Guidance for Local Authority Enforcement Officers on the Production of Cheese from Unpasteurised Milk

Produced by the Joint Specialist Cheese & Risky Foods Short-Life Working Group
October 2018

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1.1 Purpose of Guidance

This guidance aims to ensure a consistent approach to enforcement is applied throughout Scotland by Local Authority enforcement officers with regard to official controls in establishments involved in the production of cheese made from unpasteurised milk. The guidance also applies when considering applications for approval in accordance with EC 853/2004.

In particular it aims to assist officers in verifying the validation of food safety management systems (FSMS) for the production of such cheese and suggests the enforcement approach in the absence of validation/verification. It is important to emphasise that the Food Business Operator (FBO) is responsible for validating the FSMS, and verifying, on an on-going basis, that it is operating effectively. The role of the enforcement officer is to ensure appropriate validation and verification is being undertaken by the FBO, through the evaluation of the FSMS, and where necessary, additional checks to verify the efficacy of the system.

1.2 Scope of Guidance

This guidance applies to all establishments producing cheese from unpasteurised milk. The scope is not restricted to milk from a specific species and is considered applicable to cheese made from cows, goats, sheep and buffalo milk.

The guidance has been developed in relation to the control of STEC (including E. coli O157), however, it is recognised that there are currently limitations in relation to testing for STEC, including access to accredited commercial laboratories, the availability of methods for detecting all STEC strains and the interpretation of results. The implication of this is that FBOs may not be in a position to demonstrate that their FSMS is validated for the control of all STEC strains1.

This document therefore intends to provide a guide to the evidence that is needed from cheesemakers in order to demonstrate that they understand the hazards associated with STEC, that they have appropriate controls in place to reduce the risk of contamination and are implementing testing and audit regimes to verify that these controls are operating as effectively as possible.

Whilst the guidance refers primarily to the control of STEC, it is expected that FBOs will also have identified other relevant pathogens (e.g. Listeria monocytogenes, coagulase positive Staphylococcus aureus, Salmonella) as hazards and introduced validated controls for these as part of their FSMS.

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1 Additional information on STEC testing methods is provided at Annex 3. Enforcement officers are advised to consult their Food Examiner or Food Standards Scotland for advice on methods for STEC testing.
The guidance considers the potential for STEC to be present in raw milk used for the production of cheese made from unpasteurised milk and its potential to survive during the production of certain types of cheese. Subsequent to the controls at milking, it is expected that establishments will have implemented effective controls to prevent cross contamination at later stages during the production process. Therefore the control of downstream cross contamination risks are not discussed further in this guidance. (Upstream controls relate to milk production, storage and where applicable transport. Downstream controls relate to all of the stages of raw milk cheese production following receipt of raw milk.)

When upstream controls are being relied upon to ensure food safety, the principles of cross contamination and Food Safety Management will require to be applied throughout the supply chain from the earliest point onwards. This will involve establishments which would not normally be required to apply such principles such as primary producers of milk.

The importance of a close working relationship between the milk production holding and cheesemaker is therefore of critical importance, particularly where the milk is sourced externally i.e. from a dairy herd not under the control of the cheesemaker.

The European Guide for Good Hygiene Practices in the Production of Artisanal Cheese and Dairy Products and the Specialist Cheesemakers Association Assured Code of Practice provide detailed guidance on raw milk production and the cheese production process. It is expected that FBOs will be familiar with these documents and will have implemented the controls outlined in them. This guidance does not, therefore, discuss the specific controls outlined in these documents, but focuses on the evidence that is needed to demonstrate, as part of the FBO’s FSMS, that the controls they are implementing are effective.

1.3 Format of Guidance

The guidance consists of:

- An enforcement decision tree to assist officers
- Supplementary guidance to assist in verifying the validation status of the documented FSMS (Section 2, Annexes 1 & 2)
- Officer resources (Annex 3)

1.4 Revision and Adoption of Guidance

This document is intended for the purpose of the new enforcement approach proposed by SFELC for the inspection and enforcement of food safety controls applied by cheesemakers producing cheese made from unpasteurised milk.

The guidance reflects current knowledge and understanding in relation to STEC and the production of cheese from unpasteurised milk. It is intended to review and update
this document in December 2019 based on the experience of Local Authority enforcement officers following implementation of the proposed approach.

The guidance will also be updated on an on-going basis as further evidence becomes available, particularly in relation to existing gaps in scientific data relating to the microbiological quality of raw milk used in artisan cheese production, and the effect of controlling factors/control measures on the survival and growth of STEC and other pathogens. A full review of the guidance will take place in April 2022 taking into consideration all newly available scientific data to determine whether the enforcement approach outlined in this guidance is still appropriate.

This guidance accordingly recognises the potential for residual food safety risk on the part of FBOs who continue to place food upon the market pending the comprehensive validation of their procedures based upon the HACCP principles. This guidance suggests a pragmatic and an interim approach, which is considered to be balanced, proportionate and reasonable to the level of potential residual risk and which is also recognised as consistent with Food Standard Scotland’s Regulatory Strategy.

In deciding to adopt the approach within this guidance, it is suggested that Lead Officers fully advise their Authority of the implications of this guidance and that this guidance is approved by the Elected Members as an addendum to the existing Enforcement Policy.

Continued application of this guidance is only considered to be appropriate where Official Controls continue to verify that there is no actual exposure of the consumer to a food safety hazard. In circumstances where risks are verified as actual (i.e. no longer potential in terms of Procedures based upon the HACCP principles that remain to be validated) LAs must take the appropriate enforcement action in terms of their own Enforcement Policies.
Decision Tree to Support the Proposed Enforcement Approach

1. Enforcement action in accordance with Food Law Code of Practice & Enforcement Policy
2. Consider cheese in store/distribution where produced without validation or verification

- Official Control verification of validation exercise
  - Is there satisfactory evidence that the FSMS is validated and verified with regard to STEC control for each product? ¹
    - No
    - Yes
      - Is the FBO following industry best practice²
        - No
        - Yes
          - Do they have a sampling regime in place for verifying the controls according to the schedule in Annex ²³
            - No
            - Yes
              - Retain copy of FSMS and review at next official control visit

- Allow process to continue
  - Retain copy of FSMS and review at next official control visit

NOTES

1 See Section 2.1: Verification of validation
2 See Section 2.2: Industry best practice
3 See Section 2.3: Sampling
2.1 Verification of Validation

The SFELC document ‘Verification of Food Safety Management Systems: Principles for Official Controls in the Approved/Manufacturing Sector’ provides guidance for officers on the effective verification of FSMSs, including the validation process. (Note this document is currently being piloted, however, can be made available to officers on request by contacting SFELC@fss.scot)

Article 5 of EC Regulation 852/2004 requires identification of hazards which require to be prevented, eliminated or reduced to an acceptable level and identification of the critical control points at the step(s) which will achieve this.

With regard to raw milk cheese production, the validation process for each establishment will vary depending on how the FBO elects to control the significant hazards relating to their products. The FBO is required to provide sufficient evidence to satisfy the Local Authority that they have identified significant hazards and are taking appropriate measures, which will consistently prevent, eliminate or reduce these hazards to an acceptable level. As there are a variety of ways this may be achieved it is not possible to specify what evidence will require to be provided, however, this is discussed in more detail below.

It is expected that a FSMS for the production of cheese made from unpasteurised milk will identify STEC/E. coli O157 as a hazard which requires to be prevented, eliminated or reduced to an acceptable level. STEC/E. coli O157 can contaminate raw milk through the introduction of faecal material during the milking process. Stringent hygiene controls at milking therefore play a key role in preventing the introduction of faecal contamination which is particularly important when the FBO is unable to demonstrate that pathogens are either eliminated or reduced to an acceptable level further downstream during the processing/maturation stages.

Where an FBO elects to demonstrate that STEC/E. coli O157 is prevented, supporting evidence to validate this will require to demonstrate that either upstream controls are in place to prevent contamination of the raw milk or that any contamination in the incoming raw milk will be detected to allow for effective corrective actions. This is summarised in Table 1 below, with examples of evidence required. However, given the potential for contamination of raw milk and the limitations of sampling, it is considered unlikely that FBOs will choose to validate this proposition but rather consider these factors in combination with the cheese production process as discussed below.
Table 1: Validation Evidence – (Upstream Controls) ‘Prevention’

<table>
<thead>
<tr>
<th>System of control</th>
<th>‘Prevention’ – Source Controls are effective in preventing or detecting faecal (STEC) contamination of incoming raw milk i.e. further controls are not validated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard to be demonstrated</td>
<td>E. coli O157/STEC is either absent in the incoming milk or, where, present, will be detected to allow for implementation of timely and effective corrective actions</td>
</tr>
</tbody>
</table>

Examples of evidence which may contribute to a validated FSMS

(a) Evidence that upstream controls are in place to **prevent** E. coli O157/STEC contamination of the raw milk supply (considered to be unrealistic).

(b) Evidence that upstream controls are in place to **minimise** E. coli O157/STEC contamination of the raw milk supply i.e. evidence of a robust system of audit checks in place to verify that the necessary hygiene controls are being applied consistently and effectively at all stages during milking, transportation and storage of raw milk prior to processing, in conjunction with a sampling programme for every incoming batch of raw milk.

(c) Where the FBO’s proposition is that the upstream controls **minimise** E. coli O157/STEC contamination of the raw milk supply rather than prevent it, the sampling programme referred to at (b) above for a FSMS based on prevention of contamination would require to ensure that E. coli O157/STEC in the raw milk will **always** be detected where present (considered to be unrealistic)

(d) Effective internal traceability to allow for the isolation of any batch of cheese already in production from milk where E. coli O157/STEC has been detected and controls to prevent cross contamination of other batches.

Where an FBO elects to demonstrate that STEC/E. coli O157 is **reduced to an acceptable level**, it is considered necessary for consistency of enforcement to agree what the acceptable level is. The low infective dose of STEC/E. coli O157 requires the precautionary principle\(^2\) to be applied, therefore, the acceptable level is considered to be absence in the end product, in effect demonstrating that STEC/E. coli O157 has been **eliminated**. This is consistent with the **HPA Guidelines for Ready to Eat Foods** which requires absence of E. coli O157 in 25g of ready to eat food.

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\(^2\) Regulation (EC) 178/2002, Article 7
It is likely that this will involve a combination of ‘source control’ i.e. minimising contamination in the incoming milk and ‘process control’ i.e. demonstrating that the production process is effective in reducing any contamination in the raw milk to an acceptable level. This is summarised in Table 2 below.

<table>
<thead>
<tr>
<th>Table 2: Validation Evidence – (Downstream Controls) ‘Reduction to Acceptable Level/Elimination’</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>System of Control</strong></td>
</tr>
<tr>
<td>'Reduction to An Acceptable Level/Elimination’ – The milk is subject to one or more processes which eliminate STEC/E. coli O157 or results in physico-chemical parameters (i.e. the chemical and physical properties) in the product which have this effect.</td>
</tr>
<tr>
<td><strong>Standard to be demonstrated</strong></td>
</tr>
<tr>
<td>Process steps (most likely hurdle effect of individual factors) are effective in reducing E. coli O157/STEC in the raw milk to an acceptable level i.e. elimination.</td>
</tr>
</tbody>
</table>

**Examples of evidence which may contribute to a validated FSMS**

(a) Evidence of upstream controls to minimise contamination in the incoming raw milk (see table 1 (b)).

(b) Sampling programme to demonstrate the specification for incoming raw milk is consistently achieved and that the sampling programme ensures pathogen risks are being adequately managed throughout the production process. The physicochemical characteristics of the cheese should also be monitored in accordance with the food safety management system to allow any changes to be identified which could increase the risk of E. coli O157/STEC survival and growth.

(c) Scientific evidence which demonstrates the process is effective in eliminating E. coli O157/STEC e.g.
   a. Historical testing data
   b. Relevant published scientific data
   c. Mathematical modelling/challenge testing

The above is a non-exhaustive list of the types of evidence which could be provided, however, these examples should not be considered in isolation.

General mathematical models (such as ComBase) may have limited use in fermented foods such as cheese – as they do not take into account the effects of competitive microflora present, leading them to over-predict growth of pathogens. The Australian Raw Milk Cheese Decision Support has however been specially developed for this industry and can help cheesemakers assess the impact of milk quality and production methods on the safety of their cheese. The tool can be accessed here [http://www.foodsafetycentre.com.au/RMCtool.php](http://www.foodsafetycentre.com.au/RMCtool.php).

It should also be borne in mind that mathematical models and challenge tests will typically have been conducted with respect to specific STEC serotypes (usually O157), and it is possible that other serotypes (e.g. non-O157s) may behave slightly differently in terms of their ability to survive and grow during the process. This type of evidence alone would therefore not be adequate for validation and should always be backed up by other appropriate evidence (such as sampling results). It should also be noted that validation of process controls is complex and FBOs should be advised to seek technical support when designing their FSMS to ensure they understand how this evidence should be collected and used.
Whilst there is a requirement for FSMSs to be validated, it is recognised that, in the case of production of cheese from unpasteurised milk, knowledge gaps currently exist which may result in FBOs being unable to achieve the standards outlined above.

FSS and Local Authorities will continue to work in collaboration with industry with the aim of filling these knowledge gaps. However, in the interim it is considered appropriate to allow production to continue where the FBO can demonstrate that (a) industry best practice is applied; (b) is supported by a comprehensive sampling programme and (c) compliance with Regulation (EC) 852/2004 is currently demonstrated. Further guidance on these is provided in sections 2.2 and 2.3. Essentially this will result in a combination of source controls and process controls, with verification sampling at key points for indicator organisms and/or pathogens. The inherent variability in the cheesemaking process, and absence of defined critical control points means that full validation will not be achievable in many cases. This guidance is therefore intended as a pragmatic approach which will allow Local Authority enforcement officers to assess due diligence by FBOs, accepting that there will always be an element of residual microbiological risk associated with raw milk cheeses compared to other ready to eat products. It is also important to highlight that responsibility for the safety of final products placed on the market sits squarely with the FBO, and the role of the enforcement officer is to ensure that there is evidence that the FSMS is operating effectively.

In such cases the FSMS will still require to be fully documented in accordance with Regulation (EC) 852/2004, Article 5. Therefore, if the FBO is unable to demonstrate full compliance with either of the relevant standards of evidence detailed in Tables 1 or 2, the general validation requirements outlined in Annex 1 and Table 3 will still require to be included as part of the FSMS.

### 2.2 Industry Best Practice

The European Guide for Good Hygiene Practices in the Production of Artisanal Cheese and Dairy Products and the Specialist Cheesemakers Association Assured Code of Practice provide detailed guidance on raw milk production and the cheese production process. It is expected that FBO’s will be familiar with these documents and will have implemented the controls outlined in them.

It is recognised that there may be scenarios where compliance with specific aspects of these documents is not practical, justified or necessary. Where this is the case, the justification for deviation from industry best practice should demonstrate that it is of a comparable standard and be agreed with the enforcement officer and documented.

### 2.3 Sampling

Guidance on sampling plans for hygiene indicator organisms and STEC/E. coli O157 is provided in Annex 2. These recommendations are in addition to the legal requirement for FBOs to ensure that their sampling plan allows them to demonstrate compliance with Regulation (EC) 2073/2005 on The Microbiological Criteria for Foodstuffs.

Effective interpretation of sample results is critical, particularly in relation to generic E. coli and STEC. It is therefore important that the sampling plan for the establishment
identifies procedures to be followed in the event of presumptive or confirmed results to allow for an effective, proportionate and risk based response.

Guidance on the interpretation of STEC results can be found in Annex 3 Officer Resources.

2.4 Traceability

It is essential that traceability systems are in place to allow the relevant batches to be identified and isolated effectively and as soon as possible\(^3\) in the event that a breakdown in the FSMS is identified e.g. unsatisfactory results, process failure which requires a product withdrawal or recall to be initiated. To minimise the scale of any recall to affected batches only requires an effective internal traceability system to be implemented.

For the purpose of product recall or withdrawal, traceability requirements in accordance with Regulation EC 931/2011 requiring the following information to be supplied to the FBO to whom the food is supplied and to the competent authority on request shall be provided:

a) An accurate description of the food;

b) The volume or quantity of the food;

c) The name and address of the FBO from which the food has been dispatched;

d) The name and address of the consignor (owner) if different from the FBO from which the food has been dispatched;

e) The name and address of the FBO to whom the food is dispatched;

f) The name and address of the consignee (owner), if different from the FBO to whom the food is dispatched;

g) A reference identifying the lot, batch or consignment, as appropriate; and

h) The date of dispatch.

The information above (a) to (h) shall be updated on a daily basis and kept at least available until it can be reasonably assumed that the food has been consumed.

Annex 1: Validation Requirements

\(^3\) The SFELC artisan cheese group considers that the provision of traceability information within 4 hours of being requested would be appropriate in this case, in line with industry standards.
The FSMS for the production of raw milk cheeses should take account of the following key factors which can impact on microbiological safety:

- microbiological quality of raw milk
- rate and degree of the acidification step
- temperature and time of curd cooking
- temperature and time of maturation
- physico-chemical changes through production
- prevention of recontamination from the processing environment

The ability of pathogens to survive and/or grow in cheese is also dependent on the physico-chemical characteristics of the cheese (pH, salt content, water activity and the concentration of organic acids, primarily lactic acid).

In order to be able to demonstrate that their FSMS is effective in controlling the risks of STEC and other pathogens, FBOs should be required to demonstrate the following:

- that all possible steps have been taken to ensure the raw milk does not become contaminated with faecal pathogens
- that they understand how the intrinsic physico-chemical characteristics of the cheese affect the ability of pathogens to grow and survive
- that the process controls are effective in minimising the risk of STEC being present in the end product

When assessing the evidence used to validate a FSMS enforcement officers should refer to the Codex Alimentarius ‘Guideline for the Validation of Food Safety Controls’ document (reference CAC/GL 69-2008).

Further details of the type of specific evidence required to support validation of microbiological safety controls for raw milk cheese production are provided in Table 3.
Table 3: General Validation Requirements

- Evidence that the FBO has identified STEC/E. coli O157 as a potential hazard and has undertaken an evaluation of the risks associated with this hazard. Further guidance on methodology that can be used for hazard analysis and risk evaluation can be found in the Commission Notice OJEU C278 as referenced in Annex 3: Officer Resources.

- Process Flow Diagram and FSMS plan which is relevant for each product. In cases where different types of cheese are made using the same ingredients and recipes, it may be appropriate for businesses to use the same process flows. However, consideration should always be given to the need for separate FSMS plans for different types of artisan cheeses based on the nature and characteristics of each product.

- Detailed product descriptions which include the physico-chemical characteristics of each product at appropriate points throughout the production process and in the finished product. Particular regard should be given to pH at the acidification stage, salt content and water activity.

- FSMS includes controls upstream at raw milk supplier and distribution, transport and storage.

- Specification for incoming raw milk with evidence that the specification is being met through testing records.

- Records of audits of milk production holdings.

- The FBO must understand and document the controlling factors which contribute to the safety of their product. In reality, these are likely to include both source controls and process controls.

- Evidence that the FBO is following industry best practice.

- Sample results to demonstrate consistency of the physico-chemical parameters throughout production\(^4\).

- A traceability system in place which, in the event of unsatisfactory results, allows the relevant batch to be identified and isolated quickly and effectively. To minimise the scale of any recall to only the affected batch requires an effective internal traceability system to be implemented.

\(^4\) Routine testing for pH, water activity and salt content should always be undertaken to demonstrate that the process is operating consistently and no changes occurred that could affect microbiological quality.
## Annex 2: Suggested sampling plans which FBOs can use to assist in the verification of controls for STEC contamination in the production of raw milk cheeses

<table>
<thead>
<tr>
<th>Product</th>
<th>Frequency¹</th>
<th>Sample²</th>
<th>Micro-organism</th>
<th>Purpose</th>
<th>Satisfactory</th>
<th>Borderline</th>
<th>Unsatisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Incoming Raw milk</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Every batch of incoming raw milk¹</td>
<td>Sample which is representative of the batch²</td>
<td>Generic E. coli</td>
<td>To verify that hygiene controls at milking are being applied consistently</td>
<td>&lt;20 cfu/ml</td>
<td>20-≤100 cfu/ml</td>
<td>&gt;100 cfu/ml</td>
</tr>
<tr>
<td></td>
<td>Minimum 2 samples month (rolling geometric average)</td>
<td></td>
<td>Aerobic colony count at 30°C¹</td>
<td></td>
<td>&lt;10,000 cfu/ml</td>
<td>NA</td>
<td>≥10,000 cfu/ml</td>
</tr>
<tr>
<td></td>
<td>At an appropriate risk based frequency in accordance with FSMS¹</td>
<td>Milk filter, or sample which is representative of the batch²</td>
<td>E. coli O157/STEC³</td>
<td>Not detected</td>
<td>NA</td>
<td>Detected</td>
<td></td>
</tr>
<tr>
<td><strong>Curd</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>At an appropriate risk based frequency in accordance with FSMS¹</td>
<td>Sample which is representative of the batch²</td>
<td>E. coli O157/STEC</td>
<td>As an alternative or supplementary check to verify that STEC contamination is not being introduced to processing via the milk supply</td>
<td>Not detected</td>
<td>NA</td>
<td>Detected</td>
</tr>
<tr>
<td><strong>End Product⁴</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>At an appropriate risk based frequency in accordance with FSMS¹</td>
<td>Sample which is representative of the batch²</td>
<td>Generic E. coli</td>
<td>To verify hygiene controls during processing and maturation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Frequency sufficient to verify compliance with FSMS¹</td>
<td>Sample which is representative of the batch²</td>
<td>E. coli O157/STEC</td>
<td>To verify the safety of end product</td>
<td>Not detected</td>
<td>NA</td>
<td>Detected</td>
</tr>
</tbody>
</table>

¹ The frequency and sample size may need to be increased in cases of high risk or when successive results are unsatisfactory.

² The sample size is based on the geometric average of the milk production over the sampling period.

³ Micro-organisms: Species and serotypes should be identified for all samples.

⁴ End product type and frequency of sampling will depend on the type of cheese production and the safety requirements of the final product.

Notes on sampling and interpretation of test results

1. Enforcement officers should assess the appropriateness of the sampling frequency set by an FBO on a case-by-case basis. Monitoring and trend analysis should be undertaken with reference to established legislative standards/guidelines including the SCA Approved Code of Practice.

With regard to sampling for STEC/E. coli O157, frequency will depend on a number of factors including the strength of evidence for robust hygiene controls at milking and results of previous sampling programmes. Establishing an appropriate risk-based sampling frequency will require FBOs to build up a data set which demonstrates, over a suitable period of time, that generic E. coli levels are consistently within recommended limits and that the risks of STEC/E. coli O157 contamination have been minimised. This may initially require testing to be undertaken on every batch of raw milk and all appropriate stages of each production line for a sufficient period of time to capture a robust dataset which takes account of factors which could impact on contamination such as seasonality, change in milk supplier or herd management practice.

FBOs may be able to justify reducing the sampling frequency if historical results demonstrate that their hygiene controls are operating consistently and effectively. Thereafter, the need for increased pathogen checks should always be considered when the results of generic E. coli show trends which are indicative of an increased risk of contamination with faecal pathogens (i.e. when an upward trend or spike is detected).

2. When determining representative sample size FBOs should consider relevant sources of information including their scientific laboratory and ISO 707:2008 Milk and Milk Products – Guidance on Sampling.

3. Aerobic colony count results should be considered as a rolling geometric average over a two month period. Guidance on this is referenced in Annex 3: Officer Resources

4. With regard to EPT, all FBOs should be testing end product for generic E. coli and STEC/E. coli O157 at a frequency which is appropriate to the scale and type of cheese production, and which also takes account of any adverse results identified earlier in the process.

It should be noted that EPT alone is not sufficient validation that process controls eliminate STEC/E. coli O157. Evidence should be provided that the process controls in place (including hygiene controls throughout the process, and physico-chemical conditions during maturation) are capable of either preventing STEC/E. coli O157 contamination, and/or ensuring it does not survive and grow.

5. At the time of writing this guidance, testing methods covering all STEC strains are not widely available, and therefore checks for E. coli O157 (and, where possible, other known serotypes) may be accepted. For producers who are able to employ STEC testing using molecular methods (PCR or whole genome sequencing), positive results are interpreted as the identification of a stx gene in an isolated E. coli cell.
6. Actions to be taken by the FBO when adverse results are identified through testing of the raw milk supply.

The actions outlined below are generic examples which may be implemented by an FBO in the event of borderline or unsatisfactory results for raw milk. The corrective actions to be taken by the FBO in such scenarios should be clearly identified in their FSMS.

**Unsatisfactory results for STEC/E. coli O157 (i.e. detected) in raw milk supply**

- If possible, milk should be discarded or diverted for pasteurisation or heat treatment capable of eliminating STEC. If cheese production has already started, product should not be placed on the market, unless the FBO can provide robust evidence that process capability is validated i.e. control measures later in the process are capable of eliminating STEC/E. coli O157.
- Premises and equipment to be cleaned and disinfected using BS EN 1276/BS EN 13697 compliant chemicals, effectiveness being verified by use of environmental swabs.
- Conduct increased testing of other batches processed since failed sample taken.

**Borderline/Unsatisfactory results for generic E. coli in raw milk supply**

- Investigation of milk supply to ensure hygienic conditions up to the point of sampling. This should include a thorough review of production hygiene and cleaning.
- Identification of potential hygiene issues and sources of contamination with appropriate action taken where necessary.
- Effective cleaning regimes in place to prevent cross contamination.
- Sampling of cheese produced from the affected batch of milk supply to ensure pathogen results are satisfactory.
- Action should be proportionate to the levels detected, taking into account previous results.

7. The FBO’s FSMS should identify the corrective actions to be taken in the event that elevated levels of generic E. coli (specified by the FBO) are detected in finished product. This may include further pathogen testing and root cause analysis.

**FBO responsibility to self-report food suspected as not meeting food safety requirements**

Food businesses should be reminded that they have a responsibility to notify their local authority where they believe that they may have produced, processed, manufactured or distributed food that does not comply with food safety requirements. There is an expectation therefore, that FBOs will inform their local authority where cheese is being produced with milk that has returned unsatisfactory results or where product being produced is out with the physico-chemical parameters specified as critical controls in the product manufacture.

**Annex 3: Officer Resources**
HACCP

**OJEU C278 Commission Notice** on the implementation of food safety management systems covering prerequisite programmes (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses.

Codex Alimentarius *Guideline for the Validation of Food Safety Controls* document reference CAC/GL 69-2008

STEC

**UK Working Policy on Detection of STEC in Food by Official Controls and Food Business Operator Sampling and Testing.**

*Shiga Toxin Producing E. coli (STEC) in food,* ACMSF

Cheese Production

**European Guide for Good Hygiene Practices in the Production of artisanal cheese and dairy products.** Farmhouse and Artisan Cheese and Dairy Producers European Network (FACE; 2016)

The Specialist Cheesemakers Assured Code of Practice (Available from The Specialist Cheesemakers Association).


Sampling


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