SHERIFFDOM OF SOUTH STRATHCLYDE DUMFRIES AND GALLOWAY
AT LANARK

[2018] SC LAN 42

LAN B20-17
LAN B21-17
LAN B33-17

JUDGMENT OF SHERIFF R B WEIR QC

in relation to the

SUMMARY APPLICATIONS

under the Food Safety Act 1990, Section 9

by

SOUTH LANARKSHIRE COUNCIL

Applicants

against

ERRINGTON CHEESE LIMITED

Respondents

Applicants: Love, QC, Clyde & Co (Scotland) LLP
Respondent: Mr Humphrey Errington, as Lay Representative of the respondents

LANARK, 29 June 2018

The Sheriff, having resumed consideration of the cause:-

FINDS IN FACT:

The applicants, the respondents and the cheeses:

[1] That the applicants are a local authority constituted under the Local Government etc. (Scotland) Act 1994. They are a food authority in terms of section 5 of the Food Safety Act 1990 ("the 1990 Act"), and an enforcement authority for the area of South Lanarkshire for the purposes of the Food Hygiene (Scotland) Regulations 2006 ("the 2006 Regulations");

[2] Food Standards Scotland ("FSS") are the statutory successors in Scotland to the Food Standards Agency ("FSA"), and are both the "competent authority" and an "enforcement authority" with responsibility for implementing and monitoring Scottish and EU food and fees regulations.

[3] The respondents are a private limited company operating from premises at Walston Braehead, Ogscastle, Carnwath, Lanarkshire. The respondents' premises are used *inter alia* as a production, processing, storage and distribution facility for different types of cheeses, which are intended for human consumption.

[4] The respondents are members of the Specialist Cheesemakers Association ("SCA").

[5] Throughout 2016, the respondents had establishment approval from the applicants to operate for the purposes of article 4(3) of Regulation (EC) 853/2004.

[6] The respondents produce cheese from raw cows' and raw ewes' milk, and their products include Dunsyre Blue, Lanark Blue and Corra Linn cheeses.

[7] The respondents source the raw ewes' milk for cheese production from a farm at Walston Braehead, adjacent to the respondents' premises, and operated by the partnership of A&S Cairns, of which Mrs Selina Cairns is a partner.

[8] Mrs Cairns is a director of the respondents, and the daughter of Mr Humphrey Errington.

[9] Dunsyre Blue is a cows' milk cheese.

[10] Lanark Blue is a semi-hard blue cheese made from ewes' milk.

[11] Corra Linn is a hard cheese made from ewes' milk cheese.

[12] Since the autumn of 2010 Alan Dickson has been the environmental health officer authorised by the applicants to conduct the inspection and audit of the respondents' premises and operation.

[13] All of the batches of Dunsyre Blue, Lanark White, Lanark Blue and Corra Linn seized by the applicants, and referred to in the present applications, were produced using raw (ie. unpasteurised) milk, and comprise ready-to-eat foods of animal origin for the purposes of the HPA Guidelines for Assessing the Microbiological Safety of Ready to Eat Foods on the Market, published by the Health Protection Agency in November 2009.

[14] Each batch of the respondents' cheeses is alphanumerically coded, where the letter denotes the month of production and the number corresponds to the day of production.

[15] The respondents supply their cheese products to specialist cheese shops, farm shops, restaurants, hotels, and delicatessens. Their products are not supplied to supermarkets.

STEC

[16] Shiga toxin-producing Escherichia coli ("STEC") are a group of E.coli characterised by their ability to produce toxins, designated Shiga Toxins.

[17] Verocytotoxin-producing Escherichia coli ("VTEC") are a group of E.coli characterised by their ability to produce Shiga-like toxins, designated verocytotoxins.

[18] Shiga toxins are also known as verocytotoxins and the terms "STEC/*stx*" and "VTEC/*vtx*" are synonymous.

[19] The main virulence factor for STEC are Shiga toxin-producing (*stx*) (positive) genes and certain *stx* subtypes are more commonly associated with clinical illness.

[20] The "O" serogroup of an E.coli organism refers to the O antigen that the organism possesses (a type of protein found on the outer membrane of the cell).

[21] The "H" group of an E.coli organism refers to the H antigen (a protein found on the flagella of the organism i.e. the part of the E.coli cell that allows it to move).

[22] One established route of exposure to STEC is the consumption of contaminated food.

[23] Certain STEC serotypes such as O157:H7 can give rise to a range of symptoms from mild to bloody diarrhoea.

[24] A proportion of these cases can go on to develop Haemolytic Uraemic Syndrome ("HUS") which can lead to death.

[25] E.coli O157:H7, if present in an E.coli population, will represent between 0.1% and 1% of that population.

[26] There is uncertainty over what constitutes the lowest level for an infective dose.

[27] Serious illness caused by STEC infection is not common.

[28] There is no recognised specific treatment for STEC infection.

[29] Faecal contamination of food is a potential food safety risk.

[30] Not all STEC cause illness. Most E.coli serotypes are harmless, are part of the normal flora of the gut, and can benefit their hosts.

[31] Categorising the pathogenicity of E.coli strains on the basis of serotype has been useful in the past, but is now being replaced by the analysis of specific virulence factors, enabled in particular by whole genome sequencing ("WGS").

[32] Serotypes are groups within a single species of microorganism, such as bacteria or viruses, which share distinctive surface structures.

[33] STEC live in the guts of ruminant animals, including cattle and sheep, and are shed in their faeces.

[34] In the United Kingdom sheep have been known to shed in their faeces campylobacter, salmonella, listeria and STEC.

[35] All reported foodborne STEC outbreaks in Scotland have involved stx positive E.coli O157:H7.

[36] There is scientific uncertainty, and the absence of international consensus, as to the combination of genes or serotypes required to confer STEC pathogenicity.

[37] In 2013 a scientific Opinion was published, under the auspices of the European Food Safety Authority ("EFSA"), by the EFSA Panel on Biological Hazards. The Panel's remit was to deliver a scientific Opinion on STEC-seropathotype and scientific criteria regarding pathogenicity assessment.

[38] The EFSA panel proposed a molecular classification scheme which utilised encoding virulence characteristics additional to the presence of stx genes. It concluded that "any ready-to-eat product contaminated with an isolate of one of the STEC serogroups of group 1 (O157, O26, O103, O145, O111, O104), in combination with stx and [1] eae, or [2] aaiC and aggR, genes should be considered as presenting a potentially high risk for diarrhoea and HUS. For any other serogroups in combination with the same genes, the potential risk is regarded as high for diarrhoea, but currently unknown for HUS. In the absence of these genes, current available data do not allow any inference regarding potential risks".

The Specialist Cheesemakers Association Assured Code of Practice

[39] The Specialist Cheesemaker's Assured Code of Practice, Edition 1, 2015, ("the SCA Code of Practice") provides at paragraph 5.2.9, that if milk is destined for raw milk cheese, the milk producer and cheesemaker should decide between them who shall be responsible for implementing a test schedule for *inter alia* E.coli and STEC.

[40] The SCA Code of Practice provides, at paragraph 5.3.1, that frequency of testing could be anything from weekly to 6-monthly.

[41] The SCA Code of Practice also provides, at paragraph 5.3.1, that is it reasonable to screen the milk supply for organisms including E.coli.

[42] Appendix 5.2.3 of the SCA Code of Practice makes recommendations for cheese additional to criteria in EU Regulations. The recommendations include testing cheese for E.coli O157 and other STEC, with a target of "not detected" in 25g of the product and a standard of "unsatisfactory" if detected.

[43] In about October 2016, a document entitled "Guidance for Local Authority Enforcement Officers on the Production of Cheeses from Unpasteurised Milk" was drawn up by a working group comprising environmental health officers, food examiners and officers from FSS.

[44] The Guidance for Local Authority Enforcement Officers, which was stated to apply to cheese made from sheep's milk, advised *inter alia* as follows: "The guidance has been developed in relation to the control of STEC, however, it is recognised that there are currently limitations in relation to testing for STEC, including access to accredited laboratories and interpretation of results. The implication of this is that FBOs are unlikely to be able to achieve the expected level of validation referred to later in this guidance for all STEC. Therefore, in the interim period, it is deemed appropriate to consider O157 as a proxy for STEC. The guidance will therefore refer to E.coli O157 throughout, however, it is anticipated that work on STEC testing will progress and at the point of review references to E.coli O157 in this document will be changed to STEC".

[45] In March 2017, the SCA published a clarification of current SCA recommendations for the supply of milk destined for the production of raw milk cheese with regard to STEC.

The clarification provided *inter alia* as follows: "Very few laboratories in the UK are UKAS-accredited to test for STEC…Only one laboratory in the UK holds UKAS-accreditation to test for STEC and is independent of Government. The scope of Campden BRI's UKAS accreditation is restricted to sprouted seeds, grains, red meat and water. This means that the laboratory is not accredited to undertake tests to detect STEC in other food matrices, although it may be capable of doing so…Therefore, the SCA recommends that it is currently unrealistic to expect cheesemakers to implement routine testing for STEC by a UK laboratory".

Milk hygiene and other control measures

[46] At the time when the seized cheeses were produced all of the respondents' raw ewes' milk requirements were met by ewes kept on the farm operated by A&S Cairns.

[47] The respondents were aware of the measures taken by A&S Cairns to secure good flock health and husbandry, and milking parlour routine.

[48] The measures put in place by A&S Cairns to meet the respondents' requirements for hygienic milk included (i) new milking equipment and a new milking parlour and shed (installed in 2013 at a cost of £195,000; (ii) pre- and post-milking disinfection of the ewes' teats; (iii) individual somatic cell count monitoring in mid-lactation using an independent external laboratory; (iv) the culling of high somatic cell count ewes (that being indicative of possible sub-clinical infection); (v) the culling of poor udder conformation ewes (which are prone to a higher risk of infection), and (vi) monitoring of udder cleanliness and hygiene.

[49] The measures described in the preceding finding-in-fact reduce the risk not only of sub-clinical and clinical mastitis, but also reduce to a practical minimum the risk of vector

transmission via the teat skin of environmental or faecal bacteria (such as E.coli) into the raw milk used in the cheesemaking process.

[50] The respondents employed a range of chemicals in their cheese rooms to eliminate bacteria, including an acid cleaning agent which was designed to prevent biofilm build up.

[51] On the respondents' premises there were, at the time when the seized cheeses were produced, different bulk tanks and delivery pipes for cows' and ewes' milk.

[52] Before the cheesemaking process begins the vat to which the raw milk is delivered is disinfected and also heated to a temperature, and for a time, that exceeds the temperature achieved during pasteurisation.

[53] Any biofilm on the surface of the vat would be killed off before the cheesemaking process begins.

Testing for harmful micro-organisms prior to August 2016

[54] Prior to August 2016 the respondents did not test the raw milk used in the production of its cheese products for E.coli, E.coli O157 or STEC.

[55] Alan Dickson was aware that the respondents were not testing their raw milk for E.coli O157, and that the respondents had assessed E.coli O157 as low risk.

[56] Alan Dickson was aware that the respondents monitored the risk of faecal contamination by testing for generic E.coli, and the test results would have been considered by him on the inspection and auditing process which he undertook relative to the respondents.

[57] Testing for faecal indicator organisms is consistent with observations about STEC testing contained in the Codex Alimentarius Commission progress report on the joint Food and Agriculture Organisation of the United Nations/World Health Organisation expert

meetings on microbiological risk assessment, dated October 2017. Paragraph 14 of the report stated *inter alia* that: "…[T]he utility of testing for STEC presence/absence as part of monitoring programmes food safety assurance in processing is limited by the typically low levels and prevalence of STEC in food. Process performance monitoring may be accomplished more effectively and efficiently by quantitatively monitoring sanitary and hygiene indicator organisms. These indicator organisms do not indicate pathogen presence; instead they provide a quantitative measure of the control of microbial contamination in the product and processing environment."

[58] The respondents tested the curd for generic E.coli as an indicator organism.

[59] Testing the curd is a more sensitive method of detecting E.coli than testing the raw milk.

[60] The results of such testing are measured in bacteria colony forming units per gram ("cfu/g").

[61] The SCA Code of Practice, at appendix 5.2.3, identifies a target for E.coli in mature hard cheese (such as Corra Linn) of 100 cfu/g, and a target for E.coli in a semi-hard or soft cheese (such as Lanark Blue) of 10,000 cfu/g.

[62] Between 2 March and 12 June 2016, testing of the curd for Lanark Blue disclosed one result for generic E.coli of 20 cfu/g, and one result of 10 cfu/g. The remaining tests on the Lanark Blue curd for generic E.coli showed results of less than 10 cfu/g. A result of less than 10 cfu/g is deemed by scientists to be below the level of detection.

[63] All of the test results from the Lanark Blue curd between 2 March and 12 June 2016 fell within the target for a semi-hard or soft cheese in the SCA Code of Practice.

Inspections by the applicants and SALSA audits

[64] On 27 September 2012, Alan Dickson carried out an inspection of the respondents' premises in terms of *inter alia* the 1990 Act and the 2006 Regulations. The inspection included examination of cheese make sheets, temperature records, pest control records, milk and cheese sample results and verification of HACCP. The premises were found to be very clean and very well managed, and Mr Dickson noted that the respondents had traced a batch of cheese for the presence of enterobacteriacae and that the results were very satisfactory.

[65] On 20 March 2013, Alan Dickson carried out an inspection of the respondents' premises in terms of *inter alia* the 1990 Act and the 2006 Regulations. The inspection included examination of make sheets, HACCP, pest control, sample results, labels and packaging of materials. Mr Dickson noted that the business was found to be operating satisfactorily in respect of food standards.

[66] On 12 March 2015, Alan Dickson carried out an inspection of the respondents' premises in terms of *inter alia* the 1990 Act and the 2006 Regulations. The whole of the premises were the subject of inspection. Mr Dickson noted that the premises were operating highly satisfactorily in respect of food standards.

[67] On 3 September 2015 SALSA ("Safe and Local Supplier Approval") issued a certificate to the respondents. It certified that the respondents had been audited against, and demonstrated compliance with, the SALSA+SCA Standard (Issue 3, January 2012) for the following scope: "The manufacture, maturation and packing of soft blue and hard-pressed cheese made from raw cows' and ewes' milk". The certificate expired on 24 September 2016.

[68] On 16 August 2016, the respondents were the subject of an audit by SALSA+SCA auditor Jayne Hickinbotham. The audit was conducted by reference to the SCA Code of

Practice dated 4 June 2015. The respondents were found by the audit to be, substantially, fully compliant in respect of *inter alia*: (i) prerequisite controls; (ii) HACCP and management systems; (iii) documentation; (iv) premises, and (v) SCA specific requirements relative to process control and maturation. The audit also found that the respondents had met the Statement of Intent (whereby "all hazards to product safety and legality shall be identified, analysed and assessed for risk. A documented HACCP system based on *Codex Alimentarius* principles, shall be in place alongside an effective management system encompassing regular systems reviews and procedures for Corrective Action, traceability, incident management and complaint handling").

[69] In September 2016 two auditors from FSS visited the respondents' premises as part of the investigation into the July E.coli outbreak. They were accompanied by Karen Wardrope of the respondents. The auditors spent a day looking at the premises, and their inspection included the water supply and the respondents' safety management system. The respondents were advised that the auditors had not identified any systemic issues of concern.

Background to the investigation of the respondents' raw ewes' milk cheeses

[70] In July 2016 Health Protection Scotland established an Incident Management Team ("IMT") to investigate what had caused a number of people to fall ill due to E.coli O157:H7. The outbreak was initially reported as having affected twenty people and a young child died. The IMT was convened on 26 July 2016 and FSS became involved.

[71] The IMT formed the view that the probable cause of the outbreak was Dunsyre Blue cheese made by the respondents. The IMT's view was published in March 2017.

[72] The respondents do not accept that Dunsyre Blue was the cause of the outbreak.

[73] On 23 August 2016 Karen Wardrope and Alan Dickson, both of the applicants, attended the respondents' premises. The purpose of their visit was to take two samples of Dunsyre Blue, batch F15, the intention being then to submit the samples to City of Edinburgh Council Scientific Services ("ESS") for microbiological testing.

[74] ESS is an official control laboratory, designated by FSS to carry out microbiological, chemical, and environmental testing. At the material time ESS could generate only presumptive positive, as opposed to confirmed, results for STEC in food samples.

[75] Further samples of Dunsyre Blue, batch F15, were taken for submission to ESS on 26 and 29 August 2016.

[76] Since 2007, ESS have been contracted to the applicants to fulfil the functions of public analyst and food examiner for the purposes of the 2006 Regulations (and, in particular, the analysis of samples, pursuant to regulation 13 thereof).

[77] At all material times the authorised Food Examiner who was responsible for issuing certificates arising from the microbiological testing of the respondents' cheeses was Robert Beattie ("the Food Examiner").

Initial Sampling, Testing and Certification of Dunsyre Blue and Lanark White

[78] On 31 August, 2016, a sample of Lanark Blue, batch E24, was taken by Alan Dickson and submitted for examination by the Food Examiner at ESS.

[79] On 14 September, 2016, a "Food Alert for Action" ("the FAFA") was issued by FSS.

[80] A "Food Alert for Action" is a communication from FSS to food authorities, including the applicants, concerning a food hazard or other food incident, where specific action is required to be undertaken by a food authority.

[81] The FAFA stated *inter alia* that "both O157 and Non-O157 strains of E.coli have been detected in different types of cheeses produced by Errington Cheese Limited. This makes these products a potential risk to health."

[82] The FAFA covered *inter alia* all batches and all pack sizes of the products known as "Lanark Blue" and "Corra Linn".

[83] The terms of the FAFA were advised by a "Raw cheese risk assessment", also dated 14 September 2016, whose stated purpose was to assess "the potential risks to public health associated with [STEC] contamination of the raw milk cheese Dunsyre Blue from [the respondents]".

[84] The FAFA required Local Authorities to "identify food business who are likely or known to stock [the said products] and to take steps to ensure [they were] withdrawn from sale and destroyed, if necessary using powers under the Food Safety Act 1990 and Regulation 27 of the Food Hygiene (Scotland) Regulations 2006."

[85] The respondents voluntarily held all stocks of cheese produced by them from being placed on the market during the period 14 September 2016 until 16 January, 2017.

[86] Following the issue of the FAFA the respondents' SALSA approval was withdrawn.

[87] The applicants were obliged to take action in accordance with the directions contained in the FAFA.

[88] On 6 October 2016 Craig Brown wrote to the respondents on behalf of the applicants. He invited the respondents to provide, in writing and within a period of fourteen days, "adequate guarantees of the controls that will be applied during future production to ensure that final products produced by [the respondents] will not be contaminated with E.coli O157 and STEC organisms capable of being injurious to health".

[89] On 25 October 2016 the Food Examiner issued a Certificate of Examination relative to a sample of Dunsyre Blue, batch F15.

[90] The certificate proceeded on test results derived from an analysis of the sample by ESS, the Scottish E.coli O157 VTEC Reference Laboratory ("SERL"), and the Gastrointestinal Infections Reference Laboratory at Public Health England, Colindale, London ("PHE").

[91] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O unidentifiable: H20, stx2d, Sequence Type 1308.

[92] WGS is a laboratory process that is used to reveal the complete DNA make-up of an organism.

[93] The Food Examiner considered the sample of Dunsyre Blue, batch F15, to be unsafe by reason of being unfit for human consumption, due to the presence of E.coli O unidentifiable:H20, stx2d, Sequence Type 1308, within the meaning of article 14 of Regulation (EC) 178/2002.

[94] On 25 October 2016, and also on 5 April 2017, the Food Examiner issued Certificates of Examination relative to two batches of Dunsyre Blue, batch F15.

[95] The two certificates proceeded on test results derived from an analysis of the samples by ESS and SERL.

[96] The Food Examiner observed that each sample was presumptive positive for a stx2 gene, but that the stx2 gene was detected from a culture broth and not from an isolated colony. He also observed that further investigation of the samples may be warranted to determine if STEC positive colonies could be isolated and identified in order to ascertain the suitability of the product to be placed on the market. In the result, no confirmed STEC organism was isolated subsequently from either of the samples.

[97] On 25 October 2016 the Food Examiner issued Certificates of Examination relative to samples of Lanark White, batches H3, H24 and G14. The certificates proceeded on test results derived from an analysis of those samples by ESS, SERL and PHE.

[98] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O157:H42, stx negative, Sequence Type 7077.

[99] The Food Examiner considered the three batches of Lanark White to be unsafe by reason of being unfit for human consumption, due to the presence of E.coli O157:H42 within the meaning of article 14 of Regulation (EC) 178/2002. E.coli O157:H42, stx negative, is not a STEC and is not pathogenic.

[100] On 27 October 2016 the Food Examiner issued an informal Test Report relative to Dunsyre Blue, sample batch F15. The Test Report proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[101] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O unidentifiable: H20, stx2d, Sequence Type 1308.

[102] The Food Examiner considered the sample of Dunsyre Blue, batch F15, to be unsafe by reason of being unfit for human consumption, due to the presence of E.coli O unidentifiable:H20, stx2d, Sequence Type 1308, within the meaning of article 14 of Regulation (EC) 178/2002.

[103] On 9 November, 2016, FSS issued "FAFA-02-2016 (Update 3)" ("FAFA-02"), following the respondents' application for a judicial review of the FAFA instruction to cause to be withdrawn from sale, and to destroy, the cheese.

[104] As at 9 November, 2016, Food Authorities were advised by FAFA-02 that: "Shiga Toxin producing E.coli (STEC) has been detected in batches of Dunsyre Blue (F15) and Lanark Blue (E24) cheese produced by Errington Cheese Limited. 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 ewes' milk cheese. Stx gene negative strains of E.coli O157 have been isolated in cases of human illness consistent with E.coli O157 infections."

[105] FAFA-02 further communicated that FSS considered products, including all batches and all pack sizes of the products known as Lanark Blue and Corra Linn, to be a risk to health. It required local authorities, including the applicants, "to identify food businesses which are likely or known to stock products subject to this FAFA, and to take steps to ensure they are withdrawn from sale. Local authorities should ensure that this withdrawal is effective and that the products …are not placed on the market, if necessary using powers available under [the 1990 Act], the General Food Regulations 2004, and [the 2006 Regulations]".

[106] The applicants were obliged to take action in accordance with the directions contained in FAFA-02

Amendments to the respondents' safety management system after the E.coli outbreak

[107] On 29 November 2016 a meeting was held between Craig Brown and Karen Wardrope, both of the applicants, and Selina Cairns and Humphrey Errington of the respondents. At the meeting the parties agreed to final amendments to the respondents' HACCP based procedures and control validation.

[108] Until that time, the respondents had not been testing their raw milk, curd or end cheese products for either E.coli O157 or STEC, nor had they looked into the availability of testing facilities for E.coli O157 or STEC.

[109] On the basis that the amendments agreed at the meeting on 29 November 2016 would be fully implemented, Craig Brown advised, by letter dated 11 January 2017, that the applicants were satisfied that the respondents could recommence cheese production.

[110] The amendments referred to above included provision for the rejection of raw ewes' milk at more than ten degrees celsius, the daily testing of raw milk for E.coli O157, weekly testing of the curd for E.coli O157 (reverting to monthly in the event of satisfactory results over a one month period), and quarterly testing of the raw milk and finished product for STEC, to be undertaken by a company called Actalia based in France.

[111] On 9 January 2017 Selina Cairns of the respondents advised the applicants, by email, of the respondents' intention to place their products, including Lanark Blue and Corra Linn, on the market for sale from Monday 16 January 2017. She also advised the applicants "[b]ecause FSS have explained that their actions have been taken based on the Precautionary Principle, we will follow the EU Precautionary Principle guidelines on the need for communication by adding the following on our labels:

> **"Warning: Made using raw milk. Unsuitable for pregnant women, children, the elderly and anyone with low resistance to infection"**.

[112] The applicants' response to the email of 9 January 2017 was to ask the respondents voluntarily to withhold their products from the market pending more extensive testing. The respondents were unwilling to do so.

Detention, Testing and Certification of Lanark Blue and Corra Linn

[113] On 13 January, 2017, the applicants served Notices of Detention under Regulation 9 of the Food Hygiene (Scotland) Regulations 2006 ("the Notices of Detention") in respect of

inter alia the Lanark Blue and Corra Linn, to enable sampling and examination of those cheeses.

[114] The testing and analysis of the samples of Lanark Blue and Corra Linn were undertaken by ESS and SERL, with pellets or isolates then being submitted to PHE for confirmation by way of WGS.

[115] On 17 January 2017, the Food Examiner issued a Certificate of Examination relative to a sample of Lanark Blue, batch E24. The certificate proceeded on test results derived from an analysis of a sample of the said batch of the said cheese by ESS, SERL and PHE.

[116] Using WGS PHE identified the colonies submitted to them by SERL as E.coli O unidentifiable H20 with a stx2d gene, Sequence Type 1308.

[117] The Food Examiner considered Lanark Blue, batch E24, to be unsafe by reason of being unfit for human consumption, due to the presence of E.coli O unidentifiable H20 with a stx2d gene, Sequence Type 1308, within the meaning of article 14 of Regulation (EC) 178/2002.

[118] The results of WGS showed the E.coli strains from Dunsyre Blue, batch F15, and Lanark Blue, batch E24, to be genetically very closely related.

[119] It is biologically implausible that the herd supplying milk for Dunsyre Blue, batch F15, and the flock supplying milk for Lanark Blue, batch E24, would have been carrying simultaneously the particular strain of E.coli subsequently found in those batches of cheese.

[120] The most likely source of the E.coli O unidentifiable H20 with an stx2d gene, Sequence Type 1308, organism was raw milk used in the production process, as a result of an isolated episode of cross contamination at a time when batches of Dunsyre Blue and Lanark Blue were produced on the respondents' premises on the same date.

[121] On the result of the microbiological testing of the sample of Lanark Blue, batch E24, becoming known, Selina Cairns of the respondents suggested to the applicants that batch E24 should be re-tested. The applicants declined to do so.

[122] On 27 January 2017 the Court of Session suspended the Notices of Detention served on 13 January 2017 *ad interim*, and the respondents undertook to the Court *inter alia* that Lanark Blue would not be placed on the market prior to 1700 hours on 3 February 2017.

[123] On 3 February 2017, Karen Wardrope attended at the respondents' premises and seized the Lanark Blue cheeses of batch E24 specified in the Record of Inspection (B20-17, no. 8).

[124] On 3 February 2017, Karen Wardrope certified, under regulation 27 of the Food Hygiene (Scotland) Regulation 2006, that eighty three remaining batches of Lanark Blue produced by the respondents had not been produced, processed or distributed in accordance with the Hygiene Regulations.

[125] On 3 February, 2017, the applicants served notices under the Food Safety Act 1990, section 9, in respect of seventy one batches of Corra Linn cheese produced by the respondents.

[126] The Notices served on 3 February 2017 advised the respondents that the seventy one batches of Corra Linn cheese were not to be removed from their premises.

[127] In the period from 3 February 2017 until 23 February 2017 the applicants took one hundred and sixty samples from thirty two batches of Corra Linn cheese.

[128] Authorised Officers of the applicants submitted the said samples to the Food Examiner at ESS.

[129] The Food Examiner at ESS carried out a range of tests upon the Corra Linn samples in order to form an opinion as to their fitness for human consumption, and safety as a ready to eat raw milk cheese.

[130] On 9 February, 2017, the Food Examiner advised the applicants that two samples taken from Corra Linn, batch F27A, and examined by him, had returned a presumptive positive result for stx2.

[131] On 9 February, 2017, the Food Examiner advised the applicants that a sample taken from Corra Linn, batch E23A, and examined by him, had returned a presumptive positive result for stx2.

[132] The applicants submitted the results from a number of examinations taken from batches of Corra Linn to Campden BRI (Chipping Campden) Limited requesting that microbial survival predictions be carried out using said data. The results disclosed that, on average, between 180 and 200 days were required to achieve a 6-log reduction in E.coli O157.

[133] On 20 February, 2017, the Food Examiner advised the applicants that a sample taken from Corra Linn, batch B17A, had been examined, and that the result was "very strong presumptive positive stx1 but stx2 negative by PCR. Culture plates still under test."

[134] The Food Examiner submitted a pellet from said sample to SERL for confirmation of the results.

[135] On 24 February, 2017, the applicants were advised in an email from Dr Lesley Allison, Principal Scientist, SERL, that a vtx1 positive E.coli (not O157) had been isolated from the sample taken from Corra Linn, batch B17A.

[136] At that time, FAFA-02 had not been withdrawn by FSS, and remained in force.

[137] On 24 February and 8 March, 2017, Karen Wardrope of the applicants certified, under regulation 27 of the Food Hygiene (Scotland) Regulations 2006, that the batches of Corra Linn listed in the appendix to each certificate, and produced by the respondents, had not been produced, processed or distributed in accordance with the Hygiene Regulations.

[138] The certificate dated 24 February, 2017, extended, but was not limited, to Corra Linn, batches B17A, E23A, F27A, G7A, G20A, and H1A, in respect of which samples had been analysed by PHE using WGS.

[139] On 18 May, 2017, the Food Examiner issued a Certificate of Examination dated 5 April, 2017, relative to a sample of Corra Linn, batch G7A. The certificate proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[140] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O157:H42, stx negative, Sequence Type 7077.

[141] The Food Examiner considered the sample of Corra Linn, batch G7A, to be unsafe by reason of being potentially injurious to health and/or unfit for human consumption, due to the presence of E.coli O157:H42, within the meaning of article 14 of Regulation (EC) 178/2002. E.coli O157:H42, stx negative, is not a STEC and is not pathogenic.

[142] On 18 May, 2017, the Food Examiner issued a Certificate of Examination dated 5 April 2017, relative to a sample of Corra Linn, batch H1A. The certificate proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[143] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O157:H42, stx negative, Sequence Type 7077.

[144] The Food Examiner considered the sample of Corra Linn, batch H1A, to be unsafe by reason of being potentially injurious to health and/or unfit for human consumption, due to

the presence of E.coli O157:H42, within the meaning of article 14 of Regulation (EC) 178/2002. E.coli O157:H42, stx negative, is not a STEC and is not pathogenic.

[145] On 18 May, 2017, the Food Examiner issued a Certificate of Examination dated 7 April 2017, relative to a sample of Corra Linn, batch G20A. The certificate proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[146] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O157:H42, stx negative, Sequence Type 7077.

[147] The Food Examiner considered the sample of Corra Linn, batch G20A, to be unsafe by reason of being potentially injurious to health and/or unfit for human consumption, due to the presence of E.coli O157:H42, within the meaning of article 14 of Regulation (EC) 178/2002. E.coli O157:H42, stx negative, is not a STEC and is not pathogenic.

[148] On 18 May, 2017, the Food Examiner issued a Certificate of Examination dated 10 April 2017, relative to a sample of Corra Linn, batch G25A. The certificate proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[149] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O157:H42, stx negative, Sequence Type 7077.

[150] The Food Examiner considered the sample of Corra Linn, batch G25A, to be unsafe by reason of being potentially injurious to health and/or unfit for human consumption, due to the presence of E.coli O157:H42, within the meaning of article 14 of Regulation (EC) 178/2002. E.coli O157:H42, stx negative, is not a STEC and is not pathogenic.

[151] On 18 May, 2017, the Food Examiner issued a Certificate of Examination dated 7 April 2017, relative to a sample of Corra Linn, batch E23A. The certificate proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[152] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O unidentifiable: H14, stx2b, Sequence Type 7010.

[153] The Food Examiner considered the sample of Corra Linn, batch E23A, to be unsafe by reason of being potentially injurious to health and/or unfit for human consumption, due to the presence of E.coli O unidentifiable: H14, stx2b, within the meaning of article 14 of Regulation (EC) 178/2002.

[154] On 18 May, 2017, the Food Examiner issued a Certificate of Examination dated 7 April 2017, relative to a sample of Corra Linn, batch F27A. The certificate proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[155] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O8:H9, stx2e, Sequence Type 23.

[156] The Food Examiner considered the sample of Corra Linn, batch F27A, to be unsafe by reason of being potentially injurious to health and/or unfit for human consumption, due to the presence of E.coli O8:H9, stx2e, within the meaning of article 14 of Regulation (EC) 178/2002.

[157] On 18 May, 2017, the Food Examiner issued a Certificate of Examination dated 10 April 2017, relative to a sample of Corra Linn, batch B17A. The certificate proceeded on test results derived from an analysis of the sample by ESS, SERL and PHE.

[158] Using WGS, PHE identified the colonies submitted to them by SERL as E.coli O153-O178:H7, stx1c, Sequence Type 278.

[159] The Food Examiner considered the sample of Corra Linn, batch B17A, to be unsafe by reason of being potentially injurious to health and/or unfit for human consumption, due to the presence of E.coli O178:H7, stx1c, within the meaning of article 14 of Regulation (EC) 178/2002.

[160] None of the cheese samples submitted by SERL to PHE for WGS produced a positive result for either the eae gene, or the aaiC and aggR genes.

[161] Of all the samples of the respondents' Lanark Blue and Corra Linn cheeses tested by, or on behalf of, the applicants, none tested positive for E.coli O157:H7.

[162] Of the approximately three hundred samples of raw milk cheeses submitted subsequent to the outbreak by the respondents to their laboratory in Ashley, or Actalia in France, none tested positive for E.coli O157:H7.

[163] None of the organisms found, by WGS, in the respondents' cheeses fell within either the six serogroups identified as being from group 1, in the proposed molecular classification scheme of the EFSA scientific opinion, or the "other serogroups" which were regarded as high risk for diarrhoea in that opinion.

[164] There is no recorded incident of the respondents' raw ewes' milk cheese ever having caused an E.coli related illness in consumers.

FINDS IN FACT AND LAW:

The use of raw milk

[1] The sale of raw milk for human consumption is restricted in Scotland and has been since 1983. There is no such restriction on the use of raw milk as an ingredient in dairy produce such as raw milk cheese, nor is there any explicit requirement contained within article 5 of Regulation (EC) 852/2004 for a food business operator to test its raw materials or finished product.

[2] Lanark Blue, batch E24, and Corra Linn, batches B17A, E23A, and F27A, fail to comply with food safety requirements in terms of section 9 of the Food Safety Act 1990 by reason of being unfit for human consumption within the meaning of article 14 of Regulation

(EC) 178/2002, by reason of there having been isolated from samples of the said cheeses E.coli O unidentifiable:H20; stx2d, ST1308; E.coli O153-178:H7; stx1c, ST278; E.coli O unidentifiable:H14; stx2b, ST7010, and E.coli O8:O9; stx2e, ST23, respectively.

[3] Each of the batches comprising Lanark Blue Remainder comply with food safety requirements, in terms of section 9 of the Food Safety Act 1990, by reason of having been produced, processed or distributed in compliance with the Hygiene Regulations.

[4] Each of the batches of Corra Linn seized by the applicants, with the exception of batches B17A, E23A, and F27A, comply with food safety requirements, in terms of section 9 of the Food Safety Act 1990, by reason of having been produced, processed or distributed in compliance with the Hygiene Regulations.

[5] The food safety management system maintained by the respondents at the time when all of the seized cheeses were produced complied with the requirements of article 5 of Regulation (EC) 852/2005.

THEREFORE

(i) in respect of application LAN B20-17, sustains the second and third pleas-in-law for the applicants; repels the pleas-in-law of the respondents; finds that the food seized, namely Lanark Blue, batch E24, identified in the Record of Inspection Form (B20-17:8) fails to comply with food safety requirements, condemns the said food and orders that it be destroyed, or be so disposed of as to prevent it from being used for human consumption, all in terms of section 9(6) of the Food Safety Act 1990;

(ii) in respect of application LAN B21-17, sustains the second, third, fourth and fifth pleas-in-law for the respondents; repels the pleas-in-law for the applicants; finds

that the food seized, namely Lanark Blue Remainder, identified in the Record of Inspection Form (B21-17: no. 10) complies with food safety requirements;

(iii) in respect of application LAN B33-17, sustains the second plea-in-law for the applicants to the extent of finding that the batches of food seized, comprising Corra Linn, batches B17A, E23A, andF27A, fail to comply with food safety requirements, condemns the said food and orders that it be destroyed, or be so disposed of as to prevent it from being used for human consumption, all in terms of section 9(6) of the Food Safety Act 1990; *quoad ultra* sustains the second, third, fourth, fifth and sixth pleas-in-law for the respondents; finds that the remaining batches of Corra Linn cheese identified in the appendices to the certificates issued by the applicants under regulation 27 of the Food Hygiene (Scotland) Regulations 2006 (B33-17, nos. 10, 11, 12, and 13) comply with food safety requirements;

(iv) appoints parties to be heard on (i) any practical arrangements which require to be made to give effect to these orders, and (ii) the question of the expenses of the applications, at a hearing in Lanark Sheriff Court on a date to be afterwards fixed.

NOTE:

Introduction

[1] The respondents are a long established and highly respected manufacturer of raw milk cheeses. They are, perhaps, particularly well known for producing a raw cow's milk cheese called Dunsyre Blue, and a raw ewes' milk cheese called Lanark Blue. But they also manufacture, amongst others, a hard raw ewe's milk cheese called Corra Linn. The respondents' products are sold to restaurants, hotels, specialist cheesemongers and delicatessens throughout the United Kingdom, and overseas. Their cheese making process

is conducted from the farm premises at Walston Braehead, Ogscastle, Carnwath, in Lanarkshire.

[2] There are three applications before the court, each of which is made by applicants, as the relevant food authority, in terms of the Food Safety Act 1990 Act ("the 1990 Act"), and enforcement authority, in terms of the Food Hygiene (Scotland) Regulations 2006 ("the 2006 Regulations") for the area of South Lanarkshire.

[3] The first application concerns a raw ewe's milk cheese, seized by the applicants on 3 February 2017, called Lanark Blue, batch E24. In the E24 application, the applicants seek an order that Lanark Blue, batch E24, fails to comply with food safety requirements in terms of section 9 of the 1990 Act.

[4] The second application concerns a considerable number of other batches of Lanark Blue ("Lanark Blue Remainder"), also seized by the applicants on 3 February 2017. The third application concerns another raw ewe's milk cheese called Corra Linn, seized by the applicants on 24 February and 8 March, both 2017. In each of these two applications, the applicants seek an order that the cheese seized by them fails to comply with food safety requirements in terms of regulation 27 of the 2006 Regulations.

[5] As a result, in each of the applications, the applicants seek orders from the court that the seized batches of Lanark Blue and Corra Linn cheeses should be condemned in terms of section 9(6) of the 1990 Act, and thereafter destroyed or so disposed of as to prevent it from being used for human consumption in terms of section 9(6)(a) of the 1990 Act.

Representation

[6] The applicants were represented at the evidential hearing by Mr Stephen Love QC. I wish to record my appreciation of both the skill and the fairness with which he presented the applicant' case.

[7] At an earlier stage in proceedings the respondents were represented by both solicitors and counsel. That remained the position until the pre-proof hearing which took place in Lanark Sheriff Court on 8 December 2017. On that occasion I was advised by junior counsel for the respondents that the instructions of senior counsel and himself had been withdrawn. I was given to understand that the respondents' agents were in a similar position and that, accordingly, the respondents were (as at that date) unrepresented.

[8] Mr Humphrey Errington, who had been present at earlier procedural callings of the case, represented that he wished to apply to appear on behalf of the respondents at the forthcoming evidential hearing. In the first instance, I continued the case to allow Mr Errington to communicate to the court in writing his proposals for how the hearing could be conducted in the absence of the respondents' legal representatives. When the case called again on 13 December 2017 it was agreed between parties that the appropriate course of action was for Mr Errington to submit an application, under section 97 of the Courts Reform (Scotland) Act 2014, for permission to conduct proceedings on behalf of the respondents.

[9] The application having been duly submitted, and opposed by the applicants, I heard argument on 18 December. Having done so I was satisfied, under reference to the criteria specified in section 97(3) and (4) of the 2014 Act, that Mr Errington should be granted permission to represent the respondents at the evidential hearing. I would also add that I considered it to be clearly in the public interest that evidence in support of the respondents'

opposition to the applications, as set out in their answers, should be heard. Mr Errington did not wish any adjournment of the hearing. I wish to record that he represented the respondents' interests, in a very difficult situation, and at short notice, with courtesy and courage.

Statutory Regime for Food Safety Enforcement in Scotland

[10] The submissions of parties (particularly those of the respondents) made reference to numerous provisions of domestic and European law, certainly too numerous to relate here. I have, however, set out what appear to be the salient provisions, so far as disclosed in the parties' pleadings. I will address any other relevant provisions in the context of discussing parties' competing submissions.

The 1990 Act and the 2006 Regulations

(a) Part II of the 1990 Act provides *inter alia* as follows:

> "**Selling food not complying with food safety requirements**
> 8(2) For the purposes of [Part II of the 1990 Act] food fails to comply with food safety requirements if it is unsafe within the meaning of article 14 of Regulation (EC) 178/2002 and references to food safety requirements or to food complying with such requirements shall be construed accordingly…
>
> **Inspection and seizure of suspected food**
> 9(1) An authorised officer of a food authority may at all reasonable times inspect any food intended for human consumption which—
>
> (a) has been sold or is offered or exposed for sale;
> (b) is in the possession of, or has been deposited with or consigned to, any person for the purpose of sale or of preparation for sale; or
> (c) is otherwise placed on the market within the meaning of Regulation (EC) No. 178/2002
>
> and subsections (3) to (9) below shall apply where, on such an inspection, it appears to the authorised officer that any food fails to comply with food safety requirements.

(2) The following provisions shall also apply where, otherwise than on such an inspection, it appears to an authorised officer of a food authority that any food is likely to cause food poisoning or any disease communicable to human beings.

(3) The authorised officer may either—

(a) give notice to the person in charge of the food that, until the notice is withdrawn, the food or any specified portion of it—

(i) is not to be used for human consumption; and

(ii) either is not to be removed or is not to be removed except to some place specified in the notice; or

(b) seize the food and remove it in order to have it dealt with by a justice of the peace;

and any person who knowingly contravenes the requirements of a notice under paragraph (a) above shall be guilty of an offence.

(4) Where the authorised officer exercises the powers conferred by subsection (3)(a) above, he shall, as soon as is reasonably practicable and in any event within 21 days, determine whether or not he is satisfied that the food complies with food safety requirements and—

(a) if he is so satisfied, shall forthwith withdraw the notice;

(b) if he is not so satisfied, shall seize the food and remove it in order to have it dealt with by a justice of the peace.

(5) Where an authorised officer exercises the powers conferred by subsection (3)(b) or (4)(b) above, he shall inform the person in charge of the food of his intention to have it dealt with by a justice of the peace and—

(a) any person who under section 7 or regulation 4(b) of the General Food Regulations 20004 might be liable to a prosecution in respect of the food shall, if he attends before the justice of the peace by whom the food falls to be dealt with, be entitled to be heard and to call witnesses; and

(b) that justice of the peace may, but need not, be a member of the court before which any person is charged with an offence under that section in relation to that food.

(6) If it appears to a justice of the peace, on the basis of such evidence as he considers appropriate in the circumstances, that any food falling to be dealt with by him under this section fails to comply with food safety requirements, he shall condemn the food and order—

(a) the food to be destroyed or to be so disposed of as to prevent it from being used for human consumption; and

(b) any expenses reasonably incurred in connection with the destruction or disposal to be defrayed by the owner of the food.

(7) If a notice under subsection (3)(a) above is withdrawn, or the justice of the peace by whom any food falls to be dealt with under this section

refuses to condemn it, the food authority shall compensate the owner of the food for any depreciation in its value resulting from the action taken by the authorised officer.

(8) Any disputed question as to the right to or the amount of any compensation payable under subsection (7) above shall be determined by arbitration.

(9) In the application of this section to Scotland—
(a) any reference to a justice of the peace includes a reference to the sheriff and to a magistrate;
(b) paragraph (b) of subsection (5) above shall not apply;
(c) any order made under subsection (6) above shall be sufficient evidence in any proceedings under this Act of the failure of the food in question to comply with food safety requirements; and
(d) the reference in subsection (8) above to determination by arbitration shall be construed as a reference to determination by a single arbiter appointed, failing agreement between the parties, by the sheriff."

(b) The 2006 Regulations came into force on 11 January 2006 and were made by the Scottish Ministers in exercise of the powers conferred by section 2(2) of the European Communities Act 1972. They provide a national framework (including identifying the relevant national enforcement and food safety authorities) for the execution and enforcement in Scotland of EU food safety regulations. They provide, *inter alia*, as follows:

"Interpretation
2(1) In these Regulations–
"the Act" means the Food Safety Act 1990;
"authorised officer", in relation to an enforcement authority, means any person appointed by that authority under regulation 5(6);
"the Community Regulations" means Regulation 852/2004, Regulation 853/2004, Regulation 854/2004, Regulation 2073/2005 and Regulation 2075/2005;…CHECK
"enforcement authority" means the authority which, by virtue of regulation 5, is responsible for enforcing and executing the Hygiene Regulations;
"food authority" means a council constituted under section 2 of the Local Government etc. (Scotland) Act 1994;
"the Hygiene Regulations" means these Regulations and the Community Regulations;…

Application of section 9 of the Food Safety Act 1990

23. Section 9 of the Act (inspection and seizure of suspected food) shall apply for the purposes of these Regulations with the modification that it shall apply in relation to

an authorised officer of an enforcement authority as it applies in relation to an authorised officer of a food authority…

Food which has not been produced, processed or distributed in accordance with the Hygiene Regulations

27(1) On an inspection of any food, an authorised officer of an enforcement authority may certify that it has not been produced, processed or distributed in compliance with the Hygiene Regulations.

(2) Where any food is certified as mentioned in paragraph (1) it shall be treated for the purposes of section 9 of the Act as failing to comply with food safety requirements.

(3) Where any food certified as mentioned in paragraph (1) is part of a batch, lot or consignment of food of the same class or description, all the food in the batch, lot or consignment shall, until it is proved that it has been produced, processed or distributed in compliance with the Hygiene Regulations, be treated for the purposes of paragraph (2) as having been so certified."

The European Regulations

(a) Articles 5, 6 and 7 of EC Regulation No 178/2002 provides as follows:

"Article 5
General objectives

1. Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment.

2. Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter.

3. Where international standards exist or their completion is imminent, they shall be taken into consideration in the development or adaptation of food law, except where such standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives of food law or where there is a scientific justification, or where they would result in a different level of protection from the one determined as appropriate in the Community...

Article 6
Risk analysis
1. In order to achieve the general objective of a high level of

protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5…

Article 7
Precautionary principle

1. In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment…

GENERAL REQUIREMENTS OF FOOD LAW

Article 14
Food safety requirements

1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:
   (a) injurious to health;
   (b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:
   (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:
(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
(b) to the probable cumulative toxic effects;
(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof."

(b) Articles 4 and 5 of EC Regulation No 852/2004, and Annex II, Chapter IX,

Paragraphs 1 and 3 provide:

"Article 4 – General and specific hygiene requirements

1. Food business operators carrying out primary production and those associated operations listed in Annex I shall comply with the general hygiene provisions laid down in Part A of Annex I and any specific requirements provided for in Regulation (EC) No 853/2004

2. Food business operators carrying out any stage of production, processing and distribution of food after those stages to which paragraph 1 applies shall comply with the general hygiene requirements laid down in Annex II and any specific requirements provided for in Regulation (EC) No 853/2004

3. Food business operators shall, as appropriate, adopt the following specific hygiene measures:

(a) compliance with microbiological criteria for foodstuffs;
(b) procedures necessary to meet targets set to achieve the objectives of this Regulation;
(c) compliance with temperature control requirements for foodstuffs;
(d) maintenance of the cold chain;
(e) sampling and analysis.

4. The criteria, requirements and targets referred to in paragraph 3 shall be adopted in accordance with the procedure referred to in Article 14(2). Associated sampling and analysis methods shall be laid down in accordance with the same procedure.

5. When this Regulation, Regulation (EC) No 853/2004 and their implementing measures do not specify sampling or analysis methods, food business operators may use appropriate methods laid down in other Community or national legislation or, in the absence of such methods, methods that offer equivalent results to those obtained using the reference method, if they are scientifically validated in accordance with internationally recognised rules or protocols.

6. Food business operators may use the guides provided for in Articles 7, 8 and 9 as an aid to compliance with their obligations under this Regulation…

Article 5 – Hazard analysis and critical control points

1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2. The HACCP principles referred to in paragraph 1 consist of the following:

(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;
(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
(d) establishing and implementing effective monitoring procedures at critical control points;
(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4. Food business operators shall:

(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;
(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;
(c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c)…

Annex II – GENERAL HYGIENE REQUIREMENTS FOR ALL FOOD BUSINESS OPERATORS (EXCEPT WHEN ANNEX I APPLIES)

CHAPTER IX
PROVISIONS APPLICABLE TO FOODSTUFFS

1. A food business operator is not to accept raw materials or ingredients, other than live animals, or any other material used in processing products, if they are known to be, or might reasonably be expected to be, contaminated

with parasites, pathogenic microorganisms or toxic, decomposed or foreign substances to such an extent that, even after the food business operator had hygienically applied normal sorting and/or preparatory or processing procedures, the final product would be unfit for human consumption…

3. At all stages of production, processing and distribution, food is to be protected against any contamination likely to render the food unfit for human consumption, injurious to health or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state…"

(c) Article 4.2 and 4.3(a) of Regulation (EC) No 854/2004:

General principles for official controls in respect of all products of animal origin falling within the scope of this Regulation.

"2. The competent authority shall carry out official controls to verify food business operators' compliance with the requirements of:

(a) Regulation (EC) No 852/2004;
(b) Regulation (EC) No 853/2004;
and
(c) Regulation (EC) No 1774/2002

3. The official controls…shall include:

(a) audits of good hygiene practices and hazard analysis and critical control point (HACCP)-based procedures…"

Interpretation

[11] It is appropriate to record at this point that the respondents made detailed submissions on the approach to be taken by the court in analysing the actions taken by the applicants in seizing, and seeking to have condemned, the respondents' cheeses. Those submissions may be summarised in the following propositions:

(i) National law, and in particular the provisions of the 1990 Act, 2006 Regulations, and Food Law Code of Practice, must be interpreted and applied (a) in accordance with the terms of the EU Treaties; (b) compatibly with the provisions of secondary EU law in the area of food safety, and (c) consistently with the general principles of EU law, notably the principle of proportionality (cf. *Commission* v *France* [2010] ECR I-757, 2 CMLR 43, paragraphs 90-92).

(ii) The applicants' actions were subject to review in the present applications for their compliance with the provisions and principles of EU law, and the court, in determining the applications before it, was bound to ensure that EU law based rights and general principles of EU law are complied with (*Web Mind Licenses* EU:C-2015/832, paragraphs 84, 86-87, referring to the "rights of the defence").

(iii) If it is not possible to interpret and apply to the circumstances of the presents applications the provisions of domestic law in a manner compatible with EU law, then the domestic provisions are to be disapplied in accordance with the principle of primacy of EU law (cf. *R (Miller)* v *Secretary of State* [2017] UKSC 5, [2017] 2 WLR 583, at paragraph 67).

(iv) The provisions of Regulation (EC) 178/2002 (and, in particular, recitals 3-5, 17-18, 20, and 26-27, and Chapter II), as well and article 5 of Regulation (EC) 852/2004 set out the principles against which the actions of the applicants, and any national law relied on by them, have to be measured.

(v) The powers conferred on the national authorities (including the respondents) by the 2006 Regulations can go no further than is permitted under EU Regulations, and notably articles 2 and 54 of Regulation (EC) 882/2004, where official controls for verifying compliance are concerned.

(vi) The 1990 Act and 2006 Regulations, in their application to the present applications, have to be interpreted in a purposive manner (*Litster* v *Forth Dry Dock Co Limited* 1989 SC (HL) 96 at 108, per Lord Oliver of Aylmerton), and that interpretive obligation applies to national legislation even if promulgated prior to the EU law regime on food safety (*Marleasing SA* v *La Comercial Internacional de Alimentacion SA* [1990] ECR I-4153 at 4159).

(vii) As a matter of national law any aspect or provisions of the 2006 Regulations which are incompatible with the requirements of EU law will be *ultra vires* and, therefore, void as a matter of national law, because they would purportedly have been made by the Scottish Ministers beyond the limits of the powers allowed to them by the European Communities Act 1972.

[12] I observe that, if the last of those propositions is now considered to have any specific relevance to the circumstances of the present applications (as opposed to making a general statement about a hypothetical outcome) the respondents' pleadings are entirely silent on any perceived incompatibility between "any aspect or provisions" of the 2006 Regulations (whatever that may mean) and EU law, and the respondents' case appears to have been conducted (by Mr Errington, at least) on the basis that there was no such incompatibility.

[13] Otherwise, it did not seem to me that Mr Love took any substantial issue with the proposition that the 1990 Act and 2006 Regulations should be interpreted in a manner which was compatible with the European regulatory framework in this area. His position was, in essence, that adopting such an interpretation led nonetheless to the conclusion that the orders sought by the applicants should be granted.

The parties' cases on record

[14] The pleadings in all three applications are both detailed and technical, and not easy to digest. I have outlined their respective written cases in the passages which follow, under reference to the relevant application numbers.

LAN L20-17 – Lanark Blue Batch E24

[15] The applicants, in summary, aver that: it is a local authority constituted under the Local Government etc (Scotland) Act 1994, and is a Food Authority in terms of the 1990 Act, and an enforcement authority in terms of the 2006 Regulations; the respondents produce cheese intended for human consumption; on 31 August 2016 their authorised officer, Alan Dickson, visited the respondents' premises at Walston Braehead and sampled Lanark Blue cheese Batch E24; that sample was submitted, on the same day, to the applicants' Food Examiner, Robert Beattie, at ESS; the sample was tested by ESS, SERL and PHE, and certified as being unfit for human consumption within the meaning of article 14 of Regulation (EC) 178/2002 due to the presence of E.coli O unidentifiable: H20, with a stx2d gene, ST1308; separately, that the respondents' food safety management system failed to comply with article 5 of Regulation (EC) 852/2004, in respect that the respondents did not test the raw milk used to produce the cheese for E.coli O157, or STEC, in order to validate or verify whether the HACCP control measures in place were working; the respondents failed to comply with the paragraphs 5.2.9 and 5.3.1 of the SCA Code of Practice; prior to resuming production in 2017 the respondents changed their HACCP procedure to include identification of a pH of less than 4.9 within 18 hours, and adjusting the diet of their sheep, and testing of their raw milk for *E.coli O157* (my emphasis); raw milk is a raw material or ingredient which might reasonably be expected within Scotland to be contaminated with pathogenic microorganisms including STEC, and the respondents' normal processes and procedures for the production of Lanark Blue did not reduce the level of any potentially pathogenic STEC microorganism which may have been present. The applicants, responding to the averments of the respondents, assert that the results obtained on testing demonstrate

that the respondents' food safety management system was not working, and that the respondents' cheese is unfit for human consumption.

[16] On that basis the applicants contend that the seized food, being unfit for human consumption within the meaning of article 14 of Regulation (EC) 178/2002, should be condemned as it fails to comply with food safety requirements in terms of section 9 of the 1990 Act. An order is sought for its destruction.

[17] In response, the applicants aver that: they are satisfied that Lanark Blue, batch E24, is safe; their premises were approved under article 4 of Regulation (EU) 853/2004 at the time the cheese was made and no complaints had been made by the applicants, or any other regulatory body, about the respondents' cheeses causing human illness; there is, to the best of their knowledge, no epidemiological evidence linking ewes' milk cheese to human illness caused by STEC contamination; their food safety management system, which had been approved by the applicants for a period of seven years at the time when the cheese was seized, included controls such as the use of a closed flock, veterinary inspections and audits, animal husbandry measures, use of foam wipes to remove dirt before using an automated milking parlour, use of disposable milk filters, post-milking dipping of teats, use of an automatically cleaning parlour, separation of their cows' and ewes' milk vats and lines to guard against cross-contamination, use of disinfectants, use of a heated water jacket for the vat, draining on separate tables, washing moulds in acid and the training and supervision of staff in relation to the company's food manufacturing process; the respondents met the SALSA+SCA standard; there was no legal requirement to carry out STEC testing on raw milk such as is the case with other foods associated with E.coli O157 outbreaks, and the respondents had never been advised by any regulatory organisation that they should be testing raw milk for STEC; it is impractical to test for non E.coli O157 STEC in the United

Kingdom; the respondents did weekly tests for colony counts and enterobacteriaceae (an indicator for faecal contamination) and three-weekly tests for Staph Aureus and Listeria; the respondents' milk test results in the period when then the cheese was seized were very good, and it was reasonable for them (i) to expect that their ewes' milk would be free of pathogenic organisms; (ii) not to carry out STEC testing on the raw milk, and (iii) to manufacture cheese under a safety management system which had been approved by the applicants; Lanark Blue was not implicated in the outbreak; with so many samples being taken there was scope for mislabelling and/or cross-contamination; in September 2016 officers from FSS carried out an inspection of the respondents' premises and could not see any problems with the premises or the systems in place; it is biologically implausible for an unidentified strain of STEC with the same sequence (namely E.coli O unidentifiable: H20 stx2d ST 1308) to be present in cows and in sheep being kept in different geographic areas, and the most plausible explanation for the finding of such a strain in both Dunsyre Blue, batch F15, and Lanark Blue, batch E24, was, and is, a labelling error; non-pathogenic E.coli are not uncommon in raw milk and can be present even where hygienic practices are followed; as a condition of retaining their EU approval and re-commencing production, the respondents were required to test every batch of milk for E.coli O157, which goes beyond what is required by the relevant legislation; STEC testing would be unlikely to deliver meaningful results; the revised sampling plan put in place would not have produced a "fail" in respect of the test results derived from the applicants' sampling, and, in any event, Lanark Blue, batch E24, met the safety requirements of article 14 of Regulation (EC) 178/2002 and is safe.

LAN B21-17 – Lanark Blue Remainder

[18] Much of the same material as is contained in the summary of application LAN B20-17 is traversed in the pleadings for this application, and is not repeated.

[19] Distinct features of this application are that: the respondents voluntarily held stocks of cheese produced by them from being placed on the market but advised, by email dated 9 January 2017, of their intention to place their cheese, including Lanark Blue, on the market from 16 January 2017; on 13 January 2017, the applicants served Notices of Detention under Regulation 9 of the 2006 Regulations; those Notices were suspended by the Court of Session on 27 January 2017 on an undertaking by the respondents not to place Lanark Blue on the market prior to 3 February 2017 at 5pm; on 3 February 2017, the applicants' authorised officer, Ms Karen Wardope, certified that eighty three batches of Lanark Blue had not been produced, processed or distributed in accordance with the Hygiene Regulations for the reasons specified in the Certificate; separately, the respondents' food safety management system failed to comply with article 5 of Regulation (EC) 852/2004, in that it did not provide for the testing of the raw milk used to produce the cheese for E.coli O157 or STEC (to validate or verify whether the HACCP control measures that they had in place were working), and failed to comply with the SCA Code of Practice; the respondents use the same production equipment for all blue and white cheeses, irrespective of incoming milk source and STEC can persist if milky equipment and pipelines are not adequately cleaned; article 4 of Regulation (EC) 852/2004 required the respondents to comply with general hygiene requirements; in particular, Annex II, Chapter IX, paragraph 1, of that Regulation required them to reject raw materials or ingredients if they might reasonably be expected to be contaminated with pathogenic microorganisms to such an extent that, even after normal

sorting or preparatory or processing procedures, the final product would be unfit for human consumption, and that the seized food did not comply with those safety requirements.

[20] The applicants aver that different samples of cheese were secured individually and labelled accurately. Lanark Blue, batch E24, and Dunsyre Blue, batch F15, were sampled on different dates.

[21] Accordingly, the applicants aver that the seized food should be condemned, as it does not comply with food safety requirements. An order is sought for its destruction.

[22] The respondents broadly repeat their averments from application B20-17. However, they also expressly challenge (a) the Certificate of Examination issued by the Food Examiner on 17 January 2017 in relation to Lanark Blue Batch E24, and (b) the Certificate issued by Karen Wardrope under regulation 27 of the 2006 Regulations. The respondents dispute that the seized cheese was contaminated with pathogenic microorganisms, or any other substances, to such an extent that the cheese made from it would be unfit for human consumption, and aver that all batches of the seized cheeses meet food safety requirements, and are safe in terms of article 14 of Regulation (EC) 178/2002.

LAN B33-17 – Corra Linn

[23] There are again averments common to the two earlier applications. In so far as distinct, the applicants in this application aver that: on 3 February 2017 Karen Wardope served seventy one separate notices under section 9 of the 1990 Act relating to seventy batches of Corra Linn cheese; she was of the opinion that each of the batches failed to comply with food safety requirements because the raw milk used for its production might reasonably be expected to be contaminated with pathogenic microorganisms; in the period from 3 to 23 February 2017, samples of Corra Linn were taken and submitted to Mr Beattie

for testing; on 9 February 2017 Mr Beattie advised that a sample taken from Corra Linn, batch G20, had returned a presumptive positive for stx1 which was indicative of the presence of a STEC; on 9 February 2017 Mr Beattie advised that a sample taken from Corra Linn, batch E23A, had returned a presumptive positive for stx2, which was indicative of the presence of a STEC; on 16 February 2017 Mr Beattie advised that samples taken from Corra Linn, batches G7A and H1A, had indicated the presence of the rfbO157 gene; on 17 February 2017 the applicants were advised by SERL that a sorbitol fermenting Shiga toxin negative E.coli O157 had been isolated from Corra Linn, batches G7A and H1A, and that a STEC had been isolated from Corra Linn, batch F27A; the applicants obtained microbial survival predictions from Campden BRI; on various dates the Mr Beattie issued Certificates of Examination in relation to different batches of Corra Linn cheese which confirmed his opinion that samples taken from batches G7A, H1A, E23A, G20A F27A B17A and G25A, were considered to be unsafe for [sic] reason of being injurious to health and/or unfit for human consumption; on 24 February and 8 March 2017 Karen Wardope issued certificates under regulation 27 of the 2006 Regulations, and these certified that cheese from a number of batches of Corra Linn produced by the respondents had not been produced, processed or distributed in accordance with the Hygiene Regulations.

[24] Separately, the applicants aver that: the respondents' food safety management system failed to comply with article 5 of Regulation (EC) 852/2004 in that it did not provide for the testing of the raw milk, used to produce the cheese, for E.coli O157 or STEC (to validate or verify whether the HACCP control measures that they had in place were working), and failed to comply with the SCA Code of Practice; article 4 of Regulation (EC) 852/2004 required the respondents to comply with general hygiene requirements; in particular, Annex II, Chapter IX, paragraph 1 of that Regulation required them to reject raw

materials or ingredients if they might reasonably be expected to be contaminated with pathogenic microorganisms to such an extent that, even after normal sorting or preparatory or processing procedures, the final product would be unfit for human consumption; moreover, Annex II, Chapter IX, paragraph 3, of the same Regulation required the respondents, at all stages of production, processing and distribution, to protect food against any contamination likely to render it unfit for human consumption, injurious to health, or contaminated in such a way that it would be unreasonable to expect it to be consumed in that state, and that the respondents' cheese failed to comply with those provisions.

[25] In response to the respondents' answers the applicants aver that it is plain that the respondents' control measures were inadequate. In any event, primary responsibility for compliance with food safety and food hygiene regulations rests with the respondents.

[26] Accordingly, the applicants aver that the seized food should be condemned, as it does not comply with food safety requirements. An order is sought for its destruction.

[27] The respondents' answers are broadly in alignment with their answers in the two earlier applications. However, they also aver that: the O unidentifiable: H20, stx2d, lacks sufficient virulence factors to be harmful; Corra Linn is safe to eat; cheese containing E.coli O157: H42 stx negative is safe to eat; they challenge Karen Wardope's certificates on the basis that the cheese is safe; the overwhelming majority of E.coli are harmless; the bacteria found on testing performed by ESS, SERL and PHE are harmless, and normal for the production of artisan cheese; the bacteria were found by extremely sensitive testing, and would not be detectable by the human senses, and all of the seized cheeses meet food safety requirements and are safe in terms of article 14 of Regulation (EC) 178/2002.

The Cows' Milk Objection

[28] A preliminary matter requires to be disposed of before I turn to the substance of parties' submissions. It concerns an objection periodically raised by Mr Errington concerning the eliciting of evidence about the respondents' use of cows' milk in the production of Dunsyre Blue.

[29] In order to expedite matters during the course of the proof parties were content that I should hear the evidence to which objection was taken under reservation of any issue of both relevancy and competency.

[30] The broad basis underlying Mr Errington's objection, as I understood it, was that the three summary applications before the court concerned ewes' milk cheeses, and the processes by which they were produced. That being the case any reference to cows' milk was irrelevant to the issues with which the court was concerned. I did not understand Mr Errington to suggest that the evidence should be excluded by reason of a lack of record. The objection was repeated at paragraph 2.62 of the respondents' written submissions. All that was said was that Dunsyre Blue cheese was not the subject of any of the applications before the court, each of which concerned ewes' milk cheese.

[31] I am not satisfied that the objection, if I have characterised it correctly, is well-founded. I have reached that conclusion substantially for the reasons set out in section 10 of the applicants' written submissions. I observe that the reference to the objection in the respondents' written submissions closely followed a submission that the court, in determining the applications, should not be restricted to admitting, and considering, evidence only of events on the date of inspection, or seizure, of the food (see paragraph 2.41). Rather the court must consider all the evidence available at the hearing.

[32] It is in that context that I note that both parties made averments which did more than merely touch on the issue of cows' milk. I refer to the finding of E.coli O unidentifiable: H20, stx2, ST1308, the implausibility of finding such an organism simultaneously in Lanark Blue, batch E24, and Dunsyre Blue, batch F15, and the possibility of either laboratory error or cross-contamination on the respondents' premises. I also note that, before the objection was originally stated, Mr Errington had cross-examined Craig Brown of the applicants on the matter of the respondents' analysis of the risk of E.coli O157 in cows' milk. I infer that he did so in order to demonstrate that it was a risk of which the respondents were aware, and which they addressed within the overall safety management system in operation prior to the E.coli outbreak in the summer of 2016.

[33] I am also of the opinion that evidence of the condition of the cows' milk supply is potentially relevant to the applicants' case that the seized batches of Lanark Blue Remainder and Corra Linn had not been "produced, processed or distributed in compliance with the Hygiene Regulations", and that they accepted raw milk which might reasonably be expected to be contaminated with pathogenic microorganisms (as set out in Regulation (EC) 852/2004, Annex II, Chapter IX, paragraph 1). The applicants' position in evidence, and submissions, is that the respondents should have been testing their raw ewes' milk for E.coli O157 and STEC. The respondents contend that their hygiene controls and generic E.coli testing were sufficient to address what they assessed to be a low risk (at least as far as E.coli O157 was concerned). In these circumstances I am unable, at least as a matter of relevancy, to rule out evidence of that assessment just because it was also pertinent to production of a raw cows' milk cheese.

[34] I have accordingly repelled that objection and the evidence led at the proof is at large for me to consider.

[35] At paragraph 3.50 of the respondents' written submissions, it is also submitted that Dr North should have been allowed to explain to the Court the shortcomings of the FSS risk assessment of November 2016. I confess to some surprise at the terms of this paragraph. There was an objection taken by Mr Love to the leading of evidence critical of the risk assessment on grounds of want of record (transcript of 29 January 2018, p.66). It was agreed that the evidence should be led under reservation of any issues of relevancy and competency. In the result, Mr Errington's examination of Dr North strayed from that particular line. When it came up again (at p.88 of the transcript), and the objection was renewed, Mr Errington decided not to pursue the matter. It would have been open to him to have proceeded with the evidence on the previously agreed basis. He chose not to do so. I was not made aware of any issue over his ability to check the terms of the pleadings. In any event, the references in answer 3 (in applications B21-2017 and B33-2017) to which Mr Errington now points, in support of the submission that Dr North ought to have been "allowed" to explain its shortcomings, do not challenge the manner in which the risk assessment was conducted by FSS at all. Rather they challenge the conclusion which that assessment reached, and assert that the proper forum for determining the dispute as to whether the respondents' cheeses met food safety requirements is in the present proceedings. Accordingly, I reject any submission, implicit in paragraph 3.5 of the respondents' written submissions, that the respondents were unreasonably disallowed from pursuing a line which was properly foreshadowed in the respondents' pleadings.

Onus and Standard of Proof

[36] The applicants acknowledged, in their written submissions, that the onus of proof rests on the applicants to prove sufficient facts to justify the orders sought in all three

applications. In particular, it was accepted that, in relation to application B20-2017 (Lanark Blue, batch E24), the onus rests on the applicants to prove, on a balance of probabilities and (it was submitted) by the application of the precautionary principle, that (a) given the presence of the STEC variant identified, Lanark Blue, batch E24, should be regarded as unfit for human consumption within the meaning of article 14 of Regulation (EC) 178/2002; and (b) that, in the absence of a suitable and sufficient testing regime, the respondents' food safety management system failed to comply with the requirements of article 5 of Regulation (EC) 852/2004.

[37] The applicants did, however, submit that, in applications B21-17 and B33-17, an evidential burden rests on the respondents to prove, to the appropriate standard, their averments that, at the material time, the seized cheeses were produced, processed or distributed in compliance with the Hygiene Regulations, the standard of proof being that applicable to civil cases, namely on a balance of probabilities.

[38] The respondents submitted that the onus of proof that the seized cheeses are unsafe rests with the applicants. That proposition is supported by both the relevant domestic and EU law. The respondents' written submissions referred me to section 9(6) of the 1990 Act, which provides for determination of a food's compliance with food safety requirements "on the basis of such evidence as [the sheriff] considers appropriate in the circumstances". I was also reminded that section 9(5)(a) confers on a food business operator the right to be heard and to call witnesses. It was, however, submitted that there is no requirement on that food business operator to prove that a food complies with food safety requirements; it is for the applicants in the present applications to satisfy the court that the food is "unsafe" (or rather, to repeat the actual statutory wording, fails to comply with food safety requirements). Moreover (although I am not convinced that there was really any dispute about this), in

considering whether the applicants have done so, the court should not confine itself to a consideration of events on the date of the inspection, or seizure, of the food (cf. *Health and Safety Inspector* v *Chevron North Sea Ltd* [2018] UKSC 7, [2018] 1 WLR 964).

[39] The respondents submitted that regulation 27 of the 2006 Regulations (on which the certificates served in connection with applications B21-2017 and B33-2017 are founded) provides not that a food certified under that provision "shall be presumed not to comply with food safety requirements (unless the contrary is proven)", but that "it shall be treated for the purposes of section 9 of the [1990] Act as failing to comply with food safety requirements". That required the court to consider the purposes of section 9 of the 1990 Act. By doing so, it was submitted, it is plain that those purposes were twofold: (i) to seek to protect public health (by ensuring that food which is proved to be injurious to health or otherwise unfit for human consumption is destroyed or disposed of), but, at the same time, (ii) to respect the property and natural justice rights of the food business operator, by ensuring that a food condemnation order can only be made after fair procedure before an independent judge (cf. *Errington* v *Wilson* 1995 SC 550). Such a reading of section 9 ensured compatibility with at least articles 16 (freedom to conduct business), 17 (right to property), and 47 (right to an effective remedy and to a fair trial) of the Charter of Fundamental Rights of the EU.

[40] It was equally plain, it was submitted, that it would not be in accordance with the purposes of section 9 of the 1990 Act for it to be construed as permitting (or requiring) the sheriff to condemn food without it having been established, to his satisfaction, that the food to be condemned was injurious to health or otherwise unfit for human consumption, as required by article 14 of Regulation (EC) 178/2002 and section 8(2) of the 1990 Act (which

expressly incorporates into the definition of "food safety requirements" the definition set out in article 14, and cited earlier).

[41] It was further submitted that the terms of regulation 27(3) of the 2006 Regulations (which is concerned with a batch, lot or consignment of the same class or description as a food certified under regulation 27(1)) should not be interpreted as imposing any burden of proof on the food business operator. Rather, the provision falls to be interpreted compatibly with EU law, and, in particular, in light of article 14 of Regulation (EC) 178/2002, which employs the wording "unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe". It is for the enforcing authority, or the sheriff, but not the food business operator, to make that assessment. In other words, and for present purposes, the onus of proving that there has been a breach of the Hygiene Regulations (as defined in the 2006 Regulations) rests at all times (and consistent with the presumption of innocence recognised as a general principle of EU law – *Intel Corp.* v *the Commission* [2014] CMLR 9, at paragraph 63) with the applicants (cf. *South Lanarkshire Council* v *GSR Distributions* 2015 SLT (Sh. Ct.) 143, at paragraph 120).

Decision on onus of proof

[42] It must be borne in mind that, in being asked to determine this issue, I have now heard all of the evidence common to the three applications. Questions of onus usually cease to be important once the whole of the evidence is before the court (*Sanderson* v *McManus* 1997 SC (HL) 55, per Lord Hope at p.62G). That is particularly so where applications B21-17 and B33-17 are concerned. I heard a great deal of evidence about the potential hazards presented by STEC, the test results from sampling of the respondents' cheeses, the

possibility that STEC will be found in raw milk cheeses, HACCP principles, and the food safety management system in place when the seized cheeses were produced.

[43] I have already quoted the terms of article 14(6) of Regulation (EC) 178/2002. The respondents are right to identify the subtly different language in article 14(6) when compared with regulation 27(3) of the 2006 Regulations. The presumption, on which the applicants rely in respect of Lanark Blue, batch E24, is that "all the food in the batch, lot or consignment is also unsafe, *unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe* (my emphasis)".

[44] The wording in italics not easy to digest. However, in my opinion, it has to be remembered that the presumption only arises in circumstances where a food forming part of a batch, lot or consignment has been found to be unsafe. If that condition is not satisfied then it necessarily follows that no presumption arises. There is, therefore, no reversal of the onus of proof. Conversely, if it is found, following an assessment, that a food forming part of a batch has been found to be unsafe then I cannot see the requirement that a food business operator bear the burden of rebutting that presumption can offend against either the wording of article 14(6) or the presumption of innocence which is invoked by the applicants as a recognised general principle of EU law. Accordingly, if the applicants were to establish that, as a result of sampling part of a batch of cheese, a live STEC organism had been isolated (which, for present purposes, is to be treated as potentially pathogenic), and that the whole batch for the relevant day had been produced from the same batch of raw milk, then I see no reason why there should not be placed on the food business operator an evidential burden of rebutting the presumption that the whole batch, from which that organism had been isolated, should be considered unsafe. That does not involve reversing the burden of

proof because, for the presumption to operate, the burden on the food authority of establishing that food in that batch is unsafe will already have been discharged.

[45] In relation to the applications, with which regulation 27 of the 2006 Regulations are concerned, the respondents' submissions appear to proceed under a misapprehension that the mere issue of a certificate by Karen Wardrope of the applicants was, and is, sufficient to reverse the burden of proof such that the applicants need prove nothing beyond service of the certificates themselves. I do not understand that to be the position of the applicants at all. All that they submit is that, having made detailed averments about their compliance with the Hygiene Regulations, there is an evidential burden on them to prove those averments. There is nothing controversial in that proposition. Leaving aside regulation 27(3), whose wording is subtly different to that of article 14(6) of Regulation (EC) 178/2002, I did not understand the applicants to argue otherwise than that the onus was on them to prove sufficient facts to justify the court granting the orders sought in all of the applications. The respondents referred, in their submissions, to *South Lanarkshire Council* v *GSR Distributions Ltd*, 2015 SLT Sh. Ct. 143, at paragraph 120, and appeared to construe that case as an example of the court, in an application under section 9 of the 1990 Act, wrongly reversing the onus onto the food business operator. For what it is worth, I do not understand Sheriff Reid to have done any such thing. For a start, as the applicants point out, he was not concerned with the safety of the food *per se.* Enforcement action arose because of the absence of FSA operating approval for the food plant. Moreover, all that the learned sheriff did was point, correctly, to the evidential presumption, which a regulation 27 certificate carries, that the certified food does not comply with food safety requirements. In the very next paragraph, however, he made the important point that the role of the sheriff in an application under section 9(6) of the 1990 Act is to determine whether the food fails to

comply with food safety requirements. It is not to determine whether the food has been validly detained. I agree. So, while it is correct that, for as long as the certificate subsists, the food is deemed to fail to comply with food safety requirements, the onus of proving that, at any hearing which actually required to resolve that issue, it has so failed, would be on the food authority.

[46] But, even if I am wrong about that, in the view I have taken in this case the issue of onus does not arise because I have been able to reach a concluded view on applications B21-17 and B33-17, on the basis of the whole of the evidence which was laid before me.

The evidence

[47] For the applicants, I heard evidence from Craig McMillan Brown, Karen Stewart Wardrope, Professor Norval Strachan, Alan Dickson, Dr Lesley Allison, Robert Beattie, Dr Timothy James Dallman, Professor Christopher Griffith, and Dr Flemming Scheutz.

[48] For the respondents, I heard evidence from Paul Thomas, Peers Davies, Selina Mary Cairns, Professor Colin Graham Fink, Professor Hugh Pennington, and Dr Richard North.

[49] I also had the benefit of a lengthy joint minute which I have taken into account in deciding these applications.

[50] During the procedural stages of these applications, the court directed that joint discussions between the experts take place with a view to narrowing, if possible, the scope of the expert evidence. In the result there were joint reports lodged to reflect discussions between (i) Professor Strachan and Professor Noah; (ii) Professor Pennington and Dr Dallman; (iii) Professor Pennington and Dr Scheutz, and (iv) Professor Pennington and Professor Griffith.

[51] I have deliberately set out the terms of the witnesses' evidence at greater than usual length. I have done so in recognition of the wider implications of the decisions which I have been called upon to make in all three applications. It is, accordingly, important that those decisions I have reached are seen in a detailed evidential context. In any event, much of the evidence which I heard was of a highly technical nature, touching on areas in which, given the current state of scientific thought, there is legitimate cause for difference between experts. That kind of evidence does not lend itself easily to being reduced to a succinct summary.

Evidence for the applicants

Craig McMillan Brown

[52] Mr Brown is employed by the applicants as Environmental Services Manager. He has occupied that position since 2012. Since 2009, he has also been the applicants' lead food officer with responsibility for ensuring that the food safety service provided by the applicants meets the requirements of the Food Law Code of Practice (Scotland) ("the FLCP"), (no. 5/1/13 of process). He described his relevant formal academic qualifications and career path, evidencing considerable prior experience of environmental health with other local authorities. He was a straightforward witness whose evidence was helpful in describing the various decisions which the applicants took in relation to the seized cheeses.

[53] Mr Brown explained that food safety is now a devolved issue within the legislative competence of the Scottish Parliament. In 2015 Food Standards Scotland ("FSS") was established by Parliament to assume responsibility for the regulatory responsibilities of the Food Standards Agency ("FSA") in Scotland. FSS was responsible for producing the FLCP as a means of providing local authorities with a guide to recommended good practice in the

enforcement of food safety, the aim being to ensure that enforcement was effective and proportionate.

[54] The FLCP makes provision for different types of communication between FSS, local authorities and food producers. These include, at paragraph 10(1)(a), a Food Alert for Action, or FAFA. A FAFA is a communication from FSS, directed primarily towards food authorities, the purpose of which is to make food authorities aware that there is a food on the market in relation to which food authorities require to take action. It also specifies the action to be undertaken. The terms of a FAFA would be advised by a risk assessment which would be conducted by the science branch of FSS.

[55] Mr Brown explained, by reference to relevant provisions of the 2006 Regulations, how EU Regulations were given effect in domestic food safety law. FSS is now the competent authority where enforcement of EU Regulations is concerned. However, the applicants were, and are, the enforcing authority for food safety relative to a food business operator like the respondents (regulation 5(2)(b)), and responsible for its EU approval.

[56] Regulation 12 of the 2006 Regulations empowers a food authority to take samples, either by chemical analysis of bacterial examination. The applicants themselves do not undertake testing of the samples. The applicants have a contract with ESS. If the sample is to be subjected to microbiological analysis it would be submitted to a food examiner at ESS. The result would be issued in the form of a certificate prepared in accordance with the provisions of the Food Safety (Sampling and Qualifications) (Scotland) Regulations 2013.

[57] Mr Brown described the interaction between regulation 27 of the 2006 Regulations and section 9 of the 1990 Act. He also assisted in describing, in broad terms, the meaning and effect of Hazard Analysis and Critical Control Point principles ("HACCP"), article 5 of Regulation (EC) 852/2004 requiring food business operators to put in place, implement and

maintain a permanent procedure based on such principles. Acknowledging that environmental health officers could be involved in discussing, and offering advice on, food safety management systems, Mr Brown sought to emphasise that ultimate responsibility for compliance with food safety standards rests with the food business operator.

[58] Between 1996 and 2006 Mr Brown had close involvement, as a divisional environmental health inspector, with the respondents. He was involved in discussing, and offering advice in relation to, the development of a hazard analysis by the respondents during a period of significant regulatory change. He told the court that "a lot of what I know about cheese manufacturing is down to my contact with Mr Errington over that ten year period". Fiona Argo was the inspecting officer of the respondents between 2006 and 2010, and she oversaw the EU approval of the respondents when the EU Regulations came into effect. She was succeeded, in 2010, by Alan Dickson. As at July 2016, the applicants were, where the respondents' business was concerned, the enforcing authority for food safety under the 2006 Regulations. The respondents were just one of a range of businesses across South Lanarkshire who were, for surveillance purposes, subject to a routine sampling programme.

[59] Mr Brown was asked to confirm his understanding of various paragraphs of the joint minute which, so far as relevant, have been included within my findings-in-fact. I do not, therefore, propose to summarise in any detail this part of his evidence. It is, however, necessary to record his confirmation that the food examiner, Robert Beattie, was noted to be a qualified examiner during the process when ESS was contracted by the applicants to carry out food sample testing on their behalf.

[60] Mr Brown confirmed the circumstances in which, on 14 September 2016, FSS issued the FAFA (B20-17, no. 1). The FAFA was produced on the back of a risk assessment (B20-17,

no. 2), the tenor of which was that there was a risk to consumers from the consumption of all cheeses then produced by the respondents, including Lanark Blue, Lanark White and Corra Linn, which would have been purchased up until 14 September 2016.

[61] Mr Brown described how a FAFA was, in effect, a direction by the competent authority to the applicants requiring them to contact food businesses in their area with a view to removal of the cheese from sale. Steps were taken to give effect to the requirements of the FAFA, and, by letter dated 6 October 2016 Mr Brown invited the respondents to provide, in writing, and within a period of fourteen days:

> "adequate guarantees of the controls that will be applied during future production to ensure that final products produced by [the respondents] will not be contaminated with E.coli O157 and STEC organisms capable of being injurious to health".

The respondents undertook not to place any of the cheeses affected by the FAFA on the market meantime.

[62] FSS issued FAFA-02 on 9 November 2016. It was informed by an updated risk assessment, which included a table of results for STEC testing, and a Risk Management Decision update, both dated 8 November 2016 (B20-17, nos. 4 and 5). PCR testing of Lanark Blue, batch E24, had revealed a positive result for stx2. Following issue of the FAFA the position of FSS was, in summary, this: (i) shiga toxin producing E.coli (STEC) had been detected in batches of Dunsyre Blue (F15), and Lanark Blue (E24); (ii) STEC were known to cause severe illness in humans; (iii) a stx negative strain of E.coli O157 had been isolated from three batches of Lanark White ewe's milk cheese (iv) stx negative strains of E.coli O157 had been isolated from cases of human illness consistent with E.coli O157 infection, and (v) the Food Examiner (at ESS) had declared the three samples of Lanark White to be "potentially injurious to health and/or unfit for human consumption". In view of the nature

of the testing results and the range of products affected, the cheeses covered by FAFA-02 were deemed by FSS to be a risk to health.

[63] Local authorities, including the applicants, were directed to identify food businesses which were known, or were likely, to stock cheeses subject to FAFA-02, and to take steps to ensure that they were withdrawn from sale. Local authorities were also directed to ensure that that withdrawal from the market was effective, and that the affected cheeses were not placed on the market, if necessary using powers available to them under the 1990 Act and 2006 Regulations.

[64] So the position remained until 9 January 2017 when, by email, the respondents intimated their intention to place both Lanark Blue and Corra Linn on the market within seven days, subject to the addition of a warning on the packaging in these terms:

> **"Warning: Made using raw milk. Unsuitable for pregnant women, children, the elderly and anyone with low resistance to infection"**.

That warning made no difference to the applicants because, as Mr Brown put it, "the organisms we had found in the sampling would have affected a normal healthy adult, so applying that warning didn't mean that the cheese was safe to consume". The position of the applicants remained that any cheese produced by the respondents that had been on sale up until 14 September 2016 should have been removed from the market and not consumed by consumers.

[65] Mr Brown outlined the procedure whereby samples were taken at the respondents' premises and submitted to ESS for testing and analysis. He spoke to the issue, on 17 January 2017, of the certificate (B20-17, no. 7) in which the Food Examiner at ESS, Robert Beattie, certified that, in his opinion, the sample of Lanark Blue E24 submitted to ESS was:

> "unsafe for [sic.] reason of being unfit for human consumption, due to the presence of E.coli O unidentifiable, H20, with an stx2d gene, within the meaning of article 14

> of EC Regulation No. 178/2002, the enforcement and execution of which is provided for by the General Food Regulations 2004."

[66] Given that the respondents had evinced an intention to place product on the market on 16 January 2017, the issue of the certificate, in the terms that it was in, left the applicants with no option but to seize Lanark Blue, batch E24.

[67] Mr Brown explained his understanding, in the context of STEC, of what is meant by an infective dose. He explained that some bacteria will require millions of bacteria to be present before symptoms occur. With STEC, and in particular E.coli O157, the infective dose is believed to be very small (perhaps even as low as 10 in number according to some research papers), so generally a very low number of STEC organisms could result in symptoms.

[68] Mr Brown was referred to a document entitled "UK Working Policy on Detection of STEC in Food by Official Controls and Food Business Operator Sampling and Testing" (no. 6/1/150 of process). His understanding of the United Kingdom regulatory position with regard to the confirmed presence of STEC in a food such as the respondents' cheese (a profile 1 food for the purposes of the UK Working Policy) was as set out in p.3, paragraph 10. It merits quotation in full:

> "The confirmed presence of STEC in a batch of food falling into Profile 1 is considered a serious risk to public health. Evidence indicates that some strains are not pathogenic, but a precautionary approach is appropriate given the uncertainty in the evidence and the potential for severe disease".

[69] Mr Brown also explained the provenance of the "Guidance for Local Authority Enforcement Officers in the Production of Cheese from Unpasteurised Milk" (no. 6/1/151 of process) as having been produced by a working group comprising environmental health officers, food examiners and officers from FSS, following the issue of an enforcement letter by FSS dated 7 October 2016 to local authorities. Its purpose was to provide guidance to

local authorities with a view to ensuring consistent enforcement, particularly where verification of the validation of HACCP systems of food business operators for the production of raw milk cheese was concerned. Its contents will merit closer examination in the "Discussion" section of this judgment. For now, it is sufficient to notice Mr Brown's confirmation that the guidance advised the applicants' attitude to changes being made to the respondents' HACCP system, and, specifically, the inclusion of a requirement to test each batch of incoming raw milk for *E.coli 0157* (my emphasis).

[70] Mr Brown was asked to confirm the procedure for seizure of Lanark Blue, batch E24. He explained that it was physically removed from the premises using refrigerated, temperature-controlled, vehicles. It was currently in a temperature-controlled storage facility in Paisley.

[71] By reference to article 5 of EC Regulation 852/2004, Mr Brown explained that the respondents could have had more effective monitoring and verification systems which *may* have allowed them to detect that the raw milk used in the cheese manufacturing process was contaminated with potential pathogens. Ideally, that would include monitoring for STEC which, although not a legal requirement, was recommended through the Specialist Cheesemaker's Assured Code of Practice, Edition 1, 2015 ("the SCA Code of Practice") (no. 5/1/14 of process). The applicants would expect a responsible food business operator to follow the SCA Code of Practice as part of its food monitoring.

[72] The fact that a STEC organism was found in Lanark Blue, batch E24, which had already been placed on the market, indicated that the organism would not be destroyed by the cheese making process, and that, if consumers were to eat cheese from that batch, it had the potential to cause food poisoning. Accordingly, the monitoring of the raw milk was not effective. The respondents were not testing for STEC despite evidence, from

enterobacteriacae counts between May and the middle of July 2016 (no. 5/1/75 of process) that faecal contamination was becoming an increasing risk. The enterobacteriacae counts should, according to the SCA Code of Practice, have been followed up, but no steps were taken by the respondents to do so.

[73] In light of the finding of a STEC organism in Lanark Blue, batch E24, the applicants did not have confidence that the remaining batches of Lanark Blue then on the respondents' premises, were not so contaminated. Moreover, certain batches of Lanark Blue remainder had been seized under section 9 of the 1990 Act. The power to detain those batches was limited to a period of twenty one days, which was insufficient to allow for the taking and testing of samples. These considerations, together with test results from another cheese, Lanark White, were what prompted the issue of a certificate, dated 3 February 2017, by Karen Wardrope, under regulation 27 of the 2006 Regulations. This certified that the batches of Lanark Blue remainder, narrated in the appendix 1 to the certificate, had not been produced, processed, or distributed in compliance with the Hygiene Regulations, and in particular article 4 of EC Regulation 852/2004. The applicants also had to act quickly because, as a result of a decision in judicial review proceedings taken by the respondents, they had to meet a deadline on 3 February 2017 either to seize the respondents' cheese or allow it to go onto the market.

[74] The same concerns which gave rise to the seizure of Lanark Blue, batch E24, under reference to article 5 of EC Regulation 852/2004, applied with equal force to Lanark Blue remainder. The batches of Lanark Blue Remainder were seized and transported, in the same manner as batch E24, to Paisley for storage, where they have remained ever since.

[75] Mr Brown gave evidence about the sampling and testing of Dunsyre Blue, batch F15. The samples were taken by Alan Dickson on 23, 26 and 31 August 2016. The applicants

received an informal (i.e. uncorroborated) sample result from ESS, dated 27 October 2016, for the earliest of the samples. The report of the result (no. 5/1/22 of process) by Mr Beattie, the food examiner at ESS, considered Dunsyre Blue, batch F15, to be unsafe by reason of being unfit for human consumption, due to the presence of E.coli unidentifiable H20 with a stx2d gene, within the meaning of article 14 of EC Regulation 178/2002. Mr Beattie issued a certificate, dated 25 October 2016, in respect of the latest of the samples with the same conclusion (no. 5/1/21 of process).

[76] Mr Brown was involved in discussions with the respondents, subsequent to the applicants' letter of 6 October 2016, regarding amendments to the respondents' safety management systems. His letter of 11 January 2017 (no. 5/1/3 of process) comprised the applicants' acceptance of the amendments proposed by the respondents, such that the respondents were able to retain their EU approval for the purposes of article 31 of Regulation (EC) 882/2004. The proposed changes, which Mr Brown considered should already have been in place to comply with article 5 of EC Regulation 852/2004, included testing each batch of raw milk for E.coli O157, and testing for STEC, as provided for in the SCA Code of Practice. More specifically, in the summer of 2016, the respondents' critical control point chart (no. 5/1/7 of process), within their safety management system, did not identify E.coli O157 or STEC as a significant hazard. The respondents' critical control point chart dated 29 November 2016 (pro. 5/1/9 of process), by contrast, expanded on the control measures and, in relation to cheese making acidity, provided for testing of the curd for E.coli O157. A revised testing schedule, dated 7 November 2016, provided for testing of the raw milk for E.coli O157, and STEC (quarterly); curd testing for E.coli O157, and quarterly testing of the finished product for STEC, in each case the aim being to the standard "not detected". It also provided for analysis of trends in testing results, with further testing where

necessary. These were developments on the testing schedule in place in the summer of 2016 when (as subsequently confirmed by Selina Cairns) there was no provision for testing for E.coli O157 specifically, or STEC.

[77] Under reference to three certificates (nos. 5/1/24-26 of process) Mr Brown confirmed that three batches of Lanark White cheese were each certified by Mr Beattie, on 25 October 2016, as unfit for human consumption upon the finding of E.coli O157: H42, stx negative.

[78] On 9 February 2017, Mr Brown was advised by Mr Beattie of presumptive positive test results for stx 2 genes in respect of batches of Corra Linn. Mr Beattie reported again, on 20 February 2016, a strong presumptive positive test result for a stx1 gene from a further sample batch of Corra Linn. These presumptive results were each sent to SERL for possible confirmation, as the presumptive results alone would not have any public health consequences.

[79] On 24 February 2017, Karen Wardrope certified, on the back of a positive test result for a stx1 gene in a batch (B17A) of Corra Linn, that batches of that cheese appended to the certificate had, on two grounds, not been produced, processed or distributed in compliance with the Hygiene Regulations. The first ground was that the cheese had not been produced, processed, or distributed in compliance with the Hygiene Regulations, and in particular article 4 of Regulation (EC) 852/2004, Annex II, Chapter IX, paragraph 1. The second ground, invoked essentially as a precautionary measure was that, in its production, processing and distribution, the cheese had not been protected against contamination, contrary to Regulation (EC) 852/2004, Annex II, Chapter IX, paragraph 3. A further certificate followed on 8 March 2017, in respect of nine batches of Corra Linn which had been detained separately.

[80] The subsequent issue by Mr Beattie of the certificates (nos. 5/1/29-35 of process) regarding the finding of stx genes in samples of Corra Linn did not change the applicants' view that the issue of the regulation 27 certificates was the appropriate course to have taken, and that the cheese to which those certificates related, should be treated, for the purposes of section 9 of the 1990 Act, as failing to comply with food safety requirements. Indeed, taken together with the risk assessments underlying the FAFAs issued by FSS, as the competent authority, the applicants were essentially bound to take action in the manner that they did.

[81] In taking action in relation to Lanark Blue, batch E24, Lanark Blue Remainder, and Corra Linn, the applicants, according to Mr Brown, applied the precautionary principle provided for in article 7 of Regulation (EC) 178/2002. In doing so, Mr Brown volunteered that any restriction to be put in place had to be proportionate. But the applicants' approach was evidence based. There was a confirmed STEC organism in Lanark Blue, batch E24. There had been found, in three batches of Lanark White, E.coli O157. Limited testing of the batches of Corra Linn, detained under regulation 9 of the 2006 Regulations, indicated that ph. and water activity readings would not be at a level to inhibit, or eliminate, STEC. The applicants also had the risk assessment from FSS, updated to 8 November 2016, and FAFA-02 issued on 9 November 2016, which remained in force.

[82] Finally, in chief, Mr Brown was asked to express a view on the possibility of cross-contamination between Lanark Blue, batch E24, and Dunsyre Blue, batch F15. He thought that it was more likely to have occurred when the Lanark Blue, batch E24, and Dunsyre Blue, batch E24, were in the course of production on 24 May 2016. Under reference to the respondents' make sheet for that date (no. 5/1/17) Mr Brown observed that the turning times were very close together, and he postulated that a member of staff, perhaps not having washed their hands, may have unwittingly been the agent for cross-contamination.

Mr Brown also acknowledged that Lanark Blue, batch E24, and Dunsyre Blue, batch F15, were both manufactured, and tested, on different days.

[83] In cross-examination, Mr Brown confirmed that, prior to August 2016, the applicants had never had cause to take enforcement action against the respondents.

[84] Mr Brown acknowledged that one control step in the cheese making process was pasteurisation, but pasteurisation alone does not completely eliminate the bacteria present in raw milk. An accepted figure was a 5-log reduction. Pasteurisation was, however, designed to eliminate pathogens.

[85] The applicants commissioned Campden BRI (Chipping Campden) Limited to undertake microbial survival predictions with a view to establishing whether Corra Linn could be matured for a sufficiently long period of time that any STEC organism present would be eliminated as part of the cheese making process. The aim, in doing so, was to give FSS scientific information that could better inform its existing risk assessment, the possibility being that FAFA-02 might be amended to allow Corra Linn back on the market. The results reported (B33-17, no. 5) disclosed that, on average, between 180 and 200 days would be required to achieve a 6-log reduction (which was, in effect, elimination), specifically in relation to E.coli O157. The applicants interpreted the findings as showing that a maturation period could be identified, after which one would not expect STEC organisms to be present. On the modelling presented, Mr Brown acknowledged that the inhibitory effect on STEC, provided by the process of maturation, could in fact be more effective than pasteurisation. In re-examination, however, Mr Brown confirmed that, in relation to Corra Linn, batch B17A, a stx1 gene had been found by WGS one year after production of the cheese. That gave the applicants less confidence in the microbial predictions because they could not be satisfied that the other batches of Corra Linn would be safe in circumstances where three

different STEC organisms had been found after testing samples of that cheese (no. 5/1/20 of process).

[86] Mr Brown was not clear on what routine sampling was undertaken by the applicants prior to August 2016. He did not, however, "imagine" that it included testing for the presence of E.coli O157 or other STEC, because there was no statutory requirement to do so. However, article 4 of Regulation (EC) 854/2004 and article 10 of Regulation (EC) 882/2004 advised how food authorities should go about checking compliance with food safety law.

[87] In an illuminating passage of evidence Mr Brown, asked whether he ever conveyed his concerns about STEC in food to those responsible for inspecting the respondents' premises and processes, said that he had no cause to do so. The situation, he said, "never arose prior to July 2016". As the lead food officer in South Lanarkshire, Mr Brown was unaware that there was a problem with STEC in dairy products in South Lanarkshire. Had there been any advice, or enforcement letters, from FSS (or, prior to 2015, the FSA), he would have passed that information on to the Food and Business Regulation team, as he had done after FSS issued an enforcement letter on 7 October 2016 relative to food business operators who produced cheese from raw milk. Mr Brown recalled no communication from EFSA, the FSA, or any other authority in relation to problems with STEC in raw milk cheese prior to July 2016.

[88] In a document headed "Risk Analysis – Primary Production of Raw Milk" (a document bearing to relate to the farming partnership of A&S Cairns and dated 1 April 2014) (no. 6/1/38 of process), Mr Brown acknowledged the references to E.coli O157 as a potential hazard in animal husbandry, although assessed generally as low risk in that document. He was not personally aware that the respondents were not testing raw milk for E.coli O157. However, he anticipated that, if that were the case, the inspecting officer

allocated to the respondents, Alan Dickson, would have been aware of the position, and must have been content with it.

[89] Mr Brown confirmed that, in order to place their product on the market, the respondents required to have an EC approval number for the purposes of Regulations (EC) 852/2004 and 853/2004. The approval process would involve looking at the type of food produced, how it was going to be produced, and the food safety management system in place. Approval would have involved at least two visits by an environmental health officer of the applicants, and would have included checks to the food safety management system for compliance with those Regulations. The respondents (or, strictly, their predecessors) would have been approved in 2006, when they came into force, and the approval (including the food safety management system's compliance with article 5 of Regulation (EC) 852/2004) will have been kept under constant review. The respondents' approval number was last assessed in about September/October 2015, and was in place at the time when Lanark Blue, batch E24, was manufactured.

[90] Mr Brown accepted that the applicants were content with the respondents' control systems prior to August 2016, and it was only as a result of information that came to the applicants after August 2016 that the applicants considered that there were serious deficiencies. The particular information he referenced was the entero count abnormalities (no. 5/1/75 of process), and the SCA Code of Practice which stipulated that testing for E.coli O157 should be a routine part of any sampling programme. Mr Brown did not, however, feel qualified to comment on the proposition, put to him by Mr Errington, that the entero counts for May to July 2016 were consistent with the usual pattern of results, coinciding with the period when sheep were put out to graze, and were not, therefore, a cause for concern.

The results should still have been followed up as lying outside the parameters for coliforms specified in the SCA Code of Practice (at p.167).

[91] In issuing the regulation 27 certificates (for Lanark Blue Remainder and Corra Linn) the applicants applied the precautionary principle. They did so having regard to both the FSS risk assessment, and the other information available to them at the time. They did not prepare a written risk assessment of their own to advise the issue of the certificates.

[92] Mr Brown agreed that daily testing of raw milk for E.coli O157:H7, provided for in the respondents' revised HACCP documentation, would not have identified any of (i) E.coli O8:H9, stx2e, (ii) E.coli O unidentifiable: H14, stx2b, (iii) E.coli O153-O178:H7, stx1c, or (iv) E.coli, O unidentifiable: H20, stx2d, although the quarterly STEC testing provided for in the revised documents, and undertaken by a French Laboratory, Actalia, could have done so.

[93] Finally, Mr Brown was referred to a survey of the prevalence of E.coli O157 in raw meats, raw cow's milk and raw-milk cheeses in south-east Scotland from 2001. It related the results of a survey which was carried out over a two year period commencing in April 1997. The points taken from the survey were (i) that E.coli O157 was not detected in any raw cows' milk or raw milk cheeses, and (ii) by way of conclusion, that contamination of the foodstuffs surveyed for E.coli O157 occurred at a very low level, and that "this should provide some reassurance both to producers, retailers and consumers of these items in south-east Scotland". (I would observe that, beyond providing a snapshot of the position at the turn of the century, it is doubtful that, standing its age, much else can be taken from this survey).

Karen Stewart Wardrope

Karen Stewart Wardrope has been employed by the applicants since September 2006 as an environmental health officer. She has been a team leader for the Hamilton and Clydesdale area since 2014. She spoke to her earlier environmental health experience with both Dumfries and Galloway Council and Falkirk Council, her involvement in the development of a course for Falkirk College on HACCP based systems after the 2006 Regulations came into force, and other relevant formal qualifications. Ms Wardrope presented as an eager witness, and occasionally presented as being concerned to justify the applicants' approach to the respondents' cheeses. However, I was able to benefit from her clear exposition of the thinking behind the service of the regulation 27 certificates which is an important aspect of this case.

[94] The team for which Ms Wardrope has responsibility includes Alan Dickson, who, in the summer of 2016, was the inspecting officer allocated to the respondents.

[95] Ms Wardrope described her recollection of the E.coli outbreak in the last week of July 2016. After the IMT was established, Ms Wardrope and Mr Dickson were tasked with visiting the respondents' premises on 23 August 2016. The purpose of the visit was to obtain two samples of Dunsyre Blue cheese. The intention was both to determine the water and ph activity, and also to submit the samples for microbiological testing by ESS.

[96] An informal sample of Dunsyre Blue, batch F15, was submitted to ESS on 23 August. On 25 August 2016, SERL made contact to advise that they had obtained a strong presumptive positive result for the presence of stx genes. That evening Ms Wardrope and Mr Dickson attended at the respondents' premises with the intention of asking the respondents voluntarily not to place that batch of Dunsyre Blue on the market until the presumptive result could be confirmed. It is understood that they met with Mr Errington. On the following day, Mrs Cairns undertook not to market the batch until after the

respondents had consulted with their solicitors that weekend. Four further samples of Dunsyre Blue, batch E24, were taken by Mr Dickson on 26 August 2016, and submitted to ESS for analysis. On 30 August the applicants were provided, by ESS, with a presumptive positive result for the presence of a stx gene in batch E24.

[97] Further samples of Dunsyre Blue were taken on 31 August 2016, on which date the respondents confirmed that they would voluntarily hold batch F15 from the market.

[98] Presumptive stx positive test results triggered the letter from Mr Brown dated 6 October 2016, in which the applicants sought guarantees from the respondents relative to their food safety management system, and its ability to reduce the risk of STEC organisms being present in the finished product to an acceptable level. Ms Wardrope averred that, before those results were known, the applicants had no reason to suspect that the respondents' HACCP system was not operating effectively. The respondents' solicitors subsequently sent to the applicants copies of revised HACCP documentation.

[99] Ms Wardope, Mr Brown and Mr Dickson met with Mrs Cairns at the applicants' offices on 1 November 2016, the upshot of which was the production by the respondents of a revised testing schedule (no. 5/1/11 of process) which made provision for testing for E.coli O157 and (quarterly) testing for STEC in both the raw milk and the finished product. (It was Ms Wardrope's expectation, or so she maintained, that that meant testing for all STEC, and not just five highly pathogenic strains identified in the Actalia documents lodged by the respondents in process). There was a subsequent meeting on 29 November 2016, attended by Mrs Cairns and Mr Errington, at which revised critical control points, to form part of the respondents' HACCP system, were agreed. Those changes, which included rejection of incoming raw ewes' milk at more than 10 degrees Celsius, were incorporated in the schedule which forms no. 5/1/9 of process. The witness offered the view that it was not sufficient to

have controls in place relating to the hygiene of the incoming raw milk (described as "animal husbandry methods"), and assume that the milk was pathogen free, if there was no sampling thereafter for the presence of E.coli O157 or other STEC organisms. Indeed, the fact that a percentage of the batches of cheese tested were found to contain a STEC organism in the final product showed that the HACCP system employed by the respondents had not been working properly.

[100] When they received the respondents' email intimating their intention to place Lanark Blue and Corra Linn on the market on 16 January 2017, the applicants' response was to ask the respondents voluntarily to withhold their product from the market pending more extensive testing. The respondents were unwilling to do so. The addition of a health warning would not, of itself, guarantee the safety of the cheese. Accordingly, a decision was taken to issue regulation 27 certificates in respect of all batches of Lanark Blue and Corra Linn held by the respondents, and to arrange for their seizure in terms of section 9 of the 1990 Act.

[101] In respect of Lanark Blue Remainder, the certificate, dated 3 February 2017, was issued under article 4, annex II, chapter IX, paragraph 1 of EC Regulation 852/2004. The certificates in respect of Corra Linn, dated 24 February and 8 March, 2017, were issued under the same provision, but also paragraph 3. The rationale for doing so was that a STEC organism had been isolated from Corra Linn, batch B17A, (and, therefore, after a maturation period of a year). This justified the view that the respondents had been accepting raw materials that might reasonably be expected to contain pathogens. However, because the organism was isolated after longer time than expected, the applicants could not rule out the possibility of cross-contamination. Against that possibility, the additional reference to paragraph 3 was included in the Corra Linn certificates.

[102] The additional certificate of 8 March 2017 related to nine additional batches of Corra Linn which had been placed on the market before the issue of the first of the Corra Linn certificates.

[103] Ms Wardrope was present when two auditors from FSS visited the respondents' premises in September 2016. She understood that, during the visit, one of the auditors looked through the respondents' HACCP documentation.

[104] Ms Wardope shared the surprise of Mrs Cairns that the same STEC organism had been isolated from Lanark Blue, batch E24, and Dunsyre Blue, batch F15. Indeed, she agreed that it seemed biologically implausible. She could not, however, recall whether the applicants replied to an email in which Mrs Cairns had suggested re-testing the Lanark Blue sample. Ms Wardrope emphasised instead that the applicants did not consider a re-test to be necessary because, as far as I could follow her evidence, she was happy that the samples which had been taken had not been contaminated by the applicants' sampling officers; she did not think that there had been cross-contamination in the respondents' cheese room as between those two samples (because the batches had been manufactured on different dates), and there had, in any event, been a positive result for a STEC organism.

[105] Ms Wardrope rejected Mr Errington's proposition that a mix-up in the laboratory could have been the cause of the common result. Rather, she postulated that a later batch of Dunsyre Blue (E24), which was manufactured on the same day as Lanark Blue E24, could have been the source of the cross-contamination. That could have occurred if the herd supplying the raw milk was shedding the STEC organism isolated from batch F15 over the period between batches E24 and F15 being made, and if there had been a hygiene failure on the part of a member, or members, of staff during the manufacturing process.

[106] Ms Wardrope confirmed that the applicants had caused to be tested sixty five batches of ewes' milk cheese from about 261 individual samples. None of those samples revealed, on testing, E.coli O157. However, referencing the Codex Alimentarius, Ms Wardrope opined that the fact that an organism had not been found in the past was not a reason to assume that it cannot be present, without an adequate process of validation that the controls in the safety management plan were being effective in ensuring that the risk of a STEC organism ending up in the finished product was reduced to an acceptable level.

[107] Ms Wardrope did not accept the proposition that testing for E.coli on the curd was more accurate than testing the raw milk itself, despite acknowledging that the entero results for March to July 2016 (appended, as annex 4, to the document entitled "STEC contamination in raw milk cheese: risk assessment"; B20-17, no. 2) almost exclusively showed non-detectable levels of E.coli for Lanark Blue.

[108] Ms Wardrope said that she was aware that there was a risk of finding STEC organisms in raw milk cheese prior to August 2016, although she had not herself inspected a raw-milk producer. She saw no need to communicate her awareness of that risk to members of the team that she led. They were all qualified environmental health officers, and she expected them to be aware of the STEC risk, and to assess the hazards in each of the premises they inspected. Moreover, in an enforcement situation, standing the position of FSS on the matter, the applicants would be obliged to regard any STEC organism as pathogenic.

[109] Ms Wardrope gave it as her understanding that, given the scientific uncertainty over the pathogenicity of STEC and different gene combinations (cf. the EFSA Opinion, no. 6/1/160 of process), and the emergence of new STEC strains, FSS and the FSA had taken a precautionary approach and determined on a policy that for any category 1 food (which

includes raw-milk cheeses) any STEC should be regarded as a potential pathogen. Food containing such an organism should not be placed on the market. The source of this policy was, and is, the discussion document entitled "UK Policy on Detection of STEC in Food by Official Controls and Food Business Operator Sampling and Testing" (no. 6/1/150 of process).

[110] Ms Wardrope said that she had no doubt that, when she and Mr Brown discussed revisals to the respondents' HACCP documentation in November 2016, the respondents provided for testing for all STEC, not just the five highly pathogenic organisms which Actalia reported on (cf. no. 6/1/66 of process). There was no written record made of that discussion, but the witness related that they had discussed the terms of the UK Policy document just mentioned, which proceeded on the basis that any STEC organisms were to be considered pathogenic. In answer to the question whether concerns over the presence of STEC in foods was on anyone's radar prior to August 2016, Ms Wardrope replied, somewhat unhelpfully, that it should have been. Environmental health officers were aware of the issue of STEC in foods at that time.

Alan Alexander Dickson

[111] Mr Dickson is employed by the applicants as an environmental health officer. Since the autumn of 2010 he has been responsible for the inspection and audit of the respondents as part of the applicants' programme of routine inspections. He described relevant formal qualifications and his considerable experience of working in the field of environmental health over a period of many years. Karen Wardrope is his team leader. His evidence was straightforward, clear, and where necessary, candid.

[112] Between 2010 and 2015 Mr Dickson carried out approximately eight inspections of the respondents. His impression of the business was one with a culture of continuing improvement in terms of both capital outlay (in relation to the physical structure of the premises) and in the practices and procedures which he observed. Mr Dickson considered that he and the respondents had a good working relationship.

[113] Mr Dickson testified to having become aware of the 2016 E.coli O157 outbreak, and the potential for a link between that outbreak, and the respondents' cheese, on 26 July 2016. He was instructed by Craig Brown to obtain samples of Dunsyre Blue cheese. He confirmed that the table of samples (no. 5/1/73 of process), although not exhaustive, accurately recorded the taking of samples of the respondents' cheeses and their submission to ESS, and the identities of the various witnessing officers who were present when those samples were taken.

[114] Mr Dickson described the precautions taken during sampling to ensure that nothing was done which, by the introduction of microorganisms into the process, might cause contamination of the sample. Mr Dickson and his staff wore white protective coats, hair coverings and boots, as did the respondents' staff. Mr Dickson also emphasised the necessity for accurate labelling, bagging and sealing of the samples, and their swift transport to ESS for examination. On every occasion when samples were taken a member of the respondents' staff was present. Some of the samples comprised cheeses which were provided already wrapped in foil or plastic. These were bagged, sealed and placed in an insulated cool box before being dispatched to ESS. On other occasions, samples were physically taken using sterilised equipment and placed in sterile jars. When multiple samples were taken in this way the work area was cleaned and disinfected between each sample, and a fresh sampling implement was used for each individual sample. Whatever

method was employed, the cheeses were brought individually to the respondents' packing room. Each sample was ascribed a sample number. That number would be written on a label attached to the sample immediately after it was procured.

[115] Mr Dickson rejected the suggestion that any employee of the applicants could have compromised the quality of any of the samples taken. He also rejected the possibility that any sample had been mislabelled, explaining that each of the batches of cheese sampled were identified to Mr Dickson, and those assisting him, by staff of the respondents.

[116] Dunsyre Blue, batch F15, was sampled on two different dates. An informal sample was taken on 23 August, and a formal sample was taken on 29 August, both 2016. The latter sample was delivered to ESS by the witness personally. He was accompanied by a witnessing officer, David Forbes. By reference to its sample number, 046257, the formal sample could be traced to the certificate for Dunsyre Blue, batch F15, issued by the food examiner, Robert Beattie, on 25 October 2016 (no. 5/1/21 of process).

[117] Lanark Blue, batch E24, was sampled on 31 August 2016. It was submitted to ESS by the witness and a witnessing officer, David Forbes. By reference to its sample number, 046272, the formal sample could be traced to the certificate for Lanark Blue, batch E24, issued by the food examiner on 17 January 2017 (B20-17, no. 7).

[118] Mr Dickson did not think that anything was done in the sampling process which could have compromised the samples in any way. The Dunsyre Blue, which was procured on 31 August 2016, was already foil wrapped. It was not necessary to cut into the cheese; all that required to be done was to label, bag and seal the cheese and that was done on that date. The samples of Lanark Blue, batch E24, were taken, and submitted to ESS, on different dates.

[119] Mr Dickson confirmed that he was responsible for having inspected the respondents' premises, and that these inspections were detailed and thorough, lasting perhaps three hours. He was asked by Mr Errington to confirm the generally very favourable comments contained in the inspection reports for 2012, 2013 and 2015 (nos. 6/94 and 6/95 of process), and that as part of the inspection process the respondents' premises and documents (including cheese make-sheets, temperature records, pest control records, milk and cheese sample results) would have been examined, and HACCP procedures verified.

[120] In 2014 Mr Dickson was also involved in an audit, by the FSA, of his own practices and procedures. This involved an audit of what he did at an approved food business operator's premises, and the respondents' premises were selected for that purpose. The audit, which lasted between two and three hours, would have included looking at the respondents' HACCP documentation. The witness recalled thanking Mrs Cairns for accommodating the process, and passing on that the FSA had been complimentary about the respondents' premises.

[121] Mr Dickson advised that his inspection of the respondents' HACCP procedures would have included an examination of the hazards identified, the risk associated with each hazard, and what steps were in place to control the risks. He agreed that it was important to go through the HACCP procedures in that way in order to ensure that the respondents were complying with the Food Hygiene Regulations (upon which compliance the respondents' EU Approval depended).

[122] Mr Dickson was made aware of the SCA Code of Practice by Mrs Cairns in about 2011. He subsequently caused the applicants to be registered as a member of the SCA in order that they could be better informed on what was in the Code of Practice and how it was applied. He also made himself aware of its contents. Mr Dickson was aware that the

respondents received annual accreditation with the organisation which gave SALSA approval. He had seen SALSA approval documentation. It evidenced SALSA+SCA approval, meaning that the respondents had been measured against, and found to be in full compliance with, the current SCA Code of Practice.

[123] Mr Dickson was aware, from his inspection of them, that the respondents assessed E.coli O157 as low risk and that, because of that assessment, the respondents had taken the decision not to test for it specifically. The conclusion he drew was that either the respondents had an expectation that the incoming raw milk was not contaminated with E.coli O157, or the risk was being effectively managed with the procedures that were in place.

[124] Mr Dickson also knew that the respondents monitored for the risk of faecal contamination by testing for E.coli, the results of which would have been considered in the inspection or auditing process which he undertook. Mr Dickson was unaware of any other food businesses within his area of responsibility which tested for E.coli O157.

Robert Charles Beattie

[125] Robert Beattie is employed by City of Edinburgh Scientific Services ("ESS") as a public analyst, agricultural analyst and food examiner based in Edinburgh. He is a food examiner for nine local authority areas including that of the applicants. He holds a Mastership in chemical analysis from 2001, which is his formal qualification to carry out the duties of a food examiner, and has held that position since 2003. Mr Beattie provided me with a clear explanation of the involvement of ESS in the circumstances of the present applications. Although, on one particular matter, I have had cause to disagree with him, that does not detract from the clarity and care with which he gave evidence.

[126] ESS provides an official control laboratory, designated by FSS to carry out microbiological testing, chemistry testing and environmental testing. Mr Beattie's experience has extended to the regular testing of flora from dairy samples in the ESS laboratory. In the field of microbiology ESS look for particular pathogens in foods, including E.coli O157 and other STEC. ESS also undertakes private and commercial testing. There are also a number of private sector laboratories in the United Kingdom which provide food microbiology test facilities.

[127] ESS has a range of accreditations for its testing procedures from the United Kingdom Accreditation Service ("UKAS"), including microbiological accreditation tests. ESS is also one of only two or three laboratories to hold a generic, or flexible scope, accreditation which covers the testing of any foodstuff for the purpose of identifying bacterial DNA using PCR techniques. The flexible scope accreditation covers ESS for the testing of cheese products for STEC (no. 5/1/87 of process). The laboratory, and its staff, are audited and inspected annually by UKAS. Staff at ESS have experience of microbiological testing of samples of raw milk and cheese products.

[128] Mr Beattie described the process whereby ESS received samples of the respondents' cheese for analysis, and the manner in which, for the purposes of traceability, they were logged into a laboratory information management system ("LIMS"). Each sample arriving at the laboratory is allocated a unique reference number which follows the sample through the various processes to which it is subjected.

[129] Mr Beattie confirmed that, subsequent to testing at ESS, samples were handed over to SERL for confirmation of the results. Any work done at ESS was confirmed by SERL. Moreover, SERL being based in Edinburgh, it was possible to hand over the samples, appropriately packaged, to staff there without the need to involve a courier or the post, thus

maintaining the integrity of the chain of evidence. Mr Beattie was aware that SERL also sent samples to the then national reference laboratory for the United Kingdom, PHE Colindale, to undergo whole genome sequencing (SERL not then being set up to undertake such a process).

[130] Mr Beattie provided a summary of the PCR process by which, using an incubation broth, then culturing the broth onto Agar plates, a colony of bacteria can be isolated. His evidence was consistent with the evidence subsequently given by Dr Allison of SERL. Mr Beattie was aware of the policy of FSS that a positive result from the broth would be deemed a presumptive (but not a confirmed) positive result.

[131] Turning to the testing of samples of the respondents' cheese Mr Beattie explained that, after discussion with Dr Allison at SERL, four of the samples (two from Dunsyre Blue, one from Lanark Blue and one from raw milk) were tested using acid shock treatment, a treatment designed to improve detection of E.coli O157 by suppressing competing bacteria. Each of those samples yielded colonies, of which one (Lanark Blue, batch E24) led to a confirmed result, from three isolates, for a STEC organism at SERL. That, in turn, triggered the onward transmission of the isolates to PHE Colindale.

[132] The testing of samples of ready-to-eat foods, like cheese, was undertaken by reference to the Guidelines for assessing the Microbiological Safety of Ready to Eat Foods Placed on the Market, published by the Health Protection Agency (now PHE, then the national reference laboratory for the United Kingdom) in November 2009 (no. 5/1/16 of process).

[133] The HPA Guidelines, which advise food examiners like Mr Beattie on how to assess the fitness of foods to eat, have been approved for use in Scotland by a panel of experts comprising the Scottish Food Enforcement Liaison Committee. They contain Tables which

provide *inter alia* guidance on the interpretation of results for detection of high risk bacterial pathogens in ready-to-eat foods (such as raw-milk cheese) placed on the market (Table 1), and information about the major features of food borne disease due to pathogens (Table 3). It is a common practice, according to the Guidelines, for 25g of food to be tested with the assumption that absence of detection of E.coli O157 or other STEC organisms in 25g of food would be deemed "satisfactory". Conversely, detection of such organisms in 25g of food would be regarded by the Guidelines as "unsatisfactory", potentially injurious to health and/or unfit for human consumption. The Guidelines' suggested action in those circumstances would be the immediate testing of the food origin, production process and environment, investigative sampling and consideration of environmental monitoring. The Guidelines also provide that "actions should not be delayed pending specialist tests", which, according to Mr Beattie, should be understood as meaning that, where E.coli O157 or other STEC organisms are detected, there is a potentially serious health risk for which immediate action is required without awaiting the results of confirmatory testing (for example, at SERL or PHE, who tested the slopes, pellets and isolates derived from the cheese samples taken by the applicants).

[134] When Mr Beattie issued his certificates he had available to him the testing results from SERL and PHE. For the purposes of each certificate, those results confirmed Mr Beattie in his view that a STEC had been isolated and that, in terms of the Guidelines, they were dealing with an unsatisfactory sample, potentially injurious and/or unfit for human consumption. Moreover, it is the policy of the FSA and FSS to treat all confirmed STEC organisms in a ready-to-eat food as potentially pathogenic.

[135] Mr Beattie was then taken through his opinions and observations in respect of each of the certificates of examination issued by him to the applicants. Against the backdrop of

the E.coli outbreak in July 2016, and the probability that the results would be the subject of scrutiny, the certificates were deliberately detailed in relating what tests were carried out on the samples initially submitted to ESS, and by whom. To that extent, the level of detail in the certificates was, in Mr Beattie's experience, very rare.

[136] The certificate in respect of Dunsyre Blue, batch E24, (no. 5/1/18 of process) expressed no opinion on the fitness of the food because it relied only on (at that time, at least) an unconfirmed presumptive positive finding of a stx2 gene in the broth.

[137] Ultimately, the certificates in respect of both Dunsyre Blue, batch F15, (no. 5/1/21 of process) and Lanark Blue, batch E24, (B20-17, no. 7) proceeded on the identification by PHE, using WGS, of E.coli O unidentifiable:H20 with a stx2d gene, sequence type 1308, and the advice of both PHE and SERL that (in the absence of corroborating evidence in the literature to the contrary) this E.coli, if consumed, should be considered capable of causing severe illness in humans. Mr Beattie's opinion was that "the sample was unsafe for [sic.] reason of being unfit for human consumption due to the presence of E.coli O unidentifiable:H20 with a stx2d gene, within the meaning of article 14 of EC Regulation 178/2002, the enforcement and execution of which is provided for by the General Food Regulations 2004".

[138] Mr Beattie was asked about the possibility of cross-contamination of samples within the laboratory as an explanation for the finding of the STEC organism in Lanark Blue, batch E24. He was satisfied, having undertaken a check of the processes and procedures adopted by ESS, an informal DNA test (to confirm that bovine DNA was present in the Dunsyre Blue, and ovine DNA in the Lanark Blue), and also an inspection of the sample jars (which revealed that the two cheeses were different in colour and texture), that the samples in each of the sample jars were consistent with the labelling on those jars. In any event, he considered it very unlikely that the samples of the two different cheeses could have been

mixed up because they had been submitted to the laboratory on different dates and would have been tested on different dates. In cross-examination, however, Mr Beattie acknowledged that, when they were subjected to acid shock treatment, samples of Lanark Blue, batch E24, and Dunsyre Blue, batch F15, would have been tested sequentially as part of that process, albeit over a period of days.

[139] In cross-examination, Mr Beattie confirmed that ESS had tested in excess of 320 samples of the respondents' cheese, of which approximately fifty were handed over to SERL. In relation to those certificates which were based on a finding of E.coli O157:H42, stx negative, Mr Beattie persisted in the opinion that this was a potentially harmful E.coli (notwithstanding that the parties' agreement, recorded in the joint minute, that it is not a STEC, and is not pathogenic).

[140] Mr Beattie confirmed that, although it is asked by food business operators to test for STEC, ESS can only report presumptive positive, as opposed to confirmed, results. Mr Beattie's attention was drawn to differing test results on samples of Lanark Blue, batch E24, which he explained by different portions of the cheese being tested at different times (the homogeneity of the cheese meaning that one could arrive at different results from different parts of a cheese).

[141] As regards the testing procedure for Lanark Blue, batch E24, the initial cheese sample was incubated in a broth. The broth was retained for further examination and incubated again before being subjected to acid shock treatment in an attempt to identify the presence of an E.coli O157: H7 organism. No such organism was found. Although no ewes' cheese had been connected to the E.coli outbreak in July 2016, Mr Beattie considered it relevant to sample and test the respondents' ewes' milk cheeses because it was not clear how the E.coli O157, which had been linked to the outbreak, had come to be present.

[142] Mr Beattie accepted Mr Errington's proposition that, in a hostile environment (and I inferred that Mr Errington had in mind the cheese making process), the number of STEC organisms, if present at all, would reduce. He was unable to say whether they would die off altogether. He accepted that the conditions for a microorganism to be pathogenic included transmissibility, virulence and infectivity. However, it was his understanding (albeit the issue was really beyond his particular experience) that attachment to the intestinal tract was only one method by which an E.coli could cause illness.

[143] Mr Beattie confirmed he had not asked whether either the Lanark Blue, batch E24, or Corra Linn cheeses were ready for sale, or still maturing, at the point when they were sampled. His position as food examiner appeared to be that, because a live STEC organism had been detected, and assuming the product was ready-to-eat, the cheese was unfit for human consumption. One could not rely on the organism dying off at some future time or place.

[144] Under reference to the 2013 EFSA opinion (no. 6/1/160 of process) Mr Beattie confirmed that the STEC organism isolated in Lanark Blue, batch E24, did not fall within any of the sero groups which, in combination with stx and eae, or aaiC and aggR, genes, were considered, in that opinion, as presenting a potentially high risk for diarrhoea and/or HUS. He was unaware whether the proposals in the EFSA opinion had been adopted. The United Kingdom's own policy position in relation to STEC in foods was set out in the Working Policy document referred to previously (no. 6/1/150 of process).

Dr Lesley Allison

[145] Dr Allison is the Deputy Director, and Principal Clinical Scientist of SERL. She described relevant formal qualifications and extensive experience in the field of

microbiology. She has worked principally with E.coli O157, and STEC, for the best part of twenty three years. This included a period of time undertaking research into STEC in the department of Professor Pennington at Aberdeen University. I was impressed with her ability to explain highly technical evidence and she presented as a careful and knowledgeable witness.

[146] Dr Allison gave evidence about her staff and procedures at SERL. She confirmed that the laboratory is one of a handful of specialist reference laboratories in Scotland which are assigned for bacteria considered to be of public health importance, such as STEC and TB. SERL is the reference laboratory for STEC in Scotland.

[147] Dr Allison explained what a reference laboratory is, and what it does by way of testing samples, particularly with regard to SERL being accredited by UKAS (formerly the Clinical Pathology Accreditation Service) to carry out testing in relation to O157 and STEC. SERL receives samples from routine diagnostic laboratories throughout Scotland (including ESS). It seeks to confirm the identity of organisms in the samples submitted to it. SERL also has a role in the detection of outbreaks.

[148] SERL was accredited to perform all of the tests about which Dr Allison gave evidence. She explained terms such as "enrichment broth" and "enteric" and stated that the purpose of the broth was to support the growth of enteric bacteria (i.e. bacteria from the gut). If the organisms were dead, they could be detected but they couldn't be grown or cultured. It was her evidence that: one of the main genes that SERL are looking for is the shiga toxin gene which is used as a marker for the presence of STEC; after enrichment in a broth overnight, a PCR test is undertaken; if that test is positive for the shiga toxin gene it indicates that potentially there is a STEC in the original enrichment broth, and the next stage

is to isolate an organism; isolation of organisms is something that SERL does daily, and is part of its accredited service.

[149] Dr Allison advised that ESS is one of the four Scottish Public Analyst Laboratories. She had worked with them since the SERL laboratory opened in Edinburgh in April 2000, and ESS would send microbiological isolates or cultures for examination, confirmation of identity, and for typing purposes. The process of examination and testing was described, as was the recovery of extracted DNA in pellet or isolate form. PCR is applied to a tiny amount of the sample to look for three different genes, stx1, stx2 and the rfb O157 gene (which is specific for E.coli O157). PCR was described by Dr Allison as a laboratory test designed to detect the presence of certain genes in a bacterial culture or enrichment broth. The particular PCR test currently employed has been used by SERL since 2012. PCR testing multiplies the genes just referred to many thousands of times to a level where they can actually be detected. Pieces of DNA are being looked for, but not altered, and primers are used to enhance detectability. She stated that PCR testing is an accredited test methodology which is used because of its sensitivity. Non-O157 STEC would not be detected at hospital laboratories, where methodology is purely targeted at E.coli O157.

[150] Dr Allison explained that there can be a mixture of live and dead bacteria in a culture. If nothing is cultured it raises three possibilities: that the right method is not being used to culture the organism, the organism is not there, or the organism is dead. The isolation of an organism tells you that it is live and viable. Dr Allison confirmed that the applicants' table of results (no. 5/1/20 of process) was prepared by her, and lists all of the organisms that SERL managed to isolate from the samples submitted by ESS, and the test results at ESS, SERL and PHE. It shows the results of tests performed on live organisms, including the PCR presumptive positive tests submitted by ESS for confirmation.

[151] Dr Allison then explained the dilution process of testing, the plating evenly onto Agar plates (Agar being a solid nutrient medium designed to sustain and enhance the growth of bacteria), incubation overnight at 37 degrees, and then the carrying out of PCR on individual colonies in an attempt to find a colony which gives the same result as the original presumptive positive from the enrichment broth. Isolation of an organism means that the organism is "very much alive".

[152] Dr Allison explained the different methods used when carrying out PCR testing of pellets, slopes and isolates. Only samples that were presumptive positive by PCR were received by SERL from ESS. She spoke to the test results from ESS, SERL and PHE (it being the position that, until August 2017, SERL sent all potential non-O157 STEC strains to PHE for more sensitive typing; since August 2017, SERL has had the capacity to undertake its own WGS, and it no longer requires to send strains to PHE for that purpose).

[153] Dr Allison advised that the stx1 gene has three variants (A to C) and the stx2 gene has 7 variants (A to G). Stx2a and 2d are associated with more severe human illness but the presence of any shiga toxin gene indicates a potentially pathogenic organism.

[154] Professor Fink's reservations, expressed in his opinion (no. 6/1/161 of process), about PCR not distinguishing between the presence of living or dead cells, and the DNA being merely a marker of past organism activity which had long since ceased, while technically correct, was not relevant as far as Dr Allison was concerned. This was because live organisms had been isolated and confirmatory tests had been carried out on them. She also confirmed that PCR does not bring dead or dying cells back to life.

[155] Dr Allison described the system for sending isolates to PHE. When asked whether WGS was useful in terms of food safety monitoring, she replied that it was transforming public health microbiology. It was a new technology which was being embraced at

European and international level. PHE had demonstrated its utility in outbreak detection for STEC and salmonella, and had published widely on this. It was her evidence that she considered it to be the new UK gold standard method for typing both STEC and salmonella.

[156] Dr Allison was aware of scientific uncertainty in relation to the risk management of strains of STEC after detection, and said that some countries will permit the sale of ready-to-eat products infected with STEC which were in their opinion, in some way, less pathogenic. However, there was no European or international consensus as to what constitutes a pathogenic STEC. For that reason a number of countries have a zero tolerance to the presence of STEC in ready-to-eat products and, if detected, such products would not be permitted for sale. She spoke about other countries (e.g. France) having a definition of what constitutes pathogenic STEC, but the issue with that approach is that the organisms which are classified as pathogenic in France may not be of the same subset of strains that are circulating in different countries. Dr Allison was not comfortable with that approach. It was her evidence that the United Kingdom has a quite unique subset of STEC, with which SERL and PHE are familiar (because research has been carried out and already published). Although the UK does see the top five serotypes circulating in Europe, they are not necessarily the most common serotypes which are circulating in the UK, and she is not comfortable with the risk management approach taken in other countries. When asked whether other countries adopted the same approach as to France, she replied that she thought that another couple of countries were considering it. However, the Republic of Ireland had a zero tolerance approach as well as the Netherlands, which is why consensus has not been reached. She stated that the results obtained by SERL in the present applications, and set out in the table (no. 5/1/20 of process) highlighted six different STEC

strains which were isolated from a variety of different types of cheese, and that all were non-O157 STEC, but potentially pathogenic.

[157] In cross-examination, Dr Allison agreed that the outbreak organism had not been identified in any of the samples of cheese which had been tested. She was referred to the Certificate of Examination in respect of Lanark Blue Batch E24 (B20-17, no. 7) and asked whether she had identified the eae gene in the isolate and she said that SERL do not look for the eae gene. PHE do, however, look for it through WGS. She was referred to the statement within the certificate that the findings should be considered capable of causing severe illness in humans, and was asked whether this reflected advice which was provided by SERL. Dr Allison felt unable to comment because SERL had received over eighty samples from ESS. She was asked whether she recollected the advice which she had provided to Mr Beattie, and responded that she imagined that the advice would have come from her Director, Dr Mary Hanson. She imagined that there would have been some dialogue, and perhaps the comment in question related to that. When asked whether she was not personally aware of information provided to Mr Beattie, she said that there would have been some discussion regarding the particular strains, and whether or not they had been seen previously in clinical cases of infection.

[158] On being referred to the E. coli O157: H42 strains which were found in Lanark White and some Corra Linn samples, Dr Allison stated that these were not STEC in as much as no stx genes were identified in the isolates. They were, however, E. coli O157 strains. Dr Allison said that SERL had sometimes seen stx negative E. coli O157 strains in the clinical population, and they can cause disease. Dr Allison was also referred to the EFSA Scientific opinion from 2013 (no. 6/1/160 of process) and the relevance of the absence of eae, aaiC, and aggR genes (in reference to which the opinion expressed the view that "current available

data do not allow any inference regarding potential risk"). She responded that this was very much a proposal, and an opinion, as opposed to an agreed document, and there was no agreed European position. She did not personally agree with the opinion.

[159] In re-examination, she was referred to page 40 of the EFSA scientific opinion, and she was of the view that there was no consensus as to what defines a pathogenic serotype. She was referred to page 48, paragraph 5.4, which stated that no inference could be drawn in relation to potential risk, and observed that there was still uncertainty. She could relate the Scottish experience (approximately one third of isolated strains carrying clinical disease are non–O157 STEC, and the majority are serotypes other than the top five identified within the EFSA report). SERL had seen cases of HUS caused by serotypes other than those presented in the EFSA scientific opinion. Dr Allison did not elaborate on the details of any such cases, when, and in what circumstances they arose.

Professor Norval James Colin Strachan

[160] Professor Strachan has held, for nineteen years, a chair in physics at the University of Aberdeen, and is based at the School of Biological Sciences. For one half of his time he is seconded to FSS as chief scientific officer on a three year secondment, of which he has completed about half.

[161] Professor Strachan undertakes a range of duties at FSS which include challenging the science and evidence used by FSS to advise its policies, checking that the evidence used is robust and secure, and that uncertainties in that evidence are explained.

[162] Professor Strachan has an extensive CV. He holds degrees in both physics and engineering. For nine years he worked at the Torry Research Station Laboratory of the Ministry of Agriculture, Fisheries and Food. In that capacity he carried out work on the

detection of pathogenic bacteria and their toxins (including listeria and E.coli). After three years carrying out similar work at Robert Gordon University he moved to Aberdeen University where his research work over nineteen years has been in the field of infectious gastrointestinal diseases, including campylobacter, listeria, STEC, and salmonella, how they spread, and what can be done to reduce the disease burden. He has published more than one hundred scientific papers in peer-reviewed journals, of which about thirty have been concerned with pathogenic E.coli. He has written on the subject of the carriage of E.coli in sheep, and also wrote a paper in connection with an outbreak of E.coli O157 which occurred in New Deer, Aberdeenshire, which was associated with sheep (in respect of which Professor Pennington was a co-author). Along with others, he has also written on the subject of the dose response of E.coli O157.

[163] I was quite satisfied that Professor Strachan had ample relevant experience to speak to the matters with which his report (no. 5/1/36 of process) was concerned.

[164] Professor Strachan defined STEC as an E.coli that carries the Shiga-toxin gene, and the gene encodes for a toxin that can cause disease in humans. Symptoms associated with STEC include diarrhoea, bloody diarrhoea, and haemolytic uraemic syndrome ("HUS"). The infectious dose for STEC is usually quoted as being under one hundred organisms, although only one organism may be sufficient (but the probability of that occurring is – or may be – low). STEC are split into different groupings, or serotypes (O157 being one such example).

[165] For the purposes of this hearing, Professor Strachan prepared a report which addressed, and referenced, the following seven matters: (i) Evidence for the carriage and excretion of pathogens by sheep; (ii) How pathogens excreted by sheep can get into milk; (iii) Evidence for STEC in raw ewes' milk; (iv) Evidence on survival of pathogens through

the cheese making process; (v) Evidence for STEC in raw ewes' milk cheese; (vi) Dose response, and (vii) Evidence for outbreaks of human illness attributed to STEC in raw ewes' milk and raw ewes' milk cheese. In advance of the proof, Professor Strachan met with an expert witness instructed for the respondents, Professor Noah. On the court's direction, they produced a joint report, dated 23 August 2017, recording the outcome of a discussion which they held into the matters bearing upon the scope of their expert evidence. It is evident from the terms of their joint report that there was substantial agreement between the experts. Indeed, ultimately, Professor Noah was not called to give evidence. I have sought to summarise the salient points of Professor Strachan's evidence under reference to the enumerated issues which he considered.

[166] Turning, then, to issue (i) Professor Strachan explained (and Professor Noah agreed) that from time to time ewes in Scotland have been found to carry STEC. Research has shown that sometimes STEC will not be found in a flock of sheep; sometimes it is found, and the shedding levels can then vary between individual animals in the same flock. STEC are shed in the faeces of sheep.

[167] In relation to issue (ii) Professor Strachan explained that bacteria can be spread from faeces into the raw milk by a number of routes. These included (a) an animal contaminating its own teats with its own faeces; (b) through the faeces of one animal being present on the udder of another animal, which is then milked; (c) milking clusters being dropped on the floor of the milking parlour and becoming contaminated with faecal deposits, and (d) contamination by a person who has been in contact with one animal who is then in contact with another animal. Research has indicated that the highest concentrations of E.coli O157 shed by sheep would indicate a level of contamination whereby 0.1g of faeces from such a

high shedding animal could potentially introduce 100,000 E.coli O157 into the milk. Conversely, there are sheep which are "non-shedders".

[168] Turning to issue (iii) Professor Strachan's evidence was that, since the late 1990s, raw ewes' milk had been recognised as a source of STEC, as evidenced by a number of studies and risk assessments which are set out in his report. In particular, Professor Strachan referenced two studies. The first one, a 2003 study from Switzerland, detected STEC in 13% of the samples of ewes' milk tested. Moreover, all STEC isolated from the milk were non-O157 STEC, and included E.coli O187:H16 containing a stx2d variant, and O unidentifiable: H19 containing the stx2 and eae genes. This demonstrated that non-O157 STEC could be found in raw sheep's milk. The study also showed that the O unidentifiable strain had previously been associated human STEC strains that caused HUS. The second one, a 2006 study from Spain, detected E.coli in three samples of raw ewes' milk.

[169] In relation to issue (iv) Professor Strachan advised that the growth and survival of STEC in cheeses is dependent on the effect of physicochemical parameters such as ph., available water (ie. the amount of water available to the organism), and temperature. In terms of survival, Professor Strachan referred to the 2013 study by Miszczycha *et al*, which examined the fate of different STEC serotypes in a range of experimentally contaminated raw milk cheeses, including a blue cheese made from raw ewes' milk. The study found that the STEC organisms were, in some cases, still detectable at the end of ripening and storage after some 180 days. For that reason, Professor Strachan expressed the view that, unless producers collected evidence on the growth and survival of STEC during the production process, verifying the absence of STEC in the incoming raw milk becomes important. (Professor Strachan also referenced four other studies, although these related to either cows' or goats' milk or the host was unknown).

[170] In relation issue (v) Professor Strachan referenced two studies, from Spain (2007) and Italy (2016) to evidence the possibility that raw ewe's milk cheese could cause human illness. Examination of the studies (nos. 5/1/55 and 5/1/57, respectively) disclose that they demonstrated the potential for different STEC strains to survive into the final product, as opposed to identifying a link between the cheeses studied and incidents of actual human illness.

[171] In relation to issue (vi), Professor Strachan explained that dose response represents the link between exposure to a pathogen and the likelihood of disease. While studies have examined the dose response for E.coli using data from outbreaks, there is large variability depending on the strain of E.coli O157, and the vulnerability of the person exposed. For example, at greater risk will be a young child with a developing immune system, somebody who is already ill, and someone who is immune-compromised. To become ill, it is likely that these individuals would require to ingest fewer organisms.

[172] Finally, in respect of issue (vii) Professor Strachan reported that there have been no reported outbreaks of STEC originating from unpasteurised ewes' milk or ewes' milk cheeses in Europe. However, there have been reports of outbreaks resulting from the contamination of raw ewe's milk cheeses with other pathogens. STEC outbreaks have also been associated with raw cows' and goats' milk cheeses. In 2006 the Italian authorities investigated an outbreak of enteroaggregative E.coli ("EAEC") among individuals all of whom had eaten in the same restaurant. An EAEC was isolated from six patients and a member of staff, and was typed as strain O9:H33. A pecorino type cheese made from unpasteurised sheep's milk was identified as the most likely source. However, the causative organism was not found in samples of the cheese or the implicated sheep flock. In cross-examination Professor Strachan acknowledged that, in the relevant study (no. 5/1/60 of

process), it was reported that (a) poor hygiene was considered a main risk factor in acquiring EAEC, and (b) the detection of the outbreak strain in the member of staff raised the hypothesis that inappropriate food handing by one or more individuals colonised with EAEC could have been the cause of the outbreak. Professor Strachan nevertheless considered the studies to be of relevance to the present applications given that cows, sheep and goats have all been shown to shed STEC in their faeces, and that contamination of the milk from these animals can occur in the same way.

[173] Professor Strachan's conclusion was that raw ewes' milk could reasonably be expected to contain pathogenic microorganisms, which leads to the possibility that cheese manufactured from raw ewes' milk could contain these pathogens, which in turn have the potential to cause human illness unless appropriate safety controls are in place.

[174] Professor Strachan and Professor Noah prepared a written summary of their pre-proof discussions dated 22 and 23 August 2017 (B20-17, no. 22 of process). Although Professor Noah was not called as a witness for the respondents it is appropriate that I now set out the salient points to take from that agreed document.

[175] Both witnesses agreed that there are no published studies (to their knowledge) of STEC in raw ewes' milk in Scotland. Hence it is not possible to say "what might be expected to be found in ewes' milk in Scotland" (which they were asked to consider). However, there are studies from Spain, Switzerland, Greece and Italy which show that STEC is likely to be present from time to time in ewes' milk (the figures quoted ranging from a fraction of 1% to 13%). This is likely to be the case in Scotland also. Moreover, there are no recent studies of STEC in raw ewes' milk cheeses from Scotland. However, studies from Spain and Italy show that STEC can be found in raw ewes' milk cheese from time to time. It is likely that this will also be the case in Scotland. Under references to the studies from Greece and Italy

(nos. 5/1/51 and 5/1/57 of process) Professor Strachan accepted that, in the view of the reports' authors, some of the farm producers appeared to have been operating under unhygienic conditions.

[176] Both experts were asked to consider the extent to which the presence of STEC can be controlled by measures which include closed flocks, animal husbandry and milk management systems. Ensuring a flock is closed (ie. ensuring that no external sheep move into the flock) would potentially reduce the rate at which STEC organisms enter the flock. However, doing this on a commercial farm is challenging because of the variety of routes by which STEC can be introduced, and the high STEC prevalence in ruminant populations in Scotland. Thus, the efficacy of any closed flock policy would need to be verified by testing the faeces of sheep for STEC. Neither expert was aware of any studies which had consistently demonstrated under commercial farming practices that particular animal husbandry (for example, type of feed or stock density) for sheep reduced the risk of STEC contamination of the flock on a consistent basis. The witnesses did not, however, profess expertise in this area.

[177] The witnesses professed limited knowledge on the matter of milk management systems but felt that the main likely route for STEC contamination in the milk was from faecal contamination during the milking process. Cleaning and disinfection of the teats had the potential to reduce the risk of contamination but was unlikely to eliminate the risk, and its efficacy would need to be verified by the levels of commensal E.coli in the milk, and whether STEC was found in the milk.

[178] There appeared to have been only one reported STEC outbreak which could have arisen from unpasteurised ewes' milk. According to Professor Noah, it originated from Oregon, USA, and its value as a source is limited by (i) uncertainty over whether the cheese

most nearly concerned was a ewes' milk cheese, and (ii) the appalling standard of hygiene during the production process and the consequent risk of cross-contamination. There was also one reported enteroaggerative E.coli outbreak from Italy. This was concerned not with a STEC but another type of E.coli which can cause disease in humans. The witnesses noted that, in North America and northern Europe, production of ewes' milk, compared with cows' milk, is likely to be much lower. It is also likely that more ewes' milk cheese is produced in the Mediterranean area. It is, however, unclear whether overall production levels explain differences in the number of outbreaks reported between bovine and ovine cheeses.

[179] The experts' review of the literature suggests that the current frequency of outbreaks of STEC disease from raw ewes' milk cheese is low. They accept, however, that there is the potential for outbreaks to occur because it is known that, from time to time, STEC can be found in ready-to-eat raw ewes' milk cheeses.

[180] Professor Strachan and Professor Noah concluded by observing that the degree to which producers can reduce the possibility of STEC organisms breaking into the final product and causing disease depends on the type of cheese being made and whether appropriate food safety systems are in place (based on HACCP principles) verified by testing to determine the levels of faecal contamination (for example, by reference to indicator organisms such as E.coli, and testing for STEC).

[181] In cross-examination, Professor Strachan confirmed that, in his capacity as chief scientific advisor to FSS, he had seen, and was involved in the discussions leading to the production of, the FAFAs and associated risk assessment and risk management documents, and checking that they were in order.

[182] Professor Strachan was asked to comment on the survival of STEC organisms during the cheesemaking process. Under reference to a table of results from microbial testing (comprised in nos. 6/1/85 and 6/1/86 of process) he confirmed that, in a blue cheese type, E.coli O157 was not detected beyond 240 days. Professor Strachan also accepted that the test results for E.coli in the curd recorded for Lanark Blue for the period from March to July 2016, measured in cfu/g (and giving a maximum of 20cfu/g), appeared to be lower than the target level for E.coli in the finished product contained in the SCA Code of Practice, and would indicate a level of STEC considerably lower than was found in the 2013 study by Miszczycha *et al* referred to above.

Dr Timothy Dallman

[183] Dr Dallman gave evidence about his background and qualifications as a bioinformatician and public health scientist. In advance of the proof he had prepared, in conjunction with Professor Pennington, what was described as a joint report which summarised their discussions on the question whether the bacteria mentioned in Mr Beattie's certificates were pathogenic, potentially pathogenic, or non-pathogenic in humans.

[184] In so far as the applicants' written submissions criticised Mr Errington on the extent of his cross-examination of this witness, it is right that I record that the highly technical evidence given by Dr Dallman seemed to me to range considerably beyond the scope of that brief joint report. Dr Dallman did not produce a report of his own to foreshadow the extent of the evidence which he ultimately gave. Moreover, in the joint report, reference was made to a document, apparently authored by Dr Dallman, entitled "WGS Summary", which

appears to have contained information which may have been of relevance to the discussion as to the pathogenicity of certain STEC. No such document was lodged as a production.

[185] That said, Dr Dallman presented as a very knowledgeable and careful scientist with obvious expertise in the areas covered by his evidence.

[186] Dr Dallman described a bioinformatician as a scientist who performs data analysis on biological data. He had been employed by PHE for seven years working in their gastrointestinal reference unit where he led on WGS. His role was to manage a team of scientists responsible for analysis of bacterial isolates in order to characterise, and to type, them for public health investigation and surveillance. There were five members in his team, who were all similarly qualified in analytics, and they worked closely with microbiological and epidemiological colleagues.

[187] Dr Dallman explained that PHE is part of the Department of Health. Its remit is to provide expert advice on microbiological analysis of infectious disease agents which are sent for typing and characterisation. PHE hosts the National Reference Laboratory for a range of different pathogens including STEC. The role of PHE is one of national surveillance and, instead of thinking about a single patient, PHE thought about infectious disease at population level, and perhaps linked through common exposure. He indicated that PHE would compare isolates which were sent from different laboratories around the country in order to quantify and identify outbreaks of infectious disease. PHE received, historically, and continues to receive, isolates from Scottish laboratories.

[188] Dr Dallman confirmed that, after the E.coli outbreak in the summer of 2016, SERL sent isolates of bacteria to PHE for further testing. He confirmed that PHE had accreditation for the test methodology which they used in relation to the testing of those isolates. He described STEC as one of the most serious gastro-intestinal diseases, in terms of patient

outcome, in the United Kingdom and much of the western world. The reason that it is so serious is because there are severe clinical outcomes which can occur in terms of HUS. STEC is by definition capable of producing Shiga toxins. They have activity on the human kidney which can result in organ damage, and, in severe cases, death. Dr Dallman agreed that there is significant scientific uncertainty in connection with the identification of STEC, and risk management after detection.

[189] One of the characteristics of shiga toxin is that it is carried on a virus which lives in the bacteria called a bacteriophage. This is a mobile genetic element, which means that it can hop from one E.coli strain to another; so when thinking about all STEC, one talks about many different E.coli which have acquired the ability to produce shiga toxin independently. This poses challenges in terms of dealing with the moving target of the emergence of new E. coli which become STEC because they acquire the bacteriophage. Dr Dallman said that, traditionally, the way risk managers had dealt with STEC was to look at the most common serotypes. The most common serotypes are different in different countries. This has led to difficulty in quantifying which E.coli are STEC in which country.

[190] Dr Dallman was familiar with the EFSA 2013 scientific opinion (6/1/160 of process). It was in the nature of a proposal, and its purpose was to try and impose standardisation across EU Member States. There was a large amount still not known about potential pathogenicity. Of the top six known serotypes, O157 is the most common serotype for most developed countries; the others are more common in the USA. What the EFSA opinion was saying is that the serotype was not so important. It just happens to be the type of E. coli which ends up with a particular combination of genes.

[191] Dr Dallman was referred to the penultimate paragraph of p.3 of the EFSA opinion referred to previously. His understanding of the opinion, and conclusions, was that, in the

absence of a particular combination of certain genes, there simply wasn't the evidence available to say that there was no risk of disease from those types of STEC.

[192] In any event, the Member States could not agree on a proposed standardisation of risk. Dr Dallman considered the view expressed in the EFSA opinion (p.40, paragraph 4.5), that there is no single or combination of markers that define the potential of a STEC strain to cause human disease, to be accurate. He agreed that there was a developing scientific picture. Improved testing techniques made for greater understanding. The more detailed STEC could be characterised, the more evidence-based decisions on potential pathogenicity could be.

[193] Dr Dallman stated that just detecting the toxin, in the absence of the E. coli, is not a sound basis of risk. It was necessary to proceed to confirmation through culture, and that is what SERL did in the current investigations. Current knowledge and methods of surveillance recognise that there are emerging E. coli, and that the shiga toxin, or other pathogenicity factors, can move between serotypes. It is not possible to fully define human pathogenic STEC, or identify factors for STEC that absolutely predict the potential to cause human disease. He agreed that it was difficult to assess the virulence potential of a novel strain of STEC, being a strain which had rarely been seen in humans. An example of such a novel strain was the O104 strain which gave rise to the HUS outbreak in Germany in 2011. What had been considered "the big 5" strains of E.coli became, as a result, "the big 6"; as an approach to risk management it was rather like closing the door after the horse had bolted. The 2013 EFSA opinion, which classified "the big 6" (with a certain combination of other genes) as presenting a potentially high risk for diarrhoea and HUS, was abandoned in 2016.

[194] Dr Dallman described the process of WGS, and its development as a scientific methodology. From the 2000s there had been constant advancement in terms of the accurate

identification of DNA bases. There had also been significant improvements in the time and cost of the technique. Cost had dropped dramatically to the extent that, for most reference laboratories, it was now more cost effective to do sequencing rather than to use traditional methods.

[195] WGS is helpful in the realm of public health protection and food safety because it allows identification of an organism in food and characterisation of its complete blueprint. The DNA blueprint obtained from the food can then be compared with isolates obtained from human cases to ascertain whether there has been likely transmission or exposure to the food product. Dr Dallman considered WGS to be the best method currently available, and referred to the rapid adoption of WGS technology across the EU in public health and animal health.

[196] Dr Dallman was referred to the SERL table of results. He confirmed the involvement of PHE in identifying the stx profile (stx1 or stx2), stx variant, sequence type and SNP addresses. The letter typing of the stx variant is very relevant in terms of potency (ie. the outcome for someone who ingests it). Particular variants have been shown, both in animal models, and also in association with clinical outcomes, to be much more associated with severe illness like HUS. The entry in the table for "ST" reflects the sequence type of the isolates. Dr Dallman described sequence typing as an old fashioned technique for broadly grouping isolates based on their DNA similarity. It does not offer the resolution to say that two isolates are likely to be from the same source.

[197] Dr Dallman explained that the SNP address of a sample would be used to determine whether it comes from the same source. He confirmed that the SNP addresses for the first three entries in the SERL table, relating to pellets derived from Dunsyre Blue, batch F15, were identical. This indicated that the stx profile and variant came from the same source.

He was then referred to the three entries in the table which corresponded to isolates of Lanark Blue, batch E24. He confirmed that the first six digits within the SNP addresses for each isolate were identical to the first six digits for the pellets from Dunsyre Blue, batch F15. However, the final digits in the Lanark Blue pellets were different from the Dunsyre Blue SNP addresses. Dr Dallman explained that if the SNP addresses differed at the last digit, but were otherwise the same, the genomes of each sample were different. So, if the same sample had been sampled twice, then the sequence would have the same genome twice. If the same isolate had been sequenced twice, he would have expected to find the same SNP address. The difference in the SNP addresses in this instance meant that the same isolate had not been tested twice.

[198] That said, when isolates share the first six of seven digits in the SNP address, that provides strong evidence that they are from a common source. The fact that these addresses are non-identical means that some time has elapsed for a few SNPs to occur. E.coli reproduce at a much higher rate than humans, so every day for an E.coli is equivalent to several years for a human. Every time an E.coli reproduces, it copies its DNA and there is a chance that a SNP change will occur. That the SNP addresses for each of the isolates from Lanark Blue, batch E24, each differed at the last digit means that there was some variation of the E.coli strain within the batch, and that it (ie. the strain) had been in the batch over a period of time to allow those SNP variations to occur.

[199] Dr Dallman was asked to comment on virulence factors. The shiga toxin is the main virulence factor for STEC. Certain stx types are more commonly associated with illness in humans than others. The eae gene is an adherence gene that allows E.coli to form an intimate attachment to the human epithelial cells in the lining of the gut. It has, however, been seen that diarrhoea and HUS have been caused by E.coli containing shiga toxin

without any known adherence mechanism. To the suggestion that, in the absence of the adherence gene, there would be no basis for the stx gene to connect with the epithelial lining of the gut, and accordingly no potential for human illness, Dr Dallman accepted that E.coli does have to interact with human epithelial cells for transfer of the shiga toxin through the cells. Science certainly does not understand all of the mechanisms which cause that to happen, but there is evidence to suggest that it does happen in ways not yet understood. There are clinical cases of diarrhoea involving STEC with no known adherence factors.

[200] Dr Dallman stated that identification of serotype is a poor proxy for assessing pathogenicity. If it is a serotype which has been frequently seen in cases of human illness then that would be somewhat informative. Adding a stx profile or stx variant to a serotype assists in assessing the potential for human illness. The stx variant is (what Dr Dallman termed) the best proxy for clinical outcome. Asked about the pathogenicity of the isolates from Lanark Blue, batch E24, and tested by WGS, Dr Dallman explained that the stx variant (stx2d) was relatively simple. Stx 2a or stx2d are strongly associated with HUS. Other stx variants, while still likely to cause diarrhoea, are not associated with HUS. Stx 2d has two forms, activatable and non-activatable. The activatable form of stx2d has the same level of toxicity as stx 2a. The non-activatable form is equivalent to other stx subtypes such as b, c, e, f and g. Stx 2d activatable and stx 2a are the ones which are associated with HUS. The Lanark Blue, batch E24, stx2d variant was of the activatable form, and therefore the most potent.

[201] Dr Dallman stated that stx 2d strains with no known adherence genes had been known to cause disease in multiple serotypes in multiple countries. He did not, however, provide any specific examples relating to his own experience, and also made the point that routine sub-typing of stx profiles was a relatively recent phenomenon. A stx2d gene has

strong potential to be pathogenic. If the eae adherence gene is also identified then the possibility of pathogenicity is even stronger. Dr Dallman was unaware of any evidence to the effect that the stx2d finding in relation to Lanark Blue, batch E24, was harmless.

[202] It was put to Dr Dallman that Professor Pennington had expressed the view that detection of stx genes alone was not a sound scientific basis for assessing the disease risk to the human consumer. Dr Dallman agreed that detection, without isolation of a STEC, would be an unsound approach. What he had been provided with, however, was a single bacterial colony (or isolate); in other words, a viable, live colony. An isolate is a viable organism that contains detected shiga toxin.

[203] Dr Dallman had had sight of a report by Dr Scheutz in advance of giving evidence. Having considered the report, Dr Dallman did not come to any different view on the matters contained within it.

[204] Dr Dallman was referred to the other findings within the SERL table. The stx2g gene, found in an isolate from a sample of raw cow's milk (taken from the respondents' bulk tank), was a STEC of a sub-type very occasionally seen in human infection. The finding of E.coli O150:H2 relative to a pellet from a sample of raw milk was a rare serotype. The virulence profile, stx1 and stx2, was consistent with a STEC, with the potential (because of the presence of stx2a) to cause HUS. The E.coli O8:H9, stx2e, eae negative, in Corra Linn, batch F27A, was a STEC of a sub-type which was occasionally associated with human infection (in the form of diarrhoea). It was a similar presentation with Corra Linn, batch E23A, in that the 2b stx variant was not common in clinical cases, but occasionally observed. Corra Linn, batch B17A, was found to have a stx1c variant. In that context, Dr Dallman stated that the remaining stx variants (b, e, 1c, and 1a), have not generally been associated

with causing HUS. However, they are still associated with causing diarrhoea, and, in some instances, bloody diarrhoea.

[205] Dr Dallman was asked to comment on the opinion of Professor Fink (no. 6/1/161 of process) and disagreed that WGS was too labour intensive for food safety monitoring. On the contrary, once an organism has been isolated, WGS is the optimum method for characterisation of isolated organisms, and monitoring relatedness between isolates. It is less labour-intensive than other methods, such as serology or biochemical testing.

[206] Dr Dallman was aware that it was the policy of the FSA that STEC should not be present in ready-to-eat food, and that if STEC is confirmed as being present in ready-to-eat food of animal origin, that product is not safe for human consumption. He was aware of Actalia but unsure whether it was a reference laboratory, as opposed to a commercial entity. In this context Dr Dallman was asked whether high pathogenicity was a test which was recognised in the UK. He said that in the United Kingdom no distinction is made between high and low pathogenicity of STEC as a definition.

[207] Under reference to the Actalia reports (no. 6/1/ 68 of process; pp.3 and 8) Dr Dallman observed that, in France, there is no STEC surveillance in humans, only surveillance. By definition, therefore, such an approach will only identify highly pathogenic STEC which can cause HUS. Other STEC will not be identified in any systematic way. The focus is on HUS being the result. That does not mean that other STEC will not cause human illness.

[208] In cross-examination, Dr Dallman confirmed that he was a microbiologist, but not an epidemiologist. Asked whether there was an internationally accepted standard for the interpretation of WGS results, Dr Dallman replied that there was standardisation of methodology with respect to whether a gene was present or absent.

[209] Dr Dallman did not think that there were plans to revisit the EFSA 2013 opinion, although it remained the opinion of EFSA, and was a valid opinion. He confirmed that he was not familiar with either surveillance or surveys relating to the detection of STEC strains in raw milk cheeses. None of the organisms found in the respondents' cheeses using WGS fell within the category of high pathogenicity classified in France, and contained in the group of six serogroups identified in the EFSA opinion. Nor did any of the organisms correspond with those "other serogroups" identified in the EFSA opinion which were regarded as high for diarrhoea, but currently unknown for STEC. Dr Dallman accepted that what the sample results from the respondents' cheeses revealed were STEC which were possibly pathogenic, but equally possibly non-pathogenic.

[210] Dr Dallman was challenged on whether he could say whether clinical cases, involving (by way of example) H20 and O9 serotypes, had shown the organisms to have been the actual cause of illness. Dr Dallman said that he considered that identification of the cause of illness was "an unrealistic ascertainment" but accepted that, to his knowledge, the strains detected in such clinical cases had been detected from the diarrhoea of the patients concerned. He also accepted that the risk of diarrhoea/HUS was particularly high in the very young and old, or the immuno-compromised.

[211] Dr Dallman agreed that E. coli could be damaged, stressed, dead or (possibly) dying, and that stress could be caused by starvation, antibiotics, heat, or acidity. Salt water activity could also have a possible effect, as well as competing flora.

[212] Mr Errington referred Dr Dallman to the joint report of the Food and Agriculture Organisation of the United Nations and the World Health Organisation on STEC, arising out of a meeting at Geneva in July 2016. Dr Dallman was part of the expert group which prepared the report for the purpose of providing information around STEC in food,

including global information on the global burden of disease. Under the heading "Hazard identification and characterisation" the report made this observation: "There is no single trait of a STEC that can be used to assess the public health risk of its presence in the food chain; rather, a combination of criteria such as virulence and phenotypic properties and regional historical knowledge are required together with knowledge of the isolation context". Dr Dallman confirmed that the first sentence just quoted meant that if all you had was a stx gene, that alone cannot be used to assess the public health risk. Significantly, Dr Dallman explained "regional historical knowledge" as meaning knowledge "in terms of what types of STEC has been identified in that region previously".

[213] In reference to the same report (p.7) Dr Dallman confirmed that consideration was being given to a set of criteria based on current knowledge of factors known to be required in STEC pathogenesis, and that one such factor could include the intrinsic nature of the food. Asked whether account should be taken of the environment offered to the E.coli organism by a foodstuff, Dr Dallman replied that if you could culture the organism from the foodstuff, that would be enough evidence to suggest that there was an infectious dose within. Whether or not account should be taken of the intrinsic nature of a product like the respondents' cheese, if sampled during the maturing stage, would depend on whether there was supportive evidence that no STEC could survive the maturation process.

[214] Dr Dallman advised that he was unaware of a similarly extensive and intensive study of any other cheese in the United Kingdom by WGS. He also confirmed that WGS findings do not provide evidence of enumeration. He was unsure whether the respondents' ewes' milk cheeses had previously been implicated in illness, nor could he speculate as to whether it was possible that the kind of STEC, which had been found in the respondents' cheeses through WGS, had been present in cheeses made prior to the period over which

sampling was carried out. The evidence, however, pointed away from there having been a strain which was persistent, as opposed to sporadic. When put to him that the respondents' ewes' milk cheese had generally not been implicated in illness, he replied that he did not think that it was informative.

[215] Dr Dallman was asked to repeat his understanding of the FSA policy on STEC in ready-to-eat food and said that, as he understood it, it was that STEC detected and isolated in ready-to-eat food was designated as unsafe. When it was put to him that this went beyond the WHO document, to which he contributed, Dr Dallman replied that the WHO document concerned highly pathogenic STEC, it was not about a base line for STEC. He was referred to the UK Working Policy on STEC (no. 6/1/150). Although unsure whether he had seen the document before, Dr Dallman said that he had certainly seen some of the information within. He referred to p.3, part 10, as summarising what he understood the position of the FSA to be.

Dr Flemming Scheutz

[216] Dr Scheutz is a Danish national and has, since 1992, been head of the WHO Collaborating Centre for Reference and Research on Escherichia and Klebsiella, Department of Bacteriology, Statens Serum Institute, Copenhagen. He described his background and relevant qualifications by reference to an extensive CV which was lodged with the court. His background is in the field of molecular biology. His PhD related to verocytotoxin E.coli isolated from Danish patients and this was his speciality.

[217] Dr Scheutz explained the function of the Collaborating Centre. It is the National Reference Laboratory for Denmark, and receives E.coli samples for typing. It is usually responsible for the final determination of specific types, and other National Reference

Laboratories can use its results. It is also responsible for maintaining an international standard and nomenclature for E.coli. The Centre was designated as an International Reference Centre for the WHO in 2010. For reasons not fully explained in the evidence its status as such ceased in about 2014. Dr Scheutz said that he was in negotiation for its re-designation. However, he maintained that it continued to be the international centre for E.coli reference.

[218] For the past fifteen years, Dr Scheutz has run external quality assurance programmes to which National Reference Laboratories have been invited. There has been regular participation in such programmes from other countries across the world. Since 2000, the Centre has operated as the EU Reference Centre organising E.coli programmes for EU countries. His laboratory is dedicated to finding food borne outbreaks arising from enteric bacteria, including STEC.

[219] Dr Scheutz' CV listed, in his research, ninety seven accepted and peer reviewed papers, between thirty five and forty per cent of which were relevant to his opinion in the present applications. He participated as an expert in the production of an opinion for EFSA on the subject of aggregative E.coli.

[220] Dr Scheutz spoke with considerable authority on the matters which he had been invited to address, and it was plain that he had a very considerable knowledge of STEC, and the clinical outcomes associated with pathogenic E.coli. If I had any reservations about his evidence it arose from the fact that he appeared to be referencing, during his evidence, data which was not before the court. However, I was otherwise provided with a wide range of source references, and I was satisfied that Dr Scheutz was able to speak with authority on the matters with which his reports were concerned.

[221] Dr Scheutz explained that E.coli are very different, and pathogenic E.coli cannot be seen on the usual culture plates. It is necessary to use molecular methods. Dr Scheutz has written on the subject of, and advised on, the distinction between pathogenic and non-pathogenic E.coli for many years. He spoke about the serotyping of E.coli, how it used to be typed by antisera (produced in rabbits), and how, in the last five to six years, DNA sequences have been used to type bacteria. A good example was O157, which had caused many outbreaks, including in Scotland. There are six different diarrhoeagenic E.coli, and it is necessary to use different molecular methods to detect the different stx types. He described diarrhoeagenic E.coli as the most common cause of diarrhoea. However, it is very diverse, and some E.coli are associated with chronic, acute and bloody diarrhoea, some are very infectious, and some have low infectious doses.

[222] Since 2000, in a number of countries, STEC have been notifiable, and associated with quarantine measures. From early on, however, it had been seen that not all patients were suffering from HUS. There is now a focus on the types of STEC which are associated with acute kidney failure. From 2015, patients who are infected with low risk STEC, which is more than eighty per cent of Danish patients, are not quarantined. (It was unclear whether this was a reference to Danish practice only). In an interesting aside Dr Scheutz said that his interest has been in not harassing parents of children with low risk STEC infection. He identified low risk STEC infection, in Denmark, as stx 1, then stx2b, e, f, g, and (to a certain extent), c .

[223] For the purposes of the present applications, Dr Scheutz prepared a report dated 6 June 2017 (no.6/1/76 of process), the terms of which he adopted. He was also involved in the preparation, with Professor Pennington, of a Joint Report (B20-17, no. 21 of process), which recorded their discussions on the pathogenicity of the E.coli strains reported, after WGS, by

PHE. He confirmed that his discussions with Professor Pennington, and the other materials he had considered in advance of the proof, did not cause him to change the opinions expressed in his own report.

[224] E.coli strains containing stx genes originate in the bowels of ruminant animals, and the presence of E.coli with stx genes is an indicator of faecal contamination. When asked how serious a risk to public health was presented by STEC, he made reference to the Codex Alimentarius Commission progress report dated October, 2017 (no. 5/1/91 of process). This is the first document published by the WHO to estimate the global burden of foodborne diseases. It is based on figures from 2010, and includes an estimate that foodborne STEC caused an estimated one million illnesses resulting in more than one hundred deaths. That estimate is acknowledged in the report to be understated because some countries do not report STEC at all. Moreover, not all patients with diarrhoea are examined for STEC. When, in Denmark, all patients with diarrhoea were examined for STEC, the incidence of STEC was doubled or tripled. In the United Kingdom, E.coli O157 has been looked for in the last twenty five years. Only recently have non-O157 strains been looked for. In Denmark, all STEC strains have been looked for since the 1990s, and this has shown that non-O157 E.coli are represented by eighty per cent of patients. Very few countries examine for the eae gene (which allows intimate attachment in the gut) by itself. In countries which look for STEC in general, E.coli O157 represents between twenty and twenty five per cent of cases. Very few countries are detecting eae negative strains. Based primarily on Danish data, Dr Scheutz said that stx subtypes are quite commonly found in non-O157, eae negative, strains.

[225] Dr Scheutz agreed with Dr Dallman that there is scientific uncertainty regarding the risk management of STEC after detection. He explained, with particular reference to the interaction of bacteriophages, prophages and their bacterial host, that the factors which

allow bacteria to express toxin which causes illness are not fully understood by current science.

[226] Dr Scheutz was asked about the difference between detection and isolation. He said that isolation identifies live bacteria. Thus, a sample is taken and an attempt is made to grow it under optimal conditions to see whether there are live bacteria with bacteriophages inside. Detection may simply identify a free particle. The study of STEC involves a developing picture. That picture started with a grouping of five serotypes. There has now been a departure from serotyping. Since 2012, Dr Scheutz' laboratory, and six other reference laboratories (including PHE), have been focussing on the subtyping of virulence genes.

[227] Dr Scheutz explained that his laboratory has been using WGS since the end of 2013. It has been used, invariably, for samples submitted to his laboratory since 2015. WGS is faster, cheaper and has a higher typability than any other conventional method. Asked whether WGS is helpful in the realms of public health protection and food safety, he replied that it is the only method which his laboratory now uses for risk assessment in a minimum of ninety five per cent of incoming cases, and that it is used by him to detect outbreaks. He did, however, agree with Professor Fink that WGS is probably too labour intensive, and highly specialised, to be considered a method of choice for food safety monitoring.

[228] Dr Scheutz was taken through his conclusions in respect of each of the bacteria relied on by the Food Examiner in his certificates. In order to follow his evidence in as orderly manner as possible it is expedient to list the bacteria here, in the order in which they were taken in Dr Scheutz's main report and evidence (adopting his numbering):

(i) O unidentifiable:H20; stx2d, ST1308, isolated from Lanark Blue, batch E24 and Dunsyre Blue, batch F15;

(ii) O157:H42; stx negative, ST7077, isolated from Lanark White and Corra Linn, batches H1A, G7A, G20A, and G25A;

(iii) O15:H16; stx2g, STaST325, isolated from raw milk tank (cows' milk);

(iv) O150:H2; stx1a stx2a, eae P3223, isolated from raw ewes' milk;

(v) O8:O9; stx2e, ST23, isolated from Corra Linn, batch F27A;

(vi) O unidentifiable:H14; stx2b, ST7010, isolated from Corra Linn, batch E23A;

(vii) O153-178:H7, stx1c, ST278, isolated from Corra Linn, batch 17A.

[229] By way of preliminary observation, Dr Scheutz agreed that the number of pathogenic bacteria which would be required to cause disease is not known. I will summarise the evidence of Dr Scheutz in relation to each one of these strains in turn.

O unidentifiable:H20; stx2d, ST 1308, isolated from Lanark Blue, batch E24, and Dunsyre Blue, batch F15

[230] Dr Scheutz considered this to be a rare serotype, which had probably not been isolated from humans. However, stx2d strains, regardless of serotype, are considered as having the potential to be associated with HUS. He advised that he had seen several cases of HUS associated with stx2d. For reasons of precaution and because the pathogenic cause of disease is not fully understood, he considered all stx2d to be "possibly associated with severe disease in the form of HUS". Under reference to the studies and material set out on pp.1-2 of the joint report, Dr Scheutz concluded that stx2d positive STEC strains are diarrhoeagenic, and that a certain proportion of these strains, with yet unidentified gene(s), are associated with an increased risk of HUS. He therefore considered that, for reasons of patient safety and prudence, and because there was still scientific uncertainty, any E.coli

isolate positive for stx2d should be considered as pathogenic. That was the case regardless of the presence of an adherence gene such as eae, and regardless of serotype.

[231] Dr Scheutz accepted that the studies, to which he had referred, indicates an inconstant pattern between different countries, potentially explicable by geographical, reservoir and environmental factors, and the thousands of different STEC types in different combinations. In general, Dr Scheutz thought that fifty per cent of cases, worldwide, related to food and water, while the other half of cases were environmental, or were person to person.

[232] On p.1 of the joint report, Professor Pennington noted that the strain isolated from Lanark Blue, batch E24, did not contain the eae gene and had a stx2d gene with the same sequence as a mucus activatable stx 2d gene from a Spanish E.coli O157:H7 eae positive isolate from a clinical case, which was a very different E.coli. Both Dr Scheutz and Professor Pennington agreed that the particular strain had probably not been isolated from humans. However, in concluding that there is no evidence that the strain was pathogenic, Professor Pennington was looking for proof that this type of strain had been isolated from patients who had become ill. Dr Scheutz's approach was one of patient safety and prudence. New bacteria can come along and the present strain could be an example of such a new type. His position was that the stx2d subtype has been isolated from patients with diarrhoea, and in a few cases HUS. In any event, he cited as an example the E.coli outbreak in Germany in 2011, attributed to a type of STEC which had only been seen twice, in France. He stated that if a risk assessment had been based on these two cases, it would have been assumed that the strain could not cause serious disease, when in fact over fifty people died. He did not wish to perform live experiments on humans with a type of strain in respect of which he did not

know the outcome, especially where, with the stx2d subtype, there had been cases of severe disease like HUS.

O15:H16; stx2g, STaST325, isolated from raw milk tank (cows' milk)

[233] Dr Scheutz considered that this strain must be considered as a diarrhoeagenic E.coli because of the presence of two different virulence genes referred to as diarrhoeagenic. In his report (p.2) Dr Scheutz stated that the same strain had been isolated from one Danish patient with diarrhoea in 2016, and from butter, preparation of bovine meat and a bovine carcass swab in Belgium (although no date or further details were provided).

O150:H2; stx1a stx2a, eae P3223, isolated from raw ewes' milk

[234] Dr Scheutz considered that stx2a, plus eae, indicated a high risk of association with HUS. It was an example of a so-called new type, because it has not previously been isolated in Danish patients.

O8:O9; stx2e, ST23, isolated from Corra Linn, batch F27A

[235] Dr Scheutz's opinion was that this strain must be considered as a diarrhoeagenic E.coli. In his main report Dr Scheutz stated that the same strain had been isolated from one Danish patient, so there was evidence of a relationship between that strain and non-bloody diarrhoea. He explained that he had examined his laboratory's database, which recorded seven cases of Danish patients with STEC O8:H9, stx2 positive, six of whom were subtyped as stx2e (the other not being sub-typed). One patient reported bloody diarrhoea, two were seen at an outpatient clinic (which Dr Scheutz appeared to interpret as indicating severe disease in the form of abdominal pain, fever or malaise) and one patient had the same sero-

and *stx2e* type isolated with a five year span between the two isolates. Dr Scheutz expressed the view that stx2e strains could well be under-diagnosed. Most clinics use PCR, but this particular variant of stx2 required some very specific PCR primers. Some National Reference Laboratories are unable to detect it. Accordingly, if laboratories could not detect it, he suspected that clinics would also be unable to do so either (although he had been detecting it since the mid-1990s, and had seen a number of cases of with stx2e and diarrhoea). He considered all stx2e strains to be diarrhoeagenic. He then qualified that statement by saying that it was particularly true for more vulnerable people such as children and the elderly; the normal population was not so susceptible to stx2e.

[236] When it was put to him that Professor Pennington doubted whether stx2e is pathogenic, he provided a detailed response by reference to his discussion, on p.3 of the joint report, of stx2e, stx2b and stx2c (to the effect that (i) all stx2e isolates should be considered diarrhoeagenic; (ii) stx2b positive strains of E.coli are diarrhoeagenic, and (iii) all stx1c isolates are pathogenic). Professor Pennington's view might be a reflection of the fact that stx2e and stx2b have not been isolated very often in the United Kingdom, because diagnostics have been directed towards the O157 strain, which does not encode for stx2e or stx2b. In Denmark, however, stx2b has been one of the most common subtypes for over twenty years, and they have hundreds of patients who are positive for stx2b. Stx2b is found in eae negative strains and the same goes for stx1c. Dr Scheutz said that stx1 strains, without eae, are associated with references to gastroenterologists, indicating (to him) serious disease. From his subtyping Dr Scheutz could see that these strains are stx1c and that they seem to be associated with severe diarrhoea and probably abdominal pain (although Dr Scheutz said that they "did not know that yet but will look into it").

[237] Professor Pennington said, in the joint report, that isolation of strains with stx2b, stx1c and stx2e as their sole virulence factors from sporadic cases of patients with diarrhoea was not determinative. Dr Scheutz disagreed. According to a table with "preliminary data" (for a draft publication in a scientific journal) covering a period 2000-2016, which Dr Scheutz (but not the court) was looking at, 187 patients with diarrhoea had stx2b, 184 of whom were eae negative; 17 patients had stx2e, 16 of whom were eae negative, and 110 patients had stx2c, 104 of whom were eae negative. Taken together, he had more than 300 patients, with one of those three types, namely, 2e, 2b and 1c. The data would have been collected from isolates which were isolated at Danish clinical hospitals and sent to his laboratory, as their National Reference Laboratory, where the strains were typed, and as much clinical information clinical information collected as possible.

O unidentifiable:H14; stx2b, ST7010, isolated from Corra Linn, batch E23A

[238] For reasons already explained Dr Scheutz considered this strain to be a diarrhoeagenic E.coli. For completeness, I should also record that, in his main report, Dr Scheutz identified that this particular strain had actually been isolated from one Danish patient with non-bloody diarrhoea, and he did not have information about the clinical cause of disease for that particular patient.

O153-178:H7, stx1c, ST278, isolated from Corra Linn, batch B17A

[239] Dr Scheutz's opinion was that this strain was diarrhoeagenic, and it may cause bloody diarrhoea. He referenced, in the joint report, twelve Danish patients who were found positive for 0178:H7, all of whom were positive for stx1c. All five of the strains which were submitted for WGS were ST278 and determined to be sporadic cases. The cases were

not considered part of an outbreak, were not further investigated, and no common source of infection was identified. Two of the patients reported bloody diarrhoea and two were seen at an outpatient clinic (again indicating to Dr Scheutz serious disease). (Dr Scheutz also referenced a recent Danish study of STEC screening of stools which suggested a link between stx1, eae negative, isolates and long-term gastro-intestinal symptoms. That study itself was not placed before the court).

[240] In the wake of the 2011 German outbreak, a regional hospital in Denmark decided to examine all diarrhoea stools for STEC. (In other clinics, the procedure is only to test a percentage of patients for STEC). This almost tripled the number of STEC patients, and many of those patients were then found to be positive for stx1c and stx2b. The two toxin types were found more often in patients who were not usually examined by the criteria recommended by the Danish Society for Clinical Microbiology (viz. children under seven, cases of bloody diarrhoea, travellers, cases where an outbreak was suspected, and immuno-compromised patients). These criteria are widely used across the European Union, which is why Dr Scheutz suspects that STEC is under-diagnosed generally.

[241] When it was put to him that Professor Pennington stated that E.coli strains with stx genes, but lacking other pathogenicity factors, such as eae or other adherence genes, would be insufficient evidence of a food safety risk, Dr Scheutz disagreed. He gave the example of examining ETEC (enterotoxigenic E.coli) strains and looking for adhesion factors. There are more than twenty seven of these, and they are not looked for using the tools currently used by PHE. Moreover, new adhesive factors are constantly being found (including over the last two years). E.coli could be described as the most promiscuous bacteria in the bacterial world. There was a lack of knowledge of the factors which allow E.coli to colonise and persist in the human gut or in animals.

[242] Dr Scheutz was asked to comment on the Actalia Reports (no.6/1/68 of process). He considered that an approach which concentrates on serotypes, which tests only for highly pathogenic STEC strains, and which does not screen for stx genes and eae, is old fashioned. If Actalia's initial findings do not fulfil the criteria for serotype, then no attempt is made to isolate. In his opinion, that is not the correct approach as the detection signal is not routinely followed up by isolation. That being so, any STEC outside the panel which Actalia define as present will not be detected, because no attempt is made to isolate. Dr Scheutz believed that Actalia's methodology would have missed the German sprouting seeds outbreak in 2011. That outbreak was caused by O104. O104 is not listed in the panel of testing (which focusses on O157:H7, O26:H11, O103:H2, O111:H8, and O145:H28). Dr Scheutz pointed out that France also had an O104 outbreak, and this was how the sprouting seeds connection was found. The French outbreak was part of the same German outbreak.

[243] In cross examination, Dr Scheutz conceded that he was not an expert in food safety, but he had a lot of experience in epidemiology. He accepted that the presence of STEC is not the only necessary determinant of morbidity, and that it is possible that, in the clinical cases which he was investigating, other organisms may have caused the illness but could have voided the body by the time a stool sample was taken. He acknowledged that there is a geographical variation in STEC types, and accepted that one cannot necessarily apply the incidence of, say, O157 in Denmark to the situation in Scotland.

[244] Asked about evidence of the presence of STEC in the guts of healthy humans, Dr Scheutz referred to a presentation in 2015 (in Boston) which discussed the finding of a very high prevalence of STEC in people working in the food industry in Japan, and who showed no symptoms. Dr Scheutz accepted that shigella could cause bloody diarrhoea, but

confirmed that the patients, on whose illnesses he had reported, would have been tested for shigella as well as STEC. He was asked whether there was any evidence of how often STEC is found in the E.coli population and replied that some years ago there was surveillance of antibiotic resistant samples taken from healthy adults, and the consumer rate was next to zero in a healthy population, or perhaps one or two isolates over 500 individuals (although he could not specifically recall). Healthy cases could also be seen in small family outbreaks, and it was a puzzle why some family members can be infected and others do not have symptoms at all.

[245] When asked about the infectious dose for O157:H7, Dr Scheutz replied that it was probably as low as five to one hundred organisms. He was unaware of the infectious dose for non-O157 STEC. This could only be measured in an outbreak, and in the 2011 German outbreak the bacteria was only epidemiologically linked to the seeds or sprouts, so the infectious dose could not be estimated.

[246] Turning to microbiological organisms, Dr Scheutz accepted that exposure to adverse or hostile environments could change the characteristics of an organism, and in some strains it is difficult to detect a toxin. Dr Scheutz was not aware of WGS being employed by food producers in Denmark as a way of monitoring food safety, although it is now being used by the food safety authorities. He was asked about the ISO Standard for STEC detection in foods (ISO 13136). He agreed that this is the only ISO approved Standard for the detection of STEC in foods, but said that it was old-fashioned and under review. Recognition of a new ISO standard is a slow process.

[247] Dr Scheutz did not feel qualified to comment on the observations and recommendations, concerning microbiological risk management, contained in the Codex Alimentarius Commission report and, in particular, the recommendation that "[M]onitoring

programmes of STEC control measures should be based on health risks assessed within a country, should target identified high risk foods and the STEC of highest health risk". In his world, said Dr Scheutz, the high risk STEC were stx2a and eae or aggR because "that is when we see cases with increased risk for HUS". That said, he agreed with the statement in the Codex that "[T]he utility of testing for STEC presence or absence as part of monitoring programmes for food safety assurance in processing is limited by the typically low levels and prevalence of STEC in food". He also accepted as logical the further statement in the Codex that "[P]rocess performance monitoring may be accomplished more effectively and efficiently by quantitatively monitoring sanitary and hygiene indicator organisms". That means that, if sanitation and hygiene indicator organisms include E.coli and other E.coliforms, and can show that presence is very low then the risk of STEC infection is also low, so a general approach will minimise the risk of infectious bacteria. I understood Dr Scheutz to say that the Codex report was still subject to clearance by its sponsoring organisations, namely the FAO and WHO.

[248] For the purposes of his report Dr Scheutz was not provided with any WGS data beyond the four isolates from cheese samples, stx subtype, and presence or absence of eae. He, therefore, compared those isolates with clinical isolates referred to in his report to see whether there were any matches, and accepted that the ability to make an accurate comparison was limited by the information which was provided to him, and by the Danish data in his reports. In the clinical cases referred to in his reports Dr Scheutz appeared to suggest that, although mainly suspected, there were a few confirmed findings that food was the vehicle for STEC infection. Asked whether a STEC organism was identified as the cause of illness, Dr Scheutz thought that that was the case. All of the patients were examined for all entero-pathogenic bacteria, including salmonella, as well as other viruses.

[249] Dr Scheutz was asked about the position if one of the four isolates found in the respondents' cheeses had been O157:H7. He said that O157 with stx2a gene would be associated with HUS; stx2c would be considered as low risk for HUS, but diarrhoeagenic. In Denmark and Norway, even O157 with eae, and no stx gene, is considered diarrhoeagenic. When Dr Scheutz looked at the four strains from the cheese samples, he said that there was potential pathogenicity ("I would suspect them to cause diarrhoea in humans"), although one strain, O157 H42, stx negative, from Lanark White and Corra Linn had not, to his knowledge, been isolated from human diarrhoea.

[250] Dr Scheutz was unaware of any hypothetical circumstances being proposed in which toxin might not occur. Nor was he aware of any studies having been conducted into the level of STEC presence in raw milk cheese, that matter being outwith his area of competence. When asked about his personal opinion of raw milk cheese, he said that he would try to avoid any unpasteurised raw milk products. In Denmark a few producers could apply for permits to produce raw milk. In general, however, everything was pasteurised.

[251] In re-examination, Dr Scheutz was asked whether the fact that PHE did not sub-type the stx2d strain had any impact on the opinions expressed in his report. He stated that it did not really affect his report, as he had been collaborating with PHE in developing tools, and some years ago a colleague from PHE showed admirably high typability – for these reasons, he was confident that he would have reached the same results as had PHE. When asked about his personal views on raw milk cheese, and whether those impacted on the views expressed in his report, he said that he kept the report very professional and on a scientific basis, and kept out of areas beyond his competence.

Professor Christopher Griffith

[252] Professor Griffith is a quaified microbiologist, and Emeritus Professor of Food Science of the University of Wales. He has an extensive CV which discloses many years' experience working as an independent food consultant to the food industry, during which time he has worked on all aspects of food quality and safety. He is the editor of the British Food Journal and technical director of BSS Public Health, Dubai. Professor Griffith described his work since leaving university in 2009 as that of a "roving trouble shooter". In 1999 he was a member of a World Health Organisation working group which met to consider HACCP and its application to small businesses. He provided expert evidence on aspects of food safety management to the South Wales E.coli Inquiry, chaired by Professor Pennington.

[253] Professor Griffith prepared a report (no. 5/1/78 of process) for the purposes of these applications. He also held a telephone discussion with Professor Pennington, the terms of which are recorded in a short joint report (B20/17, no. 23). I found Professor Griffith to be an enthusiastic witness, anxious on occasions to communicate his views on matters which formed no part of the applicants' case. His comments on HACCP, and cross-contamination, were offered in circumstances where had not visited the respondents' premises. He did, however, express his opinions clearly, and prepared a full and careful report, the terms of which he adopted.

[254] Professor Griffith was of the view that, if it had a HACCP plan, then a food business operator required to verify that it was working, and microbiological testing was one means of carrying that out. He was referred to his joint report with Professor Pennington and agreed with the statement that: "both parties agreed that the value of microbiological testing was to act as verification that the HACCP process was working effectively". In what

subsequently turned out to be a reference to Regulation (EC) 2073/2005, recital 14, Professor Griffith expressed the view that there was an "almost implicit requirement" to test, because those regulations required verification and validation of any food safety management system.

[255] Professor Griffith spoke on the subject of biofilms. He noted from the case papers that there was a particular profile of an organism isolated from two different milk sources and samples in animals over a time period. I understood him to be referring to the finding in relation to Lanark Blue, batch E24, To him, that indicated a biofilm cross-contamination issue. He referred to page 2, paragraph 2, of the joint report with Professor Pennington where both agreed that it was highly unusual for the specific organism to have occurred in products with different milk sources. Professor Pennington's view was that there was a laboratory labelling issue whereas Professor Griffith's view, based on five years of troubleshooting contamination problems, was that it was a case of cross-contamination. He said that there could be resident or transient pathogens in any food plant (some strains were found to persist in food premises for ten and twelve years, even after cleaning and disinfection) so there was the existence of resident strains, part of the more or less permanent flora, within the premises.

[256] Professor Griffith stated that a ready-to-eat cheese from raw milk would fit the profile for a food with a greater risk of STEC infection. Not just cattle, but also other animals, carried STEC. A raw milk cheese was manufactured with no processing stage capable of destroying the organisms. By contrast, pasteurisation puts in a heat kill step which would destroy pathogens in the milk. Evidence indicates that STEC survive various cheese making processes, and can be considered a risk associated with raw milk and raw milk products. The value of microbiological testing is to act as a means of verification that

other control measures are working in the face of what should be seen as a risk. As a food business operator, he said, you have to look at your HACCP process and determine at what point to undertake your microbiological testing.

[257] Professor Griffith was referred to page 19, section 7 of his report (entitled Food Safety Management Toolkit) where he illustrated food safety management as a jigsaw. He explained that, historically, people took random end product testing combined with what was known as floors, walls and ceiling inspections, and this was how food safety was managed. The introduction of a HACCP based approach required to operate in conjunction with the establishment of prerequisite programmes. When first producing a HACCP plan, a control measure should be validated, and verification is longer term. End product testing has limitations and food safety cannot be guaranteed by testing. Moreover, no amount of sampling and testing can ensure the absence of pathogens. That does not mean that microbiological testing is no longer required. What has changed is how and why it is done. Thus, referring to table 7 of his report, Professor Griffith identified some of the continuing benefits of microbiological testing, especially in-process testing.

[258] So far as relevant to the present applications, Professor Griffith's conclusions, from section 7 of his report, were that (i) how food safety management is implemented has evolved; (ii) a toolkit of approaches exists made up of prerequisite programmes, HACCP, microbiological testing, and risk assessment; (iii) a key feature of HACCP was the correct identification of hazards, and (iv) microbiological testing still had a role to play. Ultimately, the goal was to produce safe food for the end user.

[259] Under reference to section 9 of his report (entitled ECL Cheeses, STEC and Risk), and once it was established what documents he had actually seen, Professor Griffith offered the view that the pre-outbreak testing regime demonstrated a lack of recognition of the potential

threat caused by STEC. There was a lack of recognition that STEC was not low-risk, and he could not recall seeing any documents which demonstrated that the respondents had specifically assessed the risk of STEC being present in raw ewes' milk. In any event, he disagreed with the respondents' position that E.coli O157 should be considered low risk. Although it may be lower risk than raw milk from cattle, he would not classify raw ewes' milk as low-risk. From documentation which he had seen, there were many references to confirming that sheep can be carriers of STEC and, specifically, E.coli O157.

[260] By way of justification for his opinion, Professor Griffith drew the court's attention to the risk evaluation matrices in (i) the SCA Code of Practice (no. 5/1/14 of process, appendix 8, p.178), and (ii) Commission Notice 2016/C 278/01 (no.5/1/66 of process), which assessed the risk using likelihood and severity. The terminology between the two documents was slightly different but the philosophy was the same. Taking likelihood first of all, and given the data on the contamination or carriage by cattle and sheep of STEC, including O157, Professor Griffith did not consider that a food business operator could conclude that it wasn't a reasonable probability that such organisms could be encountered in the raw milk. Moving onto severity, STEC can cause serious illness and death in a number of cases. If you combine probability and severity, Professor Griffith did not see how a food business operator, using either of the two matrices, could end up at an assessment of low risk. Thus, if the incoming raw milk was contaminated, and the production process did not eliminate that hazard, then, in his view, there was a real probability that the food business operator would end up with STEC in the end product. Professor Griffith also agreed with the definition, in the Commission Notice, of "real probability" for these purposes. It reads:

> "[F]ailing or lacking of the specific control measure does not result in the systematic presence of the hazard in the end product but the hazard can be present in a certain percentage of the end product in the associated batch".

[261] Professor Griffith described the purpose of microbiological testing, where there was a control measure, as being to verify that the control measure was being effective. In response to the question whether the respondents should have been testing their raw milk for STEC or E. coli O157, he replied that he would certainly think so.

[262] Mr Errington confined himself to asking only one question in cross-examination, namely whether Professor Griffith had visited the respondents' premises, or spoken to anyone there. He had not done so. I was anxious to confirm with Mr Errington that he had given thought to the points he wished to raise with Professor Griffith, and that there were no other matters which he wished to raise with the witness. Mr Errington confirmed that to be the position.

Evidence for the respondents

Paul Richard Thomas

[263] Mr Thomas is a freelance technical consultant advising on dairy technology and hygiene issues. He provides technical support for businesses in the United Kingdom, Europe and around the world. He holds a degree in biochemistry from the University of Dundee, and has experience of the cheese industry as cheesemaker, wholesaler and retailer. He is a Fellow of the Institute of Food Science and Technology. He was an interesting and knowledgeable witness.

[264] Mr Thomas is a member of the Technical Committee of the SCA, although his appointment post-dated the publication of the SCA Code of Practice referred to in the evidence of other witnesses. Mr Thomas also represents the SCA on the council of the Farmhouse and Artisan Cheese Makers' European Network (known as "FACE"), and sits on

its hygiene group. He described FACE as an umbrella organisation representing small scale dairy producers, many of whom use raw milk as an ingredient, at a European level.

[265] It was through his involvement with FACE that Mr Thomas was invited to join the team who were tasked with drafting the Guide to Good Hygiene Practice for the Production of Artisan Dairy Products (no. 6/1/85 of process), a European Union guide which is due for imminent publication in the Official Journal of the European Union and has been endorsed by not only the Health Directorate General of the European Commission (that being the Commission department responsible for food safety), but also the food safety agencies or departments of agricultural health of all twenty eight member states . Mr Thomas has worked with Professor Strachan on the working group set up by FSS to advise on the safety of raw milk cheeses. He also delivers courses in England and Scotland, on behalf of both the FSA and FSS, training environmental health officers in the application of HACCP principles to small cheese making businesses.

[266] The Good Hygiene Guide is intended for use by *inter alia* cheesemakers and other dairy processors, raw milk producers (whom the authors had particularly in mind), and also inspecting authorities when they are performing their official controls. It contains a section on microbiological self-monitoring and non-conformity management.

[267] Mr Thomas confirmed that occasionally even pasteurised cheeses contain generic E.coli and that does not prevent the cheese being placed on the market. Generic E.coli is expected to form during the curd formation as part of any cheese making process, and, for many raw milk cheeses, will be at its highest after about 48 hours from the addition of the starter culture which commences the cheese making process, after which it can be expected to reduce from levels measurable in the thousands to possibly below the hundreds after about ten days, and possibly below ten after about thirty days. He confirmed that there is

no specific legal requirement for producers of cheese to test for STEC, although there is a general requirement in Regulation (EC) 178/2002 that food should not be placed on the market if it is unsafe. Mr Thomas also referenced the study by Miszczycha *et al*, which looked at a number of cheese varieties, as illustrating how STEC numbers were found to decline in the cheese making process (blue cheeses showing a rapid "inactivation", or death, of O157), and that this was consistent with what he would expect to happen to non-toxigenic E.coli.

[268] The Good Hygiene Guide does not contain any criteria for testing for the presence of STEC. By way of explanation, recital 14 of Regulation (EC) 2073/2005 provides that "[A]pplying end product microbiological standard of VTEC O157 is unlikely to deliver meaningful reduction in the associated risk for the consumer. However, microbiological guidelines aimed at reducing faecal contamination along the food chain can contribute to a reduction in public health risks, including VTEC". The vital thing, Mr Thomas agreed, was to have measures in place to prevent faecal contamination and measures which were effective in monitoring that the control measures were working. Thus, a cheese maker could either test the incoming raw milk or test the curd (on the basis that the E.coli will become concentrated during the cheese making process.

[269] The principal author of the SCA Code of Practice was Dr Paul Neaves. At the time when the Code of Practice was written, PCR testing for stx genes was not widely available to cheese producers. Mr Thomas had spoken to Dr Neaves, who had apparently confirmed that, in the context of testing, the reference in the Code of Practice to "E.coli O157 and other STEC" was intended to mean testing only for E.coli O157 as an acceptable way of evaluating the risk of STEC. (I observe, in passing, that Dr Neaves was on the respondents' list of witnesses but was not called to give evidence on this, or any other, point). The Code of

Practice made no specific recommendation on the frequency of testing for E.coli O157. It did, however, provide (p.74) that the frequency of testing depended on a number of factors, principally the relationship between the milk producer and the cheese maker, the type of cheese produced, the size of the business, and any requirements imposed by customers, especially the major supermarkets. Mr Thomas's understanding from the Code of Practice was that the frequency of testing could be anything from weekly to six monthly.
Mr Thomas was aware that the respondents were not testing their raw milk for E.coli O157.

[270] I understood Mr Thomas to say that testing for E.coli O157 or STEC was a requirement of the SALSA+SCA accreditation scheme, of which the respondents were an accredited member, but not a legal requirement in terms of EC Regulation 2073/. In that sense the scheme went beyond European legislative requirements. He accepted Mr Errington's proposition that the respondents, being so accredited, would be entitled to believe that they were operating in compliance with the SCA Code of Practice. Mr Thomas reported that he was unaware of any artisan cheese maker in the United Kingdom who was testing for any STEC organisms other than E.coli O157. He explained that all the reported cases of product recall or infection in the United Kingdom, relating to raw milk cheese, were concerned with E.coli O157. Moreover, there was not a great deal of evidence of a significant E.coli O157 issue in raw milk cheese manufactured by SCA members.

[271] Turning to the availability of testing facilities in the United Kingdom, Mr Thomas thought that there would be no laboratory in the United Kingdom which cheese producers could access to confirm, after a presumptive positive result had been achieved, the presence of a viable STEC organism.

[272] Mr Thomas was not aware of any commercial laboratory in Europe that could, or would, as part of its routine methodology, look for the specific combinations of serotype and

virulence factors associated with the STEC found in the respondents' cheese. No laboratory (by which I understood the witness to mean, commercial laboratory) in the United Kingdom is offering that level of scrutiny. Mr Errington invited Mr Thomas to comment on whether the fact that, out of the hundreds of samples taken by the applicants, not one revealed the presence of E.coli O157, validated the respondents' assessment of E.coli O157 as low risk. He replied that, in terms of verification, the results (or, rather, the absence of a result) would tend to verify that the respondents' HACCP system was working effectively.

[273] Mr Thomas referred to a FACE network paper from December 2015 (no. 6/1/91 of process) in which he recorded the results of a study which he undertook into the available scientific literature which looked at the prevalence of stx genes in raw milk cheeses. From that study Mr Thomas concluded that stx genes appeared to be significantly more prevalent than the number of reported incidents of illness around Europe would have led him to expect. In other words, Mr Thomas would have expected to see a more evidence of people contracting illness. He cited, as an example, Roquefort, a raw ewes' milk cheese manufactured in France. There have, he said, been a number of instances where stx positive samples in Roquefort have been reported on the European Commission rapid alert system, such that one ought to be, but was not, finding many cases of illness.

[274] In the same study Mr Thomas stated that, within the European Union, some Member States were in favour of setting a specific criterion for STEC beyond that implied by EC Regulation 178/2002 (whereby food "shall not be placed on the market if it is unsafe"). He pointed to the existence of a draft "Guidance Document on the application of article 14 of Regulation (EC) 178/2002 as regards food contaminated with Shiga toxin-producing *Escherichia coli* (STEC)", currently being prepared by the European Union's DG Health & Food Safety. The fifth draft of that document defines "presence of STEC" as the presence of

stx genes in an isolated E.coli (stating that the presence of additional virulence factors would characterise the hazard with a lower level of uncertainty). The guide recommends that the level of uncertainty should not be higher than that of "presence of STEC", giving as an example of a higher level of uncertainty a presumptive presence of STEC (stx detected in an enrichment culture). The draft guidance provides that it is the responsibility of each Member State to evaluate the interpretation in relation to the risk profile of food and adopt their own interpretation. Mr Thomas was concerned about such an approach. He thought that the characterisation of STEC as "presence of stx in an isolated E.coli" may still result in a high number of stx positive products being recalled. His paper urged EU Member States, where possible, to consider an interpretation based upon higher levels of certainty such as "presence of stx with either eae or aggR/aaiC in an isolated E.coli" or other similar combinations of markers or virulence factors in cheese. The paper observed that "[i]f Member States based their interpretation upon lower levels of certainty they run the risk of disadvantaging small businesses within their own country while products imported from another Member State or a third country may be produced under a less strict interpretation".

[275] I sought to clarify with the witness the practical import of this evidence because it seemed to me that it was of potential significance to the circumstances of the present applications. Mr Thomas explained that, if there was no harmonised EU approach to interpreting PCR data for the presence of STEC, situations could arise where products which are deemed to be safe in one Member State will be rejected by another Member State (which could in turn trigger a Europe wide recall). A cheesemaker in a Member State which applies a very strict interpretation could be financially disadvantaged when compared with a cheesemaker in a Member State whose interpretation of PCR results is more lenient.

[276] Mr Thomas advised that, although not himself a microbiologist, he had not come across any references in the literature to the use of acid shock treatment as a technique for the testing of dairy samples for STEC. If it was validated as a technique by any competent authority, he was not himself aware of it.

[277] In cross-examination Mr Thomas acknowledged the importance of public health to any food business operator, that STEC represented a hazard in raw milk and raw milk products, and that there was, in the science surrounding STEC, much that was still not understood. He also agreed that, in circumstances of scientific uncertainty, the European Union has made provision for the application of what is known as the precautionary principle as a mechanism for determining risk management and other measures to ensure a high level of consumer protection where food safety is concerned.

[278] One of the fundamental objectives of any food business operator, Mr Thomas agreed, was to produce safe food, and primary responsibility for both food safety and food hygiene rests with the food business operator. To that end guides to good practice are intended to assist. The SCA Code of Practice is one such guide, and it provides that, where milk is destined for raw milk cheese, the milk producer and cheese maker should decide between them who shall be responsible for implementing a testing schedule for *inter alia* E.coli and STEC (para. 5.2.9; although Mr Thomas has understood that the reference to STEC ought to have particularised E.coli O157). Mr Thomas agreed, however, that if a food business operator like the respondents did not test for E.coli O157 they would not be complying with the recommendation of the SCA Code of Practice. STEC should be considered an emerging microbiological hazard which should be controlled by the food safety management system even although there was no requirement for routine testing for such a hazard in European

regulations. There was no reference to testing for E.coli O157 in those of the respondents' HACCP documents which preceded the E.coli outbreak in the summer of 2016.

[279] Mr Thomas confirmed that the fundamental purpose of his FACE network paper from December 2015 was to identify the prevalence of stx genes in raw milk cheese and the apparent disparity between that and the number of known infections. It was based on the availability of data rather than on microbiological considerations. That said, Mr Thomas felt able to write in the paper about the ability of E.coli to share genetic material with other microorganisms and, referencing the E.coli outbreak which occurred in Germany in 2011, the ability of new pathogenic strains to emerge unpredictably. His paper observed that if pathogenicity is hard to define then all STEC may need to be considered potential pathogens. In defining a STEC organism there are different variants and some have been known to cause illness without an eae adherence gene.

[280] Mr Thomas described how there is an ongoing discussion within the working group of FSS, of which Mr Thomas is a member, about whether to concentrate testing on E.coli O157, rather than PCR testing more generally, because of the poor provision of laboratory services offering PCR testing at an appropriate level. He did not know whether ESS and SERL undertook private work.

Dr Peers Davies

[281] Dr Davies qualified with a degree in veterinary medicine from the University of Cambridge in 2008. Between 2008 and 2010 he worked in clinical farm practice (principally in dairy and sheep) with a practice in Devon. He took a PhD in veterinary molecular epidemiology from the University of Nottingham, which he completed in 2016, under the title "Contagious and Environmental Streptococcus Uberis Mastitis in British Dairy Herds".

Dr Davies has been a clinical lecturer at Nottingham University since 2013, and he is a resident of the European College of Small Ruminant Health Management. His veterinary experience covers sheep, cows and goats.

[282] In 2010 Dr Davies started his own consultancy company called Pro-Ovine Limited, which is a sheep only veterinary consultancy and serves commercial sheep producers (both meat and dairy). In that line of work Dr Davies has had experience of a number of dairy flocks, including the flock serving the cheese making activities of the respondents. Through his position with the European College of Small Ruminant Health Management he has also enjoyed extensive exposure to experts in countries like Greece and Italy, which are heavily dominated by sheep dairy production.

[283] Dr Davies first became involved with the respondents and A&S Cairns in 2011, when he was asked to provide a second opinion by the local vet, and has been involved with the farm ever since. He considered standards to be unusually high at the farm and the respondents' premises, and referred to a number of very important milking routine procedures which he regarded as unusually stringent for sheep dairy production. He described the cleanliness of the sheep as very high, and the management of the straw bedded environment – a matter of critical importance to maintain cleanliness of the ewes and, in particular, their udders – he considered to be excellent.

[284] Dr Davies explained that he had been involved in the monitoring of udder health, using individual somatic cell count recordings for each ewe within the flock. Somatic cell counts are an accepted metric for assessing the level of contaminate, or infection, within an udder. If white blood cells are present in high concentration in the milk one would infer that the udder is attempting to combat infection. So the somatic cell count is used to identify ewes which may potentially have an infection. Dr Davies described this process as an

individualised testing of each ewe within the flock. As far as he was aware, it is not practised by any other milking flock in the United Kingdom, nor is it common practice elsewhere in Europe. It is a particularly stringent measure which is used to identify any potential problem animals which can then be removed from the flock as a way of improving milk quality.

[285] According to Dr Davies, the cell counts for the flock of sheep supplying the respondents are much lower than research into cell counts in sheep in Europe has disclosed. This indicates a much lower level of udder infection than would normally be expected. Sheep are normally regarded as having higher somatic cell counts than cattle; yet, the flock supplying the respondents has a lower cell count than many, if not the majority, of cattle herds. It is, he said, an unusual example of good udder health, compared with what is accepted to be the norm in Europe (where the raw milk is also used for cheese and other soft milk products).

[286] The respondents having been undertaking individualised tests once a year, timed to coincide with the middle of the seven to nine month lactation period, since 2015. Dr Davies agreed that it is a very costly and time consuming process which, hitherto, has not formed part of the culture of sheep dairying in Europe or the United Kingdom, and which he recommended be implemented.

[287] Dr Davies described the milking parlour where the ewes' are milked as a very high specification in line parlour. It replaced an earlier parlour which was not so amenable to the hygiene procedures being introduced and has allowed for far greater intervention in terms of the milking regime. In particular, it has provided the space and facilities to be able to clean, and disinfect (using wipes), the udder, before and after milking. In Dr Davies'

opinion, the most important control step for reducing or eliminating the risk of faecal contamination was pre-milking teat disinfection and cleaning.

[288] Dr Davies commented that, in the rest of Europe, the use of any kind of pre-milking preparation or disinfection does not occur and, although used intermittently, it is not common practice within the United Kingdom. What the farm's process, using disinfecting wipes, does is to remove, both chemically and physically, such contamination as environmental debris, straw bedding or faecal contamination, which can all adhere to the outside of the teat. The respondents' process allows for a space in time between disinfection and the application of the cluster to kill off bacteria on the teat skin. Moreover, the amount of sheep defecation during the milking process is much less than would be the case with dairy cattle, and the dairy milking environment is much cleaner.

[289] Dr Davies confirmed that, after milking, the teats are dipped. The significance of post-milking teat disinfection is (i) to provide a barrier of disinfectant which prevents bacteria from colonising inside the teat canal while the teat is sealing, and (ii) to aid in the control of pathogens passing between animals.

[290] Dr Davies observed that the forage based feeding system operated with the flock results in minimal amounts of concentrate. The significance of this is that the sheep faeces is firmer, and in more of a pellet form, in contrast to the very loose faeces which are common in dairy cattle milking systems. That forage based system was in operation in 2016.

[291] Dr Davies' evidence was that, at a molecular level, it is never going to be completely possible to eliminate all faecal contamination. The important thing is to suppress it to the lowest possible level at which it is biologically ineffective; that involves suppressing the colony forming units to the lowest possible level, which is a particular reason why a pre-milking teat disinfection regime is in use. In the final analysis, Dr Davies considered

that the milk hygiene measures, applied to the ewes supplying the raw milk to the respondents, are the most stringent as could practically be implemented.

[292] On the E.coli levels in the curd Dr Davies commented that the results were at the detection threshold which, as far as he was concerned, implied a very low level of E.coli from that period of the cheese making process onwards. Dr Davies agreed that an E.coli test is a good indicator of faecal contamination, the coliforms normally being taken as a metric for such contamination.

[293] In cross-examination, Dr Davies confirmed that he had a commercial relationship with A&S Cairns in connection with the provision of advice in relation to the closed flock. He agreed that the somatic cell count results set out in his routine annual visit report to A&S Cairns for July 2016 (no. 6/1/ 73 of process, p.3) disclosed a small percentage increase in udder infection between 2015 and 2016. He also confirmed that he did not, himself, do any testing for E.coli, O157 or STEC; that, he said, would not be standard practice. Dr Davies agreed that E.coli O157, and STEC, are all strains of the same E.coli which has its source in the stomachs of ruminant animals, and said that they only very rarely had any adverse effect on the health of a ewe. He considered the health of the flock to be generally very good.

[294] Dr Davies agreed that testing does not, in and of itself, make a product safe but it did provide a check that a product was likely to be so. Whether or not STEC presents a risk to public health was not a matter upon which he felt qualified to answer. He also clarified, for the benefit of the court, that the letter from Pro-Ovine Limited dated 6 March 2017 (no. 6/1/75 of process) was prepared by him at the request of Andrew and Selina Cairns (the partners of A&S Cairns) and outlines his positive impression of the management of flock health, flock husbandry and the milking parlour at the farm which supplied raw milk to the respondents.

[295] I found Dr Davies' evidence to be of particular assistance. Although not led as an expert, and even allowing for his commercial relationship with A&S Cairns, Dr Davies was able to bring to his evidence practical experience of animal hygiene, and the management of faecal contamination where ewes are concerned.

Mrs Selina Cairns

[296] Mrs Cairns is a director of the respondents. She is also a partner in the farm business of A & S Cairns, which supplies raw ewes' milk to the respondents. Her primary responsibility lies in the operations of the respondents. She spoke of her background in construction management (which involved writing method statements and risk assessments; tasks which were quite transferable to food safety management). She had been a project manager at Edinburgh Airport in the employment of Balfour Beatty Management.

[297] Mrs Cairns was, however, brought up in cheese making through her father, Humphrey Errington, and she joined his cheese making business in 2008. She has attended various courses looking at the technical aspects of cheese making, a HACCP training course run by SALSA, and engaged consultants, year on year, when required. She has also studied a range of pathogens with a view to advising on the approach to animal health.

[298] Mrs Cairns explained that, in cheese making, it is necessary to recognise that milk changes daily, especially ewes' milk. Sheep have a short lactation period, and the milk changes throughout the season, occasioning changes in both fat content and protein content. There would also be changes in the microflora depending on what fields are being grazed by the sheep, and the conditions in which they did so. So the policy of the respondents had always been to seek advice from expert consultants, and, in particular, for such consultants to come to the premises and see what the respondents were doing.

[299] Following the 2016 outbreak Mrs Cairns continued to seek out specialist advice from the SCA, in the persons of Paul Thomas and Paul Neaves, and also Valerie Michel of Actalia, in France. The outbreak had caused serious repercussions for the respondents' business. The respondents used to make more than fifty tonnes of cheese (from both cows' and ewes' milk on a 50/50 basis) a year. Between the farm and the cheese making side, about twelve people were employed in August 2016 (including both full-time and seasonal staff as well as seasonal staff). After the outbreak, the respondents stopped milking the ewes earlier than usual, and ceased all cows' milk cheese production. Annual production since the outbreak has reduced to about twenty tonnes of ewes' milk cheese. Annual turnover which, prior to the outbreak, had been about £600,000, has reduced to £85,000.

[300] Mrs Cairns considered that there had always been a good relationship between the respondents and the applicants. Inspections were firm but fair. Alan Dickson was always thorough in his inspections. After the respondents had received their SALSA approval, and their HACCP documents were in better order, Mr Dickson was happy with the set-up because it was robust. The respondents had their EU approval, and that approval had never been removed, even after the outbreak and the issue of the FAFAs.

[301] Mrs Cairns said that environmental health officer inspections took place a minimum of once, but normally twice, per year. Inspections covered labelling and HACCP. As far as she could recall, inspections had always looked at microbiological test results, and Alan Dickson had looked at the respondents' HACCP documentation, and those hazards whose risk had been assessed. No one ever queried O157 being assessed as low risk. She was referred to the Risk Analysis-Primary Production of Raw Milk (A&S Cairns), dated 1 April 2014 (no. 5/1/38 of process) which noted that E.coli O157 was identified as a hazard in grazing and silage. Mrs Cairns said that she had not written the risk assessment herself; it

had been written with the assistance of Jayne Hickinbotham of SALSA, who had monitored Mrs Cairns at the start of the process. Under "Animal Health – udders" (p.2) the risk from E.coli O157 was noted to be low/medium and this assessment had been carried out with Jayne Hickinbotham. The respondents had then been audited by different members of the SCA Technical Committee over a further period of four to five years. SALSA would also have gone through the risk analysis document, and they had not queried it.

[302] Mr Errington put to Mrs Cairns that, prior to August 2016, there had been a decision to assess the risk of O157 as low or medium, that testing was not required, and that that assessment was never queried by the applicants. Mrs Cairns' response was that she wouldn't say that she had made a decision not to test. She had inherited the testing schedule from Mr Errington. The applicants' inspector had looked at the document at each visit, SALSA had looked at both it and also the test results, and up until August, 2016, no-one suggested that she should be testing for O157.

[303] Mrs Cairns described the different types of ewes' milk cheese manufactured by the respondents. These were Lanark Blue, a semi-hard blue cheese similar to Roquefort; Corra Linn, a hard cheese made in the Cheddar style; Lanark White, a semi-hard cheese rather in the Gouda style, and (most recently) Lancelot, a soft cheese. The range of customers for these cheeses she described as specialist cheese shops, restaurants and hotels which used the cheese in their cheese boards and in dishes. Ewes' milk cheese was expensive. Purchasers tended to be quite discerning and she did not sell to supermarkets. Mrs Cairns also spoke of the investment in new equipment on the farm operated by A&S Cairns. A new milking parlour had been installed in 2013 at a cost of £95,000, as well as a shed which cost £100,000. Mrs Cairns then explained that the respondents had been involved in the establishment of

the SCA in the 1980s. The SCA has a technical committee which can give advice to members.

[304] Mrs Cairns added that she had attended a microbiology testing course in 2015 in Newcastle, given by members of the SCA technical committee, in the course of which advice was given in relation to testing for STEC. It was presented in a way that technology (understood to be the PCR testing method, and which the witness did not understand to be validated) was being worked on, was very sensitive, but could not detect between live and dead cells. There was no suggestion that the respondents should have been testing for STEC. Her notes from the time indicated that O157 testing did not need to be done with ewes' milk, which indicated to Mrs Cairns that a distinction had been drawn between cows' and ewes' milk and the risk of O157. More recently she had queried this with Paul Neaves of the SCA. He reported that he did not recollect saying this but had since changed his mind. Where the SCA Code of Practice required raw milk to be tested between weekly to six monthly for E.coli O157, she understood Mr Neaves to mean that the problem with the SCA Code of Practice was that it was written with cows' milk and milking requirements in mind, and that some parts of it were not really related to ewes' and goats' milk where the method is different.

[305] Mrs Cairns thought that the respondents were the first cheese maker in Scotland to secure SALSA+SCA accreditation. This measures compliance with the SCA Code of Practice, and the respondents had now been audited eight times. Both the SALSA and environmental health visits she considered to be useful exercises. The SALSA audit looks at every aspect of production and processes. There was a SALSA audit on 17 July 2015, which would probably have related to the SCA Code of Practice for 2011 which was then in force, but which found the respondents to be fully compliant. SALSA also audited the

respondents on 18 August 2016. That was after the outbreak, and the respondents were again found to be fully compliant. The auditor had then looked at all of her negative E.coli O157 tests (at which point she was only doing cultural tests for O157 in her laboratory, because that was what caused the outbreak, and it was the method which her laboratory used).

[306] Mrs Cairns explained that, from a cheese making point of view, her priority was to produce good quality raw milk. The respondents, therefore, try to produce it as hygienically as possible. Of the main pathogenic bacteria, listeria was always the one which she felt presented the highest risk for raw ewes' milk cheese, followed by staph aureus, then salmonella and E.coli. She tested for E.coli in the curd because that was the point when it was more detectable, after which the E.coli died off. The applicants were obviously aware that the respondents were not testing raw milk for E.coli prior to the outbreak because they had looked at the results of curd testing for E.coli. Those results, from the curd, were the best that could reasonably be achieved, the highest being 20cfu/g. To put matters in perspective, the SCA target for hard cheese was 100cfu/g, and, for soft or semi-soft cheese, 10,000 cfu/g.

[307] Mrs Cairns' evidence was that E.coli died off during the cheese maturation process. Going back six years, the respondents had experienced high E.coli counts in their cheese, but later tests showed that it did die. E.coli could not be eliminated completely and the aim was to reduce it to the minimum level by producing milk hygienically. She was asked whether there might be STEC in the cheese and she responded that she would not think so because she produced milk hygienically, and STEC died off during the maturation process. The labels for Corra Linn and Lanark Blue (nos. 6/1/156 and 6/1/157 of process) indicated "warning made using raw milk, unsuitable for pregnant women, children, the elderly and

those with low resistance to infection". There was a legal requirement to say that the cheese was made from raw milk. In January 2017, however, she had added a warning on the back of the label to say that the cheese was not suitable for the elderly, infirm, or someone with a compromised immune system.

[308] Mrs Cairns gave evidence about the milking arrangements and processes, the number of sheep milked, the protective equipment used by people doing the milking, the use of hygiene wipes and other hygienic processes. She described a range of chemicals which the respondents employed in their cheese rooms, including an acid cleaning agent which was designed to prevent biofilm build-up.

[309] Her evidence was that she could not have tested the milk for STEC in 2016. After the outbreak, she found a laboratory called Geneius, which could do PCR. It could not, however, do anything beyond a presumptive positive finding. In any event, Geneius was no longer accredited for stx testing by PCR. This was the reason why the only option available to her was to send samples to Actalia in France, and this was done, probably at the recommendation of Paul Thomas, after the finding of a stx2 gene in Dunsyre Blue, batch F15. She had spent a lot of time trying to find a place to test for STEC. The only other place she could find had been in Southern Ireland, but it seemed to follow the same process as Actalia.

[310] The last passage of her evidence was given in the context of a passage from a document issued by the SCA which bears to clarify current recommendations in respect of raw milk destined for the production of cheese (no. 6/1/104 of process, p.4). It is dated from March 2017. Mrs Cairns' evidence was that the SCA had written STEC into the Code of Practice, but it had since clarified that testing need only be for O157. She had asked if the applicants' laboratory was accredited for STEC testing. She was told that it was; however, looking at their UKAS schedule, the accreditation appeared to relate to bean sprouts.

[311] Mrs Cairns rejected the suggestion that high enterobacteriaceae counts in the summer of 2016, referred to in his evidence by Mr Brown, should have alerted the respondents to the possibility that faecal contamination was worsening. They may have been slightly elevated but the low curd results told her that E.coli was not responsible. When she was asked how long Corra Linn would be matured before it was marketed, Mrs Cairns said that she would try to sell Corra Linn at not less than six months. The optimum maturation was nine months but the cheese always sold out, so it was tempting to sell it earlier. Her understanding of the Campden BRI modelling in respect of Corra Linn was that it would take 180-200 days to proceed to a six log reduction.

[312] Mrs Cairns was referred to the decision to treat E.coli O157 in ewes' milk as low risk. She replied that she was not an expert on HACCP so she required a consultant to help write her HACCP and pre-requisite documents. Jayne Hickinbotham was initially allocated as a mentor by SALSA, and changes were made in consultation with SALSA auditors who looked at the respondents' premises over the years and discussed the hazards and risks. She did not remember allocating O157 as low risk and assumed that Jayne Hickinbotham must have done it. Monitoring was done through the respondents' sampling schedule (which mentioned generic E.coli).

[313] Mrs Cairns confirmed that, as part of the investigation into the E.coli outbreak in July 2016, two auditors from FSS had, in September, paid a visit to the respondents. They were accompanied by Karen Wardrope. Having spent a day looking at the premises, water supply, and food safety management system, the respondents were advised that the auditors had not found any systemic issues.

[314] The FSS risk assessment (B20-17, no. 4) made reference to a limited number of HACCP documents, which were not the correct documents at the time of the outbreak. FSS

did not have the whole HACCP and pre-requisites, nor did anyone speak to the respondents about them. The risk assessment made no reference to the FSS audit in September 2016. She was asked by the Court what she would have expected to have seen in the risk assessment if FSS had seen all HACCP documents. The witness replied that they could have clarified certain matters, because there were inconsistencies in their hypothesis. She said that they were not experts on dairy microbiology, so she thought that they might have spoken to someone from the SCA or some other expert. The E.coli test results in the curd were included in the risk assessment but it appeared to Mrs Cairns that no attention had been paid to them.

[315] Turning to changes to the HACCP in 2017, Mrs Cairns said that when she reviewed the HACCP with Jayne Hickinbotham in October, 2016, the recommendation was that she test the milk weekly for O157, and then, if it was satisfactory, move to monthly testing. The exercise was prompted by the outbreak, and a request from the applicants that the respondents review their HACCP. At the end of November 2016, Craig Brown had made a decision (in conjunction, she thought, with the Scottish Food Liaison Committee) that, if they were to make cheese again, the respondents would require to test all incoming raw milk for O157. Mrs Cairns' suggestion that it would be better to test the curd was rejected. In addition to daily testing of the milk, the respondents were required to test the raw milk and the finished product, quarterly, for STEC. Mrs Cairns did not think that this was reasonable when she could not achieve that within the United Kingdom. It was agreed that she would send the milk and cheese samples to Actalia. None of the respondents' cheeses had ever failed the tests to which they were subjected by Actalia.

[316] As to whether the applicants were content with the choice of Actalia, Mrs Cairns replied that they had approved her HACCP, and besides there was nowhere else to send the

samples. FSS had seen all of the certificates of testing of the respondents' cheeses, and she had discussed the results of the testing of Dunsyre Blue, Lanark Blue, and Corra Linn, produced by Actalia in 2016 and early 2017 (no. 5/1/68 of process).

[317] On cross-contamination, she described as ludicrous Karen Wardrope's hypothesis that Dunsyre Blue, batch E24, had been the source of contamination for Lanark Blue, batch E24 (the two having been turned on the same day). She pointed out that the serotype had not been isolated from that batch of Dunsyre Blue. If the milk was contaminated on the same day, the E.coli would require to have been in very high numbers, and the public analyst or SERL would have been able to isolate it in that batch of Dunsyre Blue. The Dunsyre Blue which they did isolate was made three weeks later, so it made no sense. There were, in any event, good cross-contamination policies in place. The staff had been there for a long time and knew that they had to wash their hands between batches. In the final analysis, Mrs Cairns thought it more likely that cross-contamination occurred when the samples of Dunsyre Blue, batch F15, and Lanark Blue, batch E24, were tested at the same time (even although they had not been taken on the same day), and the Lanark Blue sample had shown a stx positive result.

[318] Mrs Cairns had suggested that the Lanark Blue be re-tested but the applicants, in the person of Karen Wardrope, had declined. This refusal Mrs Cairns could not understand.

[319] Mrs Cairns said that the respondents had themselves subjected over one hundred of their own samples to their laboratory in Ashley for testing, and some two hundred went to Actalia. The O157:H7 strain of E.coli was not found in any of these tests, nor was it found in any of the samples taken by the applicants for testing.

[320] Mrs Cairns described the intricate process by which the respondents' cheese was produced. In doing so, she pointed out that the ewes' milk and the cows' milk is piped

separately, in separate buildings, to separate bulk tanks. She described how milk is pumped into heated vats before the addition of starter cultures, which cause the milk to acidify, whereafter the rennet is added. This leads to the generation, then cutting, of the curd, and separation of the whey which is then drained. The remaining curds are the filled in cheese moulds, subsequently turned by hand, and pierced, while the whey continues to drain from slits in the moulds, in a refrigerated environment. The individual cheeses so created are then wrapped in foil and the process of maturation continues. She described how Corra Linn is made in a separate building, and the different processes involved in that.

[321] Mrs Cairns was referred to, and confirmed, the terms of various procedural documents, including the respondents' safety management documents which were all contained in a HACCP folder, and which were the subject of audit by the applicants. She described the document entitled risk analysis primary production for raw milk (no. 6/1/38 of process) as the respondents' most important HACCP document (which included an assessment of the risk of O157 in the raw milk).

[322] Mrs Cairns was asked to respond to Ms Wardrope's suggestion that testing the curd for E.coli would not be as reliable as testing the milk because the milk was stirred and the curd might not be heterogenous. She replied that the milk was mixed by an automatic agitator in the bulk tank and thereafter pumped to the cheese vat, where it was mixed again. Once cut, the curds were mixed and stirred. The curd was more concentrated by this point and Mrs Cairns believed that testing, at that point, gave her a very good indication of how clean the milking hygiene process had been. The respondents also tested the end product every six months, and retained a single batch for testing at the end of its shelf life. In the past, an out of the ordinary E.coli reading on the curd would have caused the respondents to test batches individually to see if a specific batch was involved, and thereafter, if a specific

batch was isolated, further testing would be undertaken to check that the E.coli were dying off. Testing of the cheeses included sampling from the core in the centre of the cheese to the rind to give a good idea of an average. However, the E.coli counts in 2016 were all low.

[323] In an interesting aside, Mrs Cairns explained that cheese does not "go off" like milk. It is a fermented product and will just continue ripening and maturing; a soft cheese, for example, might reach a point where it is unpalatable but it will not have gone off.

[324] Mrs Cairns confirmed that, between the testing schedules of 7 November 2016 and 14 March 2017, the applicants had (in January) clarified their requirement for daily testing of the raw milk for E.coli O157, the November schedule having provided for weekly testing for O157(on Jayne Hickinbotham's advice).

[325] In cross-examination, Mrs Cairns confirmed that the respondents sold cheese direct to consumers, to wholesalers, and to delicatessens. The cheese had the respondents' labelling on it and, say, a delicatessen would advise the customer of the name of the cheese, what animal it comes from and whether it is made from raw milk, and with what type of rennet. But it was up to the retailers' own HACCP to identify how they would want to act on that. The cheese was labelled as being from raw milk and Mrs Cairns could not control what happened after the cheese left her; it was a matter of consumer choice.

[326] Mrs Cairns confirmed that, before the outbreak, the respondents did not test the raw milk for O157 or other STEC. She agreed that the SCA Code of Practice appeared to envisage testing of raw milk cheese for both O157 and STEC, and that, in terms of the United Kingdom HPA Guidelines, the finding of either would be unsatisfactory for the purposes of the Code of Practice. Mrs Cairns agreed that the HPA's suggested actions in that situation included immediate investigation of the food origin, production process and environment, the taking of investigative food samples, and consideration of environmental monitoring.

[327] Mrs Cairns confirmed that following the issue of the FAFA in August 2016 the respondents lost their SALSA approval. The respondents were not currently in a position financially to seek re-approval.

[328] Mrs Cairns accepted that the hazard of STEC could not be eliminated in the raw milk cheesemaking process. Her cheeses were ready to eat foods of animal origin and that STEC can present a serious risk to public health. It was put to her that there was no part of her cheesemaking process that would remove any pathogenic STEC prior to consumption by a consumer. She replied that she was reducing pathogens to an acceptable level by using hygienic milk. To eliminate pathogenic STEC altogether would require the raw milk to be boiled or pasteurised.

[329] Mrs Cairns accepted that it was the legal responsibility of the food business operator to have a HACCP-based system in place, as well as to perform a risk assessment. That could be done by the food business operator, and with the assistance of consultants and environmental health officers from the applicants, with whom there was still had a good relationship. She would not necessarily look out draft guidelines like the United Kingdom Draft Working Policy on Detection of STEC (no. 6/1/150 of process). Asked whether, prior to the outbreak, she was aware of the risk which STEC presented to health, Mrs Cairns replied that she was aware of E.coli O157, and that was because of various outbreaks like the one in Wishaw.

[330] Mrs Cairns explained that she did not test the curd for either O157 or STEC. She could not test for STEC because she required a laboratory to carry out the test. She had also been advised (by, she thought, Paul Neaves, at the microbiological testing course in Newcastle) that O157 was not so relevant to ewes' milk. Obviously, she was testing for it now, because she had been advised that she should be doing so. She had also sent samples,

for stx testing by PCR, to Geneius in Newcastle (although they could not isolate an organism) and to Actalia in France (whose methods are accredited in accordance with the relevant ISO standard). The respondents did now test for O157 and STEC, although she agreed that testing did not, of itself, make a product safe.

[331] Mrs Cairns stated that she had carried out a lot of O157 testing in her laboratory since 2016 and found nothing. To the suggestion that she ought to have been testing for O157 prior to July, 2016 she said that, because the concentration was on one particular organism, it didn't tell her much about the respondents' process and how well they were doing. The applicants and FSS had said that she ought to have been testing for O157. She had not, however, contemplated testing for O157 prior to the outbreak and that STEC testing was not available to her. If the laboratory employed by the respondents had been able to do such testing, and the applicants and SALSA had told her to do so, Mrs Cairns said that she would have looked into it. However, she was relying on advice from them as well as her consultant (who was part of SALSA anyway), and her father's wealth of knowledge. The SCA Code of Practice obviously said that there should be testing for O157. But the EU Guide did not do so. Other papers didn't suggest the need for such testing. Mrs Cairns accepted, in hindsight, that it might have been sensible to test for O157 every six months, however, she was not quite sure how that could have helped. She knew a lot of cheesemakers who were not testing for O157 prior to July 2016. No cheesemaker in the United Kingdom was, as far as she was aware, testing for STEC. Prior to the outbreak, the respondents' cheeses did not carry any warnings targeted at vulnerable groups; they only directed attention to the use of raw milk. Such warnings came about in around early 2017.

[332] To the suggestion that, without testing, there was no basis for knowing how effective her CCPs were, Mrs Cairns replied that she was testing for listeria, salmonella, staph aureus

and generic E.coli, of which STEC forms a part. As long as she was reducing E.coli to as low a level as she could, that was all she could do. Mrs Cairns explained that the farm which supplied the milk (and of which her husband and she were partners) undertook the somatic cell counts in individual sheep; the respondents undertook the milk and cheese testing.

[333] In a passage of evidence heard initially under reservation Mrs Cairns was asked to comment on the certificate by Mr Beattie relating to Dunsyre Blue, batch F15. She said that the respondents did test for enteros weekly in the cows' milk. When Mr Love put to her that the level for enterobacteriaceae recorded in the certificate was very high, Mrs Cairns explained that she did send an entero result away for analysis at an SCA recommended laboratory. What was isolated was hafnia alvia, which is a culture that can be added in the cheese making process. The high levels of enterobacteriaceae did not reflect E.coli or pathogenic organisms.

[334] Mrs Cairns confirmed that Lanark Blue is matured for between six weeks to eight months, and, depending on the season, can be sold from as early as six weeks. For Corra Linn, it was four months to one year, plus. She agreed that the applicants had asked for evidence as to the safety of Corra Linn. But, in reality, there was no amount of microbiological testing the respondents could have done to satisfy the respondents because they (the respondents) had not been testing for E.coli O157. The respondents had, by then, been producing Corra Linn for six or seven years.

[335] Mrs Cairns responded to the suggestion that there was no data available to show that the maturation period (for Corra Linn) over a particular period of time might have been able to demonstrate a reduction in bacteria by saying that it was widely accepted that bacteria are not able to grow in a hard cheese medium. She confirmed that Corra Linn could go on the market from four months. She remarked that the applicants and FSS appeared to have a

particular concern about blue cheeses. This was reflected in the studies arranged for Corra Linn with Campden BRI, which Mrs Cairns agreed were helpful. The applicants had said she could put Corra Linn back on the market. What may have changed their mind was the WGS finding in relation to batch B17A, although she had sent samples to Actalia which came back negative. Moreover, E.coli levels were less than 10 cfu/g, the applicants had carried out ten PCR tests on each sample, and she had done five such tests. There were only one or two positive results, and Mrs Cairns did not know whether the E.coli which was found could have been viable.

[336] Prior to August 2016, Mrs Cairns had not looked into the availability of testing facilities for O157 or STEC. Before the outbreak she was not considering testing raw milk for either O157 or STEC. If she had been, Mrs Cairns appeared (at least at one point during cross-examination) to accept that there were testing facilities available commercially to allow that testing to be done – at least for O157. To complicate matters, when Mr Beattie's evidence (that there were test facilities available in Edinburgh and Glasgow) was put to her, Mrs Cairns replied by saying that the UKAS accreditation for ESS related only to STEC testing of beansprouts. The respondents required to run a business and needed someone to collect products and use accredited and validated methods for dairy products.

[337] Mrs Cairns confirmed that, at the time of the FSS visit in September 2016, cheese was not being produced. After the outbreak, she looked at the respondents' HACCP processes and revised them with the assistance of Jayne Hickinbotham. A revised testing schedule was offered after a meeting with the applicants on 29 November 2016. The applicants had insisted on a quarterly test for STEC. Mrs Cairns accepted that she had identified Actalia because it was the only place which she could find to carry out STEC testing. She was unclear when the Actalia methodology was produced, but it had definitely been discussed.

After July 2016, environmental health officers had spent a lot of time considering STEC. She would have expected them to have understood what the Actalia methodology involved. It would be quite clear that Actalia would only test for highly pathogenic STEC strains, and she did not have to explain their methodology to an environmental health officer. The respondents could not go and test for any strain of STEC, and she could not engage PHE or SERL. Moreover, Actalia could not test for all STEC. Mrs Cairns had asked for them to go further than test for highly pathogenic STEC for Dunsyre Blue, batch F15, but they were unable to do so.

[338] On cross-contamination, Mrs Cairns did not accept that this could have occurred on the respondents' premises. Her position was that something had happened at ESS that ought not to have happened. She explained that, although Dunsyre Blue, batch F15, and Lanark Blue, batch E24, were made and sampled on different dates, they were actually tested in the laboratory at the same time. When first tested, the samples were negative for stx 2 and positive for stx1. When FAFA-02 was issued in November 2016 the results were reversed. The applicants had over a period of months been repeatedly testing Dunsyre Blue, batch F15, in the hope of finding O157, and then it turned out that the strains from the two different cheeses were identical. All of this pointed to something going wrong in the laboratory. Moreover, if the Dunsyre Blue, batch E24, had been the source of cross-contamination, the E.coli would require to have been in very high numbers.
Mrs Cairns had, however, sent a sample to Actalia and it matched the initial stx2 negative, stx1 positive, results (no. 6/1/68 of process, pp.16-17). The stx1 positive result was not explored further because it did not identify a highly pathogenic STEC.

[339] Mrs Cairns, in re-examination, said that the E.coli in Corra Linn, batch B17A, was enumerated as less than 10 cfu/g. Actalia found nothing in that batch. PHE would not be

able to enumerate what was found using WGS. Mrs Cairns thought that the evidence pointed to there being less than one colony, if there was anything there at all. Prior to the outbreak, E.coli O157 had been on the respondents' radar, and it was mentioned in their HACCP documentation. They were not testing for it (for reasons previously explained). When the HACCP was reviewed, Jayne Hickinbotham had suggested weekly, reverting to monthly, testing of the milk for O157; this would be on the same level as other cheese makers in the United Kingdom who were then doing such testing. Finally, Mrs Cairns confirmed that the Actalia certificates (which state in terms that Actalia test for the top five pathogenic STEC) were sent, via the respondents' solicitors, to FSS. She did not think that the applicants had ever asked to view the certificates (although they were entitled to view them as part of any inspection of the respondents), did not know whether or not they had them, and could not remember the applicants taking copies. The certificates were, however, retained on the respondents' premises.

[340] I found Mrs Cairns to be an honest and candid witness. She was prepared to concede that there were grounds for the view that the respondents should have been testing for E.coli O157. I considered her evidence on the absence of testing facilities in the United Kingdom for STEC to be credible, and, ultimately, I took from her evidence that the decision to test the curd for generic E.coli was a judgment that the respondents made advisedly, in the knowledge that pathogenic E.coli required to be guarded against.

Professor Colin Fink

[341] Professor Fink gave evidence about his background and experience as a physician with a major interest in virology. He holds a post-doctoral qualification in microbiology and cancer studies, is a Fellow of the Royal College of Pathologists, and is honorary professor of

microbiology at the University of Warwick. Beyond his observations about the utility of acid shock treatment, it seemed to me that Professor Fink's brief contribution to the evidence did not depart significantly from other experts from whom I heard.

[342] Professor Fink left the National Health Service in 1995 and set up Micropathology Limited, now the largest molecular diagnostic laboratory for infectious diseases, to provide rapid diagnosis of infection. Micropathology Limited has been performing WGS for about four years, but only on a research basis. It became involved in the subject matter of the present applications by involving Actalia in France, sending samples to Actalia, extracting E.coli from some of the cheeses with a view to providing WGS information, and receiving information from PHE about the isolates that they found on testing the sampled cheese using WGS.

[343] Under reference to an opinion (no. 6/1/57 of process), Professor Fink advised that what Micropathology Limited found was exactly the same as PHE had found, namely stx2d, stx2e, stx2b, stx1c genes, all eae negative. No other virulence genes were found. Professor Fink also commented, under reference to a brief report outlining the genetic molecular methods for identifying infectious organisms (no. 6/1/161 of process), on the use of WGS for that purpose. Professor Fink's evidence was that his company extracted the cheese from samples examined by PHE, undertook whole genome sequencing on the cheese they were given, and compared their results with those of PHE. (I note that, in a passage of his report to which he was specifically taken, Professor Fink observed that both the PCR method and the sequencing of any DNA found from an organism, do not require the organism itself to be viable; paragraph 5.3).

[344] It was his evidence that the virulence potential of a bacterium can change according to its situation. Simply finding a gene was not evidence of virulence. The risk of a

bacterium becoming a pathogen is dependent on the numbers, and diversity, of other organisms that are present. The gut wall has immobilised antibodies all the way down its length, and the virulence spectrum very much depends on what the individual has been exposed to during his or her lifetime. There is now a preoccupation with anti-bacterial sprays in the western civilisation, and this is frankly disastrous. So, to find evidence of virulence in a case of illness such as bloody diarrhoea, or HUS, one would first of all see what was in the gut flora. Having found a sporadic case, the population surrounding the sporadic case should be examined in order to identify whether the same organisms were being carried. Such surveillance, however, is not routinely undertaken.

[345] An isolate, if obtained and identified, does not tell you everything about the condition of the organism because cheese itself may be inhibitory to the organism. An isolate would offer a genetic profile of the organism but it would not offer an indication of the propensity of the organism to be benign or otherwise.

[346] Professor Fink said that it is known that maturation of cheese reduces bacterial numbers. An isolate shows no more than that there were viable organisms. It is necessary to look at the genes in the organism (which is what Actalia do) and to make an assessment about its pathogenic potential in food. For pathogenicity, the current thinking is that an E.coli must carry a shiga toxin gene and an adhesion gene which is recognised to be of potentially pathogenic interest.

[347] Professor Fink expressed reservations about the validity of acidification and resuscitation of organisms as a microbiological technique (which was, in any event, a laborious process within the laboratory). He was asked about cross-contamination between Dunsyre Blue, batch F15, and Lanark Blue, batch E24, and explained that his laboratory had a very different view from public health laboratories, with a philosophy that there was no

shame in admitting to errors. In the circumstances, he entirely agreed that in the instant case re-testing of the samples would have been appropriate.

[348] On the utility of WGS, Professor Fink said that, in an outbreak situation, it was an extremely valuable tool for determining both the organism within the individuals and the organism within the food. Otherwise, it was still very labour intensive and expensive. He also said that one of the problems you have with infectious disease is the failure of the host to deal with the organism, rather than the organism itself, in the normal population, being a pathogen.

[349] In cross-examination, Professor Fink acknowledged that he was not an expert in the practical aspects of WGS, and that a colleague at Micropathology Limited, Dr Sian Davies, a geneticist, undertook the practical scientific work. Micropathology Limited had used data, for the E.coli strains identified in the respondents' cheeses, downloaded from a government publication of E.coli sequences called the NCBI SRA database. He agreed that the SERL spreadsheet results had been verified by his laboratory analysis without exception, and he did not think that any deviation had been found.

[350] Asked why Micropathology Limited became involved with the respondents, Professor Fink explained that he had heard about their "problems", became interested because he had looked at the epidemiology surrounding the original outbreak, and as a microbiologist thought what he was hearing was rather unlikely. He contacted Mr Errington and offered to help.

[351] Professor Fink did not think that, while useful in a general sense in the realm of food safety, WGS would be used for regular testing. He accepted, however, that WGS had become more common since 2013, that WGS allows for more STEC strains to be typed more

accurately, was (he appeared to accept) now cheaper, and gives rise to higher typability, than any other conventional test method.

[352] Professor Fink said that he had experienced cross-contamination in his laboratory and accepted the importance of having process controls in place.

Professor Hugh Pennington

[353] Professor Pennington qualified in medicine from London University in 1962. He is a Fellow of the Royal College of Pathologists, a Fellow of the Royal College of Physicians in Edinburgh, a Fellow of the Academy of Medical Sciences, and Emeritus Professor of Bacteriology at the University of Aberdeen, having held that chair between 1979 and 2003. He described his career experience to date by reference to an extensive CV which was lodged with the court. His particular professional interest has been in the fingerprinting of E.coli organisms and trying to establish their pathogenicity ("how nasty they are").

[354] In 1996 Professor Pennington founded the Scottish E.coli Reference Laboratory, which moved to Edinburgh in 2000. In 1996, he chaired the Inquiry into the circumstances leading to the Wishaw E.coli O157 outbreak, the report of which examined the implications of the outbreak for food safety, and the lessons to be learned. He also chaired the Public Inquiry into the September 2005 E.coli O157 outbreak in South Wales.

[355] Professor Pennington is currently Vice President of the Chartered Institute of Environmental Health, which is an association of environmental health officers and food safety officers. His involvement extends to giving presentations based on his personal experience of food safety issues. He has a similar role as Honorary Vice President of the Institute of Food Science and Technology, which is similar to the Chartered Institute but whose remit is slightly broader in the sense of involving businesses and food safety

regulators. In 2013 Professor Pennington was appointed CBE for services to microbiology and food hygiene.

Professor Pennington's Report on Lanark Blue, batch E24

[356] Under reference to the first of three reports prepared by him (no. 6/1/59 of process), dated 11 March 2017, Professor Pennington explained what STEC are, how there are many different STEC, and how the shiga toxin is related to a toxin produced by shigella, which is an organism that produces dysentery. In the United Kingdom E.coli O157:H7 has been the dominant STEC in terms of causing food poisoning but, as the years have rolled on, other STEC have emerged, and different countries have had different experiences with STEC. The United Kingdom is notable worldwide for having more human cases of E.coli O157:H7 STEC than anywhere else, except perhaps Canada. For unexplained reasons, Scotland has the unenviable reputation of being the country with the highest number of E.coli O157:H7 cases of food borne infection anywhere in the world.

[357] Other STEC, which go under the name of the O and H surface antigens, have been more common in Europe (e.g. O26, O103, O145, O111, and O104). Scientists are learning more about STEC as diagnostic methods improve, and investigative methods become more assiduous. But it still remains the case that E.coli O157:H7 is the only STEC known to have caused a food borne outbreak in Scotland. Moreover, STEC is not purely a food borne type of infection. In Scotland, about half of the cases of infection with STEC are environmentally acquired.

[358] For E.coli O157:H7 to cause harm, the organism has to stick to the lining of the intestine. It has a very sophisticated mechanism for doing so, involving various genes, one of which injects protein into the cell that lines the intestine to create a sticky part, to which

the organism (using another molecule) adheres, and where it remains, producing toxin, for probably not more than a few days. The toxin produces local damage which causes diarrhoea and, in a significant minority of cases, bloody diarrhoea (thought to be caused by the toxin killing gut cells and perhaps infecting small blood vessels). The attachment to small blood vessels is also thought to cause the distant effects of the toxin, where it gets from the intestine into the blood stream. How that occurs is not understood, but the toxin is probably transmitted in the white blood cells, and moves round to the kidneys. This can lead to the complication of HUS, to which children under five are particularly prone. It was Professor Pennington's view that there must be some mechanism for the E.coli to attach to the gut for long enough for the toxin to produce its effects.

[359] STEC can pass from a carrier to a food through faecal contamination, to prevent which it is crucial to have control measures in place. Professor Pennington visited the respondents' business premises in March 2017 and saw the controls which were in place. He saw from the sheep flock through to the end product.

[360] Professor Pennington described a range of methods by which E.coli O157 has been identified, mainly in patients. Where food is concerned there are ISO methods. It would be appropriate for food business operators to test raw materials or end product using an ISO method (and for the resulting reports similarly to follow ISO methodology). Currently the major use being made of WGS was in looking at different organisms isolated from a group of patients to see if they are part of an outbreak, and making a microbiological link between them. WGS has a very high degree of discriminating power. Professor Pennington had been very interested in it for many years, and its applicability, speed and cost meant that it was being much more widely used.

[361] Professor Pennington explained that a virulence plasmid is part of the genome of an organism, and plasmids can move about from organism to organism. He observed that finding the stx gene DNA may just indicate a bacteriophage which is of no medical consequence. A bacteriophage cannot infect people and the consensus view is that a stx gene would require to be found in a live organism to be of any food safety consequence. Finding a stx gene by PCR in itself would not be a cause for finding food unfit to eat, and it would be necessary to go further than that and isolate the organism and check it for the stx gene. Even then, it does not mean that the gene will express toxin, but it is a warning signal that more investigations should be conducted.

[362] Professor Pennington referred, at p.5 of his report, to examples of STEC outbreaks in Europe associated with raw milk cheese, and confirmed that none had been connected to a raw ewes' milk cheese.

[363] Professor Pennington then discussed the finding of a STEC in Lanark Blue, batch E24. His impression was that very hard work had been required in order to find the organism. He contrasted this with the Wishaw outbreak, where there had been no difficulty in finding cultures of O157 in the food. This suggested that the organisms in the Lanark Blue, batch E24, were in very small numbers. According to Mr Beattie's certificate the number of E.coli was less than 10cfu/g, of which the number of STEC would almost certainly form a small minority. So, while accepting that there was no quantification available from the original sample, the number of STEC organisms would have been very small. Professor Pennington was also aware that acid shock treatment had been used on this sample. He explained that its purpose was to kill off competing organisms, in a mixture of organisms, so that it was easier to find an organism as a minority component.

[364] Section 7 of Professor Pennington's report referred to the finding in Dunsyre Blue, batch F15, of the same STEC organism as that isolated from Lanark Blue, batch E24. His opinion was that it was highly unlikely, and biologically implausible, that the herd of cattle at Lesmahagow, which supplied the respondents, and the geographically distant flock of sheep at Walston Braehead, were both carrying the E.coli O unidentified H2 stx 2d positive strain at about the same time, that being an E.coli strain never recorded before in Scotland or anywhere else in the world. He ruled out, as a source of the organism, both the flock and the herd. He said that the strain had unique characteristics, and there had to be some other explanation for the finding.

[365] Professor Pennington said that an explanation for the two strains being identical would have to look at labelling errors in samples, or problems of cross-contamination in the laboratory. He knew that these kinds of errors did happen. To the suggestion that the Dunsyre Blue might have been contaminated by, or contaminated, the Lanark Blue cheese on the respondents' premises, he responded that all he could say was that, in his experience, and having visited the premises this was unlikely, although he had not seen the cheese manufactured because it was not going on at that the time when he visited. There would have to have been a major breakdown for this to have happened. He noted that there were different bulk tanks and delivery pipes for cows' and ewes' milk. He also made the point that, before the cheese making process begins, the vat to which the milk is delivered is disinfected and also heated to a temperature, and for a time, that exceeds those achieved during pasteurisation. Thus, any organism in a biofilm on the surface of the vat would be killed off before the cheese making process commenced.

[366] In conclusion, Professor Pennington was of the opinion that, with so much uncertainty surrounding the evidence that Lanark Blue, batch E24, failed to comply with food safety requirements, no such conclusion should be drawn.

Professor Pennington's Report on Lanark Blue Remainder

[367] Professor Pennington's second report (no. 6/1/61 of process) concerned eighty three batches of Lanark Blue which had been certified by Ms Wardrope, on 3 February 2017, as having not been produced, processed or distributed in accordance with regulation 27 of the 2006 Regulations. The summary application B21-17 makes reference to the finding of STEC in batches of Dunsyre Blue and Lanark Blue, batch E24. It also makes reference to the finding, in batches of Lanark White, of a stx negative E.coli gene, namely 0157:H42, stx negative, eae negative, which Professor Pennington, Dr Dallman and Dr Scheutz (although not, it would seem, Mr Beattie) agree is not a STEC, and is non-pathogenic (or, as Professor Pennington put it, a "bog standard E.coli").

[368] Professor Pennington said that he was unable to find any evidence that raw ewes' milk cheese had ever caused any outbreak, either in the United Kingdom or Europe. Considering the thousands of tonnes of such cheese produced annually, this was of importance. It was his understanding that the respondents (or their predecessors) had been producing Lanark Blue, without any associated illness being linked to it, since 1982. STEC outbreaks are more likely to be investigated than any other food poisoning because of the potentially fatal, or life-changing, consequences of infection. He described the paradox of STEC occurring in sheep, which led him to think that there is a block between STEC in the sheep's intestines and the organisms appearing in the final cheese product. Surveys in Europe have quite readily found STEC in a small percentage of cheeses. The absence of any

evidence of disease associated with the consumption of those cheeses led Professor Pennington to conclude that those STEC were non-pathogenic.

[369] Professor Pennington considered the controls which he had seen evidenced at the respondents' premises and the farm relative to animal husbandry and the production of ewes' milk. He formed the view that everything was being done that could conceivably be done to achieve the lowest possible level of bacteriological contamination. The parlour itself was state of the art. The curd testing results for E.coli for March to July 2016 (in relation to seventy six batches of Lanark Blue) showed very low E.coli numbers. All but one of the results showed were less than 10cfu/g, which is below the level of detection. This showed that the respondents' processes were working. The witness did not consider that the ewes' milk produced at Walston Braehead could reasonably be expected to be contaminated with pathogenic organisms. In his opinion, the milk could reasonably be expected to be free of such organisms.

[370] With regard to the capacity of STEC to survive the cheese making process, Professor Pennington said that he was aware that a number of food authorities had placed weight on a raw cheese maturation period of several months as a measure of what would deliver a safe product and that Lanark Blue matures for up to eight or nine months at five degrees centigrade. He thought that the Food and Drug Administration of the United States looked for a maturation period of sixty days for cheese made from unpasteurised milk.

[371] Turning to STEC testing, Professor Pennington confirmed that he had looked briefly at the respondents' HACCP documents for the period prior to the summer of 2016, and had found them to be satisfactory. In particular, he considered the HACCP Plan for Critical Control Points, dated 1 March 2016, (no. 6/1/37 of process) to be comprehensive, in the sense of covering the important hazards facing the respondents' business. On the question of the

appropriateness of testing for E.coli O157 specifically, Professor Pennington said that it was difficult to answer. It could be done by testing the milk**.** It would be preferable to test the animals but the feasibility of doing so was debatable, and milk testing was obviously straightforward, it would be logical to include E. coli O157:H7 in a regime where other pathogens are tested for**.**

[372] Professor Pennington concluded, however, that the evidence did not support the orders sought in the summary application where Lanark Blue Remainder was concerned. That conclusion was based on (i) uncertainty over the origin of the STEC organism attributed to Lanark Blue, batch E24; (ii) doubts, in the absence of the eae gene, about the pathogenicity of that organism, and (iii) the likelihood that the procedures adopted by the respondents would reduce very substantially any significant contamination in the raw milk, and (allied to that) the evidence, from the test results, that the ewes were not carrying pathogenic organisms.

Professor Pennington's Report on Corra Linn

[373] Professor Pennington's third report (no. 6/1/62 of process) concerned all batches of Corra Linn seized by the applicants and which had been certified by Ms Wardrope as having not been produced, processed or distributed in accordance with regulation 27 of the 2006 Regulations. Professor Pennington was asked to comment on the microbiological evidence supporting the proposition that, by reason of microbiological contamination rendering the cheese unsafe, (for the purposes of article 14 of Regulation (EC) 178/2002), the batches of Corra Linn were a risk to health and failed to comply with food safety requirements.

[374] Professor Pennington was struck by the large number of tests which had been carried out on a product which had not been associated with any illness. Measured even against an outbreak situation, Corra Linn had been subjected to a remarkable number of tests (one hundred and sixty samples from thirty two different batches were recorded by Professor Pennington; a figure not disputed).

[375] On p.4 of his report Professor Pennington recorded that "there is a scientific consensus that the production by E. coli of stx alone is insufficient for a strain to be pathogenic and for it to cause illness". In evidence he rowed back from that statement in acknowledging that there were other scientists who might disagree with him. However, that was his view, and he adhered to it. He had not seen publications showing unequivocally that an E.coli with a stx gene on its own was pathogenic, and he believed that other scientists agreed with him.

[376] Subsequent to the preparation of his report, Professor Pennington had obtained information about the WGS results for certain of the Corra Linn samples. The results showed that no other virulence genes were present. As far as he was aware, none of the three Corra Linn STEC strains had been found in clinical cases in Scotland, at least in terms of being recorded in scientific literature. That was not to exclude the possibility that a laboratory somewhere had found it, and not recorded it.

[377] Professor Pennington confirmed that the absence of other virulence genes strengthened his opinion that no definitive microbiological evidence had been presented of the presence of harmful organisms in Corra Linn cheese, and that the proposition that the cheese was injurious to health had not been made out. In particular, Professor Pennington commented on the finding of E.coli O153-O178:H7, stx1c positive, eae negative, ST278. His

position was that this kind of E.coli had not been recorded as being able to cause disease, and that this strain was more likely to be harmless than pathogenic.

[378] He was referred to the results of the microbial survival predictions undertaken by Campden BRI (B33-17, no.7). His evidence was that the graphical information provided by Campden BRI showed that, for batch B17A, a millionfold (or 6 log) reduction in bacterial numbers would occur in 187 days. There were a range of results in which other batches were measured against different conditions of temperature, water activity and acidity, but the results were consistent with a sustained decline in the number of E.coli O157, with a reduction, in over twelve months, that would be significantly greater than a millionfold reduction. A millionfold reduction would be considered by a microbiologist to be a very significant decrease in bacterial numbers, particularly in the context of contaminated food. Professor Pennington described it as the sort of reduction one would be getting after pasteurisation.

[379] When asked whether pasteurisation eliminates STEC completely, Professor Pennington replied that it does eliminate O157:H7. There are bacteria that will survive pasteurisation but, generally speaking, those are not considered to be pathogens. End product testing is a means of checking food for microbial contamination. However, it has been largely overtaken by HACCP because it is impossible to test every meal before it is consumed. Occasional sampling should be carried out in order to check that a system was working. When asked whether testing for indicator organisms, such as E. coli, is appropriate, he replied "absolutely, yes".

[380] Finally, Professor Pennington adhered to his conclusion that the evidence relied on in the application B33-17 rested solely on incomplete scientific evidence regarding the possible pathogenic potential of three different E.coli strains, each isolated from a single batch of

Corra Linn, being strains that have never been shown to cause disease. The absence of any other virulence genes, after WGS was carried out, confirmed his view that the orders sought in the summary application were not justified.

[381] Professor Pennington was referred to his discussion with Professor Griffith. He pointed out that finding most of the four hundred (or so) STEC would be very difficult and would likely require the use of WGS. It would, however, be completely inappropriate for food producers and enforcement officers to contemplate using WGS on a routine basis. Both witnesses agreed that there was no specific requirement in article 5 of Regulation (EC) 852/2004 for a food business operator to test raw materials or the finished product, but rather a general requirement to design and implement a safety management system based on HACCP principles. How it was generated and implemented would be the responsibility of the food business operator, if necessary in consultation with an expert.

[382] Both witnesses agreed that there could be an implicit requirement to test raw materials for pathogens. Asked, in this context, about the appropriateness of E.coli indicator testing of the raw milk, Professor Pennington said that E. coli were not necessarily pathogens, but they would give an indication as to whether or not there was contamination. If the E. coli figures went right up, that would not necessarily indicate that a pathogen was present, but it would be a red light for further investigation. Professor Pennington also observed that, while Professor Griffith favoured testing of raw milk for E.coli O157, or other STEC, the only STEC recorded as having been contracted from food in Scotland was E.coli O157:H7. None of the stx positive strains identified in the extensive testing of the respondents' cheeses would have been detected using current food testing systems.

[383] Professor Pennington was then referred to p.2 of the joint report in connection with the experts' views on cross-contamination. In his view, Professor Griffith, who preferred an

explanation for the Lanark Blue/Dunsyre Blue result based on cross-contamination on the premises, was drawing on his experience of cross-contamination which was easily detected by a short inspection in poorly designed premises. The respondents' premises were quite different. There had been no swabbing of the premises to support Professor Griffith's views. Professor Pennington had the advantage of having been to the premises. He was confident that any swabs in the common vat would have been negative because of the heating process which kills any biofilms stone dead.

[384] He was then referred to his joint report with Dr Dallman. He adhered to the position that there was no evidence that E.coli O unidentifiable: H20, stx2d, ST1308, was pathogenic. The comparison with a Spanish E.coli O157:H7, stx2d, eae positive, isolate, (apparently contained within Dr Dallman's "WGS Summary" which the court has not seen), was inappropriate. The two strains were quite different. He remained of the view that, in the absence of any other virulence genes, the three strains found in Corra Linn should not be considered pathogenic. Dr Dallman had provided him with no clinical details of the patients mentioned in support of his view that the strains have the potential to be pathogenic.

[385] Professor Pennington also explained that caution was required in attributing pathogenicity to an organism just because it had been found in the stools of a patient who is ill. That was why he had cited, as an example, Aeromonus, which has been found in the stools of patients but is not looked for in routine laboratories, and is probably considered by the majority of microbiologists not to be a pathogen.

[386] Turning to his Joint Report with Dr Scheutz, Professor Pennington's response to Dr Scheutz' evidence, that eae negative strains were quite common in clinical isolates, was that he would like to see more information regarding the clinical conditions of which

patients were complaining, and whether there had been tests for other virulence factors. He would attach a degree of weight to whether or not a strain had actually caused an outbreak because it was an indicator of pathogenicity. That was relevant to the Danish cases of E.coli O153/O178:H7, stx1c (isolated from Corra Linn, batch B17A), which were cited by Dr Scheutz and considered to be sporadic, rather than part of an outbreak. Sporadic strains which did not cause an outbreak supported his view that this strain should not be considered pathogenic.

[387] Both Professor Pennington and Dr Scheutz agreed that the strain in Lanark Blue, batch E24, had not been isolated from humans. He considered Dr Scheutz to have a very aggressive sampling methodology. It was significant that he had not found a strain in patients. Professor Pennington was asked to comment on the reference to "preliminary data" from Danish patients (said, by Dr Scheutz, to indicate a significant increased risk of HUS in patients infected with stx2d STEC, regardless of serotype). He replied that he would like to see the data to which Dr Scheutz was referring. The difficulty was that it had not been published in any peer reviewed literature, or at a scientific conference, and it would be relevant to know how many strains were looked at, and how many virulence genes were identified.

[388] Professor Pennington continued that the stx2e gene was not regarded as particularly pathogenic. It may have been isolated from patients where there was a suspicion of disease. But, generally, most of the isolates have been from pigs; it was not routine in terms of following up patients with diarrhoea, and, as far as he knew, it had not been found in patients with HUS. Even if it was pathogenic, it was very much at the bottom end of the pathogenicity spectrum, even with other virulence factors present.

[389] In any event, it was significant that, unlike the Corra Linn strain, many of the Danish strains, referred to by Dr Scheutz at p.3 of the joint report, had virulence genes (and, in particular, lpfA). The reference to a case of HUS in a 65 year old Swiss patient with a stx2e, eae positive strain, did not assist because the Corra Linn strain had no eae virulence factor.

[390] In relation to Dr Scheutz's opinion that stx2b positive STEC strains (isolated from Corra Linn, batch E23A) should be considered diarrhoeagenic, Professor Pennington felt it significant that many of the strains referred to in support of that opinion had additional virulence genes. If patients are asymptomatic and have long-term carriage, that would suggest that the strains are more like non-pathogenic E.coli. It would be very important for him to see the clinical data. The information was incomplete and much more data would be needed to be able to draw any conclusion that this strain was pathogenic. He referenced the 2015 Japanese study, which had been referred to in Dr Scheutz' evidence, in relation to food handlers and care centre employees, to illustrate the point that having stx in an E.coli did not necessarily mean that the strain will cause disease. That, as far as he was aware, was the only study of any size which has looked into the finding of stx positive strains in healthy individuals.

[391] With reference to twelve Danish patients being positive to O178:H7, stx1c, (joint report, p.3) Professor Pennington commented that he would want to know what other virulence factors were present in those strains, and that information had not been provided to show whether it was comparable with the Corra Linn, batch B17A, strain. The recent study suggesting a link between stx1, eae negative, isolates and long term gastro-intestinal symptoms Professor Pennington awaited with interest. He confirmed that he still doubted whether strains with stx1e, b, or c, as their sole virulence factors, were pathogenic.

[392] Mr Errington canvassed, with Professor Pennington, Dr Scheutz's belief (as I understood it) that his approach was to look for evidence of pathogenicity, whereas Dr Scheutz was willing to say that the finding of STEC strains themselves provided circumstantial evidence that a food might be unsafe, adopting a prudent and cautious approach. Professor Pennington thought that Dr Scheutz's approach to the precautionary principle, which reflected his discipline as a microbiologist, meant that you could act on insufficient evidence, or no evidence at all, on the basis that there *might* be a problem. For the purposes of food regulation, that was a step too far. Testing for more than four hundred different STEC (many of which have been shown not to be pathogenic) was very difficult. It would be expensive, time consuming, and impracticable to use WGS and then await analysis of the results. Rather, it was necessary to have tests available in real time, validated by the international food safety community. There was uncertainty in that technological advances only increased the uncertainty. He agreed that the precautionary principle, which is essentially used by decision makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data (a reference to the Communication from the Commission on the precautionary principle; no. 6/1/154 of process, p.2, paragraph 4).

[393] So, there was a distinction to be made between scientific caution and food safety considerations, and that was the whole basis for carrying out food safety risk assessments. In assessing the risk of an uncertain pathogen one would consider the microbiological information available, and the history of the organism – what it had been doing in the past was very important. Once the organism had been isolated from an outbreak, and characterised, one could then begin to understand how it caused disease. Epidemiological evidence would, depending on its strength, be beneficial. Professor Pennington would

include in a risk assessment the absence of reports of illness arising from ewes' milk cheese, and those who are likely to be consuming it.

[394] During cross-examination various propositions were put to Professor Pennington for comment. His response to the proposition that STEC is one of the most serious gastrointestinal diseases in terms of outcome in the United Kingdom and the western world, was that the proposition applied to some, but not all, STEC, citing as examples O157, and other virulent strains like O26 and O111.

[395] Professor Pennington agreed that shiga toxin presents challenges in terms of dealing with the moving target new emerging E.coli that become STEC because they can acquire a toxin from other bacteria. He was, however, unsure of the accuracy of the proposition that diarrhoea and HUS have been caused by E.coli containing shiga toxin without any known adherence factor. Normally, apart from eae, virulence factors are not looked for. Looking for other virulence factors has only arisen in the last couple of years. It was put to him that, if virulence factors were not identified, it could not be known if they were present or not. Professor Pennington agreed. Matters were, he said, becoming better understood especially though WGS. It was, he agreed, not "a closed shop", there would certainly be developments, but it was uncertain where developments would lead in terms of evolution.

[396] Professor Pennington agreed that technology had assisted in identifying new stx variants, and that WGS was a significant step forward. When it was put to him that Dr Dallman had said that he had seen clinical cases of diarrhoea with stx and with no known adherence factors, he replied that he was not aware of any publications to that effect.

[397] Professor Pennington agreed with Dr Scheutz that there were many different variants of the stx2d gene. He also agreed with the proposition that, where there is scientific uncertainty, it is necessary to see matters in a historical perspective. He said that one always

looks at strains which were isolated in the past to see whether they have changed. With the precision of WGS, more differences were being found, so there was a more precise way of typing. New strains may be emerging; alternatively, some STEC may have been there all the time but were not seen because the technology was not available.

[398] Professor Pennington agreed that there were multiple stx variants, and their number may have to be extended with the passage of time. He was not aware (any more than the Court) of Dr Scheutz's table of more than 300 patients with eae negative strain illness. He had, however, assumed that, because the strains were eae negative, and the system he understood Dr Scheutz to employ looked at eae and stx as combined factors to determine pathogenicity, there was no point in asking for further information. Besides, Dr Scheutz noted in the joint report (p.3) that not all the stx2b strains had been subjected to WGS. When asked whether there was a lack of knowledge of the factors that allow E.coli to colonise and persist in the human gut, Professor Pennington preferred the view that we need to know more about why certain people carry certain strains.

[399] Professor Pennington said that he had not asked Dr Scheutz for more data because he felt that he had sufficient information on the position in Denmark to agree a Joint Report. However, he considered the situation in Denmark to be different to what happened in Scotland. The point which Professor Pennington wished to stress was that the data relied on by both Dr Scheutz and Dr Dallman are concerned only with clinical isolates from patients, not from food or from individuals who are not ill. He had not asked for more information from Dr Dallman because Dr Dallman was not a clinical microbiologist and would not, therefore, be able to advise on the clinical background of the patients. PHE would be sent isolates from another laboratory for WGS. A report might contain some clinical information; at other times it would be brief.

[400] Professor Pennington did not agree that, in the Scottish context, there had been too much focus on E.coli O157, and the eae gene. Although STEC were still evolving, O157 still remains a very important focus, and is the dominant strain. Although other STEC have appeared in Scotland they have not appeared in food borne outbreaks. He agreed with Dr Scheutz that we do not have a complete picture of how many different types of genes can colonise and persist in the human gut. Looking at serotypes, although in one sense old fashioned, was still useful in very preliminary investigation.

[401] Professor Pennington agreed that the presence of a STEC is considered to be confirmed when one or more stx genes are detected in a cultured E.coli strain, and that the main source of STEC is in the intestines of cattle and sheep. Ultimately, the presence of a confirmed STEC is evidence of initial faecal contamination, and that if 'good' E.coli can find their way into a raw ingredient and final product, so too might harmful E.coli strains. He accepted that a test for E.coli did not distinguish between pathogenic and non-pathogenic E.coli, but subject to the important rider that such testing looked for more than just the presence of E.coli. It looked for the amount, such that very small amounts would probably go without any kind of warning; large amounts would be taken as prima facie evidence of faecal contamination. Professor Pennington accepted that STEC can contaminate raw ewes' milk; that STEC may be a hazard in ewes' and goats' milk, and that some types of E.coli produce toxins that can cause serious illness, O157 being highly infectious.

[402] The number of O157 organisms required to cause potentially fatal infection is very difficult to assess because it cannot be tested in humans. It was Professor Pennington's evidence that it is necessary to look at outbreaks to ascertain the number of organisms in the food which cause outbreaks. A reasonable estimate from these studies is that the number of organisms is less than a hundred. It may be less than that, fifty has been quoted, as has ten.

There is, however, general agreement that the dose required is very low compared with other pathogens which cause gastroenteritis.

[403] Professor Pennington agreed that certainly O157:H7 is a STEC; that not all STEC cause illness; that most E.coli serotypes are harmless; that most E.coli strains are part of the normal flora of the gut and benefit their hosts; that the main virulence factors for STEC are stx positive genes (although he qualified this by saying that this is not sufficient); that certain stx subtypes are more commonly associated with clinical illness than others; that in the summer of 2016 the respondents' cheese making process utilised raw milk from cows and ewes; that it was used in the production of cheese as a ready-to-eat product, and that (agreeing with Professor Strachan) STEC and similar E.coli can survive the artisan cheese making process.

[404] When it was put to him that the presence of STEC in raw milk used for the manufacture of raw milk cheese should be prevented or eliminated, Professor Pennington said that he would qualify that by saying that it should be particular strains of certain STEC, known to be pathogenic. It was upon those that a cheesemaker should concentrate in constructing the HACCP plan. By "known to be pathogenic", he was referring to the food safety authorities, who carry weight, and these could include FSA, FSS, and the HPA.

[405] Professor Pennington agreed that control and prevention of contamination with pathogens are of primary importance in ensuring health, and that food business operators should ensure that their systems and procedures are capable of preventing the contamination of food with pathogenic STEC, and especially E.coli O157:H7. Food safety authorities or bodies would be providing information in relation to pathogens, and he would also include in that the Codex Alimentarius, European authorities, and international bodies who play a very significant role. Food business operators should have regard to the

advice of United Kingdom agencies, whose advice would be very significantly directed by European authorities. He would expect a responsible food business operator to pay attention to guidelines, have regard to, and generally follow, the recommendations of their advisory body.

[406] Asked, once again, about the level of uncertainty associated with the risk of STEC in food, Professor Pennington said that O157:H7 had come out of the blue in the 1970s/1980s, and it is reasonable to suppose that another similarly dangerous organism might appear in the future, and that it would be reasonable to expect new developments in terms of both stx and other virulence genes. Picking up on the German O104 outbreak in 2011, which underlined the issue of scientific uncertainty, he said that there should be good surveillance programmes which were cognisant of developments in other countries (by whom such programmes should be undertaken, and in what way, was not explored with the witness further).

[407] Asked if there was a single combination of markers that defines a pathogenic STEC, Professor Pennington replied that the organism must produce a stx toxin, and there must be the virulence factors which help the organism to stick to the gut wall. He agreed that there was no single trait of a STEC that can be used to assess the public health risk of its presence in the food chain, because, in his opinion, more than one factor is required for the organism to be able to cause damage. He was asked whether it was logical to include testing for E.coli O157 in a HACCP regime and replied that it depended on the product. For a business such as that of the respondents, his preference would be to test the animals, but it is easier to test the milk. If it is not present in the milk, the milk is safe, and testing the milk would show that, even if the animals were infected, the milking procedures had reduced it to a level that prevents the organism entering the milk.

[408] Professor Pennington explained the circumstances in which STEC from a shedding ewe does not find its way into the resulting raw milk, and related that to milking procedures which prevent contamination of the milk, udder cleanliness, and, generally, other hygiene measures. Even from an animal shedding large numbers of STEC, contamination of the milk would probably only happen infrequently because one would require faecal contamination of the udder which was not noticed by the milker. The contrast was with a milker who had no care for udder hygiene, and was milking with dirty hands which had been fouled by manure.

[409] Professor Pennington was asked whether a test for E.coli O157 would pick it up and replied that, generally speaking, tests are sound and reliable – the absence of finding an organism does not mean that it is not there but, if it is not found, it is good evidence that it is not there. He agreed that if testing does not take place, the operator would not know. While they will not prevent or eliminate E.coli O157, milking measures and techniques will substantially reduce the likelihood of an organism, if present in the animals, getting into the milk.

[410] Professor Pennington agreed that a food business operator should be reviewing its HACCP from time to time, if necessary in light of comments made by the local regulatory authority which inspected the HACCP procedure and passed comment on it (if thought to be falling short). He also concurred in the view that a HACCP plan should be validated (ie. proven to work initially) and it should establish procedures to ensure that measures are in place to demonstrate that the control measures are working effectively. It was put to him that having identified raw milk in their CCP, it was important for the respondents to verify that the HACCP was working, and that the milking technique was working, by testing. He responded that this was correct, and that record keeping would include hand washing and

other prerequisites. Whether microbiological testing and trend analysis would allow for review of their testing schedule was, however, a matter of judgement for the food business operator. It was likely that the value of microbiological testing would be to act as verification that control measures were working effectively.

[411] Professor Pennington's view on human susceptibility was that, while not completely understood, there was a robust scientific consensus that extremes of age (ie. young children and the elderly) are an important risk factor, and there were other factors which may be as yet unknown and unidentified. There is variability in the pathogenicity of different strains of STEC, and uncertainty about infective dose.

[412] Professor Pennington's view was that cross-contamination within the processing facility was much less likely an explanation for the Lanark Blue, batch E24, result than the other possibilities, and the probability of that having occurred was very low on the basis of what he had seen in the business. He agreed that the risk of cross-contamination ought to be identified by the food business operator, and should be considered from the point of view of transfer of milk from the tanker into the vats, and all parts of the process and premises.

[413] Professor Pennington agreed that the ages of the Corra Linn batches, at the point when they were microbiologically tested, ranged from between six months and a year.

[414] In re-examination Professor Pennington agreed that it was not possible to guarantee the elimination of STEC; that many food products on the market contained STEC, and that the results of the microbiological testing of their cheeses represented a relevant validation of the respondents' assessment of finding O157 as low risk. When it was put to him that the HACCP had been approved by the environmental health officers, he said that, as part of his regulatory duties, an environmental health officer would be expected to look at a HACCP plan and pass comment on it, either in terms of approving it or alternatively entering into a

discussion with the food business operator in order to ensure food safety. He agreed that the young and very old were most susceptible to E.coli O157. His evidence was that it was appropriate that the food business operator should draw the attention of the buyer to that risk and, on being referred to the labelling for Lanark Blue (no. 6/1/157 of process), agreed that this was the sort of information which a responsible food business operator should be including in such a product.

[415] Finally, Professor Pennington re-iterated that current systems for testing for STEC focus exclusively on E.coli O157 because there are approved and readily available testing systems for that particular organism. The STEC which were isolated from Corra Linn would not have been detected because they did not fall within that category of organism.

[416] Professor Pennington brought a wealth of experience to the issues he was asked to consider. There were particular aspects to his evidence (principally, the importance of historical epidemiological evidence, and the significance to be attached to the absence of virulence factors) on which I may have taken a different view. However, much of Professor Pennington's evidence I otherwise accepted, and he plainly had the relevant experience to speak to the matters covered by his reports.

Dr Richard North

[417] Dr North holds the Diploma of the Public Health Inspectors' Education Board from South East London Polytechnic (1974), and a PhD from the Leeds Metropolitan University (1995). His doctorate was concerned with an investigation into the quality of food poisoning surveillance in England and Wales, in which the then systems in Scotland were used by him as a comparator.

[418] Dr North described qualifying in 1974 as a Public Health Inspector with Croydon LBC, moving to a position as District Inspector with the Metropolitan Borough of Calderdale, and then, in 1976, to the position of Specialist Food Inspector. In 1977, Dr North launched what was, according to him, the very first independent food safety/hygiene consultancy, in association with which he has acted as a specialist adviser to (amongst others) the SCA, and this involved him in inspecting, and assisting, cheese plants across the country. He maintained a (more or less) full time consultancy up to 2000, and gave evidence to the Wishaw E.coli Inquiry. He said that he had also given evidence in an earlier case involving Lanark Blue cheese.

[419] Dr North described setting up one of the first HACCP systems in the country for a school meals project in Bradford. He had toured the United Kingdom, and also Holland and Belgium, discussing the relative merits of HACCP. He had been employed as a European Parliament Researcher, working for a political group. Now, the main core of his activities involved acting as advisor and mediator for food business operators who were concerned with compliance with food regulations. He also described having been, until two years ago, a personal adviser to the Secretary of State for the Environment, in which capacity he provided advice in respect of horse meat. Since August, 2016, he had been briefed, and become acquainted with, the circumstances of the present applications.

[420] For completeness, I should record that Dr North's CV was lodged as a production and discloses a remarkable range of areas of interest, in so far as disclosed by the variety of papers and publications, some of which bear to be focussed on food safety matters, while others quite clearly range into the political field. There was produced in advance of the proof what was described as a "Proof of Evidence" which set out the essence of Dr North's evidence. In that document he described himself as "a food safety consultant with forty

years' experience in food safety and related matters, in later years concentrating on law enforcement, political and legal aspects of food safety as part of [his] general practice of political researcher and analyst". It also recorded that Dr North had not undertaken field consultancy in food premises since the mid-2000s.

[421] Dr North's evidence was that the presence of pathogenic material was not *per se* the trigger for its unfitness. A qualitative assessment should be carried out, and the number of pathogen left in the food, after processing, must be sufficient to cause illness. Such was the importance (as I understood his evidence) of the words "to such an extent" where they appear in Regulation (EC) 852/2004, Annex II, chapter IX, paragraph 1, which words are missing from the regulation 27 certificate issued by Karen Wardope on 3 February 2017 for the batches of Lanark Blue Remainder. The level of contamination should be assessed, and the effect of processing taken into consideration. The process of cheesemaking involves the destruction of organisms and this, he said, could be seen from the Campden BRI predictions. Dr North said that he had considered the evidence regarding the recovery and testing of the microbiological organisms. It was his view that the original number of organisms must have been extremely small because of the effort required to find them. It was entirely reasonable to expect that a tiny number of organisms would be substantially reduced if they were pathogenic. The assertion in Ms Wardrope's certificate that the steps taken by the respondents would not have reduced the original burden of pathogenic micro-organisms to an acceptable level was not proven. On the contrary, the steps taken by the respondents would be expected to produce a safe product free from any material contamination. The presence of microbiological organisms was entirely normal in food products and, short of sterilisation, they cannot be eliminated from foods completely (or, for that matter, the

environment). There was no requirement on a food business operator to aim for zero risk. E.coli were part of the normal flora of the food eaten every day.

[422] From the reports of generic E.coli levels he had seen, Dr North considered that the amount of STEC, as a proportion, would have been "vanishingly small". Under reference to paragraph 4 of his report (as to what constitutes a breach of regulation 27 of the 2006 Regulations) Dr North again wished to emphasise the words "to such an extent" in the abovementioned provision of EC Regulation 852/2004. The aim was to maintain the microbial burden well within safety parameters, such that subsequent processing will easily deal with that burden and neutralise it for the purposes of public health and product quality. Any responsible cheesemaker would understand that the cheese making process involves a substantial reduction in microbial burden, which is why stringent precautions are taken to ensure milk cleanliness, quality of animal and equipment, and (with the emergence of HACCP) the instigation of systematic checks to ensure that the processes are in place and are being properly carried out.

[423] Dr North expressed the view that the effect of article 1 of Regulation (EC) 882/2004 was to change the traditional base of food safety law, in that it brought the enforcement authorities into the process, made them co-responsible for compliance with the law, and required them to attest that the premises and operations of a business were in compliance with the law such that its product was suitable for placing on the market for free circulation within the entire EU. Indeed, Dr North went as far as to observe that the enforcement officer of the local authority was the only person who could decide whether a HACCP procedure conformed with the law because it was that officer who would decide whether the business was given the EU establishment number, without which it could not trade.

[424] It was in that context that Dr North considered the regulation 27 certificates issued by the respondents to reflect a retrospective judgement, which he found bizarre because the applicants had previously approved the respondents' HACCP (and the respondents would have been entitled to believe that their operations complied with the food regulations). It was, in Dr North's experience, a situation without precedent.

[425] Dr North was referred to the Guidance on the Implementation of articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) 178/2002 (no. 5/1/72 of process). Referring to the phrase "once a hazard is identified which may make food injurious to health, an assessment of the associated risk shall be carried out" (which appears at p.8), Dr North considered this to be crucial to the whole idea of modern food safety management. Hazard and risk tend, as concepts, to be confused and used as synonyms. But they are different. A hazard is something which has the potential to cause harm. It is then necessary to assess, both qualitatively and quantitatively, the risk of actual harm being caused. In food safety there is always some risk. The moment you open your mouth and put something in it you are personally taking a risk; it is a question of balancing risks against the benefit of producing food that is necessary for survival.

[426] These considerations led Dr North to discuss the risk assessment process (outlined in his report, no. 6/1/155, p.2). His report set out the steps of the risk assessment process as comprising hazard identification, hazard characterisation, exposure assessment and risk characterisation. It is first of all necessary to look at the events, processes and items which have the potential to cause harm. Dr North said that one would then go on to consider the question – is this, in my reasoned judgement, going to potentially damage my customers to such an extent that I have to take action against it? This, he said, was the basis of HACCP, and brought into play epidemiological evidence. In that respect, the type of people who

would be eating the food should be also be considered (cf. Commission Notice 2016/C 278/01, Annex 2, p.10). Dr North was aware that the respondents' cheeses were a specialist food which was sought out by aficionados rather than a generalised commodity; indeed vulnerable groups could be excluded from consideration, especially if the food was labelled, because they are warned by the government and manufacturers to avoid these foods. So, when a product is not making a claim that it is intended for a group with particular health sensitivity, the fact that it may be harmful for that group does not automatically mean that it is injurious within the meaning of article 14 of Regulation (EC) 178/2002 (cf. Guidance on the Implementation of Regulation (EC) 178/2002, *supra*, paragraph 1.3.4).

[427] On a separate, but perhaps related, point, Dr North did not consider Mr Brown to have been justified in relying on the risk assessment of FSS to the exclusion of any risk assessment of his own. He appeared to consider the environmental health officer (which in this case was not, of course, Mr Brown but rather Mr Dickson) to be in the best position to undertake such an assessment, and that it should be his judgment which would then lead him to take enforcement action.

[428] Dr North agreed that the three components of risk analysis referred to in recital 17 of Regulation (EC) 178/2002 – risk assessment, risk management and risk communication – provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health. The risk assessment will advise what goes into the risk management programme. Where there is any residual risk that will then require to be communicated to the consumer. Risk assessment should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data (Regulation (EC) 178/2002, *supra.*, recital 18). Dr North considered that this involved more than a consideration of only the microbiological information sent by the

laboratory; it should include epidemiology, and a consideration of the nature of the food, the process, and the nature of the consumer. Dr North also agreed (following the wording of Regulation (EC) 178/2002, *supra.*, recital 19) that scientific risk assessment alone cannot (in some cases) provide all the information on which a risk management decision should be based. Other relevant factors included societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

[429] On the application of the precautionary principle, Dr North referenced examples of how it had been abused, and drew attention, in particular, to the German and French bans on British beef during the BSE episode. The precautionary principle was not a licence to invoke the better safe than sorry approach. Such was the use to which the principle had been put in banning foods that the European Commission had issued a direct, straightforward communication on the principle and its operation (Commission Communication on the precautionary principle, Brussels, 2 February 2000; no. 6/1/154 of process).

[430] The Commission Communication provides that the precautionary principle, which is essentially used by decision-makers in the management of risk, should not be confused with the element of caution that scientists apply in their assessment of scientific data. Dr North sought to distinguish between the judgment of someone applying the precautionary principle and a scientist in the position just described. In essence, he distinguished between real world judgements (citing, as an example, transport policy in which it was recognised that the three thousand or so deaths per year on the roads was a price worth paying for freedom of mobility) and the narrow judgment a medical practitioner would make in the treatment of an individual patient.

[431] In paragraph 6 of the Commission Communication on the precautionary principle it is stated that "*[p]roportionality* means tailoring measures to the chosen level of protection. Risk can rarely be reduced to zero, but incomplete risk assessments may greatly reduce the range of options open to risk managers. A total ban may not be a proportional response to a potential risk in all cases. However, in certain cases, it is the sole possible response to a given risk". Dr North agreed, it having been said in his training that any fool can condemn food; however, it takes skill and judgement to allow it to be sold. Proportionality, however, lay at the heart of what was under consideration in the present applications. The approach had to be non-discriminatory as between different food sectors.

[432] On the matter of whether or not the respondents should have carried out STEC testing, he said that HACCP had been developed as a substitute for testing. The only purpose of testing would be to validate a safety management system. Once you had established that the system was working there would be no need for further testing other than to watch routinely for slippage.

[433] As to the role of scientific uncertainty in risk analysis, touched on in the Commission Communication on the precautionary principle, Dr North appeared to encapsulate his position in the following way. It was very easy to become wrapped up in the science and to use science as a comfort blanket. This was, however, something of a "cop-out". Epidemiology rests on well-founded principles, and at their core is the proposition that anything which is done must make sense, and the findings put together must be consistent with common sense. It is a matter of not being overwhelmed by scientific data, but rather stepping back and assessing whether a course of action would be reasonable to an ordinary person, applying common sense and logic. To illustrate that approach Dr North was asked how, if he was making a risk assessment and taking a risk management decision, he would

have responded to the finding of the four STEC which were revealed by WGS. He replied that he would ask: (i) are the isolates pathogenic; (ii) whether the numbers present represent viable organisms, and (iii) what is the nature of the food (and, therefore, whether the environment, if hostile, could cause the STEC to die off, which might lead to a different approach). Epidemiology would also be looked at, both generally (in terms of the nature of the product) and specifically (in terms of the specific operation of the business). For epidemiological significance one would include such considerations as the evidence of disease burden from ewes' milk cheese throughout Europe, of which some hundreds of thousands of tonnes are produced each year. In that respect, it was, he said, a numbers game, and the disease burden was nil, despite (as he put it in re-examination) the number of poisoning opportunities.

[434] Dr North reiterated that a risk assessment needs to have in mind the intended consumer. Those most at risk are the very young or old, and the immuno-compromised are always at risk. Generally, STEC are not a problem for a normal healthy adult. In the spectrum of response to exposure one is likely to be looking at the lower end of the spectrum in terms of dose response, if any (and a significant number of such cases will actually acquire asymptomatic illness).

[435] In cross-examination, Dr North confirmed his current occupation as a self-employed author, political researcher and analyst. He had not given expert evidence in a food safety case since at least 2000. He acknowledged the existence of a European food safety regulatory framework, one of whose purposes was to provide a uniform, high level of consumer protection with regard to food safety across member states, and that there was also a Scottish statutory and regulatory framework in place.

[436] Dr North agreed that public health was of the utmost importance to any food business operator, and that one of the fundamental objectives of any food business operator should be to produce a safe product for the consumer (although he qualified that by relating his answer to the "targeted consumer" of that food business operator). Dr North also accepted that primary, although not ultimate, responsibility for food safety rests with the food business operator. Primary responsibility did not connote sole responsibility. There was, as I understood his evidence, a collegiate responsibility for food safety which is shared between the food business operator and the member state through its regulatory authorities. Nowadays, local authorities are being required to make judgments about the suitability of safety management systems. Since this involves matters of opinion there is a process whereby the food business operator and the regulator negotiate, leading to consensus on what constitutes an appropriate management system (for the purposes of the Hygiene Regulations). The end result is a process which guarantees an acceptable level of safety (there being no absolute guarantee of safety).

[437] When asked what would happen if the end product did not turn out to be safe, even when the producer had complied with all that it required to, Dr North replied that you learn from experience and make modifications to your system. That, inevitably, meant being reactive rather than proactive ("how else can it be?"). By way of illustration, when he trained as an environmental health officer, the idea that E. coli was pathogenic would have been considered laughable. Its potential toxicity became known through surveillance and the modification of systems accordingly. It was suggested to him that it was in the nature of biological systems that new pathogens might arise, and was asked whether these should be ignored until they cause harm. Dr North replied that, by and large, they should because there were potentially so many. If you are always responding to potential threats, you

would never produce any food. A balanced judgment was required. What was necessary was a sophisticated surveillance system which exists to warn of emerging threats because of the changing nature of biological systems. An example of the reactive response was the emergence of listeria which turned out to be capable of growing at certain temperatures, which had not previously been thought possible. It was not until the evidence was available that new control procedures were put in place to deal with the new threat. The surveillance system that Dr North had in mind encompassed, in Scotland, the relevant government health department, public health laboratories, hospital laboratories, private laboratories which have a statutory reporting duty, environmental health departments, the veterinary profession and food business operators themselves.

[438] It was put to Dr North that STEC represents a hazard in raw milk and raw milk products. He said that not all STEC are pathogenic. So STEC represent only a potential hazard, but not a potential risk to public health; they are a potential hazard and it is for the risk assessment to establish whether or not there is a significant risk, and whether the risk is actionable. Asked whether STEC represents (including to the respondents themselves) a potential hazard in raw milk, and raw milk products, he replied that it might be at the beginning, but not necessarily at the end, of the process (ie. in the finished product).

[439] Turning to the FAFAs, Dr North's understanding was that the applicants had done more than was required of them by the FAFA of 14 September 2016 , which he thought (inaccurately, as it turns out) was concerned only with Dunsyre Blue. They went, as he put it, to a whole range of products. His understanding of the subsequent FAFA-02 was vague, but it had not been his core concern. On being referred to the first FAFA Dr North confirmed that he had seen it before, although over a year ago ("one does forget, you know"). It contains an assertion that Errington cheese might contain E.coli, which, as it

transpired, was correct "in the sense of generic but not further". Dr North also confirmed that the FAFA identifies six different varieties of cheese.

[440] Dr North's attitude to the first FAFA was that it was "slightly presumptive", and appeared to charge the applicants with responsibilities in relation to destroying the food which verged on usurping the powers of the court. It was for the Sheriff to determine whether the food was unfit for human consumption, or not. He was referred to the FAFA update of 9 November 2016. He did not recall it, but may well have read it, because he had seen so many documents. Dr North's view on the summary of sample results in the FAFA update was that it was an assertion but that didn't make it necessarily true, any more than what the earlier FAFA had said about a potential risk to health. The fact that a statement was made by an authority did not make it true. Dr North appeared, eventually, to accept that, contrary to his impression hitherto, the applicants had indeed done no more than they were directed to do by the terms of the first FAFA, and its subsequent update.

[441] Dr North volunteered that the respondents' voluntary decision initially to withhold product from the market was the result of "force majeure". He said that "[t]hey did have no option; with the local authority camping on their doorstep, threatening all sorts of action if they didn't comply immediately, they withheld their product". When it was put to him that the applicants had considered withdrawal of approval of the respondents' business, Dr North replied that they may have been considering it, but they did not do so.

[442] Dr North's response to the suggestion that, up until the first quarter of 2017, the only indication given on the respondents' packaging was that the product was made from raw milk, was that that accorded with a statutory requirement. That Mrs Cairns sought to clarify the position, and to reinforce existing official information, made good sense. It was open to the applicants before then to have suggested that she do so.

[443] There ensued a discussion between Mr Love and Dr North about the characterisation of STEC as a hazard. Dr North sought to emphasise that STEC is the hazard; that hazard has then to be characterised. That involves asking whether it is high or low level, and whether it is likely to diminish through time; in other words, a risk assessment is undertaken, which in turn advises the control programme established to deal with that risk. That process is the responsibility of the food business operator, but in co-ordination with the local authority. That is why local authority officers must be trained. Dr North's strongly expressed view was that, while local authority officers do not need to know as much about the processes of a food business operator as the operator itself, the ultimate arbiter of whether a HACCP is adequate is the local authority. I understood Dr North to agree that a food business operator must undertake a hazard identification process in relation to its raw materials. That, however, did not extend to the end product because the process will, as near as humanly possible, ensure that there are no significant risks involved in the consumption of that food.

[444] Dr North agreed that a HACCP plan requires to be verified. The system should be set up, run through, and tested. If happy that the system is working you may let the system run, and occasionally go in and monitor it at certain points (which experience may tell you might be vulnerable) just to confirm that it is still working as intended.

[445] For completeness, I record that Dr North's cross-examination concluded with confirmation (from a reference he helpfully provided) that the volume of Roquefort – an exclusively raw milk cheese produced in France – produced in 2015 was 19,104 tonnes.

[446] In re-examination, Dr North confirmed that he was unaware of any knowledge as to the infectious dose of any STEC, other than O157:H7.

[447] Dr North's evidence was expressed with conviction. While recognising his strongly held views, it did appear that his evidence erred towards the adversarial. His views on the relationship between, and responsibilities of, the food business operator and food authority, touched on areas of law which I did not consider properly fell within the witness's expertise. Indeed the eclectic mix of experience made it hard to determine precisely where the boundaries of that expertise lay. I have, however, factored all of what Dr North had to say into my overall assessment as to whether the evidence justifies the granting of the orders sought.

Submissions

[448] There are three applications before the court. As the applicants observe in their written submissions, the proceedings primarily involve consideration of: (i) Regulations (EC) 178/2002, 852/2004 and 853/2004; (ii) the 1990 Act, and (iii) the 2006 Regulations. Different issues arise in relation to each of the three summary applications, and, accordingly, I approach them separately.

[449] Parties lodged very extensive written submissions. They are lodged in process and I do not propose to repeat their terms. What may, however, be helpful in setting a context for my consideration of each application is to record the overview of their position set out in the applicants' submissions in support of the orders sought, and an outline of the respondents' competing submissions.

Overview of the applicants' position

[450] Thus, in relation to summary application LAN B20-17, the applicants submit that:

- They are the relevant enforcement authority for the respondents' business;

- Following the outbreak, the applicants were required to follow the guidance and instructions contained within the FAFAs issued by FSS and did so;
- They were required, and entitled, to carry out the level of testing and sampling that they did in the face of an outbreak which involved a fatality;
- Cheese is not a homogeneous food product and it is plain from the range of test results obtained from a range of samples that the respondents' HACCP based food safety management system was not working;
- Following testing of Lanark Blue, batch E24, by ESS, SERL and PHE, the applicants received a Certificate of Examination from their Food Examiner certifying, *inter alia*, that: (i) testing identified the presence of E.coli O unidentifiable: H20 with a stx2d gene with Sequence Type 1308, indicative of a shiga toxin producing E.coli; (ii) the identified STEC should be considered as capable of causing severe illness in humans, and (iii) a product containing the identified STEC is unsatisfactory and potentially injurious to health and/or unfit for human consumption;
- The Food Examiner certified the sample as unsafe by reason of it being unfit for human consumption due to the presence of the identified STEC within the meaning of article 14 of Regulation (EC) 178/2002
- The applicants had, and have, no basis for challenging the opinions and observations expressed in the Certificate of Examination issued by the Food Examiner in relation to Lanark Blue Batch E24;
- The applicants required to take the steps which were taken;
- Their conduct in relation to Lanark Blue, batch E24, was justified and is borne out by the evidence in the case (particularly the evidence of Mr Robert Beattie (ESS), Dr Lesley Allison (SERL), Dr Timothy Dallman (PHE) and Dr Flemming Scheutz;

- There is no credible evidence that the sample of Lanark Blue Batch E24 was either mislabelled or cross contaminated as a result of steps taken by the applicants' officers, or anyone at ESS, and
- It is more likely that any cross-contamination arose at the respondent's premises.

[451] In relation to summary applications B21-17 (Lanark Blue Remainder) and B33-17 (Corra Linn), the applicants submit that:

- Karen Wardrope was, on the basis of the evidence available to her and having regard to the content of the FAFAs issued by FSS, fully justified in taking the steps that she did in issuing Certificates under Regulation 27 of the 2006 Regulations certifying that the respondents' Lanark Blue and Corra Linn cheeses had not been "produced, processed or distributed in compliance with the Hygiene Regulations"
- The respondents accepted raw milk which might reasonably have been expected to contain pathogenic microorganisms despite the fact that, even after normal processing steps had been applied, pathogenic microorganisms would not be reduced to an acceptable level (the presence of STEC in a batch of food is to be considered a serious risk to public health);
- Moreover, prior to the outbreak, the respondents did not test their raw milk for E.coli, E.coli O157 or STEC with a view to ascertaining whether the control measures that they had in place were working – such testing was put in place subsequent to the outbreak;
- Where a Certificate has been issued in terms of Regulation 27 of the 2006 Regulations (and there having been no challenge to the validity of the Certificates issued by Karen Wardrope and referred to in applications B21-17 and B33-17), the

food certified as being non-compliant falls to be treated for the purposes of section 9 of the 1990 Act as "failing to comply with food safety requirements";

- In terms of Regulation 27(3), the onus is on the respondents to prove that all of the seized batches of Lanark Blue and Corra Linn cheeses *were* produced, processed or distributed in compliance with the Hygiene Regulations;
- The respondents have failed to prove that those batches of Lanark Blue and Corra Linn cheeses were produced, processed or distributed in compliance with the Hygiene Regulations, and
- The orders sought should accordingly be granted in all three applications.

[452] The applicants also submit that, in general terms, their conduct throughout complied with and gave due regard to:

- The obligations incumbent upon them in terms of the "Food Law Code of Practice (Scotland)" issued by FSS in April 2015 (no. 5/1/13 of process);
- The "Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market" issued by the Health Protection Agency ("HPA") in November 2009 (no. 5/1/16 of process);
- The "UK Working Policy on Detection of STEC in Food by Official Controls and Food Business Operator Sampling and Testing" insofar as it applies to cheese as a ready-to-eat food under Profile 1 (no. 6/1/150 of process);
- The Certificates of Examination issued by the Food Examiner, and
- The precautionary principle, and the high level of protection of human life and health desiderated by the European regulatory framework.

Outline of the respondents' position

[453] The respondents submit that none of the orders sought are justified and should be refused. In summary, their position is that there is no evidence that either Lanark Blue, batch E24, all of the batches comprising Lanark Blue Remainder, or the three batches of Corra Linn found to contain STEC organisms, are likely to be injurious to health. Leaving aside questions relating to the legal and evidential burden of proof, which have been discussed earlier, the respondents submit that:

- There can only be a finding of a relevant failure by the respondents to comply with food safety requirements, under Part II the 1990 Act, if the court is satisfied, on the basis of the evidence adduced by the applicants, that the batches of cheeses seized are unsafe within the meaning of article 14 of Regulation 178/2002; in other words, that the food has been shown by the applicants to be either injurious to health or otherwise unfit for human consumption;
- In determining whether or not the seized cheeses are injurious to health regard must be had to the probable effects on the likely consumer;
- Any submission, to the effect that a breach of the food safety requirements *can* be established in the absence of a finding that the food has been proved by the applicants to be either injurious to health or otherwise unfit for human consumption, is wrong in law;
- The task for the court is not to consider the scientific wisdom or prudential merits of the opinions of Drs Scheutz, Dallman and Allison on the pathogenicity of STEC, but rather to decide whether the seized cheeses were likely, if consumed, to be injurious to health;

- The applicants have failed to prove that Lanark Blue, batch E24, was contaminated with E.coli O unidentifiable: H20 stx2d, ST1308, eae negative;
- The most likely explanation for the finding of such a STEC is a laboratory mix up between the samples of Lanark Blue, batch E24, and Dunsyre Blue, batch F15, during testing following acid shock treatment;
- The four STEC organism found by WGS in the respondents' cheeses belong to a category in the EFSA proposed provisional molecular classification scheme from which no inference can be made regarding potential risk using current available data;
- The only internationally recognised and validated standard for the detection of STEC in food is ISO 13136, being the standard adopted by Actalia in France, whom the respondents had employed to undertake product testing. That standard was not followed in the process of testing by ESS, SERL and PHE;
- WGS is not, in any event, a recommended tool in the assessment of the safety of a food product;
- Testing to the standard of ISO 13136 would not have identified the STEC strains found by PHE.
- None of the four STEC strains identified by WGS have previously been connected with human illness, and significant genetic differences exist between those strains and the strains identified in evidence by Drs Dallman and Scheutz in clinical cases.
- Raw ewes' milk cheese has never been specifically associated with STEC illness in humans;

- A logical and plausible explanation for the absence of such evidence of illness is that any STEC in ewes' milk cheese will not be pathogenic;
- Having regard to available data for generic E.coli in the Lanark Blue curd (between March and July 2016) the theoretical level of E.coli O157 would unarguably have been at an acceptable level (for the purposes of Annex II, Chapter IX, paragraph 1, of Regulation (EC) 852/2004);
- The actions of the applicants were not supported by the results of any risk assessment undertaken by them; reliance on the FSS risk assessment of November 2016 was inadequate as that assessment was based on incomplete or unknown information relative to (i) WGS results; (ii) the testing results for batches of Corra Linn; (iii) the survivability of STEC in the process of maturation, and (iv) historical information on the association of raw milk cheese with food-borne STEC illness, the rate of STEC isolation in raw milk cheese, or the genetic diversity of STEC strains in the food chain;
- The hygiene controls for milking sheep in operation at the respondents' premises were such that there was no reasonable expectation that the milk would be contaminated with pathogenic microorganisms to such an extent that the final product would be unfit for human consumption (for the purposes of Annex II, Chapter IX, paragraph 1, of Regulation (EC) 852/2004).
- A traditional cheese making process involves reduction in the microbial load of the milk, and the Campden BRI calculations lodged by the applicants demonstrated STEC die-off in both Lanark Blue and Corra Linn;

- The respondents held SALSA+SCA accreditation, demonstrating that, in substance, their food safety management system complied with the SCA Code of Practice;
- In 2014 and 2016 the respondents had been inspected by the FSA and FSS respectively without any adverse comment or the finding of any systemic difficulty, and without any suggestion that the respondents should have been testing specifically for the presence of STEC;
- STEC testing was not commercially available, nor practically possible, in 2016;
- The applicants' environmental health officer, Mr Dickson, was aware that the respondents were not testing for O157/STEC, (and analysis of O157 as low risk), but he nonetheless approved the respondents' hygiene controls and compliance with the Hygiene Regulations, and the respondents retained their EU Approval even after the outbreak in 2016 (thereby demonstrating that cheese production complied with the requirements of the Hygiene Regulations);
- None of the authors of the FSS risk assessment had visited the respondents' premises.

[454] The respondents reject the applicants' contention, that their food safety management system was deficient because incoming milk was not being tested for either E.coli O157:H7 or STEC as proceeding on the misconstruction of Annex II, Chapter IX, paragraph 1, of Regulation (EC) 852/2004). They submit that their testing arrangements complied with:

- ISO 13136;
- The EU Guide to Good Hygiene Practices in relation to the production of artisanal cheeses;

- The Codex Alimentarius Report which favours testing for faecal organisms;
- The requirements of Regulation (EC) 2073/2005 (which, by testing for *inter alia* enterobacteriaceae, and the curd for E.coli, they actually exceeded);
- The SCA Code of Practice, and, therefore,
- Article 5 of Regulation (EC) 852/2004.

[455] The respondents also submit that the numerous tests on their cheeses which have all been negative for E.coli O157:H7 (the source of all STEC food poisoning in Scotland), validated the assessment by A & S Cairns of that strain of E.coli as low risk, and also verified the HACCP operated by the respondents at the relevant time.

[456] Finally, the respondents invoke the principle of proportionality in article 7.2 of Regulation (EC) 178/2002. They submit that the actions of the applicants offend against that principle in the following respects:

- In requiring that the respondents should have been testing incoming raw milk for E.coli O157:H7/STEC;
- In seeking orders for destruction of all of the batches of the seized cheeses on the basis of the certificates of the Food Examiner, and in the absence of a comprehensive risk assessment;
- In seeking orders for destruction of all of the batches of the seized cheeses, regardless of whether they had completed their maturation period;
- In proceeding on the basis of results obtained by WGS;
- In seeking the destruction of all batches of Lanark Blue Remainder on the basis of one questionable result, attributed to Lanark Blue, batch E24, of unknown pathogenicity.

Discussion and Decisions

[457] There being three applications before the court it is appropriate that I now set out, separately, the views I have reached on the parties' competing submissions.

LAN B20-17

[458] The applicants invite the court to sustain their second and third pleas-in-law and find that the food seized, namely Lanark Blue, batch E24, identified in the Record of Inspection Form (B20-17: no. 8) fails to comply with food safety requirements, and to condemn the food and order that it be destroyed or be so disposed of as to prevent it from being used for human consumption all in terms of section 9(6) pf the 1990 Act.

[459] It is accepted that it is for the applicants to prove that (a) given the presence of the STEC variant isolated from it, Lanark Blue, batch E24, should be regarded as unfit for human consumption within the meaning of article 14 of Regulation (EC) 178/2002, and (b) that, in the absence of a suitable and sufficient testing regime, the respondents' food safety management system failed to comply with article 5 of Regulation (EC) 852/2004.

[460] It was also, as I understood it, accepted by senior counsel for the applicants that, if I were not satisfied on those points (or, for that matter, the applicants' submissions in support of the orders sought in applications B21-2107 and B33-17), then the terms of the risk assessments, which advised the issue by FSS of the FAFAs in September and November 2016, would not preclude me from finding in the respondents' favour in each, or all, of the applications. Such a concession was, in my opinion, correctly made. It is plain from the terms of section 9(6) of the 1990 Act that it is ultimately for the court to determine *on the basis of such evidence as [it] considers appropriate in the circumstances* that any food falling to be dealt

with under that section fails to comply with food safety requirements. I consider that to be the position notwithstanding the apparent infelicity in the wording of the September FAFA, which enjoined local authorities to identify food businesses "who are likely or known to stock [the respondents' products] and to take steps to *ensure* [they were] withdrawn from sale *and destroyed*, if necessary using powers under the Food Safety Act 1990 and Regulation 27 of the Food Hygiene (Scotland) Regulations 2006".

[461] The starting point for consideration of this application is article 14 of Regulation (EC) 178/2002. I have set out its terms in full earlier in this judgment. It provides that food shall not be placed on the market if it is unsafe. It will be recalled that food is deemed to be unsafe if it is considered "injurious to health" or "unfit for human consumption", and that the definitions of those labels are distinct. In the present application the concentration is on the latter label. Thus, in determining whether any food is unfit for human consumption, regard requires to be had to whether the food is "unacceptable for human consumption, according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay". Given that definition, it is not difficult to see how, in the highly regulated area of food safety, policy considerations may feed into the question of what is, and what is not, acceptable for these purposes.

[462] In deciding whether it has been proved that Lanark Blue, batch E24, is unsafe by reason of being unfit for human consumption, and given the way that the application is pled, it is, in my opinion, necessary to consider each of the following matters: (i) the issue of STEC and their pathogenicity, actual or potential; (ii) the test methodology employed by the applicants and test laboratories; (iii) the finding of E.coli O unidentifiable H20, stx2d, ST1308, in both Lanark Blue, batch E24, and Dunsyre Blue, batch F15, and (iv) the

respondents' food safety management system and compliance with article 5 of Regulation (EC) 852/2004.

(i) Pathogenicity of STEC

[463] I heard expert evidence bearing upon this issue principally from Dr Dallman and Dr Scheutz for the applicants, and Professor Pennington for the respondents. All three presented as highly qualified witnesses with a wealth of experience in the matters in reference to which they gave evidence. I also had the benefit of certain views expressed by Dr Allison while describing the testing undertaken at SERL.

[464] It is, perhaps, convenient to begin by considering where the experts were in agreement. Thus, it seemed to me to be common ground that there is scientific uncertainty about the potential of different STEC strains to cause illness in humans. Professor Pennington made specific reference to the emergence, out of the blue, of O157:H7 in the 1970s/80s, and considered it reasonable to suppose that another similarly dangerous organism might appear in the future. Moreover, in the course of his oral evidence, Professor Pennington departed from that part of his report (on Corra Linn) which maintained the existence of a scientific consensus that the production by E. coli of stx alone is insufficient for a strain to be pathogenic and for it to cause illness (although that remained his opinion). It was common ground that, with the passage of time and the emergence of new technologies (principally WGS), new and emerging stx variants are being identified. All three witnesses referenced the E.coli O104:H4 outbreak in Europe in 2011, associated with fenugreek seeds and resulting in a high number of fatalities, as an example of the potential for an emerging STEC strain to cause serious illness. There was, as I understood it, no dispute as to the

existence of a consensus amongst scientists that, in terms of susceptibility, extremes of age, and the immuno-compromised, represented an important risk factor.

[465] Many of the characteristics of STEC were otherwise agreed between the parties and I have sought to record the position in a section of my findings-in-fact. What was not, however, common ground between the experts was whether the E.coli strain isolated from Lanark Blue, batch E24, had the potential to be pathogenic, and what the implications of its isolation were from a food safety point of view. Since those matters have a direct bearing upon the outcome of this application it is necessary that they are now addressed.

[466] Leaving aside for the moment how it got there, Professor Pennington considered it doubtful whether E.coli O unidentifiable H20, stx2d, ST1308, had any pathogenicity in the absence of the eae adherence gene. It was his view that there must be some mechanism for the E.coli to attach to the gut for long enough for the toxin to produce its effects. Moreover, he had not seen any publications showing unequivocally that an E.coli with a stx gene on its own was pathogenic, and he believed that other scientists would agree. Moreover, Professor Pennington and Dr Scheutz both agreed that the strain had not previously been isolated from humans. Professor Pennington thought it significant that Dr Scheutz, who had an aggressive sampling methodology, had not found the strain in patients. It all pointed away from the strain in Lanark Blue, batch E24, being pathogenic. There was no evidence that it was pathogenic.

[467] Dr Scheutz took a different approach to the E.coli strain isolated from Lanark Blue, batch E24. I have already set out, at considerable length, his evidence on the pathogenicity of the strains isolated from the respondents' cheeses. Dr Scheutz considered that, for reasons of patient safety and prudence, and because there was scientific uncertainty, any

E.coli isolate which was positive for stx2d should be considered pathogenic. That was the case regardless of the presence of an adherence gene such as eae, and regardless of serotype.

[468] This difference of approach will be apparent and was commented upon in the evidence. Dr Scheutz considered that Professor Pennington, in concluding that the stx2d strain isolated from Lanark Blue, batch E24, was not pathogenic, was looking for proof that this type of strain had been isolated from patients who had become ill. Dr Scheutz preferred an approach based on patient safety and prudence, and which recognised that new bacteria can emerge and this strain might be one such example. He cited, in his report, and also the joint report with Professor Pennington, examples from around Europe (although not the United Kingdom) where the stx2d sub-type has been associated with human illness, even in the absence of the eae gene.

[469] Professor Pennington viewed Dr Scheutz' approach as being too restrictive. It was an approach which reflected his discipline as a microbiologist, and held out the prospect of action being taken on the basis of insufficient evidence – or no evidence at all – on the basis that there *might* be a problem. From the perspective of food regulation, that was a step too far. Application of the precautionary principle should not be confused with the element of caution that scientists apply in their assessment of scientific data. Accordingly, while Professor Pennington had also applied his mircrobiological expertise to the issue, it was not solely a matter of microbiology. Pathogenicity required to be considered from a food safety perspective and the absence of published epidemiological evidence linking the strain to human illness was significant.

[470] For completeness I should record that Dr Dallman, in his joint report with Professor Pennington, noted that the absence of previously identified O unidentifiable H20, stx2d, ST1308, strains does not impact on the potential virulence of the strain. Activatable stx2d

strains that are eae negative have been found to cause severe human illness in an array of different strain backgrounds. (I understood Dr Dallman to be here referring to Dr Scheutz's material). Dr Dallman agreed with the proposition put to him by Mr Errington that the STEC strains found by WGS from the respondents' cheeses were possibly pathogenic, but equally possibly not pathogenic. The proposition and the answer were equally illuminating.

[471] Finally, Dr Allison sought to emphasise that the six different STEC strains isolated by PHE (including the two from samples of raw milk) highlighted six different STEC strains which were isolated from a variety of different cheeses and raw materials. All were non-O157 STEC but potentially pathogenic.

[472] Against that background it is necessary to consider (i) whether any conclusion can be drawn as to the pathogenicity of the strain identified in Lanark Blue, batch E24, and (ii) for the purposes of this application, whether it is necessary to do so.

[473] In relation to the first of those issues I agree with the applicants' submission that it is hard to define what is meant by a "pathogenic STEC". I also agree that the evidence disclosed uncertainty, and the absence of international consensus, as to the combination of genes or serotypes required to confer pathogenicity (cf. *EFSA Scientific Opinion on VTEC – seropathotype and scientific criteria regarding pathogenicity assessment, 2013*, paragraphs 4.5 and 5.4; *Joint Report on the Meeting of the Core Expert Group on VTEC/STEC of the Food and Agriculture Organisation of the United Nations and World Health Organisation Core Expert Group, Geneva, Switzerland, July 2016*, pp6-8).

[474] Dr Scheutz' conclusion that any E.coli isolate positive for stx2d should be considered pathogenic was reached on a precautionary basis and advised by data from clinical cases from France, Spain and Denmark. However, data from Germany, Norway and Japan showed that the pattern was inconsistent, and that not all stx2d strains cause severe disease

(ie. HUS). Faced with these contradictory indications I have found it hard to draw any firm conclusion as to the potential of the Lanark Blue, batch E24, strain to cause human illness. It was far from clear from his evidence how many of the clinical cases, referred to in his reports, Dr Scheutz was able to relate to confirmed findings that food was the vehicle for STEC infection. I confess that I was also troubled at being asked to rely on "preliminary data", apparently prepared for a draft publication in an unspecified scientific journal, but not produced to the court (although, it appears, available to the witness). I was not surprised that Professor Pennington, when asked to comment on this preliminary data, replied that it was problematic because it had not been published in any peer reviewed literature, and that he would like to have seen the data, or at least a summary of it, at a scientific conference before he was able to offer informed comment. It was, he said, relevant to known how many STEC strains were looked at and how many virulence genes were identified.

[475] Professor Pennington's evidence was that E.coli O157 has been the dominant STEC for causing food poisoning in the United Kingdom. Other STEC have come to light over the years but E.coli O157:H7 remains the only STEC known to have caused a food-borne E.coli outbreak in Scotland. Both he and Dr Scheutz were in agreement that different countries have had different experiences with STEC illness. In cross-examination Dr Scheutz specifically acknowledged that there was a geographical variation in STEC types. He accepted that one could not necessarily apply the incidence of, say, O157 in Denmark to the situation in Scotland. Indeed, a good example of such geographical variation can be found in the joint report of Professor Pennington and Dr Scheutz, which made reference to the incidence of stx2d-related illness in Denmark, and contrasted that with the German study which found that none of the 268 HUS patients concerned were found positive for stx2d.

[476] Dr Dallman's opinion was that a stx2d gene had the strong potential to be pathogenic. If the eae gene was also identified the possibility of pathogenicity would be stronger. (Mr Thomas happened to express a similar view on the matter of the absence of the eae gene). Stx2d genes with no adherence genes had been known to cause disease in multiple sero-types in multiple countries. (Dr Dallman did not, however, relate this opinion to any specific examples from his own experience and it was not apparent (to me at least) whether he was discussing food-borne illnesses). The absence of previously identified O unidentifiable: H20, stx2d, ST1308, strains did not impact on the potential virulence of the strain. In his joint report with Professor Pennington, Dr Dallman referred to a document entitled "WGS Summary" which was not produced to the court. It is unclear to what extent this document recorded relevant information beyond that which was isolated by WGS at PHE, and no further literature was lodged in support of the views of Dr Dallman which I have endeavoured to record.

[477] In that state of the scientific evidence, I find it impossible to find it established that, as a matter of probability, the STEC strain isolated from Lanark Blue, batch E24, is pathogenic. However, careful scrutiny of the applicants' written submissions reveals that it is not argued that I should (or need to) go as far as to determine that the strain is pathogenic. It is instructive to note that the terms of reference for the joint discussions between Drs Scheutz and Dallman, and Professor Pennington, invited consideration of the question whether the STEC strains identified in Mr Beattie's certificates were pathogenic, potentially pathogenic or non-pathogenic in humans. Although Dr Scheutz' position, as set out in the joint report, was that the strain should be considered as pathogenic, it was expressed from the point of view of "patient safety and prudence". Dr Dallman referred to its "strong potential" to be pathogenic. Dr Scheutz and Professor Pennington agreed that the particular

strain had probably not previously been isolated from humans. In these circumstances, while the experts were asked to consider whether it was pathogenic, the discussion really focussed on the potential pathogenicity of O unidentifiable H20, stx2d, ST1308 (or lack of it).

[478] Dr Scheutz relied on a weight of scientific data, derived from Europe to support his approach to pathogenicity. None of that data derived from United Kingdom clinical cases. Dr Scheutz himself acknowledged that different countries had different experiences of STEC. Dr Dallman's evidence about stx2d strains, with no eae gene, causing disease in multiple serotypes in multiple countries was not backed up by reference to any published data. It illustrated a particular difficulty which I encountered with his evidence.

Dr Dallman was clearly, and necessarily, called to give evidence about the involvement of PHE and the WGS performed on the samples of the respondents' cheeses. He did not provide a report of his own such as might illuminate any expert evidence which he was to give (beyond the detail of the WGS results and how they were arrived at). He was, however, involved in the joint discussions with Professor Pennington, for which the joint report previously mentioned was completed. It contained no specific references (beyond the "WGS Summary" which was not placed before me).

[479] In that state of circumstances, I considered that, intentionally or otherwise, Mr Errington accurately encapsulated the current state of scientific knowledge (at least in so far as disclosed in the evidence presented to me) when he put to Dr Dallman that the strains isolated from the respondents' cheeses were possibly pathogenic, but equally possibly not pathogenic (to which proposition he agreed). It is, of course, relevant to the process of assessment that no non-O157 STEC strain has been recorded as having previously been the cause of human illness in the United Kingdom. Nor, in reaching this conclusion, am I

disregarding Professor Pennington's view that the absence of such evidence points away from the stx2d gene being pathogenic, as does the absence of the eae gene.

[480] However, what I require to address is whether, from a food safety perspective, and given the scientific uncertainty discussed earlier, the strain should be treated as having the potential to cause human illness. On that matter, the absence of scientific consensus as to which combination of genes or serotypes is required to confer pathogenicity, and the degree of unpredictability associated with the emergence of hitherto unknown strains (illustrated by the multi-fatality E.coli O104:H4 outbreak in Europe in 2011) leads me clearly to the view that such a conclusion should indeed be drawn.

[481] During the proof I heard evidence about how, as a matter of policy, the isolation of a STEC organism from a ready-to-eat food sample should be treated as unsatisfactory from a food safety point of view. In that regard it is important to have in mind certain passages from the HPA Guidelines (published by the Health Protection Agency in November 2009), and the UK Working Policy on the Detection of STEC in Food address (all documents agreed in the joint minute).

[482] The HPA Guidelines include the following provisions:

> "1.3 **Intended use of the guidelines**
>
> These guidelines are for use by Food Examiners and enforcement officers in identifying situations requiring investigation for public health or food safety reasons…
>
> 2.2 **Detection of pathogenic micro-organisms in ready-to-eat food**
>
> Detection of the foodborne pathogenic bacteria shown in Table 1 in ready-to-eat food represents an unacceptable risk to health regardless of the number of bacteria present. The pathogens listed in Table 1 [which include E.coli 0157, and other STEC] should not be found in ready-to-eat food that has been adequately prepared…

2.2.2 **Escherichia coli O157 and other veracytotoxin-producing E.coli (VTEC)**

The most important [E.coli] from a food safety perspective are the veracytotoxin-producing E.coli (VTEC). Despite the relatively low number of cases of VTEC infection compared with that of *salmonella* or *Campylobacter*, the potentially fatal consequence of this disease particularly in the young and the elderly give it a high public health significance. It is estimated that VTEC infection is the cause of approximately 70% of the cases of renal failure in children. The consumption of very low numbers of viable VTEC in food is sufficient to cause infection.

Not all cases of VTEC are foodborne and different transmission routes can occur within the same outbreak. Most infections in the United Kingdom are due to a single serotype of VTEC, ie. O157, but other serotypes have been associated with sporadic cases of illness or outbreaks of foodborne disease. In continental Europe and Australia, infections from a broader range of VTEC serotypes are reported. The other serotypes of VTEC that have been associated most frequently with disease in humans include O26, O103, O111 and O145.

…*Escherichia coli* may sometimes be found in soft, mould-ripened or washed-rind cheese made from raw milk. Although Regulation (EC) 2073/2005 has no criteria for E.coli in cheese made from raw milk it is recommended that these cheese types be routinely tested for E.coli and investigation undertaken if a change of trend is detected. It is also recommended that a risk assessment is performed to assess the need for periodic monitoring for VTEC O157. Tests should be urgently applied where there is epidemiological evidence linking VTEC infection with specific foods…"

[483] The UK Working Policy document bears to have been drawn up following a review by FSS and the FSA of the available evidence on STEC in foods with a view to informing EU discussions and agreeing appropriate interventions following detection of STEC in foods by official controls or food business operator sampling and testing programmes. It draws an important distinction, from the point of view of risk management intervention, between detection of stx gene(s) in a food sample and confirmation of the presence of such gene(s). Thus, on p.3, at paragraphs 8 and 10, it is provided:

> "8. Detection of stx gene(s) alone would therefore not generally require action to withdraw or prevent product being placed on the market. Confirmation of the presence of stx gene(s) in an isolated E.coli strain is generally required before such action is taken. However, if one or more stx genes are detected in foods included in investigations associated with outbreaks of illness, then this may, when taken with epidemiological information potentially linking the food to human illness, be sufficient to support action to withdraw product from the market…
> 10. The confirmed presence of STEC in a batch of food falling into Profile 1 is considered a serious risk to public health. Evidence indicates that some strains are not pathogenic, but a precautionary approach is appropriate given the uncertainty in the evidence and the potential for severe disease".

[484] The respondents did not seek to criticise the approach thus illustrated in either the HPA Guidelines or the Working Policy document. It was an approach which, in my opinion, was engaged in the circumstances of the seizure of Lanark Blue, batch E24, because I am satisfied, on the evidence that I have heard, that it is appropriate to treat the O unidentifiable, stx2d, ST1308, strain as having potential pathogenicity from a food safety point of view, and should be treated as a STEC. It is also an approach that, in my view,is justified by the evidence of Dr Dallman (which I accepted) that the stx2d variant was of the activatable form and, therefore, the most potent.

[485] In reaching that conclusion I am not to be understood as rejecting as unimportant the absence of epidemiological evidence of that, or any other, strain – or, indeed, a particular product such as raw milk cheese, being the cause of human illness in the past. I appreciate that Professor Pennington attached weight to such a consideration. However, as it seems to me, that is a matter which might well feed into a further discussion about the setting of food safety policy, with which I cannot be concerned. It may also have resonance when considering a proportionate approach to those seized products which have either not been the subject of microbiological testing by the applicants, or have been tested but without any STEC organism being isolated.

(ii) Test methodology employed by the applicants and test laboratories

[486] At various points during the evidence Mr Errington challenged witnesses about the test methodologies applied to the respondents' cheese samples. I confess that I found it hard, at times, to follow the direction in which this line of questioning was taking because, as the applicants' submissions point out, there is nothing in the respondents' answers which gives any hint that the testing methods employed were either (a) inappropriate, or (b) produced results which were, in any way, inaccurate.

[487] The respondents' position in this respect is now encapsulated in paragraphs 3.13 to 3.22 of their written submissions. The essence of the respondents' position appears to be that any testing to which the samples of cheese were subjected should have been to the standard of ISO 13136. Such testing (which is adopted by the Actalia laboratory used by the respondents in France) would not have identified the STEC strains in the summary applications.

[488] I do not consider that there is substance to any criticism of the use of either WGS or acid shock treatment, in place of ISO methods, for assessing food safety significance. Against the background of scientific uncertainty, to which I have already referred, it is clear that WGS is considered to be a test methodology of increasing value in food safety terms. It is important to recall what was said by Professor Pennington in each of his joint reports with both Dr Scheutz and Dr Dallman:

> "…categorising the pathogenicity of E.coli strains on the basis of serotype has been useful in the past but is now being replaced by the analysis of specific virulence factors, enabled in particular by whole genome sequencing."

[489] During pre-proof procedural hearings time was taken up in discussion as to whether there might be merit in treating the pathogenicity of the STEC strains isolated by PHE as a preliminary issue for proof. There was no suggestion that a criticism would be advanced that the results derived from WGS were, in some way, illegitimate. Be that as it may, I am quite satisfied, from the unchallenged evidence of Mr Beattie, and Doctors Allison, Dallman, and Scheutz, and Professor Pennington's own opinion, just quoted, that WGS has a legitimate place in the realm of food safety. Moreover, Professor Fink offered the view that, not only had WGS become more common since 2013, it allows for more STEC strains to be typed more accurately, was now cheaper, and gives rise to higher typability than any other conventional test method. There is no suggestion that PHE was not accredited to perform WGS. I am, here, concerned with the results of testing that was undertaken to ascertain whether, as part of a widespread investigation, precipitated by an E.coli outbreak which an IMT was linking to one of the respondents' cheeses, the respondents' products contained harmful STEC organisms. The criticisms of WGS in paragraphs 3.18 and 3.22 of the respondents' written submissions seem to me to be concerned with the utility of WGS in the routine monitoring of food safety, which is a separate issue (which I will come on to deal with in the context of the applicants' submission under article 5 of Regulation (EC) 852/2004). The weight of expert testimony, on both sides, was clearly in favour of the efficacy of WGS as a means of typing STEC strains in food samples, and I can see no justification for excluding from consideration the results produced by that technique, and relied on by the applicants, in the present applications.

[490] I also agree with the applicants' submission that there is no evidence to justify the proposition (if that be the respondents' position) that acid shock test methodology should not have been used in the testing of the respondents' cheeses. Professor Fink expressed only

general reservations about the technique of acidification and resuscitation of organism. It was not Professor Pennington's evidence that acid shock treatment, which kills off competing bacteria to make it easier to find an organism as a minority component, should not have been employed. In so far as Mr Beattie was challenged at all on the use of acid shock treatment, it appeared to be under reference to a provision of Regulation (EC) 2073/2005, in reference to which the applicants were not testing. I accept Mr Beattie's unchallenged evidence that acid shock methodology was within the flexible scope of ESS's UKAS accreditation (no. 5/1/88 of process). Fundamentally, I have heard no evidence from which I could conclude that the use of acid shock methodology in any way affected the outcome, where the E.coli strain isolated from Lanark Blue, batch E24, is concerned. In particular, I agree that there is no evidence that its use resurrected dead organisms, altered the DNA of any organism, or gave rise to false positive results. That ought to be an end to the matter.

(iii) *the finding of E.coli O unidentifiable H20, stx2d, ST1308, in both Lanark Blue, batch E24, and Dunsyre Blue, batch F15*

[491] The finding of virtually identical STEC organisms in these batches of different cheeses was much discussed in the evidence. In answer 4 the respondents aver that, on the hypothesis that E.coli O unidentifiable H20, stx2d, ST1308, was found in Lanark Blue, batch E24, then a labelling error is the most plausible explanation for this. The applicants contend that the result, as far as Lanark Blue, batch E24 is concerned, is sound, and the explanation lies in cross-contamination on the respondents' premises. Resolving the issue is not helped by the seeming unwillingness of any witness from the applicants, or ESS, or the

respondents, to accept as a possibility that any process for which they were responsible could account for the finding.

[492] Although the issue of mislabelling was raised in the pleadings it was not explored in any detail in the evidence. Indeed, Mrs Cairns appeared to suggest that the most plausible explanation for the result was cross-contamination when the samples of Lanark Blue, batch E24, and Dunsyre Blue, batch F15, were subjected to acid shock treatment at the same time (albeit they were sampled on different days, and, according to Mr Beattie, would have been tested sequentially).

[493] That said, I was impressed by the detailed evidence given by Mr Beattie about both the laboratory procedures which were in place to avoid undermining the traceability of particular samples, or their contamination in the laboratory, and the steps he had taken, once an issue of cross-contamination had been made known to him by the applicants, to check the integrity of the testing process at ESS (which appeared, ultimately, to be the subject of the respondents' focus in this chapter of the evidence). It seemed to me to be significant that Lanark Blue, batch E24, and Dunsyre Blue, batch F15, were sampled on different dates, and that when they were tested, as described by Mr Beattie, the testing was done sequentially. I regarded as important Mr Beattie's evidence about having undertaken a visual inspection of the respective sample tubes, which he was able to retrieve from storage, and having satisfied himself from the differences in colour and texture, that the samples had been correctly labelled. Mr Beattie also described a process by which an analyst was able to undertake, blind, an informal DNA test in the laboratory which showed the samples of Dunsyre Blue, batch F15, and Lanark Blue, batch E24, to be consistent with bovine and ovine DNA, respectively.

[494] I heard detailed evidence on the system operated by ESS to protect the trail of evidence using the individual LIMS numbers, and how individual LIMS numbers were ascribed to each dilution, plate, and sample bottle. The purpose of the system was to facilitate full traceability, and the control of samples, with separate equipment being used for each sample. My overriding impression was one in which the laboratory processes were tightly controlled and the chances of a labelling error, or cross-contamination, highly unlikely. In short, the evidence did not identify any particular part of the laboratory testing process which I considered to present a risk of these events occurring.

[495] Finally, I regarded it as significant that the SNP addresses for Dunsyre Blue, batch F15, and Lanark Blue, batch E24, were, according to Dr Dallman, very slightly different. This showed that there was some variation in the E.coli strain between the batches, and that the strain had been in the batch, showing the SNP change in the last digit, over a period of time to allow the SNP variations to occur.

[496] Despite its many criticisms by the applicants, I have actually taken a much more favourable view of the respondents' food safety management system. However, I have come to the view that, in explaining what is agreed to be a very improbable result, it is more probable that any cross-contamination occurred on the respondents' premises where, in the normal course of events, batches of different types of cheeses are produced, using the same equipment, turned by the same food handlers, and stored in close proximity to each other. It seemed to me that the evidence pointed to there being greater opportunity for cross-contamination at the site of manufacture rather than the sterile laboratory environment, and that such contamination could (and, in this case, did) occur in circumstances which do not infer a systemic failure on the respondents' part. Even

Professor Pennington recognised that it was not possible to guarantee that STEC would be eliminated from food products.

[497] I have not found it possible from the evidence to determine at what precise point a cross-contamination event occurred. In particular, I do not feel able to accept Professor Griffith's evidence about biofilm contamination (which Mr Love did not adopt in his submissions), not least because it rested on a theoretical consideration of the position which was not advised by any visit to either the farm or the respondents' premises. Nor does the evidence allow me to draw any conclusion as to which of the Dunsyre Blue and Lanark Blue contaminated the other. The way in which the evidence unfolded gave me the impression that parties were proceeding on the basis that, if cross-contamination occurred at all, the raw cows' milk was the orginal source (see, for example, the applicants' submissions at p.199). I am unable to make any finding to that effect. All that I can do is proceed on the basis that a STEC strain has been isolated from Lanark Blue, batch E24, and that the more probable explanation for the finding is that a cross-contamination event occurred on the respondents' premises rather than in laboratory conditions, and at a time when batches of Lanark Blue and Dunsyre Blue were being produced at the same time.

(iv) The respondents' food safety management system and compliance with article 5 of Regulation (EC) 852/2004

[498] The applicants submit that the respondents' food safety management system failed to comply with article 5 of Regulation (EC) 852/2004, and that, by virtue of that failure (specifically, to comply with the Hygiene Regulations), the seized Lanark Blue, batch E24, falls to be regarded as unsafe within the meaning of article 14 of Regulation (EC) 178/2002.

The failure in compliance is argued to arise because the respondents failed to perform any testing of their raw milk for E.coli, E.coli O157 and STEC.

[499] It is right that I should own that this has been one of the hardest issues to resolve in these already complex applications. Lying behind it is the singular feature that the results of a remarkably extensive programme of testing are already known. Those results arguably provide a means of assessing the effectiveness of the respondents' control measures, in so far as relating to harmful E.coli, just as the isolation of the six STEC strains, from cheese and milk samples, appears to have advised the view, strongly expressed by Ms Wardrope in her evidence (but with justifiably greater circumspection by Mr Brown), that those control measures "failed" to meet the requirements of the Food Hygiene Regulations (notwithstanding the consistently positive inspections conducted by her subordinate, Mr Dickson, the audits of SALSA, and the FSS audit in September 2016).

[500] The respondents, at paragraph 5.37 of their written submissions, place a gloss on the applicants' position about testing which is inaccurate. The applicants do not contend that raw milk should have been "routinely rejected". As I understood their argument, the applicants submit that the raw milk should have been routinely *tested* for the presence of E.coli O157 and STEC. The revisals to the respondents' food safety management system in November 2016 provided for quarterly testing for STEC. Accordingly, I do not understand the basis for the respondents' argument that testing for STEC would be "disproportionate and absurd". Moreover, it does appear, with respect, that some of the arguments advanced in the respondents' written submissions, on the matter of article 5, become confused with the separate, although related, question as to whether the respondents acceptance of raw milk was in contravention of Annex II, Chapter IX, paragraph 1, of Regulation (EC) 852/2004.

[501] Be that as it may, I will approach this exercise by considering, first of all whether it has been established that the respondents, prior to the summer of 2016, should have been testing the incoming raw milk for all STEC. I will then consider the more specific question whether the respondents' food safety management system should have provided for testing of the raw milk for E.coli O157. I will then address what conclusions can be drawn from a consideration of those issues, and what the respondents actually did prior to the outbreak.

[502] On the first of those issues, I am not satisfied that it has been established that the respondents should have been undertaking such testing. It follows that, at least in that respect, the absence of testing for all STEC would not alone justify the conclusion that the respondents' food safety management system failed to comply with article 5.

[503] I reach that conclusion having regard to a variety of different sources of evidence which I have accepted. Dr Peers Davies, albeit linked by a consultancy role with A&S Cairns, was a both a careful and informative witness. I noted that he did not regard testing for either O157 or STEC (in what I took to be 2016) as standard practice and had not advised any such testing. Mr Thomas, a member of SCA Technical Committee, gave evidence, which I accepted, that the SCA Code of Practice references to testing for "E.coli O157 and other STEC" were intended to communicate that testing for E.coli O157 was an acceptable way of evaluating the risk of STEC. He was unaware of any artisan cheesemaker in the United Kingdom who was testing for STEC organisms other than E.coli O157. Besides, all the reported cases of product recall or infection in the United Kingdom relating to raw milk cheese concerned E.coli O157, and even then there was a paucity of evidence that it was a problem amongst members of the SCA. Mr Thomas also alluded to the poor provision of laboratory services offering PCR testing to a level beyond testing only for O157.

[504] I heard evidence from Mr Brown that, prior to the summer of 2016, he had no cause to convey any concerns, about the presence of STEC in foods generally, to those responsible for inspecting the respondents' premises and processes. As lead food officer in South Lanarkshire, he was unaware that there was any problem with STEC in dairy products in his area, and FSS had issued no advice, or enforcement letters in that respect. He could recall no communication on the subject of STEC in raw milk cheese from EFSA, the FSA or any other authority prior to July 2016. I found Mr Brown's evidence to be consistent with other evidence I have already touched on (and particularly that of Professor Pennington) that the focus had hitherto been on E.coli O157 in the United Kingdom. His evidence falls to be contrasted with that of Ms Wardrope. Her reply, to the question whether concerns over the presence of STEC in foods was on anyone's radar prior to the summer of 2016, that "it should have been" was somewhat evasive.

[505] I am also not persuaded that, even had testing for all STEC been identified as a suitable control measure at whatever intervals, there was (or, indeed, is) a practical means by which any confirmed STEC sample results could be yielded. The applicants submit that I can hold that there were suitable facilities available which would have enabled testing for all STEC to produce practical results. They point to the unchallenged evidence of Mr Beattie that other laboratories in Scotland can test for STEC. They also rely on a passage in Mr Brown's evidence that a company, employed by the respondents, called Geneius, in Newcastle, could test for STEC. (On the last point, the evidence went no further than to disclose that Geneius could generate presumptive results which could not confirm the presence of a STEC organism). While recognising that it is unfortunate that Mr Beattie was not pressed on this point by Mr Errington, his evidence was very limited and general on the matter of the commercial testing said to have been available in Scotland. Plainly, ESS were

not themselves set up in 2016 to undertake the level of intrusive testing required to isolate and confirm the results ultimately reached by PHE. But, more to the point, the suggestion that facilities were available is entirely at odds with position which appears to have been taken by (i) the working group which issued, in about October 2016, the Guidance for Local Authority Enforcement Officers (no. 6/1/151 of process), and (ii) the SCA itself when it published, in March 2017, the clarification to the SCA Code of Practice (no. 6/1/104 of process), to the effect that it was currently considered unrealistic to expect cheesemakers to implement routine testing for STEC (as opposed to E.coli O157) by a United Kingdom laboratory. It was, in my opinion, no less instructive that Mr Thomas gave evidence of an ongoing discussion within the working group of FSS, of which he (and Professor Strachan) was a member, about whether to concentrate testing on E.coli O157, rather than PCR testing more generally, because of the poor provision of laboratory services offering PCR at an appropriate level. All of that lends force to the view of Professor Pennington, which I readily accept, that finding most of the (approximately) four hundred STEC thought to exist would be very difficult. It would likely require the use of WGS, which would, in the present circumstances, be completely inappropriate for both food business operators and enforcement officers to contemplate using on a *routine* basis.

[506] It is in that context that I view the terms of paragraph 5.2.9 of the SCA Code of Practice (which provides that the milk producer and cheesemaker should decide between themselves who should be responsible for implementing a test schedule for *inter alia* E.coli and STEC). It also seems to me to reflect more accurately the reality of the position at that time, spoken to by Mr Thomas, and to confirm Professor Pennington's further observation that none of the stx positive strains identified in the extensive testing of the respondents' cheeses would have been detected using then current food testing systems. I heard no

evidence that access to WGS was routinely available to food producers like the respondents. Indeed, Dr Allison explained that it was only in August 2017 that SERL stopped sending all potential non-O157 STEC strains to PHE from more sensitive typing.

[507] In all the circumstances I do not consider that the evidence justifies a finding that the respondents should have been routinely testing the incoming raw milk, used in the manufacture of the seized cheeses, for all STEC, and I decline to do so.

[508] The next issue to invite consideration is whether it has been established that, to comply with article 5, the respondents ought to have been testing the incoming raw milk for E.coli O157. There are, in my opinion, two distinct aspects to this issue. The first issue arises from the fact that the respondents were admittedly not testing the incoming raw milk. Rather they were testing the curd which is generated in the course of the production process. So, the question is whether that was an appropriate approach to adopt as part of a food safety management system. The second issue is whether the respondents' food safety management system ought to have provided, specifically, for testing for E.coli O157 (and, if so, why).

[509] In relation to the first issue, Professor Pennington and Professor Griffith agreed that there was no specific requirement, in article 5 of Regulation (EC) 852/2004, for a food business operator to test raw materials or the finished product. Rather, there was a general requirement to design and implement a safety management system based on HACCP principles. How it was implemented was the responsibility of the food business operator. In that respect, Mrs Cairns explained to me why the respondents preferred to conduct testing on the curd. She did so in terms that left me to conclude that the absence of any testing of the incoming raw milk was not so much an omission as the result of a conscious decision by the food business operator to conduct testing for E.coli at a stage in the

production process where it was most likely to yield results. What Mrs Cairns said was that she tested for E.coli on the curd because it was at that point that the E.coli was most detectable. She explained, in a manner which gave me confidence that the approach was a considered one, that the milk was mixed by an automatic agitator in the bulk tank and thereafter pumped to the cheese vat, where it was mixed again. The curd was more concentrated at this point. The results of curd testing were routinely looked at during inspections and the results (as demonstrated in the figures contained in annex 4 to the September FAFA) were the best that could reasonably be achieved. Mrs Cairns also explained how, in the past, any E.coli reading on the curd which was out of the ordinary would have caused the respondents to test batches individually, and, if a specific batch was isolated, it would be subjected to further testing (from the centre to the rind) to check that the E.coli was dying off.

[510] Mr Thomas considered that a cheesemaker could test either the incoming raw milk or test the curd because E.coli is expected to form during curd formation, and for many raw milk cheeses will be at its highest after about forty eight hours from the addition of starter culture (being the start of the cheesemaking process). That testing was undertaken on the curd seems to me to have been a matter of judgment which was supported by the respondents' consultants at the time. Leaving aside the question whether there should have been testing, specifically, for E.coli O157, I have not been persuaded that it is a judgment call that can, or should, be criticised.

[511] On the second matter, it appears that the risk of finding E.coli O157 in raw milk was assessed by A&S Cairns (of whom Mrs Cairns of the respondents was a partner, and which supplied the raw ewes' milk to them) as low. Mr Dickson was well aware that the respondents were not testing the raw milk for E.coli O157 on that basis (although he was

aware of a STEC risk). He had not suggested that the respondents should do so, and was satisfied with the situation. So too were the auditors who tested the respondents' operation against the SCA Code of Practice, resulting in the respondents' SALSA+SCA accreditation. Officials from the FSA, FSS, and the applicants, who had actually visited the respondents' premises for the purposes of auditing or inspection, had approved the respondents' food hygiene controls. There is some force, in my opinion, in the criticism advanced by the respondents, that those who now sought to criticise their controls (including the authors of the FSS risk assessment) had never visited the premises for the purposes of an audit.

[512] One of those who had not visited the respondents' premises in advance of the proof was Professor Griffith. The applicants are right to point to the virtually non-existent cross-examination of this witness by Mr Errington. It was a matter of sufficient concern to me at the time that I specifically challenged Mr Errington on whether he wished to put other matters to the witness. It makes the task of assessing Professor Griffith's even more challenging than it would otherwise have been. I have already commented on that witness's approach to the issue of cross-contamination. Suffice it to say that I was surprised at the confidence with which he expressed himself on that matter in circumstances where he had not visited the premises. But that was not the only matter on which Professor Griffith gave evidence. He considered that the respondents should have been testing the incoming raw milk for STEC and E.coli O157. I have already dealt with the position regarding all STEC, largely on practical grounds pertaining at the material time. However, E.coli O157 testing is a different matter. It seemed to me that, ultimately, Professor Pennington did not disagree that the respondents' food safety management system could have made provision for O157 testing of raw materials, whether that be the milk or the curd, and that it would be logical to do so.

[513] That being so, I am of the opinion that, at least as matter of good practice, there were grounds for including testing for E.coli O157 in the respondents' food safety management system prior to the summer of 2016. Had they done so, as Mr Thomas himself confirmed, the respondents would have been operating in compliance with the SCA Code of Practice. I confess that I found it hard to reconcile what was, ultimately, an essentially common position amongst the witnesses I have just mentioned (that testing for E.coli O157 was at least, logical, and, at most, essential) with the SALSA+SCA audits which bear to have certified compliance with the Code of Practice. Ultimately, I did not hear evidence from the auditor, Jayne Hickinbotham, who undertook the relevant audit after the SCA Code of Practice was in force (and who appears to have been on the technical committee of the SCA when it was produced). I do not, therefore, know whether there was an explanation for the apparent tension, and, if so, what it is. Nor did I hear from Dr Paul Neaves of the SCA, whom Mrs Cairns asserted had said, at a course she attended at Newcastle in 2015, that O157 testing did not need to be done with ewes', as opposed to cows', milk. On a matter of this importance it is a matter of surprise, that Dr Neaves (who was on the respondents' list of witnesses) was not called to give evidence. Without having heard from him, and standing Mr Thomas' own evidence that testing for O157 would have been compliant with the SCA Code of Practice, I am satisfied that good practice would have justified testing of the raw milk, or curd, for E.coli O157.

[514] In reaching that conclusion I have not regarded as significant the decision taken by the respondents to include testing of the raw milk for E.coli O157, or, for that matter, STEC generally, as an admission that they should have been doing so prior to the E.coli outbreak in July 2016. Their position in that respect was explained by Mrs Cairns to the effect that the changes were made in order to satisfy the applicants' concerns, not long after an outbreak

had occurred, that there should be a review of the microbiological testing arrangements then in place.

[515] Finally, however, and against a recognition that there is no specific requirement, in article 5 of Regulation (EC) 852/2004, for a food business operator to test raw materials or the finished product, it is necessary to consider whether the food safety management system which the respondents did implement nonetheless complied with article 5. It is common ground between the parties that STEC is likely to be present from time to time in ewes' milk in Scotland. In addressing this issue, the difficulty faced by the court is the uncertainty in the evidence surrounding the question how the respondents arrived at their assessment of E.coli O157 as low (or low/medium risk). Much of the discussion in the evidence focussed on that assessment. It is, however, far from clear how that assessment came to be made, at least as far as ewes' milk was concerned. Mrs Cairns stated, under reference to the Risk Analysis (no. 6/1/38) dated 1 April 2014 – a document apparently concerned with the primary production of raw cows' milk – that this assessment had been prepared with the assistance of Jayne Hickinbotham of SALSA, who had been a mentor of Mrs Cairns. The analysis in that document of E.coli O157 as low or medium risk appeared to relate to issues of cattle health and husbandry. Careful scrutiny of the respondents' other pre-July 2016 food safety management paperwork does, however, disclose E.coli O157 as a potential hazard at the process step described as "raw milk intake and storage" (no. 6/1/41 of process). The source of that assessment is the document entitled "Risk Analysis and Prerequisite Programme: Purchased Raw Milk, intake and storage", and it makes reference to ewes' milk and justifies the risk assessment by reason of there being no evidence of the occurrence of E.coli O157 in the finished product.

[516] Mrs Cairns' evidence was that she was aware of the risk of E.coli O157, and had been since the Wishaw E.coli outbreak in 2006. I was satisfied that, although Jayne Hickinbotham was the originator of the low/medium risk assessment, Mrs Cairns was alive to the risk presented by pathogenic E.coli. I noted that she was able to point to the fact that the curd testing results for Lanark Blue between March and July 2016 demonstrated that the levels of E.coli (and, therefore, the presence of any potential pathogens) were minimal. When asked, specifically, about the elevated enterobacteriaceae results for raw ewes' milk contained in the schedule, no. 5/1/75 of process, and that the respondents should have been alerted to the possibility that faecal contamination was worsening, Mrs Cairns responded (I have to say, quite convincingly) that those low curd results told her that E.coli was not responsible. Indeed, Professor Pennington made the point that all but one of the results (which was, itself, very low) were to be considered below the level of detection. Support for Mrs Cairns' position may also be found in the apparent fact that, with the exception of batch E24, none of the supposedly elevated enterobacteriaceae results, contained in the schedule referred to by Mr Brown, coincides with any of the batches of cheese from which PHE were able to confirm a STEC organism.

[517] I do not regard it as sufficient to look simply at the absence of testing for STEC and E.coli O157 as a justification for condemning the respondents' food safety management system. I heard evidence from Mrs Cairns about the controls which were in place to ensure, so far as possible, hygienic milk. The farm operated by A&S Cairns sits adjacent to the respondents' premises. Mrs Cairns is a director of the respondents as well as a partner of A&S Cairns. It is artificial to view the respondents' food safety management system without regard to these controls. The measures adopted, cumulatively, by A&S Cairns and the respondents, included maintaining a closed flock, somatic cell count recordings for each ewe

in the flock, a state of the art milking parlour, and associated cleaning and disinfection procedures to protect the teats of the ewes during the milking process, which Dr Davies considered to be a very important control step in for reducing or eliminating the risk of faecal contamination. Dr Davies also observed that the somatic cell count recording process was both time consuming and costly, and had not formed part of the culture of sheep dairying in Europe or the United Kingdom, and that the results showed unusually good udder health. Dr Davies considered that the respondents' hygiene measures were the most stringent as could practically be implemented. His evidence carried weight because it dealt, in a practical way, with the manner in which good animal husbandry and hygienic milking practices assist in minimising the risk of faecal contamination. Professor Pennington too had the benefit of having visited the respondents' premises and considered that everything was being done that could conceivably be done to achieve the lowest possible level of bacteriological contamination.

[518] In the final analysis, the evidence left me with the clear impression that the respondents were aware of, and took seriously, the acknowledged risk of finding pathological microorganisms in raw ewes' milk, were mindful of the risk where E.coli O157 was concerned, and invested in processes, procedures, and facilities, which were intended to address that risk, from flock to end product. In reaching that view I acknowledge, as the applicants submitted, that the joint report of Professor Strachan (absent Professor Noah) had expressed the opinion that (i) the extent to which STEC presence can be controlled by ensuring a flock is "closed" (i.e. ensuring no external sheep move into the flock) would need to be verified by testing the faeces of the sheep for STEC; (ii) there are no studies published which would confirm, in practice, the extent to which animal husbandry measures can control the presence of STEC, and (iii) milking management systems are unlikely to

eliminate the risk of the presence of STEC and the efficacy of such a measure would need to be verified, for example, by the levels of commensal E.coli in the milk and whether STEC was found in the milk. To these submissions I would say that (i) it is no part of the evidence that testing the faeces of sheep would have been practicable (and the applicants make no case on record that it should have been done); (ii) there may be no such studies, but the joint report did draw attention to the perhaps imperfect example of the STEC outbreak in Oregon, USA, in which poor hygiene procedures may have played a significant role in what occurred, and (iii) the respondents were testing the curd for E.coli as a means of determining levels of faecal contamination, and I have already held that it would not have been practicable for the respondents to have been testing for all STEC. The respondents' approach of testing for faecal indicator organisms would also appear to be consistent with such independent guidance as that contained in the Codex Alimentarius Commission Report which, I note, was described as a progress report on the joint expert meetings of the WHO and the Food and Agriculture Organisation of the UN on microbiological risk assessment dated October 2017. The legal status of such a document, if any, was not explored in either the evidence or submissions. I was given to understand that it had not been adopted in any formal sense, but it is instructive in informing the respondents' general approach.

[519] Moreover, the evidence does not persuade me that, as the applicants submitted, it is plain from the range of test results obtained from a range of samples that the respondents' HACCP based food safety management system was not working. For a start, Professor Pennington's evidence was that all previously reported STEC-related illness in Scotland has been caused by E.coli O157:H7. But none of the results disclosed an E.coli O157 pathogen. In this respect, I reject Mr Beattie's evidence, which was at odds with the evidence of both

Dr Scheutz and Dr Dallman, and Professor Pennington, that the finding of E.coli O157:H42, stx negative, represented a potentially harmful E.coli. These stx negative strains, isolated in Lanark White cheese samples, were relied on by FSS, in relation to the issue of the FAFA in November, as having been "isolated from cases of human illness consistent with E.coli O157 infection". They were referred to by Mr Brown as having, in part, advised the issue of Ms Wardrope's regulation 27 certificate, at least in relation to Lanark Blue Remainder. I accepted the evidence of both Dr Scheutz and Dr Dallman, and Professor Pennington, that the Lanark White strains are not pathogenic. In fact, they are not STEC at all.

[520] Both Professor Pennington and Dr North expressed the view that the failure to find O157:H7 in the numerous cheese samples tested was, in itself, validation of the A&S Cairns assessment of E.coli O157 as low risk. While recognising that end product testing in itself may not, because of the heterogeneous nature of cheese, identify all pathogenic organisms, it is difficult to avoid the conclusion that the same might be said of the revised HACCP plan approved by the applicants, which provides for only quarterly STEC testing . What can equally be said is that the absence of any evidence of pathogenic E.coli O157 brought out in the testing of the respondents' cheeses is consistent with the very low E.coli numbers shown in the curd testing results for March to July 2016. I acknowledge, of course, that those results relate to Lanark Blue (which, aside of batch E24, was not apparently tested at all). But, as I understood the position, the results fell easily within the criteria for both a semi-hard blue cheese (like Lanark Blue) and a hard cheese (like Corra Linn) set by the SCA Code of Practice (at appendix 5.2.3). The levels of E.coli appear to have been consistently very low over a period of months, and it is a curious feature of the risk assessment associated with the September FAFA that, aside of narrating the results in annex 4, no mention is made of them, and no comment passed upon them.

[521] What has been established by the closest scrutiny of their cheeses and raw ingredients is that six E.coli strains, of potential but unproven pathogenicity (as far as the United Kingdom is concerned) have been isolated. Professor Strachan's evidence, with whom Professor Noah agreed and which I accept, is that it is known that, from time to time, STEC can be found in ready-to-eat raw ewes' milk cheese, and that this is likely to be the case in Scotland. Moreover, Dr Davies made the point that, at a molecular level, it is never going to be completely possible to eliminate all contamination; it is, therefore, important to suppress it to the lowest level possible. Professor Pennington said that it was not possible to guarantee the elimination of STEC, and that food products on the market do contain STEC. No doubt this evidence advised the respondents' submission (at paragraph 5.3) that raw milk is not a sterile product, nor is it possible to make it so. From the evidence I heard, it seems to me that, for as long as there is no restriction on the use of raw milk as an ingredient, there will always be a risk of STEC being present in the end-product. To acknowledge this is to recognise that no testing system can be full proof. Professor Pennington acknowledged that if a sample test does not disclose an organism it does not mean definitively that the organism is not there. It is simply good evidence that it is not present.

[522] It is in that context that I conclude that the finding of the six STEC, which were confirmed, using WGS, by PHE, should not be determinative of the question whether the respondents' HACCP based food safety management system was working. Rather, the curd results, taken together with the detailed evidence I heard about the milking procedures adopted by the respondents (under the guidance of Dr Davies), and also the sheer volume of testing, to which the respondents' products have been subjected for the PHE results to be produced, and, to a lesser extent, the test results for the samples submitted by the

respondents to Actalia and, according to Mrs Cairns, Ashley, lead me to conclude that the finding of six isolated STEC does not point to a systemic failure. Besides, I have already held that it would not have been practicable for the respondents to have been testing for all STEC prior to the summer of 2016. Since I heard unchallenged evidence from Professor Pennington that these six STEC would not otherwise have been found on the basis of existing testing systems available to the respondents, it is difficult to see how, even applying hindsight, their discovery could evidence a failure in the respondents' HACCP based systems and processes.

[523] The applicants emphasised the primary responsibility of the food business operator to produce safe food (which, for the avoidance of doubt, I accept). That approach, though, tended to elide the clear and obvious point that, over a period of many years, the respondents' processes were given a clean bill of health by their regulator. It was my clear impression that Ms Wardrope's evidence, that the respondents had "failed" to comply with article 5 of Regulation (EC) 852/2004 prior to the 2016 E.coli outbreak, was a judgment made with the benefit of hindsight. I accept that the absence of criticism in the annual inspections and audits preceding the summer of 2016, and the events which followed, is not in any way determinative of the issue of compliance with article 5. However, that lack of criticism is still available as evidence that experienced environmental health officers like Mr Dickson had examined the respondents' processes and found no systemic issues of any concern, and I have taken that evidence into account.

[524] In all of these circumstances, it is my opinion that, where the seized cheeses are concerned, the applicants' submission that the respondents' food safety management system failed to comply with article 5 of Regulation (EC) 852/2004 is not well-founded.

[525] I wish to add two further points. In the first place, I acknowledge that, in so concluding, I am necessarily disagreeing with conclusions of Professor Griffith which were essentially unchallenged. In particular, I have not accepted his criticism of the assessment of E.coli O157 as low risk. Professor Griffith, it will be recalled expressed the opinion that the respondents were in error in reaching that assessment. He illustrated that position by reference to the risk evaluation matrices in the SCA Code of Practice and Commission Notice 2016/C 278/01. Mr Errington did not establish directly any basis upon which those matrices should be regarded as unreliable. However, it seems to me that it is still open to me to consider the results of the whole of the testing exercise undertaken by, or on behalf of, the applicants, and, to the extent that they were spoken to by Mrs Cairns, the absence of any finding of E.coli O157 in any samples submitted to Ashley or Actalia, in reaching a conclusion as to whether the respondents' assessment of the risk has been borne out. In that respect the only E.coli identified with the serotype O157 was the O157:H42, stx negative strains isolated from Lanark White and Corra Linn. These are the strains described by Professor Pennington as a "bog standard" E.coli. I have accepted Professor Pennington's evidence (and, to the extent that he was in agreement in this respect), the evidence of Dr North, that the assessment of risk made by the respondents, or on their behalf, has been validated by the testing results which were placed before me. I preferred Professor Pennington's evidence, in particular, because he spoke from a position of having informed himself, not just about those test results, but also about the processes which formed part of the respondents' food safety management system. He had visited the respondents' premises. By contrast, Professor Griffith had not visited the premises, he was far from clear what HACCP documents he had examined for the purposes of his report, and he seemed to me to be overly anxious to comment on other matters (notably, the possibility of biofilm

contamination on the premises) which formed no part of the applicants' cases. He should have been challenged more effectively, but, in a matter of such importance, I do not feel able to conclude that his evidence must be preferred simply because it was not adequately challenged. It is for the court to determine, in applications of this kind, what evidence it considers appropriate in advising the question whether any food fails to comply with food safety requirements (1990 Act, section 9(6)). That has advised the approach I have taken to this issue.

[526] In the second place, my assessment of the respondents' food safety management system, for the purposes of these applications, should not be read, in any way, as an endorsement of any particular approach to testing for STEC as of June 2018. The applicants submitted that it was plain from the evidence of Dr Scheutz and Dr Dallman that, with the passage of time, new and emerging STEC strains are being encountered, and associated with illness. I accept that evidence. The applicants also submitted that testing for the top serogroups (whether that be the so-called "big five" – O26, O103, O111, O145, and O157 – or some other combination, including O104, which was responsible for the sprouted seeds outbreak of 2011) was too restrictive. Standing the views I have already expressed on the article 5 case, it is unnecessary for me to reach any concluded view on those submissions. Indeed, I doubt whether it would even be appropriate to determine what must ultimately be a matter of food safety policy for government and its regulators. As Mr Love pointed out during a brief hearing for oral submissions, it is not for any court to second-guess the value which a domestic legislator may decide to put on health. It is for the EU member states to decide what degree of protection they wish to assure (*Scotch Whisky Association and others* v *The Lord Advocate and another*, [2017] UKSC 76, at paragraph 48).

[527] That said, the applicants' submissions do illustrate the moving picture which pathogenic E.coli present, and it will doubtless be the case that HACCP based food safety management systems, which Professor Griffith pointed out required correctly to identify existing hazards, cannot stand still in a world of developing risk. What was sound for 2016 may not be sound for 2018. The applicants' submissions also served to focus on a peculiar feature of the evidence. Article 1 of Regulation (EC) 178/2002 provides the basis for

> "…the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market…"

The evidence I heard about the lack of consensus on the EFSA scientific opinion, and its proposed molecular classification scheme, and apparently differing definitions of what constitutes pathogenic STEC across member states in Europe (spoken to, particularly, by Dr Allison and Dr Scheutz), disclose the clear potential for lack of consistency in the internal market, and, in particular, variability in the application of food safety standards as between member states in respect of products which are then exported, and consumed, throughout the internal market. Balancing fairness and food safety in this highly complex field, will doubtless be a challenge for food regulators.

Conclusion in relation to application B20-17

[528] I have reached the conclusion that the applicants have succeeded in establishing that the seized Lanark Blue, batch E24, is to be considered unsafe within the meaning of article 14 of Regulation (EC) 178/2002 by reason of being unfit for human consumption.

[529] The applicants submit that, in determining whether this batch is to be considered unsafe, the precautionary principle, set out in article 7 of Regulation (EC) 178/2002, is

engaged, and it justified the actions taken by both FSS and the applicants to have the cheese seized pending microbiological testing. During his evidence, Dr North gave evidence to the effect that, notwithstanding the terms of the FSS risk assessments, it was for the applicants to undertake their own risk assessment before taking action in relation to the seized cheeses. It was not always easy to follow Dr North's evidence about precisely when it was said that this risk assessment should have been undertaken, and how it inter-related with the risk assessments undertaken by FSS. That situation was not made any easier by the absence of any pleadings that I could see identifying the content of any such risk assessment, and whether it was intended to address the seizure of the cheese batches (and, for that matter, which batches), or the applications for their destruction which are now before me. Compounding these difficulties is the contention which is made on record by the respondents to the effect that the present proceedings are the proper forum for determining whether their cheeses meet food safety requirements.

[530] It is far from clear to me that, in the face of two FAFAs from FSS, an investigation of an outbreak of E.coli in the summer of 2016, and by the application of a precautionary approach to risk management which is justified by the provisions of article 7 of Regulation (EC) 178/2002, there was any real scope for the applicants to do other than comply with the directions which had, in effect, been given by FSS. In any event, evidence having been led in each of the applications, it does not seem to me to serve any useful purpose to revisit the decision taken by the applicants to seize the cheeses. I am faced with having to decide whether or not it has been established that the cheeses that have now been seized fall to be condemned.

[531] In that respect, my conclusion in this particular application is advised by the following considerations:

(i) Lanark Blue, batch E24, is a ready-to-eat product;

(ii) A live organism was isolated from batch E24;

(iii) On testing by ESS, SERL, and PHE, the live organism was found to have E.coli O unidentifiable:H20, stx2d, ST1308, which is a STEC.

(iv) The STEC so isolated is potentially injurious to health;

(v) The HPA Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market provide that detection of *any* STEC gives rise to a high microbiological risk category and falls to be treated as "Unsatisfactory: Potentially injurious to health and/or unfit for human consumption";

(vi) Paragraph 10 of the "Working Policy on the Detection of STEC in foods" provides that the confirmed presence of STEC in a batch of food falling into profile 1 is considered a serious risk to public health. Evidence indicates that some strains are not pathogenic, but a precautionary approach is appropriate given the uncertainty in the evidence and the potential for severe disease";

(vii) On the evidence I do not consider that the test result is explicable by a labelling error. In other words, I am satisfied that a viable STEC has been isolated and confirmed;

(viii) For reasons discussed earlier in this Opinion, I agree with the applicants' submission that, a STEC having been isolated from a sample of Lanark Blue, batch E24, the onus is indeed on the respondents to rebut the presumption in article 14.6 that the whole of the batch is unsafe, and

(ix) I do not consider that the evidence leads to the conclusion that "there is no evidence that the rest of the batch, lot or consignment, is unsafe". The fact remains that a STEC was isolated and confirmed. It is impossible to know the extent to which the cross-contamination event may ultimately have affected the remainder of the batch. But, the

heterogeneous nature of cheese means that I cannot be satisfied that, whatever the nature of the contaminating event (which is, I emphasise, a circumstance peculiar to application B20-17), the remainder of the batch will be free of other such live organisms.

[532] These particular considerations, coupled with the expert evidence I heard, under reference to clinical cases, about the potential of this organism to cause human illness and to which I have already made extensive reference, lead me to conclude that Lanark Blue, batch E24, should be regarded as unsafe by reason of being unfit for human consumption for the purposes of article 14 of Regulation (EC) 178/2002, in the sense of being "unacceptable for human consumption...for reasons of contamination".

[533] For completeness, I should clarify that I have not heard any evidence or submissions, specific to this application, such that I should have regard to the cheese maturing process in determining whether the isolated strain would, by now, have died off. It is a curious feature of these applications, and one for which there has never been a satisfactory answer, that orders are sought in respect of foodstuffs which will have continued maturing in their seized conditions. In respect of Lanark Blue, batch E24 (and the batches of Corra Linn from which STEC strains were isolated), it is sufficient to proceed on the basis that STEC strains of potential pathogenicity were isolated, and a precautionary approach merits the granting of the orders sought.

[534] I have reached that conclusion notwithstanding my rejection of the applicants' submission under reference to article 5 of Regulation (EC) 852/2004. Rejection of that submission has significance for the other applications, but does not, in my view, affect the outcome here.

LAN B21-17

[535] Much of what has already been discussed is relevant to this and the third application before the court.

[536] The starting point for the applicants' submission is the evidence contained in the joint report by Professor Strachan and Professor Noah. At p.209 of their written submissions the applicants set out various matters on which the two Professors were in agreement. It is unnecessary for me to repeat the submissions. They can be condensed to a common position that STEC are likely to be present from time to time in ewes' milk in Scotland, and that STEC can survive the cheese ripening process in the production of ewes' milk cheeses. The applicants submit that it can be taken from the joint report that raw ewes' milk in Scotland might reasonably be expected to be contaminated with pathogenic organisms.

[537] On that aspect of the applicants' case it seemed to me that the respondents' own evidence recognised that it is not possible guarantee that faecal contamination, and therefore the presence of STEC in the raw milk ingredient, can be eliminated. However, the respondents' response makes the point that the regulation 27 certificate issued by Karen Wardrope on 3 February 2017 was related, by her, to a breach by the respondents of Regulation (EC) 852/2004, Annex II, Chapter IX, paragraph 1. In terms of that provision it is not enough for the applicants to demonstrate, whether by reference to the evidence of Professor Strachan or elsewhere, that raw ewes' milk in Scotland might reasonably be expected to be contaminated with pathogenic organisms. The part of the Regulation invoked by Ms Wardrope carries the qualification "to such an extent that, even after the food business operator had hygienically applied normal and/or preparatory or processing procedures, the final product would be unfit for human consumption". For these purposes

"unfit for human consumption" has the same meaning as in Regulation (EC) 178/2002 (Regulation (EC) 852/2004, article 2.

[538] The question which then has to be considered is whether, taking into account the respondents' safety management system at the time, and viewed objectively, all batches of Lanark Blue Remainder might reasonably be expected to be contaminated with harmful E.coli to such an extent that it would be unacceptable for human consumption for reasons of contamination. To answer that question requires, in my opinion, consideration of the procedures and processes which were in place when the cheese was produced, the maturing process of the cheese itself, and the test results, and to which I have already made reference.

[539] I have already explained why I disagree with the submission that the respondents' food safety management system failed to comply with article 5 of Regulation (EC) 852/2004 (and, therefore, the Hygiene Regulations). For the avoidance of doubt I include in the food safety management system all of the hygiene controls intended to address faecal contamination or infection, from the somatic cell count monitoring of the ewes, and culling of animals, to disinfection arrangements during the milking process, as well as the steps taken to disinfect the cheese rooms, the heating of the cheese vat, the employment of separate milk lines and, of course, monitoring of E.coli levels during the actual production process. (In that respect I reject the further submission by the applicants that Lanark Blue Remainder should, by reason of a breach of article 5, be regarded as unsafe within the meaning of article 14 of Regulation (EC) 178/2002).

[540] As regards the maturing process of the cheese itself, there appears to be a consensus that E.coli do die off in the process of cheese maturation. The microbial predictions undertaken and BRI Campden, on the applicants' instructions, with a view to advising on the die-off rate of microbial organisms in the production of Corra Linn, disclosed that, on

average, between 180 and 200 days would be required to achieve a 6-log reduction in E.coli O157 numbers (that being, in effect, elimination). But, as Mr Brown confirmed, one STEC strain from Corra Linn, batch B17A, was still capable of isolation one year after manufacture. That demonstrates that predicting precisely when E.coli are completely eliminated is not an exact science. Having taken a positive view of the food safety management system, however, I do not consider that such an isolated result justifies the conclusion that all of the batches of Lanark Blue Remainder might reasonably be expected to be contaminated with harmful E.coli to such an extent that they are unacceptable for human consumption, without consideration of the stage of maturation that the seized batches had reached, or of any labelling (of the kind proposed by the respondents in January 2017) identifying the product as a raw milk cheese.

[541] I have also discussed the results of curd testing for Lanark Blue, and the consistently low levels of E.coli which they disclose. In these circumstances it seems to me to be both legitimate, and necessary for the purposes of Annex II, Chapter IX, paragraph 1, to have regard to the implications of those results for the presence of harmful E.coli in the end product. The respondents point to Professor Strachan's evidence that O157:H7, if present in a population of generic E.coli, might represent between 0.1% and 1% if the total population. They also refer to Professor Pennington's evidence when he expressed the view that the lowest level for an infective dose might be of the order of 50cfu/g, with anything less being guesswork. Either way, the curd results for faecal indicator organisms, which are at or below the level of detection, would place a very small number indeed on the numbers of pathogenic organisms, if any. The term "vanishingly small" employed by Dr North would, therefore, appear apposite.

[542] That conclusion seems to me to be well illustrated by the results in fact produced in the whole process of testing the respondents' cheeses. Those results, of course, reveal nothing about any levels of harmful E.coli in Lanark Blue Remainder. There are none across the whole of the eighty three batches in respect of which an order for condemnation is sought. In relation to Corra Linn, however, the results of testing the hundreds of cheese samples taken disclosed only three STEC strains. Of these, closer inspection of the applicants' own evidence discloses that (i) if it has any harmful effects at all, the general population are less susceptible to stx2e; (ii) Dr Scheutz' assessment that the stx1c strain may be associated with severe diarrhoea, and probably abdominal pain, was qualified by his acknowledgement that that was still being looked into, and (iii) the stx2b strain should be considered to be only diarrhoeagenic.

[543] I conclude that the test results alone do not justify the applicants' submission that the entire stock of Lanark Blue Remainder, seized in February 2017, should be condemned by reason of any breach by the respondents of the terms of Regulation (EC) 852/2004, Annex II, Chapter IX, paragraph 1. At the same time, I have discounted as a relevant factor, in my assessment of this application, the finding in relation to Lanark Blue, batch E24. The unusual background to that finding, which I have endeavoured to resolve, is such that I find myself unable to conclude that it points to any more general problem about the production of Lanark Blue cheese, and I do not regard the limited findings on testing to evidence a general problem of cross-contamination. To have done so, I would have required to hear evidence of hygienic practices which were far removed from those to which Dr Davies spoke.

[544] The applicants rely, in support of this application, on the terms of Annex II, Chapter IX, paragraph 3 of Regulation (EC) 852/2004. My only further observation is that that particular provision did not form the basis of Ms Wardrope's certificate.

[545] However, the applicants submit that I should also have regard to the circumstances of the issue by Ms Wardrope of the regulation 27 certificate, including the FAFA background, and the advice being furnished by ESS/SERL, and Ms Wardrope's own experience and understanding. To the extent that the evidence available to Ms Wardrope in February 2017 could advise that issue, it is worth recalling that the issue of the FAFA and FAFA-02 are not determinative. As I have previously said, it is for the court to decide, on the basis of such evidence as it considers appropriate in the circumstances, whether the orders sought in these applications should be granted. In any event, it is instructive that both FAFAs were advised, to an extent, by the finding of a E.coli O157:H42, stx negative, strain in Lanark White, which is not a STEC and is not pathogenic. It is no less instructive that Mr Beattie of ESS and Dr Allison of SERL both thought that this organism had the potential to cause human illness – a position which runs contrary to that of Drs Scheutz and Dallman, and Professor Pennington, whose evidence on that matter I preferred.

[546] The applicants submit that the fact of a requirement for testing in itself indicates that it ought to be foreseeable that raw ewes' milk might be contaminated. I am uncertain what that submission is intended to convey. What I have already held is that the processes and procedures adopted by the respondents at the time when the seized cheeses were produced, demonstrated that the respondents were aware of the risk of harmful E.coli and other pathogens in the raw milk, and had identified what they conceived to be the best way of monitoring that risk through testing the of the curd.

[547] The respondents argue (at section 6 of their written submissions) that there is a lack of proportionality in the proposed enforcement measures. They invoke article 7.2 of Regulation (EC) 178/2002. Under reference also to the Communication from the Commission on the Precautionary Principle (no. 6/1/154 of process) the respondents argue that steps taken in pursuance of that principle must be proportionate and not have a greater impact on the free movement of goods than is necessary to achieve the high level of protection underpinning European Regulations in the area of food safety. Accordingly, so it is argued, it would be disproportionate to condemn all batches of Lanark Blue Remainder, regardless of whether it had completed its maturation period, in circumstances where the applicants were aware that E.coli would continue to die off (in both Lanark Blue and Corra Linn).

[548] In my opinion, even on a precautionary approach to the pathogenicity of the strains isolated from Corra Linn, no justification has been established for condemning all eighty three batches of Lanark Blue Remainder. Putting it another way, I am satisfied that Lanark Blue Remainder was "produced, processed or distributed" in compliance with the Hygiene Regulations. In my opinion, the evidence establishes that the respondents did not accept raw milk for the production of Lanark Blue Remainder which might reasonably be expected to contain pathogenic organisms to such an extent that, even after the normal processing procedures had been applied, the resulting batches would have been unfit for human consumption. That is sufficient to deal with the application on its merits. However, for completeness, I would agree that an order for destruction of the batches of Lanark Blue Remainder would represent a disproportionate response to what the test results disclose about the respondents' processes and products.

[549] Before moving, more briefly, to the final application before me, I should make it clear that, in reaching this decision, I am not ignoring the stx1a, stx2a, result for the raw milk sample set out in the table of results from PHE and SERL. I heard no evidence about the circumstances in which the two samples of raw milk were taken, beyond the agreed fact that they were taken on 29 September and 19 October 2016. Scrutiny of the productions would appear to demonstrate that none of the batches of seized cheese would have been manufactured using raw milk from September and October of 2016. Indeed, there is no evidence before me that the milk which was sampled would, at that stage in the year, have been destined for cheese production anyway. In the absence of more detailed evidence as to these matters I have not drawn any adverse inference from this particular result.

LAN B33-17

[550] In view of the conclusions I have reached in relation to applications B20-17 and B21-17, I can deal more briefly with the application which is concerned with the seized batches of Corra Linn.

[551] In the first place, I have already rejected the applicants' submission that Lanark Blue Remainder should be condemned by reason of having been produced, processed or distributed by the respondents in compliance with the Hygiene Regulations, and, specifically, Article 4, Annex II, Chapter IX, paragraph 1 of Regulation (EC) 852/2004. For the same reasons, I do not consider that the evidence justifies such an order in relation to Corra Linn. The applicants concede that there is no direct evidence before the court of actual contamination of the respondents' cheeses. I quite understand the applicants' position that that does not of itself matter because their position is predicated on the acceptance of raw ewes' milk and the processes by which the cheese was manufactured, including the testing

regime which operated at the relevant time, and what the respondents' reasonable expectations ought to have been about contamination by pathogenic microorganisms. However, for reasons which I do not propose to repeat, I do not accept that those processes lead to the conclusion which the applicants invite me to draw.

[552] There are, of course, two specific differences between this application and the Lanark Blue Remainder application. In the first place, PHE did manage to isolate STEC strains from three different batches of Corra Linn. In the second place, the certificates dated 24 February and 18 March 2017 were issued under reference to an additional provision of Regulation (EC) 852/2004, namely Article 4, Annex II, Chapter IX, paragraph 3. I will deal with each of these in turn.

[553] On the matter of the STEC strains found to be present in the samples of Corra Linn, I adopt the same approach to pathogenicity as I deemed appropriate in relation to Lanark Blue, batch E24. I have carefully considered the evidence of both Professor Pennington and Dr North which points to the absence of any previous recorded instance of human illness in the United Kingdom attributable to any of these strains. I have also taken account of Professor Pennington's opinion that the absence of an adherence gene points away from these strains being pathogenic. However, ultimately, I have accepted the applicants' submission which is to the effect that the direction of travel, in food safety terms, is away from a purely reactive approach to one where "a precautionary approach [to the finding of a confirmed STEC] is appropriate given the uncertainty in the evidence and the potential for severe disease" (UK Working Policy, no. 6/1/150 of process, paragraph 10). Accordingly, I consider that the three STEC strains, which were isolated from samples from Corra Linn, should be regarded as potentially pathogenic. In the absence of any evidence that the

remainder of each batch did not contain such an organism, I have made the orders sought in relation to batches B17A, E23A, and F27A only.

[554] In doing so, I recognise that the application is brought under regulation 27 of the 2006 Regulations. However, I consider the powers of the court under section 9(6) of the 1990 Act to be wide enough to permit me to make the orders on the basis that the evidence I have heard satisfies me that it is necessary to do so.

[555] That approach has its limitations. I have found it impossible to accept the proposition (at p.216 of the applicants' written submissions), made under reference to the HPA Guidelines, that E.coli O157:H42 should be regarded as potentially injurious to health and/or unfit for human consumption. The applicants have, at various points, made reference to, and relied upon, the UK Working Policy document. My interpretation of that policy is that, for a batch of food falling into Profile 1 to be considered a serious risk to public health, the presence of a STEC requires to be confirmed. Confirmation for these purposes falls to be contrasted with *detection* (my emphasis), and the Working Policy states (p.3, paragraph 8) that "[C]onfirmation of the presence of stx genes in an isolated E.coli strain is generally required before [action to withdraw or prevent product being placed on the market] is taken". It is far from clear to me that the excerpt from the HPA Guidelines, relied on by the applicants, is intended to apply to a situation where, under the most exhaustive testing conditions, a stx negative result is confirmed. Indeed, it seems to me that the opposite is true. What Table 1 in the HPA Guidelines requires, on detection of E.coli O157 and *other* STEC, is for the process of confirmation to take place. In relation to the E.coli O157:H42, stx negative, strain that has happened. It is not a STEC. I, therefore, reject the submission that the finding of O157:H42 has any relevance to the outcome of this application.

[556] Nor do I consider that the fact that these strains were isolated affords a justification for condemning the remaining batches of Corra Linn. Unlike the situation with Lanark Blue, the respondents' Corra Linn cheese was the subject of a very sizeable sampling exercise. Although Mr Brown and Dr Allison were not quite at one on the number of samples taken or submitted, the number can be measured in hundreds. The results, involving three possible examples of a diarrhoeagenic E.coli (and, in one case, possibly bloody diarrhoea), arrived at in such a context may justify action where the individual batches are concerned. Ultimately, however, Dr Scheutz identified all three strains as representing a low risk, in Denmark, for STEC infection. They do not justify the destruction of all other batches, regardless of stage of maturation or of any labelling which might otherwise be applied to the sold product.

[557] In the second place, my assessment of the respondents' milk hygiene procedures, processes within the milking parlour and cheese room, and the investment in modern state of the art facilities at the farm, is such that I did not regard the conclusion I reached on the source of cross-contamination in relation to Lanark Blue, batch E24, as indicating a systemic problem any more than it appears to have done the applicants' own inspector and the SALSA auditors. Mr Brown may have noted that cross-contamination could not be ruled out because the respondents' process of making cheese involved handling by their personnel. If there was a systemic problem around cross-contamination one might have expected to see very different test results to the ones evidenced at the proof. Professor Pennington said that E.coli O157 remained the dominant strain in Scotland. None was found in all of the tests which were carried out.

Postscript

[558] The applicants submitted, in application B21-2017, that the respondents had not sought to challenge the certificate under regulation 27 of the 2006 Regulations. On reading this submission it occurred to me that it may be the product of the record, in that application, being without a plea-in-law seeking reduction *ope exceptionis*. Such a plea was, however, included in a minute of amendment tendered on 22 May 2017. I was not addressed by either party on the necessity for reduction in this way, and I doubt whether, in summary applications of this kind, it would be necessary to sustain the relevant pleas-in-law to give effect to the decisions I have reached. However, if either party considers that the court should give effect to those pleas in applications B21-17 and B33-17, respectively, the matter can be addressed at the hearing which I have fixed in terms of the interlocutor issued with this judgment.