

RISK MANAGEMENT DECISION UPDATE IN RESPECT OF THE ISSUE OF A REVISED FOOD ALERT FOR ACTION (FAFA) RELATING TO ALL PRODUCTS WHICH WERE THE SUBJECT OF THE FAFAS OF 14th And 15th SEPTEMBER CONCERNING CHEESES PRODUCED BY ERRINGTON CHEESE LTD (ECL)

Executive Summary

1. This risk management document updates those produced on 9th and 14th of September to consider the further information and evidence provided to Food Standards Scotland (FSS) in the interim, and reflects the revised updated risk assessment document. This update completes the risk assessment and related risk analysis process envisaged by EC Regulation 178/2002 and concludes that in the opinion of FSS, all of the products which were the subject of the above mentioned FAFAs should be considered to not comply with food safety requirement as defined in Article 14 of 178/2002 and are therefore unsafe and not fit for human consumption. A revised FAFA should be issued by FSS under its powers contained in Regulation 3(2) of The General Food Regulations 2004, and the local food authorities invited to enforce the FAFA in terms of Regulation 6(b) of the 2004 Regulations, if necessary using their seizure powers under Section 9 of the Food Safety Act 1990 and Regulations 23 and 27 of the Food Hygiene (Scotland) Regulations 2006. FSS's analysis, culminating in the development of a revised Food Alert For Action is outlined below.

Background

2. FSS undertook a risk assessment, finalised on 7th September, which highlighted the uncertainty of the safety of products produced by ECL, specifically Dunsyre Blue batches F15 and E24. This led us to develop a Risk Management Decision document dated 9th September, which concluded that the evidence presented in the risk assessment document warranted consideration of whether action was required, on the basis of the precautionary principle, to initiate a product withdrawal of all batches of Dunsyre Blue cheese produced by ECL which had been distributed for sale. Later that day, 9th Sept, FSS received confirmation from the Food Examiner that Batch G14 of Lanark White cheese was "*unsatisfactory; potentially injurious to health and/or unfit for human consumption*", due to *E. coli* O157 being detected in the sample.
3. This decision document was updated on the 14th September to reflect additional information which FSS had received (in relation to two additional cases with the same MLVA profile as the national outbreak strain, one who was known to have consumed Dunsyre Blue, and a positive sample result for Batch H24 of Lanark White cheese) which was evaluated in a revised risk assessment finalised on 14th September. The updated risk management decision document also finalised on 14th September, concluded that following the precautionary principle, all cheeses produced by ECL which were on the market at that time, should be the subject of a product recall. This was agreed at a joint meeting of members of the Incident Management Team (IMT) representing Food Standards Scotland, Scottish Government, NHS

Highland, Scottish *E. coli* O157/VTEC Reference Laboratory, South Lanarkshire Council and Health Protection Scotland. The FBO was given the opportunity to carry out this withdrawal on a voluntary basis, but chose not to do so. For that reason, a Food Alert For Action (FAFA) intended to execute this product withdrawal was issued to Food Authorities on that date. In accordance with the provisions of Regulation 178/2002, FSS has continued to keep its risk assessment and risk management under review.

4. The FAFA issued on 14th September using the powers contained in Regulation 3 of the General Food Regulations 2004 and the recall to which it applies was based on the risk assessment that had been undertaken and risk management decision that brought together the risk assessment as well as all the other evidence available. The rationale for the recall was based on the information that we held, and summarised in material posted on FSS's website on 15th September which stated:

“Errington Cheese Ltd has publically commented that E. coli O157 has not been found in its cheese. This is inaccurate. Some samples submitted for testing by SLC have tested positive for E. coli O157 and for another (non-O157) strain of E. coli. These organisms are considered a serious risk to public health by the Food Examiner and the Scottish E.coli O157/VTEC reference laboratory. In addition, further samples have tested positive for shiga toxin (stx) genes. These samples have tested “presumptive positive” for shiga toxin producing E. coli (STEC) and therefore are considered to be potentially hazardous to health.

Analysis of samples taken by SLC has been carried out using accredited methods in official laboratories. All results from these samples were shared with Errington Cheese Ltd as soon as they were available. The decisions FSS has taken to recall Errington Cheese Ltd products are evidence-based and informed by interpretation from experts including legally designated Food Examiners.

E. coli O157 and non-O157 have been detected in different batches of Dunsyre Blue and Lanark White produced by Errington Cheese Ltd. Batch numbers relate to the dates the batches were produced.

•Batch F15 Dunsyre Blue: Shiga toxin producing E. coli (STEC) has been cultured and isolated from a sample taken from batch F15 (Dunsyre Blue). This sample has been confirmed as a non-O157 E. coli (STEC). This type of E. coli has been known to cause severe illness. Nine further samples were subsequently taken from this batch, and all have also been found to contain the stx2 gene and one for the stx1 gene (all nine samples are therefore considered presumptive positive for STEC), FSS is awaiting further confirmatory testing on these samples. This product has not been placed on the market.

•Batch G14 Lanark White: E. coli O157 has been cultured and isolated from a sample taken from batch G14 (Lanark White). This isolate has not been shown to contain the stx genes and is undergoing further analysis. Stx gene negative strains of E. coli O157 have been isolated from cases of human illness consistent with E. coli O157 infection. The Food Examiner declared this sample to be “potentially

injurious to health and/or unfit for human consumption". Therefore this batch was withdrawn by FSS following the refusal of the food business to withdraw it voluntarily.

•Batch E24 Dunsyre Blue: two samples from batch E24 (Dunsyre Blue) have been found to contain the stx2 gene – these samples would therefore be considered as presumptive positives for STEC whilst FSS awaits further confirmatory testing. This batch was withdrawn voluntarily by the food business.

•Batch G12 Dunsyre Blue: a sample from batch G12 (Dunsyre Blue) has been found to contain the stx2 gene (a presumptive positive for STEC) and FSS is awaiting further confirmatory testing on this sample. This product has not been placed on the market

•Batch H24 Lanark White: A sample from batch H24 (Lanark White) has been found to contain the stx2 gene. This sample would be considered a presumptive positive for STEC whilst FSS awaits confirmatory testing. This product has not been placed on the market.

Potentially harmful strains of E.coli and the shiga toxin (stx) genes that can cause illness in humans have been found in a number of different batches of different cheeses produced by Errington Cheese Ltd. This means that FSS is not satisfied that the controls and production methods used by the business are producing safe food. Furthermore, the reliance on a limited number of negative test results as evidence that the food is safe provides insufficient assurance, as it is clear that multiple samples across different cheese batches have had positive results."

This was the information that was known to us on 14 September.

Sampling and Testing Results Received since 14 September

5. Information in Annex 1 attached contains full, updated information of all positive sample results, and dates when each result was reported to FSS. Of particular relevance are the results described below:

Shiga toxin producing *E. coli* (STEC) has been detected in batches of Dunsyre Blue (F15) and Lanark Blue (E24) cheese produced by Errington Cheese Ltd. STEC are known to cause severe illness in humans. A stx gene negative strain of *E. coli* O157 has been isolated from three batches (G14, H3 and H24) of Lanark White ewe's milk cheese. Stx gene negative strains of *E. coli* O157 have been isolated from cases of human illness consistent with *E. coli* O157 infection. The Food Examiner declared these samples of Lanark White cheese to be "potentially injurious to health and/or unfit for human consumption".

In addition to positive results from both cows' and ewes' milk cheeses, we have since 14 Sept received positive results on cows' milk taken at the farm that supplied ECL.

Food Safety Management System

6. Since 14th September FSS has also received further information from South Lanarkshire Council (their letters to ECL dated 22 September, 6th October and 1st November 2016).
7. The 6th October letter confirms that in the view of SLC as the Competent Authority responsible for ECL, their assessment is that SLC "...is satisfied that serious deficiencies exist in relation to food safety controls at the premises..." This letter includes the testing information referred to above and also confirms that "*The presence of these organisms in ready to eat food produced by you clearly demonstrates that your current procedures have not been adequate to prevent or eliminate these organisms and therefore the potential for injury to health to consumers exists...*"

Analysis of the significance of additional information since 14 September

8. Sample results (Annex 1) have now been received confirming contamination of 3 separate types of cheese produced by the company from both ewes' and cows' milk – Dunsyre Blue, Lanark Blue and Lanark White. The HACCP (food safety management) system applied by the company at the time of production was generic to all types of cheese produced, and the presence of potentially pathogenic organisms in more than one batch of three separate types of cheese indicates systemic failures in this system, as identified by SLC in their letter of 6 October.
9. In addition, contamination has been found in 3 separate batches of Lanark White ewes' milk cheese, with exactly the same type of *E.coli* O157. Based on our understanding of the FBO batch coding system, these batches were produced from a period from mid-July (G14) through early August (H3) to late August (H24). In addition there is evidence that at least one of these batches - G14 of Lanark White - had been placed on the market by the company. This product was surrendered to SLC by a hotel in Lanarkshire, in response to a FAFA issued by FSS on 10 September that was specific to this batch of cheese. We know that different samples from the cheese that was recovered from the hotel tested negative and positive for *E. coli* O157. This was the same type of *E coli* O157 that was detected from a sample of the same batch of Lanark White taken on 31 August. This confirms that this cheese was in circulation on the market and available for public consumption, and posed a clear risk to public health.
10. In addition, the presence of the same organism, in different batches of cheese, over this elongated time period is of significance in that it indicates that, given the information we have that individual batches of cheese are made from individual milk supply batches, either:

The organism was persisting in the processing environment, following exposure to an initial contamination source, over this period of time and due

to deficiencies in cleaning, cross-contamination was taking place at some stage within the production process, rendering the final product unsafe or;
There was contamination of a common ingredient source of each of the cheeses batches, most likely the incoming raw milk supply, and that supply of contaminated ingredient was recurring frequently over this extended time frame;

There was a persistent source of recurring 'environmental' contamination within the premises over that time, the most likely being the private water supply or a food handler.

11. The last sample failure of H24 Lanark White was linked to a batch produced at a time which roughly coincides with the time when all ewes' milk cheese production stopped. So, whichever of these factors resulted in the contamination, the problem appears to have been persisting up until cheese production stopped. Therefore it will be important to ensure that all three potential routes are thoroughly investigated, as part of the review of food safety management systems and appropriate control measures introduced to eliminate future risk before the premises can be considered safe to recommence food production.
12. Further, the fact that positive results were obtained from different cheeses for different production dates and for both cows' and ewes' milk cheeses would also strongly indicate a failure of effective food safety controls throughout this period of time. Given the breadth of tests which show both positive and negative results, it also means that testing *per se* would not provide sufficient assurance to enable a targeted approach to positive release or specifically defined recalls, which is what the approach prior to 14th September was confined to.
13. This is consistent with the rationale behind the European Commission revisions to food hygiene legislation in 2006, which considered that reliance on end-product testing could not provide satisfactory assurance of the high level of public health protection envisaged by EC Regulation 178/2002. To help address this problem the requirements of Article 5 of EC Regulation 852/2004 placed specific emphasis on the importance of food safety management systems based on HACCP, to require businesses to identify all potential hazards and apply sufficient controls to eliminate or reduce the risks associated with these hazards to an acceptable level and change the balance of using end-product testing as a means of assuring safety to one where these test results would be used to help verify the effectiveness of the HACCP systems.
14. SLC have concluded that there were serious deficiencies in the FBO systems and in particular there was no testing of incoming raw milk supplies as envisaged by the Specialist Cheesemakers' Guide, which would help to identify and reject incoming contaminated milk, which could have been anticipated as outlined in FSS's risk assessment, and has since been demonstrated in the recent sample failures of incoming cows' milk. In addition the current physico-chemical parameters of the cheese during the maturation period do not appear to control, reduce or eliminate any pathogens present in

incoming raw materials to an acceptable level. The range of sample failures in final product further demonstrates the ineffectiveness of the control systems in place when these products were manufactured and indicates that all of the cheeses had not been produced or processed in accordance with the EU Hygiene Regulations as required by Regulation 27 of the Food Hygiene (Scotland) Regulations 2006.

Conclusion

15. The original risk management decision of 14th September was partly based on incomplete analysis, including some presumptive positive test results for certain products.
16. In addition whilst deficiencies in the FBO's food safety management systems had been identified at that stage, the extent to which they were systemic across the premises was not completely certain. For this reason the precautionary principle was adopted to extend the scope of the FAFA withdrawal to all product ranges and batches.
17. Our risk assessment and associated risk analysis is now complete. This follows confirmation that there is sufficient evidence, comprising of confirmed sample results and evidence of serious deficiencies with the FBO's HACCP, and receipt of copies of the formal certificates of analysis from the Food Examiner. We have concluded as follows:

Based on the information we have received from South Lanarkshire Council on ECL's generic HACCP plan that serious deficiencies existed in food safety controls, and our own assessment as described in the risk assessment and risk management documents, of the FBO's food safety management systems, **all of the cheese** produced by ECL (which were covered by the same food safety management system) was not produced and processed in accordance with the EU Hygiene Regulations as detailed in Regulation 27 of the Food Hygiene (Scotland) Regulations 2006

There are sample failures confirming unsafe product in multiple separate batches of cheese produced over the time period from 24th May until 24th August (Annex 1). *E. coli* O157 and shiga-toxin producing non O157 strains of *E. coli* have been detected in three separate cheese types, namely Dunsyre Blue cheese, Lanark White cheese and Lanark Blue cheese. In the case of Lanark White, there is evidence that the same pathogen persisted in the premises over a period of six weeks. As well as demonstrating that these individual batches of cheese were unsafe, this provides further verification that the food safety management controls were seriously deficient over this period of time when all of the cheeses subject to the withdrawal were produced.

It remains the opinion of the IMT that Dunsyre Blue cheese remains the most probable cause of the national outbreak of *E. coli* O157 phage type 21/28 which resulted in serious illness and one fatality.

18. It is the conclusion of FSS that all of the products currently withdrawn from sale by virtue of the FAFAs issued on 14th and 15th September do not comply with food safety requirements, and are therefore unsafe and not fit for human consumption as defined by Article 14 of Regulation 178/2002 and Regulation 27 of the Food Hygiene (Scotland) Regulations 2006. A revised FAFA updating our position will be issued in accordance with the provisions outlined in the Executive Summary to this risk management decision document.

Food Standards Scotland
8 November 2016