

Lead Food officers
REHIS
SFELC

ENF/16/015

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Dear Colleagues

Food Manufacturing Establishments producing Cheese from unpasteurised milk within Scotland

As you will probably be aware, Food Standards Scotland (FSS) has been involved in the recent high profile incident relating to an outbreak of *E. coli* O157 phage type 21/28, associated with the consumption of unpasteurised cheese produced by a Scottish approved establishment cheese maker. This outbreak involved a number of cases of human illness where a number of individuals required hospital treatment including one patient who sadly died. During investigations, a range of products manufactured by the business implicated were sampled and found positive for pathogenic *E. coli*. This letter intends to provide clarity of the FSS expectations of all Scottish Local Authorities who approve and or inspect cheese makers in their area with a focus on those producing cheeses from any unpasteurised milk source. It further provides direction as to the role of the Local Competent Authority in instances of enforcement related to this subject.

As well as the evidence from the recent incident, cheeses made from raw milk have been shown to be contaminated with a range of different pathogens evidenced through past surveys and outbreaks, and extensively in the scientific literature. This demonstrates why these products are considered to be intrinsically of potential high risk and it is imperative that the food manufacturer has adequate steps in place to control the known hazards associated with this type of production. To this end Authorised Officers in Local Authorities must be satisfied that the food business operators food safety management systems are able to demonstrate that the product has been produced using a validated system of controls which have been verified as providing an acceptable level of pathogen control to achieve compliance with the regulations and industry guidance. It is the responsibility of the food business to provide a safe product as required by EU food safety law and to demonstrate how they achieve and maintain this to the competent authorities.

It is likely that on completion of the current Crown Office investigations into the fatality and lessons learned from the review of the recent outbreak, more specific guidance will be provided. However,

in the interim our advice is that, as a minimum, it is expected that the manufacturer will have a working knowledge of and apply in full the guidance provided by The Specialist Cheesemakers Association and their Assured Code of Practice which stipulates in detail the steps to be taken to demonstrate that adequate controls are in place within the businesses. A link to the association can be found here; http://www.specialistcheesemakers.co.uk/best_practice/index.htm , the Code can be obtained free of charge for authorised officers of Local Authorities.

Where a business relies on different controls from those stipulated in this Industry Code, they must clearly demonstrate their controls provide equivalent protection.

Food business either seeking approval or already having approval for the production of unpasteurised cheese should follow the above mentioned Code of Practice or equivalent and be able to demonstrate this to the satisfaction of the local authority. Conditional approval should not be granted where there are deficiencies on any aspects of control systems relating to critical areas. Full approval should only be given after conditional approval has demonstrated that adequate controls are in place to minimise the risks associated with unpasteurised cheese.

It is also strongly recommended that food businesses at wholesale, catering and retail level have evidence as part of their due diligence that cheese supplied to them has been produced in accordance with The Specialist Cheese Makers Assured Code of Practice and that they are able to distinguish clearly full traceability to batch level and that within their establishment the risks of cross contamination have been considered.

Where authorised officers identify issues of concern consideration should be given to the use of Regulation 27 of the Food Hygiene (Scotland) Regulations 2006, which provides that where on inspection an authorised officer of an enforcement authority considers that food which has not been produced processed or distributed in accordance with The Hygiene Regulations (those regulations and the EC Regulation 852/853/854/2073 and 2075) they may certify the food as not complying and in such cases it should be treated for the purposes of Section 9 of the Food Safety Act 1990 as failing to comply with food safety requirements. It is expected that cheese manufacturers will have identified STECs and other relevant pathogens as a hazard that must be prevented, eliminated or reduced to acceptable levels in accordance with Article 5 para 2 (a) of 852/2004.

It is expected that Local Authorities will consider that cheese manufactured in the absence of verified controls is unsafe and take measures to inform FSS that a withdrawal is required. In these instances please contact Incidents@fss.scot.

Officers should consider the Article 5 requirements in the context of the recitals to the regulation which states that the purpose of the Regulation is the pursuit of a high level of protection of human life and the principle objective is to ensure a high level of consumer protection with regard to food safety.

In addition Chapter IX of Annex II of 852 requires that food business operators are not to accept raw materials or ingredients if they are known or might reasonably be expected to be contaminated with pathogenic organisms to such an extent that even after normal preparation or processing procedures the final product would be unfit for human consumption. If food businesses do not believe that potential raw material contamination will be addressed during their

manufacturing process they have a legal obligation to check for the presence of such contamination and reject these raw materials if contamination is identified. With respect to the manufacture of unpasteurised cheese this in effect requires adequate checks on incoming raw milk required to detect and reject incoming materials that are contaminated at a level if the preparation or processing procedures thereafter will not sufficiently reduce contamination to a safe level.

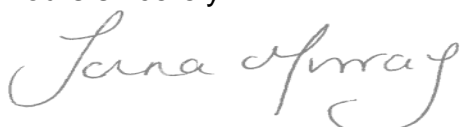
In addition there are general obligations under (EC) No 853/2004 that all milk purchasers must be aware of and demonstrate compliance with, these are detailed below,

- 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.

Regulation 3 of the General Food Regulations 2004 provides that both FSS and each food authority are designated as competent authorities to take appropriate measures to impose restrictions on placing food on the market or to require its withdrawal in certain circumstances in line with Article 14 of 178/2002. Article 14 (8) specifies that conformity of a food with the specific Community provisions for that food shall not bar competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or withdrawn from the market where there are reasons to suspect that despite such conformity it is unsafe. Therefore even in circumstances where a business is otherwise compliant with food hygiene law, if, for example, there are sample results which confirm the presence of pathogenic STEC it would be anticipated the food examiner will certify such foods as unfit and products should be withdrawn using the provisions of Regulation 3. In such circumstances please contact Incidents@fss.scot so that an assessment can be made as to whether or not a local or wider product recall would be appropriate.

If you have any queries regarding this correspondence please contact me using the contact details contained in this letter.

Yours sincerely



Lorna Murray
Head of Enforcement Delivery
Food Standards Scotland