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

Version 2

Updated based on feedback from enforcement officers and the Specialist Cheesemakers Association on behalf of Scottish raw milk cheese producers

March 2019

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

1.1 Purpose of Guidance

This guidance aims to ensure that a consistent approach is applied to enforcement by Local Authority (LA) enforcement officers throughout Scotland 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 Regulation (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 that should be taken 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 made 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.

It intends to provide a guide to the type of evidence that is needed from FBOs in order to demonstrate that they understand the risks associated with Shiga-toxin-producing *E. coli* (STEC), which is a recognised hazard in unpasteurised cheese. STEC can be excreted in the faeces of ruminant animals such as cattle and sheep, and contamination with this pathogen can occur during the milking process. In the absence of a pasteurisation step to eliminate the pathogen in the milk, producers must be able to demonstrate that they have appropriate controls in place which reduce the risk of contamination, and inhibit the growth and survival of any STEC that may be present. Producers must also provide evidence that they are undertaking appropriate testing and audit regimes to verify that these controls are operating as effectively as possible.

STEC is a diverse group of bacteria comprising *E. coli* cells which possess a toxin producing gene called *stx*. Although the most commonly occurring STEC in Scotland is *E. coli* O157, other types of STEC (non-O157) have been implicated in human illness. Identifying all bacteria included in the diverse group of organisms which meet the definition of STEC requires testing to be undertaken using molecular isolation methods that are only currently available in a limited number of laboratories and are not yet widely used to assess food safety. 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 strains.[1]

This guidance refers to control and testing for STEC/*E. coli* O157 in recognition of the limited availability of commercial laboratory services for detecting all STECs. It therefore offers a

[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 identifying STEC contamination in food.

pragmatic approach to testing which is aimed at monitoring levels of hygiene indicators to assess the control of faecal contamination with risk based verification for either STEC (where such testing methods are available) or by testing for *E. coli* O157 which may be used as a proxy by food businesses unable to access methods which are capable of detecting all STEC strains.

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.

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 and grow 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 hygiene controls that apply to raw milk production and the cheese making 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 & 3)
- Officer resources (Annex 4)

1.4 Revision and Adoption of Guidance

This document is intended to support a 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. This version updates an earlier draft (published in December 2018) based on feedback received in March 2019 from Local Authority enforcement officers, Scottish raw milk cheese producers and the Specialist Cheesemakers Association (SCA).

The guidance will continue to be updated on an on-going basis following any further feedback received from enforcement officers and businesses as more practical experience is gained. It will also be reviewed in light of emerging scientific evidence relating to current knowledge gaps on the microbiological quality of raw milk used in artisan cheese production, and evidence on the extent to which controlling factors/control measures impact on the ability of STEC to survive during the cheesemaking process. 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.

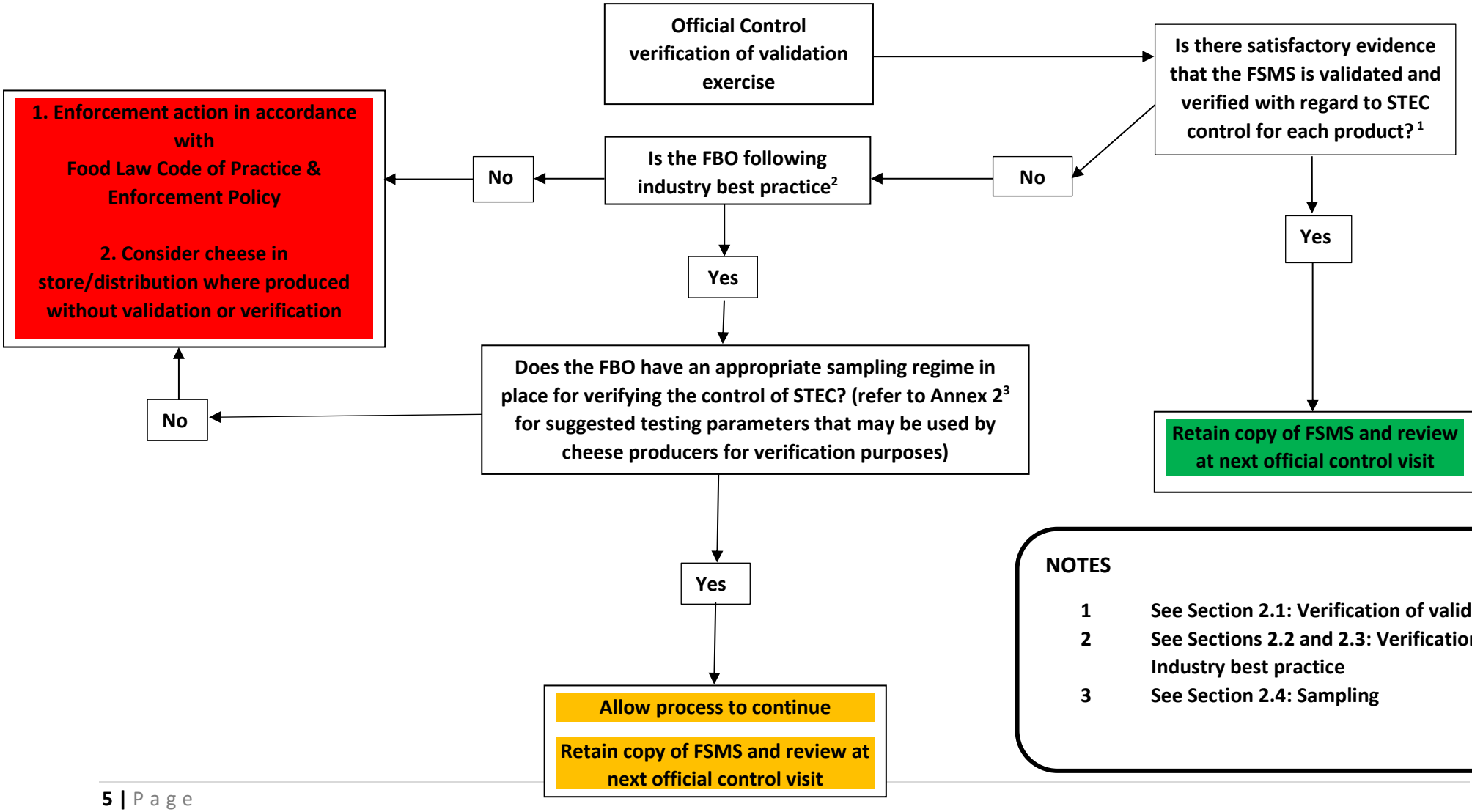
This guidance accordingly recognises the potential for residual food safety risk on the part of FBOs who continue to place these products on the market pending the comprehensive validation of their procedures based upon the HACCP principles. The guidance provides a pragmatic approach which will enable enforcement officers to verify the control of STEC in raw milk cheese production until which time there is evidence available to support fully validated controls in this sector. This approach 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[2].

In deciding to adopt the approach within this guidance, it is suggested that Lead Officers fully advise their Authority of the implications of the enforcement approach proposed. It is also suggested 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 the food safety hazard (STEC) is under control. In circumstances where the risks associated with the food safety hazard are realised (i.e. where products are identified which are contaminated with STEC and/or are linked to human illness), Local Authorities must take the appropriate enforcement action in terms of their own Enforcement Policies.

[2] https://www.foodstandards.gov.scot/business-and-industry/safety-and-regulation/regulation-legislation/fss-regulatory-strategy

Decision Tree to Support the Proposed Enforcement Approach



NOTES

1 See Section 2.1: Verification of validation
2 See Sections 2.2 and 2.3: Verification and Industry best practice
3 See Section 2.4: 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, but can be made available to officers on request by contacting SFELC@fss.scot)

Article 5 of Regulation (EC) 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. However, validation is more challenging for this sector due to the absence of a defined critical control point at the milk production stage (i.e. pasteurisation), which is capable of eliminating microbiological hazards associated with these products. Furthermore, current limitations in both the scientific evidence relating to the reduction/die-off of pathogens during the cheesemaking process, and the availability of STEC testing methods, make it difficult for producers to demonstrate full scientific validation of the production process. This guidance therefore sets out the standard that FBOs in this sector should be aiming for as scientific knowledge and testing techniques improve.

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 a 'one size fits all' approach that would be suitable for every business. However, this guidance document outlines in more detail how cheese producers can demonstrate that their FSMS is effective in controlling STEC, and the sampling and testing that may be used to verify this.

It is expected that a FSMS for the production of cheese made from unpasteurised milk will identify STEC as a hazard which requires to be prevented, eliminated or reduced to an acceptable level. STEC 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 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 is **prevented**, supporting evidence to validate this will require them to demonstrate that either upstream controls are in place which prevent contamination of every batch of incoming raw milk or that any potential 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 in Table 2 below.

Table 1: Validation Evidence – (Upstream Controls) 'Prevention'	
System of control	**'Prevention'** – Source Controls are effective in preventing or detecting faecal (STEC) contamination of incoming raw milk i.e. further controls are not validated
Standard to be demonstrated	STEC/ *E. coli* O157 is either absent in the incoming milk or, where, present, will be detected to allow for implementation of timely and effective corrective actions
Examples of evidence which may contribute to a validated FSMS	
(a) Evidence that upstream controls are in place which are capable of consistently **preventing** STEC contamination of the raw milk supply (considered to be unrealistic). (b) Evidence that upstream controls are in place to **minimise** 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 that is capable of verifying that STEC contamination has been effectively controlled in every incoming batch of milk (considered to be unrealistic). (c) Where the FBO's proposition is that the upstream controls **minimise** STEC contamination of the raw milk supply the sampling programme referred to at (b) above would be required to ensure that any potential STEC/ *E. coli* O157 contamination of 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 STEC/ *E. coli* O157 has been detected and controls in place to prevent cross contamination of other batches.	

Where an FBO elects to demonstrate that STEC 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 requires that the acceptable level should be considered to be absence in a ready to eat product such as cheese which is consistent with the ***HPA Guidelines for Ready to Eat Foods***. It is therefore necessary for cheese producers to provide evidence that their FSMS recognises STEC as a hazard and includes controls which ensure that this pathogen is not present in the end product.

In order to achieve this, it is more likely that producers will elect to demonstrate a combination of 'source control' i.e. that all of the necessary hygiene measures are in place to minimise contamination in the incoming milk **and** 'process control' i.e. that the production process is effective in reducing any STEC contamination that may be present to an acceptable level (i.e. absence in the end product). This is summarised in Table 2 below.

Table 2: Validation Evidence – (Downstream Controls) 'Reduction to Acceptable Level/Elimination'	
System of Control	**'Reduction to An Acceptable Level/Elimination'**– The milk is subject to one or more processes which eliminate STEC or the cheesemaking process results in appropriate physicochemical changes (i.e. in the chemical and physical properties) of the product which have this effect.
Standard to be demonstrated	Process steps (most likely hurdle effect of individual factors) are effective in reducing any STEC that may be present in the raw milk/cheese to an acceptable level i.e. ensuring it is absent from the end product.
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 is able to determine that the risks of contamination with pathogens including STEC/ *E. coli* O157 are being adequately managed throughout the production process. The physicochemical characteristics of the cheese should also be monitored in accordance with the FSMS to allow any changes to be identified which could increase the risk of STEC/*E. coli* O157 survival and growth.

(c) Scientific evidence which demonstrates the process is effective in eliminating STEC/*E. coli* O157 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, which can lead 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

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.

It should be noted that the producer may not be able to demonstrate that downstream hurdle effects will eliminate all STEC from the end product if introduced in the raw milk. However, in such circumstances it is important that they are able to demonstrate that they are routinely monitoring process parameters e.g. acidity and composition, in order to ensure any inhibitory factors are working as intended, thereby minimising the risk of STEC being present in the final product.

2.2 Verification of STEC controls in raw milk cheese production

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 fully achieve the standards outlined in Tables 1 and 2 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 the following:

(a) they are following industry best practice;

(b) this is supported by a comprehensive sampling programme, and;

(c) they are able to demonstrate compliance with Regulations (EC) 852/2004 and (EC) 853/2004.

Further guidance on these is provided in sections 2.3 and 2.4. Essentially this will result in a combination of source controls (milking) and process controls (cheesemaking), with verification sampling at key points for indicator organisms and/or pathogens. The inherent variability in the cheesemaking process (e.g. in terms of milk supply and seasonal effects), and lack of defined critical control points for certain products means that full validation will not be achievable in some 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. 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.

Even where full validation is not achievable, 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 accompanied by an appropriate verification sampling plan (referring to parameters in Table 3) will still require to be included as part of the FSMS.

2.3 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 FBOs 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 be supported by evidence, agreed with the enforcement officer and the rationale documented.

2.4 Sampling

Guidance on sampling plans that could be used by cheese producers for verifying that the risks of STEC are being controlled is provided in Annex 2. The sampling plans in Annex 2 are based on the monitoring of hygiene indicator organisms such as generic *E. coli* to verify that contamination with faecal bacteria is under control. Reference to additional risk based verification checks for STEC/*E. coli* O157 reflects the allowance for producers to test raw milk for all STEC (where possible) or *E. coli* O157, which is the most commonly occurring STEC in Scotland, and considered to be a suitable proxy until methods for identifying all STEC strains become more widely available.

It should also be noted that sampling plans must also take account of any additional legal requirements for FBOs to undertake sampling to demonstrate compliance with Regulation (EC) 2073/2005 on The Microbiological Criteria for Foodstuffs.

Sampling frequency is an important consideration and should be supported by evidence. Initially, it may be necessary for FBOs to monitor every batch of incoming raw milk for indicator organisms with regular periodic checks for STEC/ *E. coli* O157 until they have built up a body of evidence to demonstrate consistent trends in hygiene standards and pathogen control. However sampling frequency may be reduced where FBOs have already collected a comprehensive data set over time, which is representative of production and takes account of factors that could impact on the risk of contamination. These include the potential for seasonal variations in STEC shedding, animal husbandry practices, changes in milk supply, or any other modification to the production process that would trigger a review of the business's FSMS.

Effective interpretation of sample results is critical, particularly in relation to generic *E. coli* and STEC/ *E. coli* O157. It is important to understand how results relate to the type of product and the point in the process where the sample is taken. The sampling plan for the establishment should also identify 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 results can be found in Annex 3.

2.5 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 in the event that a breakdown in the FSMS is identified e.g. unsatisfactory results, or a process failure which requires a product withdrawal or recall to be initiated. To minimise the scale of any recall to only affected batches 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 require 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 regular basis and kept at least available until it can be reasonably assumed that the food has been consumed.

Annex 1: Validation Requirements

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
- salting
- temperature and time of maturation
- physicochemical 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 physicochemical 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 provide evidence for 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 physicochemical 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 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 4: 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 flow charts. 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 physicochemical 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, and salt content and water activity at maturation.

- 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 appropriate 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, or justification for deviation from industry best practice and evidence that practices are of a comparable standard.

- Sample results to demonstrate consistency of the physicochemical parameters throughout production. This requires routine testing for pH, water activity and salt content to be undertaken at appropriate points throughout the process to demonstrate that it is operating consistently and no changes have occurred that could affect microbiological quality. It is acknowledged that cheese producers may prefer to monitor salt in moisture rather than water activity. This is acceptable where they are able to provide evidence of the level of microbiological control associated with such measurements.

- 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.

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>
<tr><th>Product</th><th>Frequency</th><th>Sample</th><th>Microorganism</th><th>Target</th><th>Investigation Range</th><th>Action Limit/
Unsatisfactory Result</th><th>Purpose</th></tr>
<tr><td rowspan="4">Incoming Raw milk</td><td>Every batch of incoming raw milk or risk based frequency based on historical data</td><td rowspan="3">Sample which is representative of the batch</td><td>Generic
E. coli</td><td><20 cfu/ml</td><td>20-≤100 cfu/ml</td><td>>100 cfu/ml</td><td rowspan="4">To verify that hygiene controls at milking are being applied consistently and are effective in controlling faecal contamination</td></tr>
<tr><td rowspan="2">Rolling geometric mean over a 2 month period (minimum 2 samples per month)</td><td rowspan="2">Aerobic colony count (ACC) at 30°C</td><td rowspan="2"><10,000 cfu/ml</td><td>>10,000-<100,000 cfu/ml (cow's milk)</td><td>Refer to Regulation (EC) 854/2004[3]</td></tr>
<tr><td>>10,000-<500,000 cfu/ml (milk from other species)</td><td>Refer to Regulation (EC) 854/2004[3]</td></tr>
<tr><td>At an appropriate risk based frequency in accordance with FSMS</td><td>Milk filter, or sample of liquid raw milk which is representative of the batch</td><td>E. coli
O157/STEC</td><td>Not detected</td><td>NA</td><td>Detected</td></tr>
<tr><td rowspan="2">Curd</td><td rowspan="2">At an appropriate risk based frequency in accordance with FSMS</td><td rowspan="2">Sample which is representative of the batch</td><td>Generic
E. coli</td><td colspan="3">Routine monitoring results consistent with type of cheese (refer to the SCA Assured Code of Practice)
A target level of <100 cfu/g is considered to be achievable for some cheese types.
Where this is exceeded, further evidence should be provided to verify food safety</td><td rowspan="2">As a check to verify that contamination is not being introduced during processing</td></tr>
<tr><td>E.coli
O157/STEC</td><td>Not detected</td><td>NA</td><td>Detected</td></tr>
<tr><td>End Product</td><td>At an appropriate risk based frequency in accordance with FSMS</td><td>Sample which is representative of the batch</td><td>Generic
E. coli</td><td colspan="3">Routine monitoring results consistent with type of cheese (refer to the SCA Assured Code of Practice)
A target level of <100 cfu/g is considered to be achievable for some cheese types.
Where this is exceeded, further evidence should be provided to verify food safety</td><td>To verify hygiene controls during processing and maturation</td></tr>
</table>

[3] These requirements apply to the raw milk producer. The Food Law Practice Guidance (Scotland) pg 164 states: *Annex IV of Regulation 854/2004 provides Food Authorities with the power to suspend the supply of milk or make requirements as to its treatment and use sufficient to protect public health where the producer fails to meet that standard within 3 months of first notifying such a failure. Heat treatment in accordance with Annex III, Section IX, Chapter II (II) of Regulation 853/2004 should be sufficient to protect public health. In normal circumstances, it should therefore only be necessary to consider requiring additional measures if the raw milk is intended for supply for use in milk products without undergoing sufficient treatment during production to ensure protection of public health.*

	Frequency **sufficient to verify compliance with FSMS**	Sample which is representative of the batch	*E. coli* O157/STEC	**Not detected**	**NA**	**Detected**	**To verify the safety of end product**

Annex 3

Notes on sampling and interpretation of test results

It should be noted that Annex 2 provides a range of sampling options that can be used by raw milk cheese producers to verify the effectiveness of their FSMS in controlling STEC. FBOs would not be expected to include all of the criteria listed in Annex 2, but should choose the most appropriate sampling points for their verification tests and be able to demonstrate that the criteria employed are able to identify the food safety risks that are associated with the type of cheese being produced.

A. Testing methods and interpretation of results

1. FBOs should ensure testing is undertaken using accredited methods, which align with legislative requirements where these exist. With regard to hygiene indicator organisms (ACCs and generic *E. coli*), alternative methods to those specified in regulations may be used, provided there is evidence for equivalence, allowing results to be compared to legal criteria. For example, BactoScan is a method which is widely used for measuring cell counts in milk, and requires the application of a conversion factor to translate results into equivalent ACC values[4].

2. At the time of writing this guidance, testing methods covering all STEC strains are not widely available, and therefore the use of verification checks for *E. coli* O157 (and, where possible, other known serotypes) is acceptable as a proxy. A range of culturing methods for *E. coli* O157 are available commercially which provide either presumptive or confirmed results. Presumptive results are indicative of a potential risk and should be followed up as soon as possible to confirm whether the pathogen is present.

3. Molecular methods employing PCR or whole genome sequencing are being used increasingly by enforcement and public health bodies for official controls and incident investigations, and officers may also encounter FBOs who are able to access these methods. Where molecular methods are being used, presumptive results will be reported following an initial screen of the food sample as the identification of a *stx* gene. Further tests are required to confirm positive results, which are interpreted as the identification of a *stx* gene in an isolated *E. coli* cell.

4. The detection, in a ready to eat food, of *E. coli* O157 (or other STEC serotypes) by culturing methods, or the identification of a *stx* gene in an isolated *E. coli* cell through molecular methods, should always be considered a potentially serious risk to public health.

B. Determining an appropriate sampling frequency

5. Enforcement officers should assess the appropriateness of the sampling frequency set by an FBO on a case-by-case basis. Sampling frequency for raw milk will depend on a number of factors including the strength of evidence for robust hygiene controls at milking and results of previous sampling programmes.

6. Establishing an appropriate sampling frequency will require FBOs to build up a data set which demonstrates, over a suitable period of time, that the trends in levels of ACCs and generic *E. coli* are consistent and do not breach regulatory or

[4] LA Enforcement Officers may contact FSS for further guidance on use of BactoScan results

target levels. This may initially require FBOs to undertake more frequent routine testing of their raw milk supply and end product lines for a sufficient period of time to take account of factors which have the potential to impact on contamination, such as seasonality and herd management practice.

7. Once they have built up a robust dataset, 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). FBOs should also consider the need to review sampling frequency in light of any modifications made to the production process that would trigger a review of the business's FSMS.

C. Upstream controls – sampling plans to verify the control of faecal contamination in raw milk

Hygiene monitoring of raw milk supply

8. It is recommended that FBOs should base their hygiene monitoring on the analysis of trends in the levels of hygiene indicators (ACCs and generic *E. coli*) in the incoming raw milk supply.

9. When determining a representative sample size for monitoring ACCs and generic *E. coli*, FBOs should consider relevant sources of information including advice from their scientific laboratory and ISO 707:2008 Milk and Milk Products – Guidance on Sampling. Monitoring and trend analysis should be undertaken with reference to established legislative standards/guidelines including the SCA Assured Code of Practice.

10. Monitoring of ACC results in raw milk should be based on a rolling geometric mean over a two month period. Guidance on this method is referenced in Annex 4: Officer Resources. The sampling plan in Annex 2 recommends a target level for ACCs of <10,000 cfu/ml which aligns with SCA recommendations. However, exceedance of this target would not require investigation or action unless a deviation above expected values was identified through on-going monitoring and graphical plotting of testing results. Action would also be expected where the levels were considered to breach legal requirements outlined in Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004. In such cases any action taken should be based on requirements of Annex IV, Chapter II of Regulation (EC) No 854/2004 (as outlined in The Food Law Practice Guidance (Scotland)).

11. Monitoring of generic *E. coli* results in raw milk should also be based on trend analysis, aiming to achieve the target of <20 cfu/ml whenever possible. Although there are no legislative requirements for generic *E. coli* in raw milk, elevated results are indicative of a potential loss of hygiene control and faecal contamination, so producers should undertake an investigation when this target is breached or where a deviation above expected values is identified through the plotting of testing results. Action should be proportionate to the levels detected, taking into account previous results and may include:

    - A thorough review of production hygiene, cleaning and storage conditions up to the point of sampling.

- 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.

Periodic and risk based checks for STEC/E. coli O157 in raw milk supply

12. Sampling programmes must also be able to provide evidence that the system in place to control and monitor faecal contamination is effective in minimising the risks of STEC. This will require producers to develop a programme of checks to verify absence of STEC (or *E. coli* O157), but does not require every batch of raw milk to be routinely tested for the pathogen(s). Sampling should be based on risk, taking account of evidence for any seasonal variations in STEC and elevated trends in levels of generic *E. coli* detected through monitoring which could be indicative of an increased contamination risk.

13. When testing for the presence of STEC/*E. coli* O157, producers may choose to sample at a number of different points in the process to verify that contamination is under control. At the start of the process, checks may be undertaken on samples of liquid milk, or alternatively at points where any milkborne pathogens are likely to be more concentrated (and therefore more likely to be detected) such as the filter used to remove particulate matter from the incoming raw milk supply, or the curd. All of these methods are acceptable, but must be undertaken in accordance with established protocols, and FBOs should seek technical advice on the most appropriate method to use.

14. In circumstances where STEC or *E. coli* O157 is identified in the raw milk, filter or curd, producers should take immediate action to ensure any pathogen contamination is not carried through to the final product. The corrective actions to be taken by the FBO in the event that STEC or *E. coli* O157 is detected at this stage should be clearly identified in the FSMS. Examples of the type of action which may be implemented in such scenarios are provided below:

    - Although in most cases, cheese production will have begun by the time a result is obtained, consideration should be given to the possibility of discarding or diverting milk 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.
    - Premises and equipment are to be cleaned and disinfected using BS EN 1276/BS EN 13697 compliant chemicals, the effectiveness being verified by use of environmental swabs.
    - An investigation and increased testing should be conducted on other batches processed since the last satisfactory sample was taken.

D. Downstream controls- sampling plans to verify end product safety

15. It should be noted that end product testing (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 minimising the risks of STEC/*E. coli* O157 contamination being present in the final product.

16. With regard to EPT, all FBOs should be testing end product 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.

17. End product monitoring for generic *E. coli* should again be based on trend analysis, with investigation, and, where appropriate, action taken, when levels exceed recommended targets or expected norms. For some of the younger, softer cheese types, producers may elect to test for generic *E. coli* at the curd stage, where the levels would be expected to be highest. In such circumstances, FBOs should provide justification that this is an appropriate approach for assessing the safety of the end product, and that contamination will not be introduced later in the process.

18. It is recognised that the SCA Assured Code of Practice allows for different target levels of generic *E. coli* in end product for soft and hard cheese types, however, the presence of elevated levels of *E. coli* in end product could be indicative of bacterial growth. This guidance therefore recommends a *target* of 100 cfu/g regardless of the type of cheese. Where this level is exceeded, FBOs should provide additional evidence to verify the safety of the product, based on demonstration of upstream controls and historical testing records.

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

20. The detection of STEC or *E. coli* O157 in end product should always trigger a risk assessment by the FBO and appropriate action taken to ensure unsafe food is not placed on the market. The type of action to be taken will depend on a number of factors including:

    - whether the result is presumptive or confirmed, and the need for additional testing to verify product safety.
    - the number of batches that could be affected.
    - the onward supply of the product and whether a product withdrawal is required to allow for confirmation of presumptive results or to prevent the sale of contaminated food.

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

21. FBOs 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 legal food safety requirements and where sampling results could be indicative of a risk to public health.

Annex 4: 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. FSA/FSS (August 2016)

Food Standards Scotland. Public Information Advice Statement: Food Standards Scotland's Advice on Measures Required to Protect Consumers from Infection with Shiga-toxin Producing *E. coli* (STEC) (February 2019)

Shiga Toxin-Producing *E. coli* (STEC) in food. ACMSF Discussion Paper ACM/1191 (October 2015)

Updated ACMSF Opinion on Shigatoxin Producing *E. coli* (STEC) in Food (October 2018) Discussion Paper ACM/1281 and Minutes

Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and monitoring. Report by the Food and Agriculture Organisation of the United Nations and World Health Organisation (2018)

E. coli O157 control of cross contamination: Guidance for Food Business Operators and Local Authorities. Food Standards Scotland

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).

The Australian Raw Milk Cheese Decision Support Tool http://www.foodsafetycentre.com.au/RMCtool.php

Sampling

ISO 707:2008 Milk and Milk Products – Guidance on Sampling.

Fresh Produce Tool – Rolling Geometric Mean Guidance. Food Standards Scotland http://freshproducetool.foodstandards.gov.scot/node/21880

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