structured questions or have sufficient detail recorded to demonstrate the officer's assessment of compliance (LA recommendations no's 3-4).

- Overall there was evidence of appropriate LA follow up action being taken for deficiencies noted in relation to general hygiene requirements but some examples were identified where this had not been carried out effectively (LA recommendation no 5).
- Whilst the majority of LAs were undertaking some type of internal monitoring, the procedures and systems in place for monitoring the interventions at approved dairy establishments were not sufficiently robust to verify the effectiveness of the official controls carried out by officers (LA recommendation no 6).
- In general LAs had appropriate systems in place to respond to incidents and notifications of OTF notifications. However the process of notifying LAs from the APHA requires review as some LAs raised concerns about missing or delayed notifications about the loss of OTF status (FSA recommendation no 3).
- The resources required to deliver official controls, including those at approved establishments, compared to those available needs to be reviewed and clearly identified in Service Plans, to ensure sufficient competent resource is available and maintained to carry out interventions at approved dairy establishments (LA recommendation no 1).

3.0 Summary of Findings

The following is a summary of audit findings which are divided into two sections. The first section focusses on the issues identified following the FVO mission audit of UK dairy control systems and were highlighted in the enforcement letters sent to LAs for their consideration and appropriate action when carrying out official controls at approved dairy establishments. Reference is made to the previous FVO audit recommendations and concerns identified to provide background context for each official control considered, followed by the audit findings and conclusion.

The second section relates to the findings for those relevant sections of the Standard which were audited within the context of this focussed audit of LAs delivery of dairy official controls.

Controls relating to the safety of milk and dairy products referenced in enforcement letters ENF/E/13/011 (England) and ENF/W/14/007 (Wales).

3.1 FBO checks on raw milk quality with particular regard to somatic cell counts and antibiotic residues.

- 3.1.1 The FVO auditors had raised serious concerns that FBO checks on raw milk quality were not always being carried out in accordance with the requirements in Regulation (EC) No 853/2004, Section IX, Chapter III and furthermore that LAs were not always identifying deficiencies in the checks. Regulation (EC) No 854/2004 Annex IV Chapter II requires the competent authority (CA) to monitor the checks being carried out. Regulation (EC) No 853/2004 stipulates raw milk criteria for both plate count and somatic cell count (SCC) for cow's milk and plate count for milk from other species. The FBO is required to take a minimum number of representative samples per month which must meet specified criteria. The results are determined by taking a rolling geometric mean over a two month period for plate count samples and a three month period for SCC samples. If the raw milk fails to comply with either of the criteria the FBO is required to notify the CA and take measures to correct the situation. If either the plate count or SCC criteria are exceeded over a period of three months from first notifying the CA of a failure, then delivery of the milk from the production holding must be suspended or, in accordance with specific authorisation or instruction from the CA, subjected to requirements concerning its treatment and use necessary to protect public health. The suspension of these requirements is to remain in place until the FBO has proved the raw milk again complies with the criteria. Whilst there is no stipulated sampling frequency for monitoring antibiotic residues in milk, this should be determined by the FBO on a risk basis and corrective action taken where non-compliant results are identified.
- 3.1.2 LAs were asked to ensure all milk purchasers were aware of their obligations under Regulation (EC) No 853/2004 and that first purchasers advised the CCA if the milk failed to meet the specified criteria. LA checks should verify that the testing and where necessary, reporting of failures is being carried out by the FBO or first purchasers on their behalf, if processing was on farm and milk was supplied by their own farm. For processing establishments supplied with raw milk by first purchasers, the LA should also check that the FBO has verified that testing of raw milk has been carried out in accordance with Regulation (EC) No 853/2004. This could form part of their pre-requisite checks and the FBO must be able to demonstrate they understand the need for the results to be in a rolling geometric mean.

Audit Findings

- 3.1.3 There was evidence in five LAs that sufficient checks were being carried out by the FBO with appropriately structured questions on the LA inspection aide memoires to verify this was the case.

In nine LAs there was variable reference on inspection aide memoires to the raw milk criteria checks required. These checks were not always included and there was an insufficient level of detail recorded to gain assurance that the FBO checks were being carried out in accordance with requirements. There was a lack of evidence of verification of FBO HACCP based food safety management systems to ensure inclusion of reference to compliance with raw milk criteria with corrective actions to be taken for non-compliances.

At one LA, verification that the FBO was checking that goat milk used for the manufacture of goat cheese met the relevant raw milk criteria in Regulation (EC) No 853/2004 had not been carried out following approval of the establishment. In one LA officers were not aware that the milk supplier undertook the raw milk criteria testing and in another LA there were insufficient records to determine whether FBO checks on raw milk criteria had been properly assessed.

- 3.1.4 There was a lack of clear understanding of the rolling geometric mean expressed by some LA officers and FBO sampling and testing for this was not always being verified. It was not evident that the need to provide monthly reports or nil returns to the Agency as referenced in the enforcement letter had been communicated to all FBOs. One FBO queried the need to file a nil return if the results were satisfactory as they were used to exception reporting.

Conclusion on LA monitoring of FBO raw milk quality checks

Whilst there was generally regard to the raw milk quality checks required to be undertaken by the FBO, in the majority of LAs there was a lack of sufficient detail on inspection records available to gain assurance that this requirement had always been sufficiently assessed to verify the FBO was compliant.

3.2 Ensuring HACCP- based procedures in dairy processing establishments are effective

- 3.2.1 Regulation (EC) No 852/2004 requires that FBOs put in place, implement and maintain a permanent procedure based on the HACCP principles. The FVO auditors noted deficiencies in some of the HACCP based procedures and had concerns over LA monitoring and enforcement of FBO controls, including those for the testing of water in accordance with Council Directive 98/83/EC. LAs were asked to review HACCP based plans with FBOs in their authority to ensure they were fit for purpose in the enforcement letters (see Annex I).

Audit Findings

- 3.2.2 Overall LAs were considering HACCP as part of their interventions and HACCP was included on inspection aide memoires for officers to record their findings in most LAs. In three LAs there was evidence of effective assessment of HACCP and verification of HACCP plans.
- 3.2.3 In the majority of LAs there was insufficient or variable detail recorded on inspection aide memoires to provide assurance that the HACCP plans had been reviewed with the FBO and verified to ensure they were fit for purpose and included reference to compliance with raw milk criteria and corrective actions in all cases. The inspection aide memoire covering the assessment of HACCP was not available for completion in some LAs and in one LA was not specific to official controls relevant to approved dairy establishments. Auditors observed that in one LA there had been a trend of failing to ensure the FBO had carried out an effective shelf life assessment with no scientific basis being available for some high risk product durability dates.
- 3.2.4 There was evidence of checks on the type of water supply being used within dairy establishments with public water supplies being identified as the main source. In six LAs there was evidence that officers had regard to the testing carried out by the FBO in accordance with Council Directive 98/83/EC. There was insufficient detail on the other LA records to verify the LA had checked that the FBO monitored the official checks carried out by the municipal water company. In one LA on site verification visit there was a lack of evidence of officer checks of the FBO testing of a private water supply to confirm compliance with the Directive.

Conclusions on ensuring HACCP procedures are effective

- 3.2.5 Whilst an assessment of HACCP formed part of programmed interventions for LAs, the majority did not keep sufficiently detailed records of the HACCP verification and assessments carried out by the LA. Auditors were therefore unable to determine that HACCP based plans and procedures had been reviewed with FBOs in dairy processing establishments to ensure they were effective and fit for purpose. Furthermore there was a lack of evidence that LAs had verified that FBO controls and monitoring of potable water testing in accordance with Council Directive 98/83/EC were in place and compliant.

3.3 Microbiological Criteria for foodstuffs – Regulation (EC) No 2073/2005

- 3.3.1 FVO auditors identified issues with regard to official controls to ensure that FBOs were in compliance with the requirements in Regulation (EC) No 2073/2005 on the microbiological criteria for foodstuffs. Microbiological criteria can be used in validation and verification of HACCP procedures and other hygiene control measures. This Regulation sets microbiological criteria defining the acceptability of the processes and also food safety microbiological criteria setting a limit above which the foodstuff should be

considered unacceptably contaminated with the micro-organisms for which the criteria are set. LAs were to ensure the FBO had sampling protocols and procedures in place in compliance with the Regulation and that appropriate corrective actions were taken by the FBO following unsatisfactory microbiological results.

Audit Findings

- 3.3.2 There was evidence that microbiological criteria were being assessed and implemented in full in three LAs with suitable checks and detail provided on the inspection aide memoire.
- 3.3.3 Whilst some evidence of assessment of FBO compliance was being carried out in ten LAs, in general the inspection records were not sufficiently detailed to be assured that all the microbiological requirements had been properly assessed to verify implementation by the FBO.
- 3.3.3 In one LA there was insufficient detail maintained and the inspection aide memoire lacked appropriate checks relating to the microbiological criteria for officers to consider. It was observed that another LA failed to ensure establishment of a risk based sampling plan by the FBO, with acceptance of unrepresentative end product testing without validating HACCP shelf life determination.

Conclusion on microbiological requirements

- 3.3.4 The LA records of controls undertaken by the FBO did not, in the majority of cases, provide sufficient detail to gain assurance that the requirements of Regulation (EC) No 2073/2005 had been fully assessed to verify FBO compliance. Further training on the legislative requirements and implementation of the Regulation would be beneficial to assist officers' delivery of this official control.

3.4 Animal by-products in dairy establishments

- 3.4.1 FVO auditors identified issues with the systems in place for the collection and identification of animal by-products (ABP). Article 4.4 of Regulation (EC) 1069/2009 requires FBOs to have in place systems to identify, and collect ABP and also to ensure disposal in accordance with the legal requirements. The enforcement letter asked LAs to ensure that when inspecting, visiting and auditing dairy premises, that documented procedures and practices were in place to ensure ABP were correctly labelled (category 1, 2 or 3), handled and disposed of.

Audit Findings

- 3.4.2 Six LAs were able to demonstrate appropriate checks had been carried out to verify appropriate systems were in place. This was in conjunction with trading standards colleagues in three authorities.

In the remaining nine LAs it was not possible to determine that this had been appropriately assessed by officers. Insufficient details were held on records and there was a lack of suitable structured questions on some inspection aide memoires for officers to consider and record their findings.

Conclusion on ensuring ABP systems were in place

- 3.4.3 The majority of LAs were not able to demonstrate their verification of systems in place for the identification, handling and collection of ABP following their interventions.

3.5 Traceability

- 3.5.1 Regulation (EC) No.178/2002 introduced the traceability requirement with the objective to ensure food safety and to assist in enabling unsafe food/feed to be removed from the market³. FVO auditors identified occasions where FBOs' documentation did not contain records of suppliers for incoming raw materials and FBOs were unable to confirm who the suppliers of ingredients were. This highlighted the need for LAs to ensure that FBOs' documentation is reviewed regularly and that their traceability systems are verified, for example by conducting traceability exercises during interventions.

Audit Findings

- 3.5.2 There was evidence of suitable verification of FBO systems in place for traceability, being undertaken in six LAs with appropriate records on inspection aide memoires. A specific traceability aide memoire for officers to use had been developed in one LA and there was evidence of proactive traceability exercises being undertaken in another LA on both food and packaging at a first purchaser.

In nine LAs appropriate prompts on traceability systems were not always provided on inspection aide memoires and/or there was insufficient detail recorded to verify this had always been assessed or that officers had conducted traceability exercises during interventions.

³ For products of animal origin there are additional traceability requirements in Regulation EC (No) 931/2011 which amends the traceability requirements in Regulation (EC) No 178/2001

Conclusion on assessment of traceability systems

- 3.5.3 There were some good examples of LA verification of FBO traceability systems. However it was not possible for all LAs to demonstrate this had always been adequately assessed by officers due to the lack of detail recorded on inspection aide memoires.

3.6 Deficiencies noted in relation to the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004

- 3.6.1 FVO auditors identified instances where LAs had not taken adequate action to ensure FBO compliance with this regulation. The enforcement letters asked LAs to ensure that FBOs address any non-compliances within a reasonable timescale. If serious deficiencies were found and the LA were not satisfied that they would be rectified immediately or within an appropriate timescale then appropriate enforcement action should be taken.

Audit Findings

- 3.6.2 Overall there was evidence of appropriate LA follow up action being taken where necessary and the FBOs being advised of the requirements needing addressing with timescales and distinction of the legal requirements and recommendations. However there were observations of outstanding structural requirements during some on site verification visits which were not noted on the previous inspection record and evidence that some establishments had been approved before the infrastructure requirements had been met. One LA had adopted a system of self-certification by the FBO that hygiene contraventions which were sometimes more serious had been rectified without being checked by the LA. One audit prompted further action by the LA at a dairy establishment to investigate further deficiencies in hygiene requirements which had been identified at the last intervention.

3.6.3 Conclusions on LA follow up action to general hygiene requirements

In general LAs were taking appropriate follow up action when necessary and communicating the works required to the FBO. However some shortcomings were observed in some cases examined by auditors which weakened the effectiveness of this control and the approval process.

4.0 Relevant Sections of the 'Standard' in the Framework Agreement Delivery Issues

4.1 Organisation and Management- Service Planning

- 4.1.1 It should be noted the audit programme was undertaken during a period of possible restructuring of services in some LAs due to the current financial climate which had potential impact on the way services were delivered in the future.
- 4.1.2 With the exception of one LA, all the LAs audited had some form of Service planning in place, with seven LAs meeting the requirements of the Standard and contained reference to the delivery of official controls in approved establishments. The main omission in a number of the Service Plans related to a lack of clear information on the impact of the delivery of official controls in accordance with the FLCoP, including the demands of approved establishments compared to available local resources i.e. the full time equivalent staff available compared to the resources assessed by the LA as necessary to deliver the service taking account all statutory responsibilities. An assessment of the resources required to deal with approved establishments in service planning should provide an objective basis for prioritising known workloads, to inform local resource allocation decisions and to identify resource shortfalls.
- 4.1.3 It was clear from discussion with LA staff that the delivery of official controls in relation to approved dairy establishments had an impact on LA resources, particularly in terms of the specialist training required. An issue for some LAs was consideration of contingency arrangements with responsibility for dealing with the delivery of official controls in their approved dairy establishments resting with one officer.

Conclusion on Service Planning arrangements

- 4.1.4 Whilst the majority of LAs had Food Service Plans in place they did not contain all the relevant food enforcement information in accordance with the Service Planning Guidance in the Framework Agreement. In particular the resource allocation required in terms of service demands arising from the delivery of dairy official controls compared to resource availability.

4.2 Officer Authorisation and Training

- 4.2.1 EU legislation requires the competent authority to ensure there is sufficient qualified, authorised and experienced staff to carry out their duties (EC Regulation 882/2004 Chapter II, Article 4 paragraph 2.) Overall auditors found that LAs had procedures in place for authorisation of officers and that officers undertaking official controls in approved dairy establishments were appropriately authorised. There was a need to review the legislation officers were authorised under in some LAs to include specific legislation such as the

Animal By Products (Enforcement) Regulations to enable them take appropriate enforcement action where necessary. There were some good examples of authorisation and training matrices being used which were linked to an assessment of competencies but not all LAs were able to demonstrate this. There was evidence some officers had received appropriate training for the delivery of official controls in approved dairy establishments but this was not the case in all LAs with some officers not having received appropriate specialist dairy training. The main issue identified was a need for further refresher training and guidance to ensure officers had the required knowledge to support them whilst undertaking interventions in approved dairy establishments.

4.2.2 Conclusion on officer authorisation and training

In general LAs had appointed suitably qualified and experienced officers to deliver dairy official controls and whilst a number had received appropriate training to undertake this role there was a need to ensure all staff performing official controls relevant to approved dairy establishments received ongoing appropriate specialist training, supported with relevant guidance to enable them to undertake their duties in a competent and consistent manner.

4.3 Identifying Relevant Businesses - Food Premises Databases

4.3.1 LAs are required to set up, implement and maintain a database of the food establishments in their area to support them in their planning and delivery of their intervention programme. Audit checks found 13 LAs were able to identify on their database the approved dairy establishments which matched the Agency list. In two LAs the approved dairy establishments did not match the Agency's list. One LA was able to demonstrate notifying the Agency but the other LA had not informed the Agency of some change in status of establishments.

4.3.2 Conclusion on Food Premises Database

Overall LAs had an appropriate database for their approved dairy establishments to support them in planning their official control programme.

4.4 Inspections / Interventions

4.4.1 The initial response following receipt of the enforcement letter was variable with some LAs noting the contents. Others advised there had been some resulting contact with FBOs, which included in one LA writing to the FBOs advising of them of the requirements. However there was evidence not all LAs had responded to what was advised and amended their approach to inspections to take into account all the key issues identified in the enforcement letter. As a result of the scheduled audit some LAs were in the process of reviewing the requirements highlighted in the letter with FBOs in their area. The majority of LAs had developed an inspection aide-memoire for use in approved dairy establishments to prompt officers during inspections

and to record officer's inspection findings. A common issue identified from the aide-memoires reviewed was that there was variable or insufficient level of detail recorded to support the officer's assessment of the FBO implementation of legislative requirements. Some aide memoires did not contain sufficient structured questions relating to all relevant official controls for officers to record their inspection findings. This made it difficult for officers to demonstrate that the FBOs implementation of those official controls highlighted in the enforcement letter had always been assessed as part of their interventions.

- 4.4.2 Most LAs were inspecting the dairy establishments at the required frequency in accordance with the FLCoP but this was not evident in all LAs and in one LA a number was significantly overdue by 12-20 months from the scheduled date. An issue of giving advance notification to the FBO of planned interventions was observed in one LA contrary to the FLCoP.
- 4.4.3 Some of the approved establishments files examined did not always contain the relevant information as required in Annexe 10 of the Food Law Practice Guidance (FLPG) and in some establishments approval had been granted without all the required infrastructure requirements being in place in accordance with legislation and guidance issued by the Agency for LA officers on the approval of establishments.
- 4.4.4 Although sampling must be risk based there will be some establishments in which there is no routine official sampling. An effective routine sampling plan for the LA in general is considered an essential part of a well-balanced food law enforcement service. Enforcement bodies should prepare a suitable risk based sampling policy and develop and implement a food sampling programme, with due consideration of all the products and premises in the area and any national enforcement priorities. The extent of sampling undertaken was variable; the majority of LAs had sampling policies and programmes in place which included sampling at approved dairy establishments. Where there had been failures, appropriate follow up had been carried out by the LA. Some LAs had taken few or no samples due to resource issues and one LA had reduced sampling in approved establishments following a risk assessment taking into account the sampling carried out by the FBO.
- 4.4.5 The use by an authority of a pre-emptive questionnaire to collect relevant information about the business prior to planning an inspection was found to assist officers in having an overall awareness of the controls in the establishment and to be able to concentrate their intervention on the areas considered as requiring attention whilst on site.

Good Practice

South Lanarkshire Council had developed a useful pre-emptive questionnaire that allowed the effective planning of interventions without giving prior notice of an official control.

Conclusion on establishment interventions and inspections

4.4.6 The majority of LAs were carrying out interventions at dairy establishments at the required frequency. Whilst sector specific inspection aide memoires were being used, they did not always contain enough structured questions to help officers to demonstrate that businesses were being assessed against all the relevant legislation required for official controls in approved dairy establishments. Also, sufficient detail supporting officers' assessments were not always recorded which weakened the evidence that effective official controls had been undertaken.

4.5 Reality Checks

4.5.1 As part of the audit programme, verification visits with officers from the LAs involved were carried out at 16 approved dairy establishments in total. The purpose was to determine the effectiveness of the Authorities' implementation of official controls relevant to approved dairy establishments based on the record of the most recent inspection carried out by officers. Overall, officers were able to demonstrate an understanding of relevant official controls but had not necessarily considered all the issues highlighted in the enforcement letter at the last intervention and records did not always contain sufficient detail to support the officer's assessment. In three LA's there were more significant issues identified in respect of the official controls and approval standards. Deficiencies in the infrastructure requirements required by the Hygiene Regulations which an FBO must comply with prior to approval being granted were identified. In one establishment auditors observed the need to carry out raw milk criteria checks had not been understood by the officer and the FBO. Auditors considered the establishment should not have been approved due to non-compliances with infrastructure requirements and a lack of scientific basis for shelf lives of soft, semi-soft and hard goat's cheeses (i.e. HACCP validation and the presence of infrastructure failures at the time of approval). On the verification visit in one LA the officer informed the auditors he had never seen the process in operation, having only inspected when production of pasteurised product had finished; this is contrary to the FLCoP.

4.6 Documented Procedures at Competent Authorities

4.6.1 EU legislation requires CAs to carry out official controls in accordance with documented procedures which shall contain information and instructions for officers performing official controls (EC Regulation 882/2004 Article 8(3)). The majority had documented procedures in place with a number being able to demonstrate appropriate document control systems. However an overall finding was the procedures needed review to ensure they contained relevant information relating to the implementation of official controls in approved dairy establishments, including the process for dealing with OTF notifications and raw milk criteria failures. One LA had developed an inspection protocol which provided useful guidance for officers. In one LA the procedures had not been

reviewed and did not include a procedure for the approval of establishments and the response to OTF notifications relied on the knowledge of one officer.

Good Practice

Perth and Kinross Unitary Authority had developed a useful inspection protocol covering the detailed requirements of the subject specific legislation, with clarification on pre-requisites and HACCP, showing acceptable standards and compliance examples which were linked to the inspection checklist, so ensuring consistency and coverage for officers.

Conclusion: Documented Procedures

- 4.6.2 Whilst in general documented procedures were provided, some shortcomings were noted in the level of information and instruction provided to officers in some LAs on procedures concerning the delivery of official controls relevant to approved dairy establishments.

4.7 Enforcement

- 4.7.1 Overall authorities had a documented enforcement policy in place. In the majority of LAs auditors were informed no formal enforcement action had been necessary in their approved dairy establishments in the two years preceding the audit. However two reality visits indicated there were establishments requiring LA enforcement action to deal with non-compliances. Where enforcement notices had been served these were found to be appropriate for the circumstances. In one LA an issue was identified with failure to escalate repeated non compliances beyond the notice stage over a considerable period of time. Auditors also noted the LA in question had not frequently monitored progress with remedial action notices served and withdrawal of approval notices had been incorrectly served to formalise surrenders by closed businesses. Another LA had adopted a system of self-certification by the FBO without appropriate follow up monitoring by the LA to verify compliance.

Conclusion on Enforcement

- 4.7.2 As the majority of LAs advised auditors no enforcement action had been necessary in the two years preceding the audit it was difficult to draw a conclusion on the approach to enforcement. However auditors noted that in general appropriate enforcement policies and procedures were in place but had not always been implemented when non compliances were found at establishments. When more formal action had been taken the enforcement notices had been appropriately served and followed up by the LA with one exception.

4.8 Incidents/Reporting of OTF notifications

- 4.8.1 EU legislation requires that there is efficient and effective co-ordination and co-operation between all designated competent authorities conducting official controls (EC Regulation 882/2004 Chapter II, Article 4). Overall LAs had procedures in place to deal with food incidents and alerts and there had been no recent food incidents relating to dairy establishments in the majority of LAs visited. Audit checks considered the process for dealing with notifications issued by APHA to the LA when loss of OTF status occurred and the dairy herd is placed under a TB movement restriction notice. Audit checks confirmed that in general LAs had appropriate systems in place to deal with the OTF notifications with appropriate follow up to inform FBOs of the conditions which apply to milk products produced. Appropriate documented procedures were available in a number of LAs but these needed to be reviewed to include reference to appropriate follow up action to OTF and raw milk criteria failure notifications in some LAs.
- 4.8.2 An issue was highlighted by some LAs regarding their experience of the APHA notification process which had impacted on their response and subsequent contact with FBO's in accordance with Annex 6 of the FPLG. Notifications placing a herd under TB movement restriction (TB2) were reported as sometimes being missing, late, or out of sequence with notifications lifting a herd restriction (TB10). This affected the effectiveness of the LAs initial response and contact with the FBO to ensure that milk from the herd is no longer used for raw milk based products. One LA advised overdue notifications were not being prioritised for follow up as they did not have sufficient resources to deal with all the notifications received. A concern was expressed in one LA about the difficulty in receiving support from the Agency to assist them in undertaking a risk assessment of an unpasteurised cheese product which had been produced before the herd lost its OTF status to determine if it was safe to consume, in accordance with the FPLG.

Conclusion on Incidents/reporting of OTF notifications

- 4.8.3 In general LAs had appropriate systems in place to respond to incidents and notifications of OTF notifications. However some potential shortcomings were noted in respect of the process of notifying LAs of the loss of OTF status and the support provided to LAs in understanding the risk assessment for products made after the loss of OTF status. This has potential to impair the effectiveness of the required LA follow up contact with the FBO, as was the case in the example noted during the audit.

4.9 Internal Monitoring

- 4.9.1 EU legislation requires LAs to have procedures in place to verify the effectiveness of official controls and ensure corrective actions are carried out

when needed (EC Regulation 882/2004 Article 8 (3)). LAs need to carry out appropriate quantitative and qualitative internal monitoring checks to verify conformance with their legal obligations, official guidance and their own policies and procedures across the full range of service activities including any activities relating to approved dairy establishments. Whilst most of the LAs in the audit programme were carrying out some form of quantitative or qualitative internal monitoring, the extent and implementation of LA internal monitoring arrangements varied. Not all LAs had a documented internal monitoring procedure and the majority of LAs audited could not demonstrate that qualitative monitoring relating to the delivery of official controls in approved dairy establishments was routinely being carried out. An issue was highlighted in one LA that as a result of the way the service was structured, officers carrying out official controls were reporting to managers who lacked experience in the requirements of the FLCoP and centrally issued guidance. Without competent supervision or qualitative monitoring there is the potential for non-compliance to be unregulated.

Conclusion on Internal Monitoring

- 4.9.2 Whilst the majority of LAs were undertaking some type of internal monitoring, the procedures and systems in place were not sufficiently robust to verify the effectiveness of the official controls carried out by officers in approved dairy establishments. Not all LAs are therefore effectively monitoring their officers' approach to ensuring FBO compliance with all the relevant requirements in legislation, including the issues highlighted in the enforcement letter.

5.0 Overall Conclusions

- 5.0.1 With some exceptions, in general the LAs audited were undertaking planned interventions at the required frequency in their approved dairy establishments and officers were appropriately authorised to undertake the activity. Whilst most officers had received relevant training, a need for further appropriate training and guidance to support their delivery of official controls in approved dairy establishments was identified.
- 5.0.2 The demands of the service in respect of the delivery of official controls, including those relating to approved dairy establishments, in comparison to the resources available needs to be clearly identified in Service Plans to ensure sufficient competent resource is maintained to undertake the required interventions.
- 5.0.3 Whilst most LAs were carrying out inspections using sector specific aide memoires, these did not always contain relevant structured questions or have sufficient detail recorded to support the officer's assessment of compliance. This made it difficult for auditors to gain assurance that all the official controls which were highlighted in the enforcement letter for LAs to consider at the next intervention had always been sufficiently assessed to verify FBO compliance.

- 5.0.4 The LA internal monitoring procedures to verify the effectiveness of the official controls were not always sufficiently robust to ensure appropriate corrective action was taken if needed.
- 5.0.5 In general LA procedures for dealing with incidents and OTF notifications were satisfactory. However, the subsequent follow up with FBOs when a herd had lost the OTF status was not always as effective due to issues identified in the notification system which had sometimes resulted in the absence of, or delays in receipt of the notification by the LA.

6.0 Other delivery issues raised by LAs

- 6.0.1 During the audit LAs were provided the opportunity to raise any issues for consideration by the FSA concerning the delivery of dairy official controls. The following is a summary of the key issues raised:
- LAs felt enforcement letters issued to LAs by the FSA would be improved if there was more clarity and prioritisation of action required.
 - There is a need for more training and guidance on approved dairy establishments to support officers in their delivery of dairy official controls. This should include those requirements highlighted in the enforcement letter and the LA response to TB notifications.
 - Consideration should be given to prioritising officers for future training who have previously applied to attend specialist dairy training courses.
 - Review the current TB notification process to LAs with APHA to see if the process can be improved to ensure timely notification of herd restriction and lifting of restriction notices. This will ensure there is an effective LA response to notifications received.
 - LAs would like a better understanding of the role of other agencies involved in the delivery of dairy controls.
 - There should be a consideration of centrally issued sector specific aide memoires and procedures to improve LA consistency in their delivery of dairy controls.
 - Review the need for nil returns to the FSA for the raw milk criteria sampling results.
 - Ensure the FSA approved premises list is updated in a timely manner following LA notifications of changes.
 - Query if there is a need to contact the FSA following LA sampling failures of private water supplies in dairies.

7.0 Recommendations

The following recommendations are based on the findings and resulting conclusions and have been separated into two sections; those directed at the FSA and those recommendations LAs have to consider.

No	Recommendations for the FSA.
1.	The FSA should consider the findings from this audit programme with the aim of providing further guidance and training for LA officers on the approval process and delivery of official controls relevant to approved dairy establishments. Specific training on the microbiological criteria of Regulation (EC) No 2073/2005 would also be beneficial for officers. This is to ensure officers have access to appropriate guidance and are appropriately trained and competent to carry out an assessment of FBO compliance with relevant legislative requirements during interventions.
2.	Provide further guidance for officers in respect of the checks required by the FBO to comply with the raw milk criteria requirements under Regulation (EC) No 853/2004 and the action to be taken if failures are identified by the CA.
3.	The FSA should review with APHA the current process of OTF notifications to LAs. This will enable LAs to take effective follow up action where necessary.
4.	The FSA should review the process for providing support to LAs when undertaking risk assessments of dairy products produced before loss of OTF herd status.
5.	The FSA should review the current method of communicating to LAs via enforcement letters to ensure it is clear to LAs what action is to be taken and the level of priority required.

No	Recommendations for LAs.
1.	LAs should review the resources available to ensure there are sufficient suitably trained and competent officers available to deliver official controls at their approved dairy establishments.
2.	LAs should consider the findings from this audit programme with the aim of providing further guidance and training for their officers on the approval process, application of EC Regulation 2073/2005 on Microbiological Criteria for Foodstuffs and the delivery of official controls relevant to approved dairy establishments. This is to ensure officers are appropriately trained and competent to carry out an assessment of FBO compliance with relevant legislative requirements during interventions
3.	LAs should review and develop their inspection aide memoires to ensure they contain structured questions relevant to official controls in approved dairy establishments. This will assist officers in carrying out an appropriate assessment of FBO compliance with relevant legislative requirements.
4.	LAs should ensure sufficient detail is held on inspection records to qualify the officer's assessment of FBO compliance with official controls following an intervention at approved dairy establishments.
5.	LAs should review and implement their procedures to ensure they provide appropriate guidance to officers on the delivery of official controls in approved dairy establishments and to verify the effectiveness of official controls they carry out.
6.	LAs should incorporate a consideration of the FVO recommendations highlighted in the previously referenced enforcement letters in their internal monitoring procedures. This will ensure there is effective monitoring of officers delivery of official controls at approved dairy establishments. There should be a process within LAs to ensure that follow up actions resulting from relevant FVO audits are incorporated into their procedures.

Annex 1 - FSA Enforcement Letters to LAs

The letters which summarised the recommendations and additional concerns raised by the FVO auditors and where relevant the action to be taken by the LA can be found at:

[Enforcement letter Ref: ENF/E/13/011 \(England\)](#)

[Enforcement letter Ref: ENF/W/14/007 \(Wales\)](#)

Annex 2 - Audit Methodology and Design

The audits assessed LA implementation of official controls through:

- (i) Use of structured audit protocols and checklists for checks of LA file and database records relating to routine official controls relating to food establishments audits/inspections, sampling and any resulting follow-up enforcement activities
- (ii) Meetings with LA officers
- (iii) Document reviews including all relevant LA food law enforcement service plans, policies and procedures
- (iv) Accompanied reality visits to selected approved dairy establishments.

Annex 3 - Local Authorities Audited by Type

(October 2014 – March 2015)

The FSA is grateful for the assistance and views provided by officers of the following LAs who were audited during the programme:

	Local Authority	Type of LA
1	Aberdeenshire	Unitary
2	Carmarthenshire	Unitary
3	East Riding	Unitary
4	Herefordshire	Unitary
5	Isle of Wight	Unitary
6	Mendip	District
7	Mid Devon	District
8	Perth & Kinross	Unitary
9	Ribble Valley	District
10	Richmondshire	District
11	South Lanarkshire	Unitary
12	Torridge	District
13	West Dorset	District
14	Winchester City Council	District
15	Wrexham	Unitary

Annex 4 - Summary Report Circulation

All local authorities participating in this audit programme
Local Government Association Regulatory Control Unit (formerly LG
Regulation/LACORS)
Chartered Institute of Environmental Health (CIEH)
Trading Standards Institute
Animal Plant Health Agency (APHA)
Copyright Library
British Library
National Assembly for Wales Library

Annex 5 - Glossary

ABP	Animal By Products
APHA	Animal Plant Health Agency
CA	Competent Authority
CCA	Central Competent Authority
Defra	Department for Environment, Food and Rural Affairs
EC	European Commission
EU	European Union
FBO(s)	Food Business Operator(s)
FLCoP	Food Law Code of Practice
FLPG	Food Law Practice Guidance
FVO	Food and Veterinary Office
HACCP	Hazard Analysis Critical Control Point
LA	Local Authority
OTF	Officially Tuberculosis Free
PLC	Public Limited Company
SCC	Somatic Cell Count
TB	Tuberculosis