To: Heads of Environmental Health Services and Directors of Trading Standards (England)

CC CIEH, TSI, LGR

28 March 2014

Ref: ENF/E/13/011

Dear Colleagues,

Update and outcomes from the FVO audit on controls related to safety of milk and dairy products in the UK

In April 2013 the Food and Veterinary Office (FVO) carried out an audit of the controls related to safety of milk and dairy products in the UK, as part of its routine audit programme. Since the audit the FSA has been clarifying a number of issues raised in the FVO’s audit report and agreeing the action required. I am now able to provide you with feedback on this audit and summarise the agreed recommendations for information and, where relevant, action. I would also like to take this opportunity to thank all of you who were involved in facilitating the visits which took place for your time and support during the audit.

The FVO auditors visited four milk production holdings, 14 dairy processing establishments and two official laboratories throughout the UK. The auditors concluded that the UK has in place an adequate general framework for official controls and that the procedures in place for carrying out and documenting official controls are well established.

However, the auditors noted deficiencies in the implementation of controls in some instances and highlighted areas for concern where improvements are needed. The final report makes seven recommendations to the FSA as the Central Competent Authority which can be found in Annex 2. The FSA has provided a response to the FVO recommendations that sets out our proposed course of action, it can be found at the links below.

Based on the FVO audit findings I would like to draw your attention to key issues that officers should bear in mind when carrying out official controls at dairy establishments.

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

The FVO auditors raised serious concerns that FBO checks on raw milk quality are not always being carried out in accordance with the requirements in Regulation (EC) No 853/2004 and furthermore that LAs are not always identifying deficiencies in the checks.

I would like to ask you to ensure that all milk purchasers are aware of their obligations under Regulation (EC) No 853/2004:

- Geometric means must be calculated accurately using definitive numerical results. It is not acceptable to insert a threshold value into the calculation i.e. where the actual value could be somewhere in excess of the threshold value.
- Procedures must be initiated to ensure that raw milk meets the criteria laid down in Regulation (EC) 853/2004, Annex III, Section IX, Chapter 1, III, points 3 and 4. Where this is not the case, the competent authority (CA) must be informed and measures taken to correct the situation.
- Where the criteria set for plate count and somatic cell count are exceeded over a period of three months from first detection, this milk must be excluded from the food chain.
- Although there is no stipulated sampling frequency for monitoring antibiotic residues in raw milk, this should be determined by the food business operator on a risk basis. Where non-compliant results are identified, corrective action should include an increased sampling frequency, until such times as it can be demonstrated that the situation has been rectified.

In order to effectively demonstrate compliance with these requirements LAs should expect FBOs to maintain evidence of the following:

- HACCP based food safety management plans to include reference to compliance with raw milk criteria with corrective actions to be taken.
- Corrective action taken – to include communications with producers (including those to highlight problems, seek improvements and outline
sanctions if problems persist) and the cessation of milk collection where required.

- Monthly reporting of non-compliant plate count and somatic cell count results or nil return to the FSA Central Operations Hub (COH)
- Monthly reporting of non-compliant antibiotic levels or nil return to COH
- Monthly reporting of all incidents of tanker failures, due to high levels of antibiotic residues, or nil return, to COH
- Disposal of non-compliant milk in accordance with Regulation (EC) 1069/2009

Returns to the COH should be sent to the COH mailbox:

dairyhygienedata@foodstandards.gov.uk

You may find it useful to refer to the FSA guidance on the testing of milk for antibiotic residues. Although this is due to be further updated very shortly, the advice in this guidance will help LAs and FBOs to comply with the requirements in Regulation (EC) No 853/2004 as regards the testing of milk for antibiotic residues:

http://www.food.gov.uk/business-industry/guidancenotes/dairy-guidance/guidancemilktestantibioticres

A link to the FVO final report and recommendations and the FSA response to them can be found at the links below. The recommendations made in the final report are also attached in annex 1 to this letter. Further detail on areas of concern raised by the FVO which LAs need to note and action are in Annex 2.

If you have any questions, please contact Nick Laverty:

nicholas.laverty@foodstandards.gsi.gov.uk

Yours sincerely

John Barnes
Head of Local Delivery Division

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1 In accordance with Reg. (EC) 854/2004 Annex IV, Chapter II - Control of Raw Milk upon Collection.
Annex 1- Recommendations made by the FVO auditors in the final report of an audit carried out in the United Kingdom from 08 to 19 April 2013 with regard to official controls related to the safety of milk and dairy products

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<tr>
<th>No.</th>
<th>Recommendation</th>
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<tr>
<td>1</td>
<td>To ensure that the monitoring by the Competent Authorities of the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853 is carried out as required in Chapter II of Annex IV to Regulation ((EC) No 854/2004. Furthermore, to ensure that the monitoring is effective and that the quality of the monitoring is ensured, as required in Article 4 of Regulation (EC) No 882/2004, and that it guarantees that the food business operators’ systems in place for the control of raw milk and colostrum are in compliance with the requirements of Regulation (EC) No 853/2004.</td>
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<td>2</td>
<td>To ensure that audits of Hazard Analysis Critical Control Points-based procedures (Article 4 (3) (a) and (5) of Regulation (EC) No 854/2004) are effective.</td>
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<td>3</td>
<td>To ensure that the official controls on potable water cover all the requirements of Council Directive 98/83/EC and that effective corrective action is taken when relevant parameters are exceeded.</td>
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<td>4</td>
<td>To ensure that the official controls on microbiological criteria are effective and cover the verification of the compliance of the food business operators with the rules and criteria of Regulation (EC) No 2073/2005.</td>
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<td>5</td>
<td>To ensure that animal by-products in dairy establishments are subject to an adequate control system, including their collection and identification, as required in Article 4.4 of Regulation (EC) 1069/2009.</td>
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<td>6</td>
<td>To ensure that the deficiencies noted in relation to the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004 are addressed in dairy establishments.</td>
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<td>7</td>
<td>To ensure that all milk and colostrum production holdings undergo regular official controls to verify that hygiene requirements are being complied with, as required in point 3, Chapter I, Annex IV to regulation (EC) No 854/2004.</td>
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Annex 2. Additional concerns raised by FVO auditors and action for LAs

1. Ensuring HACCP-based procedures in dairy processing establishments are effective

As you will be aware, Article 5 of Regulation (EC) No 852/2004 requires that FBOs put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. The FVO auditors noted deficiencies in some of the HACCP-based procedures in place and furthermore had concerns over the enforcement of FBO controls by LAs, including those for the testing of water. LAs are asked to ensure that:

- HACCP-based procedures in place at dairy processing establishments in your area are kept up to date and reviewed on a regular basis.
- HACCP-based plans and procedures are reviewed with the FBO to ensure they are fit for purpose
- What is documented within FBOs’ food safety management systems is put into practice by the FBO effectively in line with the requirements in Article 4 (3) (a) and (5) of Regulation (EC) No 854/2004.
- Official controls on potable water take into account all the requirements of Council Directive 98/83/EC
- FBOs take effective corrective action when relevant parameters for potable water are exceeded
- Where multiple sources of water are used in an establishment (e.g. municipal and private supplies), there are clearly documented procedures which detail what the different water supplies are used for


FVO auditors identified issues with regard to official controls to ensure that FBOs are in compliance with the requirements in Regulation (EC) No 2073/2005 on the microbiological criteria for foodstuffs. LAs should ensure that:

- FBOs’ own sampling protocols are appropriate for the activities conducted at the establishment in question, for example frequency of sampling and the organisms tested for are those stipulated in Regulation (EC) No 2073/2005, unless justification is provided where alternative sampling frequencies are applied as described in Articles 4 and 5 in the Regulation or there is no prescribed sampling frequency.
- FBOs either use the ISO reference methods for testing their own samples or alternative methods that have been validated and, where appropriate, certified as required by Article 5 of the Regulation. The
testing laboratory should provide the necessary evidence on validation of methods but is recommended that this is also held by the FBO

- The correct numbers of units, comprising a sample are taken (FBO or official control sample), or evidence is provided to support the application of alternative sampling plans as described in Article 5 in the Regulation.
- Shelf life assessments for products are fit for purpose and appropriate for the intended use, taking into account handling and storage by final consumer
- There are documented procedures in regard to sampling, including for environmental contamination, for example *Listeria monocytogenes* in the production environment, and the procedures are appropriate
- Sampling records are checked during inspections and visits and that there is a documented procedure in place within the food safety management system for corrective actions following failures or unsatisfactory results.
- Corrective actions are taken following unsatisfactory microbiological results, in accordance with the procedures documented

3. **Animal by-products in dairy establishments**

In the majority of dairy processing establishments visited FVO auditors picked up 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 requirements elsewhere in the same Regulation (articles 12 – 14 refer). LAs are asked that when inspecting, visiting and auditing dairy premises, they ensure that:

- Containers used for collection of ABP are clearly labelled and easily distinguishable from containers used for collection of products destined for human consumption
- Documented procedures and practices are in place to ensure ABP are correctly labelled (cat 1, 2 or 3), handled and disposed of.

4. **Concerns with traceability**

There were 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 FBO documentation is reviewed regularly and that their traceability systems are verified, for example by conducting traceability exercises during interventions.
5. Deficiencies noted in relation to the general hygiene requirements laid down in Annex II to Regulation (EC) No 852/2004

The majority of establishments visited were found to be compliant with the general hygiene requirements in Annex II to Regulation (EC) No 852/2004. However, there were instances where this was not the case and for which LAs had not taken adequate action to ensure compliance. Examples of non-compliances include:

- Poor construction and maintenance of premises such as worn floors, cracked pipework, evidence of rust, mould growth on walls/ceilings
- Inadequate drainage and pooling of water on floors
- Poor wrapping of product leaving it exposed
- Refrigeration units with build-up of ice
- Lack of adequate space

Where non-compliances exist, LAs must ensure that procedures are put in place by the FBO to address them within a reasonable timescale. If serious deficiencies are found and you as the CA are not satisfied that there are assurances that they can be addressed immediately or within a reasonable timescale, consideration should be given to enforcement action and suspension or withdrawal of approval where appropriate. Guidance on this process can be found in the FSA guidance to LAs on the approval of establishments:
http://www.food.gov.uk/multimedia/pdfs/enforcement/approvalsguidance.pdf