REPORT

FSA Project FS102128

A study to review current evidence and outline work-streams to support the development of a policy for smoked, skin-on sheep meat

Dragan Antic[1], Phil Jones[2], Eleni Michalopoulou[1], Rita Papoula Pereira[1], Robert Smith[1], Kalep Bulus Filli[3] and Martin Rose[4]

[1] School of Veterinary Science, University of Liverpool
[2] Institute of Infection and Global Health, University of Liverpool
[3] Department of Food Science and Technology, Modibbo Adama University of Technology, Nigeria
[4] The Food and Environment Research Agency (FERA)

November 2015

Table of Contents

ABBREVIATIONS **5**
1 EXECUTIVE SUMMARY **6**
2 INTRODUCTION **13**
2.1 BACKGROUND 13
2.2 THE PRODUCTION OF SMOKED, SKIN-ON MEAT IN WEST AFRICA 14
3 SYSTEMATIC REVIEW ON SMOKED, SKIN-ON SHEEP MEAT **16**
3.1 SUMMARY 16
3.2 INTRODUCTION 17
3.3 METHODS 17
3.3.1 Study design *17*
3.3.2 Eligibility criteria *18*
3.3.3 Information sources *18*
3.3.4 Search strategy *19*
3.4 RESULTS AND DISCUSSION 19
3.4.1 Studies and literature sources selected *19*
3.4.2 Research on smoked, skin-on sheep meat undertaken by the FSA *21*
3.4.2.1 Production related aspects and official controls 22
3.4.2.2 Microbiological aspects 24
3.4.2.3 Chemical aspects 28
3.4.3 Other studies on smoked, skin-on meat and similar meat products *29*
3.4.3.1 Skin-on goat meat produced in Australia 30
3.4.3.2 Singed skin-on sheep heads ("svið" and "smalahove") 31
3.4.3.3 Smoked/singed, skin-on meat and singed cattle hides ("ponmo" and "welle") produced in Africa 31
3.5 CONCLUSIONS 33
4 CRITICAL REVIEW ON THE SMOKED, SKIN-ON SHEEP MEAT PRODUCTION **36**
4.1 SUMMARY 36
4.2 INTRODUCTION 37
4.3 ANIMAL VARIABLES 38
4.3.1 Sheep production variables *38*
4.3.2 Sheep skin diseases *40*
4.4 IDENTIFICATION OF PUBLIC HEALTH HAZARDS ASSOCIATED WITH SKIN-ON SHEEP MEAT 42
4.4.1 Biological hazards *42*
4.4.1.1 Methodology 42
4.4.1.2 Results 43
4.4.1.3 Effect of the skin-on sheep meat processing on biological hazards 59
4.4.1.3.1 Sourcing of animals 59
4.4.1.3.2 Shearing 61
4.4.1.3.3 Singeing 61
4.4.1.3.4 High pressure water washing 63
4.4.1.3.5 Toasting 64
4.4.1.3.6 Chilling 65
4.4.1.4 Final product (Skin-on sheep meat) 65
4.4.2 Chemical hazards *66*
4.4.2.1 Veterinary medicine residues 66
4.4.2.1.1 Veterinary residues risks from smoked, skin-on sheep meat 66
4.4.2.1.2 Residues from systemically administered compounds 68
4.4.2.2 Environmental and process contaminants 76
4.4.2.2.1 Contaminants as a result of environmental factors 76
4.4.2.2.2 Special considerations in relation to the composition of the sheep fleece 76
4.4.2.2.3 Contaminants as a result of processing 77
4.4.2.2.4 Temperatures and cooking conditions associated with the production of skin-on sheep meat 77
4.4.2.2.5 Polycyclic Aromatic Hydrocarbons (PAHs) 77
4.4.2.2.6 Dioxins 79

4.4.2.2.7 Heterocyclic aromatic amines ... 79
4.4.2.2.8 Nitrosamines ... 80
4.5 SUMMARY OF HAZARDS ... 81
4.6 OFFICIAL CONTROLS IN RELATION TO SKIN-ON SHEEP MEAT PRODUCTION ... 82
4.6.1 Ante-mortem inspection including pre-requisites, monitoring of animal welfare and lairage maintenance ... 82
4.6.1.1 Evaluation of the Food Chain Information (FCI) ... 82
4.6.1.2 Ante-mortem assessment of animal health ... 82
4.6.1.3 Assessment of cleanliness/dryness state ... 84
4.6.2 Logistics of slaughter ... 84
4.6.3 Potential effects of the production of smoked, skin-on sheep carcasses on regulatory controls - Hazards associated with the changing physical characteristics of carcass ... 85
4.6.3.1 Developing and evaluating Standard Operating Procedures (SOP) and HACCP ... 85
4.6.3.2 Adequacy of dressed carcass for final inspection ... 86
4.6.3.2.1 Possible effects on the inspection process ... 86
4.6.3.2.2 Possible inspection stages of benefit if the skin-on sheep process is adopted ... 89
4.6.3.2.3 Further suggestions on prerequisites if smoking is adapted as a dressing process ... 89
4.6.4 TSE controls ... 90
4.6.4.1 TSE testing ... 90
4.6.4.2 Removal of SRM ... 90
4.6.5 National monitoring of drug residues ... 91
4.6.6 Health marking ... 91
4.6.7 Recommendations regarding official controls in relation to skin-on sheep meat production ... 91
4.7 OTHER ASPECTS IN THE CONTEXT OF PUBLIC HEALTH ... 92
4.7.1 Animal welfare implications of the legalisation of the smoked, skin-on meat production ... 92
4.7.2 Environmental / Occupational Health (by-products) ... 93
4.7.2.1 Heat and smoke ... 93
4.7.2.2 Effluents ... 94
4.7.2.3 Biological occupational hazards ... 94
4.8 ALTERNATIVE PRODUCTION ... 95
4.8.1 General considerations ... 95
4.8.2 Production of smoked skin separately from carcass meat ... 95
4.8.3 Skin-on goat meat produced in Australia ... 96
4.8.4 Modifications of the process proposed in the FSA studies ... 96
4.8.4.1 Hot air singeing ... 96
4.8.4.2 Rotating singeing frame vs hand torch ... 96
4.8.4.3 Washing step ... 97
4.9 CONCLUSIONS ... 98

5 SURVEY OF SLAUGHTERHOUSE OPERATORS' ATTITUDES TOWARDS THE LEGALISATION OF SKIN-ON SHEEP MEAT PRODUCTION ... 100

5.1 SUMMARY ... 100
5.2 INTRODUCTION ... 100
5.3 SURVEY STRUCTURE ... 100
5.4 RESULTS ... 101
5.4.1 Sample characteristics ... 101
5.4.2 Interest and concerns for the process, the data ... 102
5.4.3 Insight and opinion ... 104
5.4.4 Information and consultation ... 107
5.5 CONCLUSIONS ... 108

6 A REVIEW AND UPDATE OF HYBU CIG CYMRU'S (HCC) REPORT "APPRAISAL OF THE OPPORTUNITIES IN THE SKIN ON SHEEP MEAT MARKET FOR WALES" 109

6.1 SUMMARY 109
6.2 INTRODUCTION 109
6.3 CONSUMER DEMANDS ACCORDING TO THE PRODUCTION OF SMOKED, SKIN-ON MEAT IN WEST AFRICA 109
6.3.1 Changes in UK population of West African Origin between 2008 and 2014 109
6.3.2 Calculation of demand 111
6.4 CHANGES IN LEGISLATION 113
6.5 CONCLUSIONS 114

7 CONCLUSIONS AND RECOMMENDATIONS 115

7.1 CONCLUSIONS 115
7.2 RECOMMENDATIONS 116
7.2.1 Recommendations on biological hazards 116
7.2.2 Recommendations on chemical hazards 117
7.2.3 Recommendations on official controls 117

8 FURTHER RESEARCH REQUIREMENTS IDENTIFIED 119

9 REFERENCES 127

ANNEXES 137

ANNEX 1. SURVEY OF SLAUGHTERHOUSE OPERATOR ATTITUDES TOWARDS THE LEGALISATION OF THE PRODUCTION OF SKIN-ON SHEEP MEAT 137
ANNEX 2. A DESCRIPTION OF SKIN-ON SHEEP MEAT PROCESSING 142

Abbreviations

ACC	Aerobic Colony Counts
CCP	Critical Control Point
CVMP	Committee for Medicinal Products for Veterinary Use
EFSA	European Food Safety Authority
EMA	European Medicines Agency
FBO	Food Business Operator
FCI	Food Chain Information
FSA	Food Standards Agency
GHP	Good Hygienic Practices
HAA	Heterocyclic aromatic amines
HACCP	Hazard Analysis Critical Control Point
PAH	Polycyclic Aromatic Hydrocarbons
PAH4	Sum of benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene
PCB	Polychlorinated Biphenyls
SOP	Standard Operating Procedure
SRM	Specified Risk Material
TSE	Transmissible Spongiform Encephalopathies
TVC	Total Viable Counts
VMD	Veterinary Medicines Directorate
VTEC	Verocitotoxigenic *Escherichia coli*

1 Executive Summary

Background and introduction

Smoked, skin-on sheep meat[1] is produced from sheep whose wool has been burnt off as part of the dressing process. There is a demand in the UK for sheep meat with the "skin-on", traditionally from consumers of West African origin whose native culture embraces singed and smoked carcasses of a range of mammalian species[2]. However, current EU legislation prohibits the production of ruminant carcasses with the skin left on and skinning during the dressing procedure is a statutory requirement (Regulation (EC) 853/2004). Food Standards Agency (FSA) has commissioned several scientific studies to explore the potential for the safe production of smoked, skin-on sheep meat. In recent opinions on the scientific validity of these studies, the European Food Safety Authority (EFSA) concluded that more evidence needs to be gathered in order to develop a process for the production of skin-on sheep carcasses that are suitable for human consumption. This study aims to review current evidence and outline work-streams to support the development of a policy for smoked, skin-on sheep meat.

Objectives

There were four objectives of this study:

i. A critical review of the research work undertaken to date alongside the EFSA scientific opinion as it relates to safety aspects;

ii. Identification of appropriate research that will inform the decisions on the risks associated with the production and consumption of skin-on sheep meat;

iii. Exploration and identification of social and market perceptions; and

iv. To update Hybu Cig Cymru's "Appraisal of the Opportunities in the Skin on Sheep Meat Market for Wales" based on the findings of the critical review.

---

[1] The term "smoking" in food technology refers to the process in which food is exposed to natural smoke originated from smouldering wood shavings (EFSA, 2008). The production process described in the FSA studies differs from this definition in terms that the smoke flavour and colour on the skin originate from burnt fleece and not from incomplete combustion of wood. However, for the purpose of this report, term "smoked, skin-on meat/carcass" will be used.

[2] The species of meat smoked for food include goat, cow, sheep, dog and pig, with goats being predominantly used for this production.

Approach

To realise objectives one and two, the work has been carried out in two stages:

i. Systematic review on the safety of smoked, skin-on meat from sheep, compared to conventionally produced skin-off carcasses; and

ii. Critical review on the smoked, skin-on sheep meat production. This part included the identification of relevant public health hazards associated with this production and also possible effects that this process could have on these hazards. Also, other relevant aspects for delivering a safe and hygienic process for the production of smoked, skin-on sheep meat were identified and considered such as official controls and animal welfare implications. Furthermore, the results of this report have highlighted areas of research that need to be addressed before making a case to legalise the production of smoked, skin-on sheep meat in the UK and EU.

Objective three of the study was realised through a survey of slaughterhouse operators' attitudes towards the legalisation of skin-on sheep meat production, but also through the information obtained from consumers of this product from Nigeria. Finally, objective four was realised through the update of Hybu Cig Cymru's "Appraisal of the Opportunities in the Skin on Sheep Meat Market for Wales", based on the findings of the critical review (objective 1).

Systematic Review on smoked, skin-on sheep meat

Initially, the systematic review was conducted to answer the question "What is the level of microbiological and chemical safety of smoked, skin-on sheep/goat/cattle meat compared to conventionally produced skin-off carcasses?" Also, information on other similar products produced worldwide were reviewed, including: (i) skin-on goat meat, produced in Australia; (ii) singed sheep heads (called "svið" in Iceland and "smalahove" in Norway); (iii) smoked, skin-on meat of different species, in West Africa; and, (iv) singed cattle hides (called "ponmo" in Nigeria and "welle" in Ghana).

A review of previous FSA commissioned studies concluded that the evidence (reviewed in this report) does not provide a definitive answer to the microbiological and chemical safety of smoked, skin-on sheep meat, nor its relation to conventionally produced skin-off carcasses. However, the FSA studies do provide an important stepping stone and basis for further development of the process for safe production of smoked, skin-on meat. Furthermore, a systematic review of other studies on smoked, skin-on meat products worldwide found that it was only partly possible to answer the question set out in this study since there are scarce data in the literature regarding smoked/singed, skin-on sheep/goat/cattle meat products. The review identified some gaps in current knowledge about this product that need to be addressed in further research: (i) the effect of the smoked, skin-on process on public health hazards is not known; (ii) there is no information available in scientific literature on the microbiological profile of smoked, skin-on sheep meat, and (iii) the effect of the smoked, skin-on production and changes in the dressing process of the carcass on official controls need to be evaluated. Overall, further evidence is required to determine whether smoked, skin-on sheep/goat/cattle meat poses greater or lower risk to consumers when compared to conventionally produced skin-off carcasses. Consequently, further studies are necessary to address the gaps in knowledge and to inform the discussion relating to legalising the production of this product.

Critical Review on the smoked, skin-on sheep meat production

In the next step, a critical review was performed to evaluate available evidence on a proposed production method for smoked, skin-on sheep meat and to identify appropriate research required to fill the gaps in scientific knowledge regarding this production. The main aspects covered were to identify the relevant public health hazards arising from this production and the possible effects of the smoked, skin-on sheep meat production process on these hazards, as well as its effects on official controls. Also, animal welfare and occupational health implications were briefly discussed. Some alternative methods for production of smoked, skin-on sheep meat to the one described in FSA commissioned studies were reviewed and proposed.

Different sheep variables were considered. The main source of animals for smoked, skin-on meat production is cull ewes. Animals with specific health problems are identified for culling and sent for slaughter. Different sheep diseases which might affect the skin, particularly Blow Fly strike and sheep scab should be considered in Food Chain Information and/or when developing SOPs for this production. Treatment or prevention of these diseases may pose a risk of high levels of skin residues at the time of slaughter. Also, sheep wool and skin composition could be a significant factor for this production since the meat is consumed with the skin left on. However, there is not much specific data on animal variables affecting skin and wool composition.

Furthermore, a comprehensive list of biological and chemical hazards of public health relevance was created, taking into account different criteria. Bacterial hazards relevant for consideration for assessment of the safety of smoked, skin-on sheep meat were identified as *Bacillus cereus*, *Clostridium perfringens*, pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) and *Salmonella* spp. The assessment of their relevance for this production was undertaken based on the likely occurrence in sheep (particularly on skin) and the evidence that sheep carcass meat is an important source for human exposure to these particular pathogens. Furthermore, the likely effects of this production process on these biological hazards were reviewed. Hence, sourcing of animals, shearing, singeing, high pressure water washing, toasting and chilling appear to be the steps that could have significant effect on pathogen numbers. However, further research is needed to determine the microbiological profile of smoked, skin-on sheep meat and the true effect of the process on the most relevant bacterial pathogens.

The primary chemical hazards that may be formed during the production of skin-on sheep meat are dioxins, PAHs and heterocyclic aromatic amines. The uniformity of these contaminants across the treated carcass should be established, and dioxins and PAHs should comply with statutory limits. If HAAs are found to be formed by the production of skin-on sheep meat, the quantities produced should be compared with other meat products to determine relative risk.

Several sheep skin diseases could alter the aesthetic quality of the final product due to associated skin damage, scarring or subcutaneous abscess formation. Treatment of these diseases may pose a risk of skin residues. The list of veterinary medicines currently authorised in the UK for use in sheep and considered as most likely to represent an increased hazard for skin-on sheep meat production due to the risk of residues, is provided. The levels of chemical residues from these veterinary medicines in sheep skin should be assessed following treatment with them (especially, with 'pour-on' products). This should include the possible bio-transformation effect on such residues, of the smoked, skin-on production process when withdrawal periods have been observed at slaughter.

The official controls are informed by both statutory requirements and the risk assessment of the regulated processes. Their application and modification will depend on the results of research on identified hazards and the practical observation and application of the process during production. All aspects of official controls, from ante-mortem inspection to HACCP verification, post-mortem inspection, TSE, residue, and chemical contaminant controls should be evaluated on public health, animal health and welfare grounds. A range of relevant conditions for smoked, skin-on sheep carcasses were reviewed and discussed. Any change in the sheep carcass dressing process will require official control procedures to be evaluated and amended. Also, some of the practices may have positive or negative effect on animal welfare, so these implications should also be considered when developing SOPs for this production.

Alongside all the above mentioned aspects, further research requirements were identified, including laboratory based experiments and those needed for validation purposes in commercial settings. These are all listed under the recommendations section.

The current proposed production method for smoked, skin-on sheep meat involves singeing to efficiently remove wool and impart a smoked colour and odour to the carcass. However, some other alternative production methods could also be investigated. These could be used to create a smoked flavour under controlled conditions with a temperature assured to be below 500^{o}C (to minimise formation of toxic contaminants), and/or facilitate standard post-mortem carcass inspection. Production of smoked skin separately from carcass meat and sheep wool removal by scalding and dehairing prior to singeing are some options that merit further attention.

Survey of slaughterhouse operators' attitudes towards the legalisation of skin-on sheep meat production

Slaughterhouse operator's attitudes towards the legalisation of skin-on sheep meat production were examined using semi-structured telephone interviews. 10% of all operators slaughtering sheep, in addition to all operators slaughtering high numbers of adult sheep, in England and Wales were approached (n=54, 28,9% of all slaughterhouses licenced for the slaughter of sheep). The survey of food business operators (FBOs) indicates that 50% of the responders are inclined to undertake the process. Interest in the production of smoked, skin-on sheep meat was predominantly shown by slaughterhouses with an established client base within the community that traditionally consume this type of product. It is concluded that interest is driven by business considerations and it is supported by interest from existing clients, the prospect of new markets (including exports). Concerns were expressed regarding the structural and operational requirements and the effect that the process would have on the safety, aesthetic and organoleptic characteristics of other products produced in the same establishment.

A review and update of Hybu Cig Cymru's (HCC) report "Appraisal of the Opportunities in the Skin on Sheep Meat Market for Wales"

The original HCC report (2008) was updated using the information gathered in the current report. In addition, using information from the Office of National Statistics, the potential UK consumer population was determined and an increase in the demographic group of 133,000 (85%) was identified between 2008 and 2014. The number of carcasses needed to meet this demand was calculated using the ONS estimates for West African born population in the UK. It is estimated that, based on these calculations, the proportion of carcasses that may be used for skin-on sheep meat production ranges between 1.89 and 3.81% of the UK adult sheep slaughtered in 2014.

Recommendations

The following recommendations on areas that merit further research were suggested:

<u>Recommendations on biological hazards</u>

- An assessment of individual steps in the production of smoked, skin-on sheep meat on their effect on four identified important biological hazards (VTEC, *Salmonella* spp., *Bacillus cereus* and *Clostridium perfringens*) should be performed taking into account different variables.
- Microbiological methods, including those for sampling and laboratory investigation, aimed to be used for trials in this specific smoked, skin-on sheep meat production, should be validated in experimental conditions prior to use.

- The effects of the process on microbiological safety of derived carcasses should be evaluated both in low and high production speed settings, under varied conditions.
- Based on this assessment, clear production protocols should be developed based on HACCP principles, with indication of critical control points, clear set limits, monitoring procedures and corrective actions.

Recommendations on chemical hazards

- Establish the uniformity of formation and presence of PAHs over the treated carcasses and between carcasses, and to ensure that quantities of PAH present are always within regulatory limits.
- Establish whether or not dioxins can be formed in the production of smoked, skin-on sheep meat, and if so, the uniformity of formation and presence of dioxins over the treated carcasses and between carcasses, and to ensure that quantities of dioxins present comply with regulatory limits.
- Because heterocyclic amines may be generated under conditions that may occur during the production of smoked, skin-on sheep meat, analyses for these compounds should be undertaken to give an indication of their potential formation.
- An assessment of the levels of chemical residues in sheep skin following treatment with pharmaceutical products (especially, ‘pour-on’ products) should be performed along with the evaluation of the effect of smoked, skin-on production process on these residues at the time of authorised withhold and slaughter.

Recommendations on official controls

- It is important to evaluate the information that should be included in the FCI given both the nature of the process and that of the source of animal supply.
- Ante-mortem inspection requirements and associated facilities should be examined in the light of the changes in the post mortem inspection and the risk assessment of the process.
- Both research and practical application should be used for the evaluation of operational/structural requirements as part of a risk assessment for the development of SOPs and HACCP.
- Animal welfare implications should be taken into account when developing SOPs for smoked, skin-on meat production.
- The effects of the process on meat inspection practices and protocols should be evaluated both in low and high production speed settings.

- The labelling, packaging, legal characterisation and health marking requirements should be investigated.
- The effect of the process on the application and validity of official controls for TSEs, drug residues should be evaluated;
- If smoked skin of sheep meat were to become legal, skin and finished product may need to be added to surveillance sampling frames including all carcasses and not just those designated to be used for this type of food production;
- Products should be tested to ensure compliance with regulations for dioxins and PAHs;
- In order to minimise occupational health and safety risks for the staff involved in the production of smoked, skin-on sheep meat, FBOs will need to comply with all related procedures.
- If skin is designated as an edible part of a sheep carcass it may be added to the list of sites for which residues information are required to support applications for Marketing Authorisations of new veterinary products. VMD and EMEA views on this and any requirement for adding sheep skin to the residues surveillance system will be needed.

2 Introduction

2.1 Background

Smoked, skin-on sheep meat (commonly called “smokies”), are carcasses from sheep whose wool has been burnt off as part of the dressing process. Currently, such carcasses are produced illegally in the UK. The specific hygiene rules for food of animal origin require the complete skinning of the carcass intended for human consumption (EC, 2004). Therefore, “smokies” cannot be produced legally in the EU and UK. The only exemption from these rules is the production of skin-on sheep heads (from lambs under 12 months of age), calves heads and sheep and cattle feet (EC, 2004). These products are legally available for human consumption in the EU and are produced in some UK abattoirs (Anon., 2010).

However, there is a concern over the safety for human consumption of skin-on sheep meat, related to the possible microbiological and chemical risks present on the skin and/or acquired during the production process. Such risks are associated with the presence of pathogenic microorganisms and the residues of approved veterinary medicines on/in the skin/wool and their fate during the process, but also the formation of other chemical contaminants such as dioxins, PAHs (Polycyclic Aromatic Hydrocarbons) and heterocyclic aromatic amines during the process (i.e. during the burning of the skin to remove the wool). An additional problem of illegal production is that is not subjected to official controls, so there are concerns that some animals may be diseased, there is no meat inspection and also TSE controls are not in place as required (i.e. removal of Specified Risk Material from older sheep). In addition, there are concerns over the protection of animal welfare, as well as increased risk of occupational hazards arising from this production.

Therefore, following the need to address all these aspects, the Food Standards Agency (FSA) has commissioned several scientific studies to explore the potential for the safe production of smoked, skin-on sheep meat, including relevant microbiological, chemical and production aspects (Anon., 2010). However, European Food Safety Authority (EFSA) in the scientific opinion issued by the Panel on Biological Hazards (BIOHAZ) and the Panel on Contaminants in the food chain (CONTAM) concluded that the studies commissioned by the FSA were insufficient to conclude that the burnt fleece skin-on sheep carcasses were suitable for human consumption and provide the same safety level as conventionally produced skin-off carcasses (EFSA, 2011a). EFSA also highlighted a number of issues that need to be considered for the development of process for the production of smoked, skin-on sheep carcasses suitable for human consumption. The most important highlighted were: i) the need for identification of all potential biological hazards, including addressing risk from bacterial spores; ii) the effect of the process on vegetative microbiological pathogens; iii) the formation of dioxins, PAHs (Polycyclic Aromatic Hydrocarbons) and heterocyclic amines during process; iv) production of skin-on sheep carcasses under variable conditions; and v) the development of production standards and protocols, based on Good Hygienic Practices (GHP) and Hazard Analysis Critical Control Point (HACCP) principles (EFSA, 2011a, 2012).

2.2 The production of smoked, skin-on meat in West Africa

There is an existing market for sheep meat with the “skin-on” in the UK, primarily from consumers of West African origin whose native culture embraces singed and smoked carcasses of a range of mammalian species. West African member countries share some common cultures, including foods and ‘skin-on goat/sheep meat is a common food product within the region. The species of meat smoked for food include goat, cow, sheep, dog and pig. Among the domesticated ruminants in Nigeria, goats are most important in meat production due to their larger population and the wider acceptability of goat meat ‘chevon” by the populace (Nwosu, Iwuoha, Torru, & Mohammed, 2006). Also, cattle hide, known as “*ponmo*” in South-Western Nigeria, and “welle” in Southern Ghana are delicacies in several parts of Africa (Obiri-Danso, Hogarh, & Antwi-Agyei, 2008).

The process of smoked, skin-on meat production in West Africa starts with the goats raised by small farm holders, under extensive management systems, which feed freely from what they find from the environment. The location of animals and a market for meat determines where abattoir sites are set up by the butchers rather than government designation. The slaughterhouses are usually not registered and there are no government controls or regulation on the production of smoked meats in Nigeria, which also appears to be the case with other West African countries. Animals are killed by cutting the neck with a knife and allowing the animals to bleed until they are dead. Animals are not skinned, but are normally singed to remove hair, but also to provide a desired smoked flavour (Akwetey, Eremong, & Donkoh, 2013; Amfo-Otu, Agyenim, & Adzraku, 2014; Obiri-Danso et al., 2008). Traditionally, singeing uses an open fire fuelled by firewood, but sometimes heat sources are also other solid fuels such as coal, charcoal and waste plastic or tyres. Removal of hair from cattle hide for “ponmo” production in Nigeria is traditionally done by tenderization in hot water followed by scraping with a metal blade (Okiei, Ogunlesi, Alabi, Osiughwu, & Sojinrin, 2009). Usually, meat is not cooked during the singeing and smoking operation but the process facilitates the removal of the hair. Further cleaning is achieved by scrapping the skin to remove the ash from the surface and by washing with water. Singeing of slaughtered goats is also practiced in local markets in rural areas, designated small markets in cities, local beer parlours, eatery joints, and at home. After singeing, the evisceration is carried out without much delay. Sometimes the head, tail and the feet may be cut off completely, especially in cattle. They are smoked separately and used for the preparation of special meals. The head and feet of the goat smoked, skin-on meat are essentially used for special meals called *Isewu*.

Smoked meat products are most commonly consumed during festivities like Christmas, Wedding ceremonies, funerals etc. Consumption does not depend strictly on religious affiliation. Most consumers of skin-on goat/sheep meat in Nigeria indicate that it is traditionally eaten, depending on the purchasing power of families, at least three times a week. Smoked meat is usually used in preparing delicacies in form of a soup prepared with other ingredients like leafy vegetables, pepper, spices, onions etc. The cooking time is usually about three hours for household cooking of about 1 kg, but if it is for commercial cooking of about 30 kg or more especially for restaurants the cooking time can last for two hours or more. Deep or shallow frying in oil may also be used.

There is interest in the production of smoked, skin-on sheep meat by the slaughterhouse Food Business Operators in the UK, particularly by those that have an established client base within the community that traditionally consume this type of product. However, before making a case to legalise the production of smoked, skin-on sheep meat in the UK and EU, studies are required to address production variables and their impact on public health hazards and official controls.

The overall expected outcome of this project is to identify the further research needed to respond to the recommendations in the EFSA opinion and any further work required to support a UK approach to the Commission.

3 Systematic Review on smoked, skin-on sheep meat

3.1 Summary

There is a concern over the safety for human consumption of skin-on sheep meat, related to the possible microbiological and chemical risks present on the skin and/or acquired during the production process. This systematic review was conducted to evaluate available evidence in literature on the safety of smoked, skin-on meat from sheep, compared to conventionally produced skin-off carcasses. In addition, available information on similar products from goats and cattle were also reviewed. Only 16 literature sources were identified to meet predefined criteria and those were subjected to full text analysis.

Systematic review of the FSA commissioned studies on smoked, skin-on sheep meat found that the evidence gathered from these studies were incomplete in respect of the microbiological and chemical safety of smoked, skin-on sheep meat and did not explore comparison to conventionally produced skin-off carcasses. The information reviewed from other studies on similar smoked, skin-on meat products found that it is not possible to assess their microbiological safety due to lack of data, and that in some cases (like production of singed cattle hides in Africa) results clearly indicate the increased risk for consumers of this product due to the presence of heavy metals and PAHs.

The results of this systematic review outlined gaps in current knowledge about this product that need to be addressed in further research: (i) the effect of the smoked, skin-on process on public health hazards; (ii) on the microbiological profile of smoked, skin-on sheep meat, and (iii) the effect of the smoked, skin-on production and changes in the dressing process of the carcass on official controls. It is concluded that the evidence gathered, and the production protocol developed, in the FSA studies provide a solid basis for further development of the process for safe production of smoked, skin-on meat.

3.2 Introduction

The aim of this study was to conduct a systematic review on the safety of smoked, skin-on meat from sheep, compared to conventionally produced skin-off carcasses. Since a preliminary search retrieved very few studies on sheep meat, other ruminant species (i.e. goats and cattle) were included in the systematic review, to obtain more literature sources related to this topic. In line with the review of existing evidence on production of smoked, skin-on sheep/goat/cattle meat, the findings of all recent research undertaken by the Food Standards Agency (FSA) alongside the European Food Safety Authority scientific opinions (EFSA, 2011a, 2012) on smoked, skin-on sheep meat and feet were considered and an overview of the current situation based on this finding is presented.

A systematic review is an overview of existing evidence pertinent to a clearly formulated question, which uses pre-specified and standardised methods to identify and critically appraise relevant research, and to collect, report and analyse data from the studies that are included in the review (EFSA, 2010). In this study, a pre-defined structured question was used, to address two main aspects of the meat product in question: (i) sheep/goat/cattle meat with the skin left on at the end of the production process; and, (ii) the smoking/burning/singeing process as a part of the dressing procedures used to remove hair/wool from the skin.

Other types of smoked, skin-on meat, produced in the processes similar to that used for smoked, skin-on sheep meat and readily available for consumption in some parts of the world include: (i) skin-on goat meat, legally produced in Australia and mainly for export to Asian and US market; (ii) singed sheep heads (called "svið" in Iceland and "smalahove" in Norway); (iii) smoked, skin-on meat of different species, predominantly goats, in the region of West Africa; and, (iv) singed cattle hides (called "ponmo" in Nigeria and "welle" in Ghana). However, some of these products and processes might not fully resemble the process used for smoked, skin-on sheep meat production as proposed in the FSA studies. That is the case with the production of smoked, skin-on meat and singed hides in Africa, where the firewood (and in the lack of this discarded tyres, spent engine oil or plastics) is used for singeing cattle hides.

3.3 Methods

3.3.1 Study design

This systematic review was conducted using the PRISMA guidelines[3] and EFSA guidance (EFSA, 2010)[4]. This approach requires the definition of the central question, which in this case was agreed upon in the project team. The question was defined as: "What is the level

[3] http://www.prisma-statement.org
[4] http://www.efsa.europa.eu/en/efsajournal/pub/1637

of microbiological and chemical safety of smoked, skin-on sheep/goat/cattle meat compared to conventionally produced skin-off carcasses?" Other ruminant species (i.e. goats and cattle) were included on purpose in the question, since preliminary search retrieved very few studies on sheep meat, so to obtain more literature sources related to this topic from similar products and processes. The study addressed microbiological and chemical safety of this type of meat product taking into account the two main aspects: (i) sheep/goat/cattle meat with the skin left on at the end of the production process; and, (ii) smoking/burning/singeing heat treatment as a part of the dressing procedures used to remove hair/wool from the skin. Therefore, predefined criterion for studies' inclusion was that the carcass with the skin left on has undergone a heat treatment in the process, aiming to remove hair and impart smoked flavour to the meat.

In line with the review of existing evidence on production of smoked, skin-on sheep/goat/cattle meat, the findings of all recent research undertaken by the FSA and alongside the EFSA scientific opinions (EFSA, 2011a, 2012) on smoked, skin-on sheep meat and feet were considered and an overview of the current situation based on this finding is presented (table 3.1). The main aspects covered include: (i) production process and protocols developed, including official controls; (ii) microbiological safety; and, (iii) chemical safety.

3.3.2 Eligibility criteria

Eligible citations were those identified from the search terms and satisfying predefined criterion (i.e. skin-on meat that has undergone heat treatment). Other citations irrelevant to this criterion were excluded. Those were commonly relevant to the microbiological and chemical safety and shelf life of smoked, skin-off meat, smoked pig/poultry/fish products, other pig singeing processes and different studies on cancer.

3.3.3 Information sources

The choice of information sources to be searched was agreed amongst the project team. The objective in choosing the databases was to identify a range of different forms of publications and unpublished work, so to retrieve as many studies as possible which were relevant to the review question. Usually, publication in peer reviewed journals and books are relatively easy to identify in electronic databases, however some research reports publicly unavailable were obtained from the FSA upon request. Information sources used in this systematic review included Pubmed, Medline, Cab abstracts, Food Science and Technology Abstracts, Agricola, Agris International and Google Scholar. The information sources were limited to publications in English language published up to 15th October 2015.

3.3.4 Search strategy

Search strategies were based upon screening titles and abstracts. A very few relevant studies were retrieved during search and screening, therefore only citations from eligible studies were downloaded into EndNote (Version X7; Thomson Reuters). The final database contained only 14 citations, including some FSA reports and EFSA opinions on this topic. A further two relevant research reports publicly unavailable were obtained from the FSA upon request, resulting in a total of 16 citations.

The search strategy included combinations of keywords (search terms) designed to retrieve as many studies as possible which were relevant to the review question. Search terms used were sheep, mutton, goat, cattle, meat, skin-on, hide, feet, head, smoked, singed, burnt, flamed, scorched and also some regional smoked products, like welle, ponmo and smalahove. Six search strings were used:

1. (Sheep OR mutton OR goat OR cattle OR meat) AND smoked NOT chicken NOT turkey NOT cancer NOT fish NOT pork;

2. (Sheep OR mutton OR goat OR cattle OR meat) AND singed NOT chicken NOT turkey NOT cancer NOT fish NOT pork;

3. (Sheep OR mutton OR goat OR cattle OR meat) AND burnt NOT chicken NOT turkey NOT cancer NOT fish NOT pork;

4. (Sheep OR mutton OR goat OR cattle OR meat) AND flamed NOT chicken NOT turkey NOT cancer NOT fish NOT pork;

5. (Sheep OR mutton OR goat OR cattle OR meat) AND scorched NOT chicken NOT turkey NOT cancer NOT fish NOT pork;

6. Skin-on meat OR skin-on goat OR smoked feet OR singed sheep head OR singed cattle hide OR welle OR ponmo OR smalahove.

3.4 Results and discussion

3.4.1 Studies and literature sources selected

The initial search using six search strings in eight databases retrieved more than 1,300 citations, many of those irrelevant and some limited to other types of smoked meat. However, only few were selected as to meet predefined eligibility criteria. These were subjected to full text analysis. The final list of eligible studies and literature sources for review is shown in Table 3.1.

Table 3.1: Overview of eligible studies and literature sources

Citation	Title	Description
FSA research related literature sources		
(Fisher, Wilkin, & Purnell, 2006)	A practical investigation into the hygienic production of 'skin-on' sheep carcasses and cattle and sheep feet	Detailed report on production process and microbiological safety including comparison with conventionally dressed carcasses
(Fisher, Wilkin, & Purnell, 2007)	The production and microbiological status of skin-on sheep carcasses	Published parts of the aforementioned report on microbiological safety
(P. Bates, 2006)	An assessment of the available information regarding the consumption of “skin-on” sheep meat treated with veterinary medicines	Desk study on the available information on residues of veterinary medicines in sheep meat
(Anon., 2009)	A detailed study of the prevalence of veterinary medicine residues (e.g. parasiticides) in “skin-on” sheep feet	Report from the study of the prevalence of veterinary medicine residues in skin-on sheep feet
(Anon., 2010)	Report on research into the production of smoked skin-on sheep meat	Summary of all FSA studies, including the observations from trial undertaken in a commercial abattoir and study of PAHs in carcasses
(EFSA, 2011a)	Scientific Opinion on a summary of scientific studies undertaken by the UK Food Standards Agency to support a proposed production method for smoked “skin-on” sheep meat	EFSA scientific opinion about the scientific validity of the FSA studies on the safety of smoked, skin-on sheep meat, including their microbiological and chemical aspects
(EFSA, 2012)	Clarifications on the interpretation of technical issues about the Scientific Opinion on a summary of scientific studies undertaken by the UK Food Standards Agency (FSA) to support a proposed production method for smoked, “skin-on” sheep meat	Some clarifications about the aforementioned opinion, including on microbiological and chemical safety and study design
Other studies on smoked, skin-on meat and similar meat products		
(Hjartardottir, Gunnarsson, & Sigvaldadóttir, 2002)	Salmonella in sheep in Iceland	The prevalence of salmonella in sheep, including singed sheep heads at slaughter
(Obiri-Danso et al., 2008)	Assessment of contamination of singed hides from cattle and goats by heavy metals in Ghana	The levels of heavy metals generated in hides during singeing of cattle and goats
(L. Duffy, Barlow, Fegan, & Vanderlinde, 2009)	Prevalence and serotypes of Salmonella associated with goats at two Australian abattoirs	The prevalence of salmonella in skin-on goats at slaughter, including singed
(Okiei et al., 2009)	Determination of toxic metal concentrations in flame-treated meat products, *ponmo*	The levels of heavy metals generated in hides during singeing of cattle
(Awosanya & Cole, 2011)	Comparative assessment of lead and cadmium contaminants in singed hides, skin and muscle from cattle and goats in Nigeria	The levels of heavy metals generated in hides and meat during singeing of cattle and goats
(Essumang, Dodoo, & Hadzi, 2011)	Distribution, Levels, and Risk Assessment of Polycyclic Aromatic Hydrocarbons (PAHs) in Singed Cattle Hide	The levels of PAHs generated in hides during singeing of cattle
(Akwetey et al., 2013)	Chemical and Nutrient Composition of Cattle Hide (“Welle”) Using Different Processing Methods	The levels of heavy metals generated in hides during singeing of cattle
(Amfo-Otu et al., 2014)	Meat contamination through singeing with scrap tyres in Akropong-Akuapem abattoir, Ghana	The levels of heavy metals generated in hides and meat during singeing of cattle and goats
(Ekenma, Anelon, & Ottah, 2015)	Determination of the presence and concentration of heavy metal in cattle hides singed in Nsukka abattoir	The levels of heavy metals generated in hides during singeing of cattle

3.4.2 Research on smoked, skin-on sheep meat undertaken by the FSA

The FSA has commissioned several scientific studies to explore the potential for the safe production of smoked, skin-on sheep meat, including relevant microbiological, chemical and production aspects (Anon., 2010). The list of FSA studies is presented in Table 3.1.

The first research project commissioned by the FSA and undertaken in 2003 to 2005 (Fisher et al., 2006) was aiming to develop a production protocol for smoked, skin-on sheep meat, based on Good Hygiene Practices (GHP) and Hazard Analysis Critical Control Point (HACCP) principles, including evaluation of microbiological aspects (safety and shelf life) and organoleptic properties to satisfy consumer expectations. Also, the aim was to provide evidence to support the development of the protocol needed for the official controls of this product. Parts of this report were published in a peer-reviewed scientific journal (Fisher et al., 2007).

Subsequently, two studies were commissioned on veterinary medicine residues that could pose public health risks to consumers of skin-on sheep meat. A desk study was undertaken in 2005 (P. Bates, 2006) to assess the available information concerning medicines licensed for use in sheep produced for meat and risks arising from the consumption of 'skin-on' sheep meat treated with veterinary medicines. In response to the findings from this study, a research project was undertaken in 2008 (Anon., 2009) aiming to investigate whether detectable residues from certain licensed veterinary medicines were present in skin-on sheep feet (these were used to represent skin-on sheep meat since they are legally available for human consumption in the UK) compared with the set maximum levels in muscle and fat.

Finally, an abattoir mock-up trial was undertaken in 2009 in a commercial abattoir on a non-operational day, following the processes and inspection protocols developed in the first research project. The whole production process of smoked, skin-on sheep carcasses was supervised by two official veterinarians and the main objective was to provide results that would be useful in the development of a guidance document on this production (Anon., 2010). Within the scope of this trial, microbiological testing for indicator bacteria was performed and a study of PAHs potentially formed during the production process (i.e. burning the wool). Also, an assessment of meat inspection and other production practicalities as well as assessment of organoleptic properties and authenticity of the final products were performed.

The FSA summary report compiled in 2010, concluded that smoked, skin-on sheep meat meeting the quality attributes required by potential consumers, could be safely and hygienically produced in approved slaughterhouses (Anon., 2010).

The only available literature sources on the production process and safety of the smoked, skin-on sheep meat were those arising from the FSA funded research. No other published literature sources describing this product were available in the databases searched.

3.4.2.1 Production related aspects and official controls

The protocol to produce smoked, skin-on sheep meat was developed and described in detail in the project performed by Fisher et al. (2006). The main aim was to develop a hygienic and practical method to remove the wool, impart the desired smoked colour and odour to the meat and explore other steps in the process required to achieve acceptable carcass microbiological status and facilitate required official controls (i.e. meat inspection).

Initial trials were performed to explore the practicalities of hygienically removing the wool. Three different methods were explored, including: (i) one similar to that used for dehairing pigs (i.e. hot water scalding and wool removal by manual scraping or putting the carcass through a mechanical pig dehairer); (ii) hot air singeing; and, (iii) naked gas flame singeing.

Hot water scalding and subsequent manual wool scraping proved to be very laborious and technically difficult to perform in automated pig dehairers. Also, the wool was not consistently and effectively removed from the skin, suggesting that more should be done to develop an automated dehairing process adjusted to sheep that have a different type of wool. Indeed, some information from Australia indicated that a new automated method had to be developed to de-hair goat carcasses for markets that require skin-on carcasses (Anon., 2001, 2011). However, that is the case only with feral goats since domestic fibre (Angora) goats do not go into the skin-on trade as the fibre creates difficulties with processing. A similar method to remove the hair from the skin is commonly used for the production of skin-on sheep feet. Key steps in this process are hot water scalding of the feet and subsequent singeing, followed by removal of coil (sebaceous) glands of the interdigital pouch. The process itself was not evaluated in this study and only limited microbiological investigation was undertaken to examine this legal production under commercial conditions (results shown in the following section). Therefore, considering that a commercial dehairing process already exist for pigs, goats and sheep feet, investigation into hot water scalding and automated dehairing for sheep merits further attention.

The second investigated method was hot air singeing and included two groups of carcasses: one with the wool on and one where the wool had been previously removed by scalding and scraping. However, it revealed that hot air blowers were too slow in singeing the wool to be of practical application.

The third method, wool burning by gas torch singeing (as allegedly used for illegal "smokies" production in the UK) was investigated, to evaluate primarily the effect of the fleece length and the time of singeing (i.e. prior to or after evisceration). The conclusion was that wool should be previously shorn to a length of about 5 mm to reduce time for singeing and amount of smoke produced. Also, non-eviscerated carcasses were preferable since there was no risk of the cooking of exposed meat surface and subsequent washing after singeing would not contaminate inner carcass surface.

Following these trials, a custom-made singeing rig for use in the subsequent experimental trials was constructed. The aim was to facilitate singeing that was more consistent and repeatable. Gas burners were selected as the main singeing heat source due to their low cost, speed of action and current use in industry for singeing pork carcasses. The details of the singeing device are given in the report of Fisher et al. (2006). During the process, the temperature was measured with infrared thermometers, and would reach 515°C directly under the burners, while the carcass surface temperature examined immediately after singeing was “reasonably” uniform at 70-85°C. Even though the singeing rig was constructed and used to allow for consistency, authors acknowledged that it was difficult to control the temperature on carcass surface due to their irregular shape. Also, there was no attempt to make a temperature profile of carcass surface, to determine which sites received more or less heating, which could lead to creation of hot and/or cold spots on the surface. This could have the effect on the microbiological hazards potentially present on the skin and on the amount of chemical contaminants created during wool burning process.

Alongside the singeing process, high pressure water washing to remove charred wool residues and yield golden skin colour was essential. Also, the final singeing step (“toasting”, to distinguish it from the previous singeing) after evisceration and carcass inspection was performed, in order to dry it, destroy microbial contamination, and improve the brown colour on insufficiently singed carcass areas. Therefore, the final sequence of processing steps used in the experimental trials was as follows: (i) removal of the feet after bleeding; (ii) singeing of the carcass with gas burners; (iii) high pressure water washing to remove burnt wool; (iv) evisceration; (v) removal of head; (vi) splitting of the carcass; (vii) carcass inspection; and, (viii) singeing or “toasting” of the carcass.

A similar sequence of processing steps was used in an abattoir mock-up trial, but instead of a custom-made singeing rig, two hand-held gas burners were used to burn the wool, from the top to the bottom of carcasses. Washed carcasses were left to drain before being taken to the dressing area for evisceration, head removal, splitting, and removal of specified risk material (SRM). A final light toasting was applied after the carcasses had been inspected by an official veterinarian.

Along with the development of a production process for smoked, skin-on sheep meat, the FSA sponsored a 12-month survey in a commercial abattoir slaughtering older sheep, to determine the frequency of pathological conditions that might be obscured by leaving the skin on in sheep suitable for smoked skin-on production. The most frequent conditions appeared to be abscesses, following by bruising, arthritis and emaciation. It was noted that abscesses are the most likely condition not to be detected by traditional inspection. Following this observation, a post-mortem inspection protocol for smoked, skin-on sheep carcasses was developed, pointing out the need for TSEs controls and routine palpation of the shoulder/neck and rump area as the main injection site (and abscesses) locations. The carcasses processed in the abattoir mock-up trial were inspected by official veterinarians observing the process and following this protocol. It was noted that no evidence exists to suggest that the process is detrimental to the validity of post-mortem inspection. However, since the microbiological hazards commonly associated with abscesses (i.e. *Staphylococcus spp.*, *Streptoccocous* spp., *Corynebacterium pseudotuberculosis*, *Arcanobacterium pyogenes*) are known to be occupational rather than foodborne related hazards, routine use of palpation without risk based decision could even worsen situation due to cross contamination with some foodborne pathogens (EFSA, 2013). It can be argued that older sheep destined for this production could carry particular diseases, but this could be addressed in the HACCP based procedures developed for this process including the selection of suitable animals for this production and slaughter. Therefore, the risk categorisation of particular flock or individual animals based on the use of detailed Food Chain Information (FCI) could be a valuable tool for risk management decisions (EFSA, 2013), so to reflect the extensive production system and older sheep used for smoked, skin-on sheep meat production.

3.4.2.2 Microbiological aspects

The microbiological part of the study by Fisher et al. (2006) was designed primarily to assess the effect of different process steps (specifically toasting and chilling) on the changes of the levels of microbiota on skin-on sheep carcasses, then to compare the microbiological quality of final smoked, skin-on sheep carcasses with conventionally produced skin-off carcasses and to assess the shelf life of skin-on sheep meat produced according to the protocol developed. The authors recognised the importance of certain microbiological foodborne pathogens arising from sheep meat, like *Salmonella* and VTEC (Fisher et al., 2007), but decided to use only indicator bacteria instead (i.e. Total Viable Count and *Enterobacteriaceae* Count) to achieve these objectives. The decision was based upon the expected low pathogen prevalence and levels on carcasses, which would hinder statistical analyses in the case of low number of carcasses/samples. It is well known however, that live animals can carry many different public health hazards (including foodborne ones), often in very high levels on the skin and in the guts (Antic, Blagojevic, Ducic, Mitrovic, et al., 2010; Koutsoumanis & Sofos, 2004). Also, animal coats, including fleece of a sheep, are recognised as a primary vehicle for the introduction of contamination to the slaughterhouse and the carcass meat surface (Antic, Blagojevic, Ducic, Mitrovic, et al., 2010). Therefore, microbiological aspects covered in this study appeared to have been used to characterise the production process of smoked, skin-on sheep meat and to compare this process with the conventional one used to produce skin-off sheep carcasses. For this purpose, indicator bacteria proved to be useful, but they are not necessarily indicators of pathogen presence or absence (Blagojevic, Antic, Ducic, & Buncic, 2011). Therefore, they cannot be used to assess the safety of the smoked, skin-on sheep meat and no public health hazards presence or levels were investigated in this study.

For all carcass production trials, old female sheep from the Shetland breed over 12 months of age were used, and supplied by the same producer. They were shorn within a week of slaughter so as to have a wool length of approximately 5 mm. Only clean animals were used for this purpose, as the hygiene legislation requires animals to be clean (EC, 2004). During the trials conducted to examine potential wool removal methods, and in subsequent abattoir trials, it was observed that some carcass sites were more difficult to singe, for example the flank area where the longest wool was regularly found. Differences in wool length were examined to the point where the author stated that "longer wool was more difficult to singe with a larger amount of smoke produced". Neither a microbiological nor a chemical investigation was performed to take into account this variable. Other animal related differences were not examined in this study, like wool thickness (only one sheep breed was used in the study), differences in wool composition (depending on breed and environment husbandry) and fleece cleanliness. With regard to sheep cleanliness, it has been widely assumed that the 'dirtier hide/fleece' leads to the 'dirtier carcass'; therefore, hide/fleece cleanliness is considered important in meat hygiene of the ruminants (Blagojevic, Antic, Ducic, & Buncic, 2012). Several studies found a positive relationship between the degree of fleece/hide dirtiness and the microbiological contamination of sheep (C. Byrne, Bolton, Sheridan, McDowell, & Blair, 2000; Hadley, Holder, & Hinton, 1997) and beef carcasses (Blagojevic et al., 2012; Hauge, Nafstad, Røtterud, & Nesbakken, 2012). Furthermore, it is well known that air can act as an important source of carcass contamination, including during mechanical fleece pulling (Burfoot et al., 2006). Clipping/shearing dirty animals before slaughter generate significant amount of bacterial aerosols, which could facilitate cross contamination of the slaughterline and the final product (Okraszewska-Lasica, Bolton, Sheridan, & McDowell, 2012), including with *Salmonella* and *Listeria monocytogenes* (Okraszewska-Lasica, Bolton, Sheridan, & McDowell, 2014). It can be argued in this case that these animal variables would be controlled in the framework of HACCP based procedures developed, to meet clear set limits, monitoring procedures and corrective actions, but in reality that situation could happen ("worst case scenario") and a study including these aspects should be conducted to give a scientific answer to these possibilities.

The methods to determine the extent of microbiological contamination of the carcasses and to evaluate this production process were based on European Commission Directive EU/471/2001 (EC, 2001), which specifies methods for quantifying aerobic colony counts and *Enterobacteriaceae*. Skin samples were taken by excision method (5 cm^2) from six carcass sites identified as most likely to be contaminated during process (i.e., rump, belly, flank, brisket, shoulder and neck). In all trials, twenty sheep carcasses were used for the experiments, half of them used as a control. Three key steps in the process that could have had significant impact to microbiological contamination were identified as being carcass singeing to remove wool, pressure washing to clean the carcass and then evisceration. Several trials were performed to assess the "toasting" efficiency at the end of production process on carcass microbiology, using indicator bacteria. Hence, toasting after evisceration significantly reduced *Enterobacteriaceae* and TVC counts on carcasses before chilling by roughly 0.5 and 1.5 log_{10} cfu/cm^2 overall, respectively. Also, the trial to include toasting as the final step after carcass splitting and inspection, aiming to control contamination possibly introduced by handling/inspection, indicated that the microbiological quality measured by TVC was improved by roughly 0.5 log_{10} cfu/cm^2 overall (Fisher et al., 2007). Finally, following the protocol evaluated in previous trials with the defined sequence of processing steps, the attempt was made to compare microbiological quality of final smoked, skin-on sheep carcasses with conventionally produced skin-off carcasses produced in the same abattoir. In total, there were 58 of the possible 60 counts of *Enterobacteriaceae* below detectable levels in the skin-on carcasses compared with 34 of 60 in the conventionally dressed carcasses and the reduction effect achieved of roughly 0.5 and 2 log_{10} cfu/cm^2 of *Enterobacteriaceae* and TVC overall, respectively. This was measured before chilling, while chilling appeared to reduce indicator bacteria counts on conventional carcasses by approximately 0.4 log_{10} cfu/cm^2, but had no effect on the low bacterial level present on skin-on carcasses. Therefore, authors concluded that skin-on sheep carcasses can be produced to an acceptable hygienic status using the proposed methods with even lower microbial counts comparing to conventionally produced skin-off carcasses.

This study also investigated the shelf life of skin-on meat compared to conventional carcass meat. It was reported that levels of monitored spoilage bacteria (lactic acid bacteria, *Pseudomonas* spp., yeasts and moulds and TVC) after several days of chilling were similar or slightly higher for skin-on meat (particularly for yeasts and moulds).

The mock-up trial subsequently performed in a commercial abattoir on six skin-on sheep carcasses also included a microbiological investigation for indicator bacteria, according to European Commission Regulation 2073/2005 (EC, 2005). Briefly, carcasses were sampled by two methods, sponge swabbing and excision, and samples were analysed for aerobic colony count (ACC) and *Enterobacteriaceae* count. This limited trial showed large variability in the microbial counts, with the mean value for ACC of 4.3 and 2.2 log_{10} cfu/cm^2 for excision and swab samples respectively. *Enterobacteriaceae* were found on only one carcass (excision method) and two carcasses (swabbing method).

A limited microbiological study was also undertaken to characterise legal production of skin-on feet from a commercial abattoir. Since there is lack of information in literature on this production, this was the first such attempt. Microbial analysis of 12 feet revealed that processing steps following feet singeing (usually coil gland removal and further handling) significantly increased microbial contamination as measured by TVC and *Enterobacteriaceae*. Feet had TVC in the range of 3.1 to 6.9 log_{10} cfu/cm^2, depending on whether they were intact or handled and *Enterobacteriaceae* counts below the detection limit in intact sheep feet, but detected from further handled feet.

This study obviously attempted to characterise the new production process, but without risk assessment and validation of each critical step in the process (i.e. shearing, singeing, power washing, toasting, chilling) to evaluate how these steps would affect the fate of certain bacterial pathogens (including vegetative and sporeforming bacteria). Therefore, only the toasting step was evaluated, and its decontamination effect to microbial contamination possibly introduced in previous steps (specifically evisceration, carcass splitting and carcass meat inspection). While toasting could be performed as a technological step to improve carcass sensory properties, it should be discouraged from being used as a decontamination measure to control microbiological contamination arising from possible diminished hygiene practices in the previous steps. Therefore, any meat decontamination treatment aiming to control microbiological contamination should not and cannot be taken as a substitute for, but only as an addition to, prerequisite good hygienic practices in abattoir operations (Antic, Blagojevic, & Buncic, 2011).

The carcass surface temperature achieved during singeing was 70-85^{o}C, which would have a certain lethal effect on some bacterial cells, but not on all. Spores are known to survive temperatures below 100^{o}C and also non uniformity of singeing can create some cold spots on the carcass surface where bacterial survival could be possible. The immediate antimicrobial effect of singeing was not explored in this study, rather only of the second singeing step (toasting), with around 2 log units of TVC reduction achieved. Water washing used to remove charred wool in this study is known to have a limited antimicrobial effect. Spraying/washing of animal carcasses with water (at temperatures that do not injure or kill bacteria) has been extensively researched, and on average, provides approximately 1 log unit physical reduction of microbial populations (Byelashov & Sofos, 2009). However, there is a concern that high pressure washing may enhance penetration of bacterial cell deeper into tissue (J. N. Sofos & Smith, 1998).

Heating processes such as singeing and toasting are also known to affect bacterial cell viability and recoverability, sometimes resulting in sub-lethally injured bacterial cells which are at the time of sampling and laboratory processing unable to multiply, leading to lower counts or false negative results (Wu, 2008). Sub-lethally injured cells have the capability to repair themselves under favourable conditions and return to a normal physiological state with growth and multiplication. That could have public health implication and in this type of studies it should be addressed.

Excised skin samples (or swab samples) taken after wool singeing, could contain different bacteriostatic compounds produced during this process, that could have additional antimicrobial effect falsely attributed to the singeing process investigated. In that situation, using the standard ISO method recommended for conventionally produced skin-off carcasses seems inappropriate. It is common practice to use neutralising media in studies involving the assessment of decontamination effects of different physical or chemical treatments (Bosilevac et al., 2004). Those media can adequately neutralize the decontaminant evaluated or other compounds present in the sample that could exert antimicrobial activity. Furthermore, all microbiological methods (including use of different materials and media for sampling and laboratory investigation) aimed to be used for trials in this specific smoked, skin-on sheep meat production, should be validated in experimental conditions prior to use.

3.4.2.3 Chemical aspects

Other research studies commissioned by the FSA aimed to identify and characterise the likely risks of certain chemical hazards being present in smoked, skin-on sheep meat. The desk study (P. Bates, 2006) was undertaken to assess the available information concerning medicines licensed for use in sheep produced for meat and risks arising from the consumption of 'skin-on' sheep meat treated with veterinary medicines. There are approximately 37 licenced veterinary medicines currently used for administration to sheep in the UK and their residual concentrations in the skin or skin fat could have potential harmful effects on the consumer of skin-on meat products. The study came to the conclusion that it was unlikely (though not certain) that antibacterials, vaccines and miscellaneous products administered to sheep would pose any significant risk to consumers of skin-on meat products due to their frequency and methods of application. However, topically applied ectoparasiticides and macrocyclic lactone based anthelmintic, drenches or injections may be a risk to the consumer of skin-on meat, through their method of application and/or their lipophilic activity.

Following the findings from this study, a research project was undertaken (Anon., 2009) aiming to investigate whether detectable residues from certain licensed veterinary medicines were present in skin-on sheep feet compared with the set maximum levels in muscle and fat. Skin-on sheep feet were used to represent skin-on sheep meat since they are legally available for human consumption in the UK. They were collected from a commercial slaughterhouse, having previously subjected to the process of scalding, dehairing and singeing. No veterinary medicine residues of 30 analysed compounds, above the EU MRLs for ovine fat were found in any of the 300 samples tested. Low concentrations of diazinon were found in two samples, at 58 µg/kg and 13 µg/kg and only one sample with residues at 58 µg/kg was above the MRL for diazinon in muscle (20 µg/kg). In addition, cypermethrin levels and changes due to the washing and singeing process were investigated in six sheep. Washed animals had lower concentrations of cypermethrin compared to non-washed animals and generally the treated samples contained lower amounts of cypermethrin residues than the controls. It should be noted however that sheep feet might not be representative of the whole sheep skin due to its different composition. No study was undertaken to investigate possible presence of veterinary medicine residues from smoked, skin-on sheep carcasses subjected to the production process described in Fisher et al. (2006). Also, possible biotransformation of residues to produce new compounds as a result of the heating process during singeing/toasting, of veterinary medicines including pour-on ectoparasiticides was not considered.

Another study on the presence of polycyclic aromatic hydrocarbons (PAHs) in smoked, skin-on sheep meat was undertaken alongside the abattoir mock-up trial (Anon., 2010). It is known that PAHs can be formed by incomplete combustion or pyrolysis of organic matter and some compounds in this class are known to be genotoxic and carcinogenic. Due to the way in which smoked, skin-on sheep meat is produced, there is likely to be considerable variation in the amounts of chemical contaminants such as PAHs that may be formed (particularly during wool burning). Samples from six processed sheep were taken during the abattoir trial (from shoulder, loin, leg and brisket from both sides of the respective carcass) and tested for 27 compounds including the 16 PAHs recognised as being of concern for human health. The levels determined were below the current limits set for benzo[a]pyrene and PAH4 (sum of benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene) and ranged from <0.09-0.76 and <0.5-10.74 µg/kg wet weight, respectively. There were also differences between levels determined in different carcass sites, which could indicate that they varied as a result of the variability in the singeing process. Indeed, it was observed during this abattoir trial that some carcass sites had to be scorched for a longer time due to longer and thicker wool present, and that those spots had a darker skin. The singeing was in this case performed using two hand-held blow torches, which was different method prone to greater variability than the custom-made singeing rig used in the trials of Fisher et al. (2006). This variable and relationship between the duration of singeing and the levels of PAHs produced at the respective carcass site was not examined in this study.

According to Fisher et al. (2006), the temperature during wool singeing reached 515°C directly under the burners and around 70-85^{o}C on the carcass surface. Besides PAHs, it is known that other contaminants can be formed at these temperatures, such as polychlorinated dibenzo-p-dioxins and dibenzofurans (PCDD/Fs), together often termed "dioxins". Also, besides burning the wool and skin, potential exposure of meat to high temperatures can generate heterocyclic aromatic amines. Both these groups are known to be harmful to human health and were not examined in this study.

3.4.3 Other studies on smoked, skin-on meat and similar meat products

Following a preliminary internet search, several types of smoked, skin-on meat products were identified, which are commonly produced and consumed in some parts of the world. Eligible meat products, similar to smoked, skin-on sheep meat illegally produced in the UK, were chosen to satisfy predetermined criteria, i.e. skin-on meat that has undergone a heat treatment in the process aiming to remove hair and impart smoked flavour to the meat. Those included: (i) skin-on goat meat, legally produced in Australia and mainly for export to the Asian market; (ii) singed sheep heads (called "svið" in Iceland and "smalahove" in

Norway); (iii) smoked, skin-on meat of different species, predominantly goats, in the region of West Africa; and, (iv) singed cattle hides (called "ponmo" in Nigeria and "welle" in Ghana). However, extrapolation of the results from these studies should be taken with caution, since they describe the production processes which often don't reflect that proposed for smoked, skin-on meat production in the UK, even though performed with the same purpose. They could give, however, some useful insight into potential risks arising from the heating process used to remove hair, or other risks that might be naturally present on the skin (L. Duffy et al., 2009). Furthermore, some of these studies don't provide the comparison between the level of microbiological and chemical safety of smoked, skin-on sheep/goat/cattle meat compared to conventionally produced skin-off carcasses. Rather, they present the findings *per se* and in some cases (like for chemical contaminants) make a comparison with the existing limits set out in legislation.

3.4.3.1 Skin-on goat meat produced in Australia

Goat meat with the skin-on is produced and eaten in a number of non-EU countries. Australia is a major producer and exporter of skin-on goat meat, mainly for the Asian and US markets (L. Duffy et al., 2009). The rangeland (feral) goats are the major source of goats for the goat meat processing industry, accounting for approximately 90% of total goat meat production. These animals range free on private land and are not typically raised for production. According to some very limited information on skin-on goat meat production in Australia, it seems that feral goats are the preferable option for this production since the fibre of domestic (Boer and Angora) goats creates difficulties with processing. The Australian meat industry now utilises a new automated method to dehair feral goats, which includes scalding in hot water at 65^{o}C and subsequent automated dehairing, with some slaughterhouses using singeing in addition (Anon., 2001, 2011). However, there are no available published studies specifically designed to evaluate this production process and the safety of skin-on goat meat. In one study, aiming to determine the prevalence and serotype of *Salmonella* in goats presented for slaughter (L. Duffy et al., 2009), authors investigated a total of 121 goats processed as a "skin-on" in two abattoirs, for the presence of *Salmonella* in matching rumen, faecal and carcass samples (prior to refrigeration). Almost the same numbers of animals were tested in both abattoirs. It was stated that one abattoir used singeing in addition to scalding and automated dehairing, while another did not. *Salmonella* was isolated from 46.3% of faecal samples, 45.5% rumen samples and 28.9% carcass samples, with the dominant serotypes *S*. Saintpaul (31%), *S*. Typhimurium (13%) and *S*. Chester (11%). Even though the aim of this study was not to investigate the impact of the process on the safety of skin-on goat meat, it can be observed that the prevalence of *Salmonella* on the carcasses from the abattoir that used singeing in the process was actually higher than on carcasses from the other abattoir that did not (40% versus 24.6%), even though the *Salmonella* prevalence from rumen and faeces (known to be the sources for carcass contamination) was lower in the abattoir without singeing step. Obviously, some other factors might have contributed to this result, but were not investigated in this study.

There were no available published studies to compare the safety of skin-on goat meat with the produced skin-off carcasses.

3.4.3.2 Singed skin-on sheep heads ("svið" and "smalahove")

Singed skin-on sheep heads are traditional Icelandic ("svið") and Norwegian ("smalahove") dishes, consisting of a sheep's head cut in half, singed to remove the hair, and boiled with the brain removed. There is scarce information regarding the evaluation of this production process and the resulting safety of this product. Only one study, followed up on the several outbreaks of food poisoning in humans that had occurred in Iceland in 1995, and had been traced back to salmonella contamination of singed sheep heads, aimed to investigate the prevalence of salmonella infection in sheep destined for slaughter (Hjartardottir et al., 2002). In this study, *Salmonella* was not found in sheep faeces, but was found in very low prevalence in intestinal content (2%). Also, 8% of tonsillar cultures from lambs were positive, whereas no *Salmonella* was found in tonsillar cultures from singed lamb heads. No explanation was given about the production process, nor was discussed about the safety of this product.

3.4.3.3 Smoked/singed, skin-on meat and singed cattle hides ("ponmo" and "welle") produced in Africa

Production of smoked/singed, skin-on meat and singed cattle hides has a long held tradition in some regions in Africa, particularly in West Africa. Different animal species are used for this production, but the goat meat is believed to be a preferred option. Also, singed cattle hides, popularly called "ponmo" in South-Western Nigeria and "welle" in Southern Ghana, are consumed as a delicacy in these African countries (Obiri-Danso et al., 2008). Traditionally, removal of the hair from the hides is done by tenderizing the hides in hot water (scalding) followed by shaving with a razor blade to give the finished product "ponmo" or "welle". However, other methods have been introduced and adopted by many meat processors in the last few decades. Such methods include singeing off the hair in flames fuelled by various substances such as wood mixed with spent engine oil, plastics mixed with refuse or tyres. The burnt hides are scraped to remove ash and thereafter boiled in water for about one hour to obtain the finished product, "ponmo" (Okiei et al., 2009). Carcasses of other animal species, including goats, would be subjected to the burning process only, followed by scraping and cleaning. As with cattle hides, singeing of carcasses is performed over open fire using firewood as fuel, but in recent times more and more local butchers use scrap tyres as alternative source of fuel to singe slaughtered livestock (Obiri-Danso et al., 2008). Obviously, these processes differ significantly from that used for production of smoked, skin-on sheep meat as proposed in the FSA studies, to the point of using poor quality fuels for singeing step which can introduce significant chemical contamination to the skin-on smoked meat and singed hides. Hides/skins and meat processed with flame fuelled by firewood and spent engine oil may contain toxic organic compounds such as PAHs, dioxins, furan and benzene. Spent tyres also contain several heavy metals such as lead, mercury, cadmium, chromium, zinc and arsenic and plastics mixed with refuse release polychlorinated biphenyls (PCBs), contaminating not only hides but also the environment and represent occupational health hazards for the processors (Okiei et al., 2009). Usually, the reason for this potentially dangerous practice is due to butcher's literacy level, low economic power and lack of awareness on the potential risks involved. One study revealed that only 29.4 % of the butchers were aware of any potential health risks involved in burning tyres for singeing goat carcasses (Mohammed et al., 2015).

Several studies have investigated the safety of singed cattle hides ("ponmo" and "welle") for the presence of heavy metals (Akwetey et al., 2013; Amfo-Otu et al., 2014; Awosanya & Cole, 2011; Ekenma et al., 2015; Obiri-Danso et al., 2008; Okiei et al., 2009) and one for the presence of polycyclic aromatic hydrocarbons (PAHs) (Essumang et al., 2011). Heavy metals, such as cadmium (Cd), lead (Pb), Copper (Cu), Zinc (Zn), Chromium (Cr), Arsenic (As), Mercury (Hg) and Iron (Fe), were regularly found in increased levels (above the maximum permissible levels set by the European Commission Regulation or WHO) in hides singed using scrap tyres or plastics mixed with refuse comparing to those that were unsinged. In the study comparing the difference between singed and unsinged cattle hides for the levels of PAHs (Essumang et al., 2011), it was determined that treated hides had higher levels of naphthalene and benzo[b]fluoranthene.

No microbiological studies aiming to characterise the production processes and/or assess the safety of smoked, skin-on meat and/or singed cattle hides from Africa were available in published literature.

3.5 Conclusions

The primary aim of this study was to systematically review the available scientific evidence on the safety of smoked, skin-on meat from sheep, compared to conventionally produced skin-off carcasses. The available information on the safety of smoked, skin-on meat from other ruminant species (i.e. goats and cattle) was also reviewed to obtain more literature sources related to this topic. The study addressed microbiological and chemical safety of this type of meat product taking into account the two main aspects: (i) sheep/goat/cattle meat with the skin left on at the end of the production process; and, (ii) smoking/burning/singeing heat treatment as a part of the dressing procedures used to remove hair/wool from the skin. Very few literature sources were retrieved using predefined criteria, and the only available on the production process and safety of the smoked, skin-on sheep meat were those arising from the FSA funded research. An overview of the current situation based on this finding is presented. Other published studies on similar products, such as skin-on goats, singed sheep head, smoked/singed, skin-on meat and singed cattle hides from Africa, were analysed and findings presented.

A systematic review of the FSA commissioned studies found that it was not possible to answer the question set out in this study due to several factors. The microbiological safety of the smoked, skin-on sheep meat produced according to the protocol developed in the FSA studies was not examined due to the fact that: (i) no microbiological hazards associated with the process or product were investigated; (ii) the effects of the process steps on their fate was not examined; and (iii) no comparisons were made of microbiological pathogens with conventionally produced skin-off carcasses. Since no available information in scientific literature exist on the microbiological profile of smoked, skin-on sheep meat, the attempt should be made to identify microbiological hazards associated with this production and evaluate how different process steps would affect those hazards. Indicator bacteria used in these studies could also be used to assess process hygienic performance, but not to indicate pathogen reduction or to assess product safety. Also, the microbiological methodology should be designed and pre-validated to address specific nature of this process and product, i.e. its antimicrobial nature and decontamination step(s) introduced in the process. Experimental model based studies are necessary to explore and evaluate different production options, and to gather sufficient evidence for the development of thorough SOPs and HACCP based procedures. Based on these findings, validation under a commercial setting seems to be required since the process is to be introduced as a new production system.

The production protocol developed in the FSA studies provides a solid basis for further development of the process for safe production of smoked, skin-on meat. Based on the evidence gathered from the experimental model based studies on risk assessment of the individual steps in the process, it is possible to develop a detailed production protocol based on HACCP principles, with validated critical control points, set limits, monitoring procedures and corrective actions. It is necessary to explore different animal, environmental and process related variables, and also abattoir related variables when validating this process in a real-life operational environment. The HACCP based plan should give a clear indication of what animals should be used for this production, and also to meet official control requirements (i.e. Food Chain Information analyses and meat inspection procedures including TSE controls). It could also be worth exploring other alternative options for the production of smoked, skin-on sheep meat that would meet consumer demands but to ensure the same or better level of protection compared to conventionally produced skin-off carcasses.

The chemical safety of the smoked, skin-on sheep meat was partly examined in the FSA studies, but not of the products produced according to the protocol developed, and not covering all potential contaminants. Presence and levels of the residues of veterinary medicines were examined in the skin-on sheep feet only. It is necessary to include an evaluation of their presence and possible biotransformation due to the heating process during singeing/toasting, using different animal and process related variables. With respect to other chemical contaminants potentially formed during the production of smoked, skin-on sheep meat, only the study of the presence and levels of PAHs was performed on a limited number of samples. Other potential chemical contaminants such as dioxins and heterocyclic aromatic amines were not investigated. The samples for PAHs analyses were taken after the abattoir trial that involved a singeing method different to the one described previously (i.e. using hand-held gas burners instead of the developed singeing rig), which would allow for greater variability in singeing. All the PAHs concentrations measured were below regulated limits, but with significant variables between carcass sites. It is important in the development of a detailed production protocol based on HACCP principles, to address animal, environmental and process related variables and set clear parameters to be followed allowing for uniformity and consistency.

Therefore, the evidence gathered from the FSA studies and reviewed in this study do not provide a definitive answer with respect to the microbiological and chemical safety of smoked, skin-on sheep meat, nor about its relation to conventionally produced skin-off carcasses. However, the FSA studies do provide a stepping stone and basis for further development of the process for safe production of smoked, skin-on meat.

A systematic review of other studies on smoked, skin-on meat products worldwide found that it was only partly possible to answer the question set out in this study. There are scarce data in literature regarding smoked/singed, skin-on sheep/goat/cattle meat products. One explanation could be that most of these products are banned from being produced legally in developed countries and often represent very traditional foods in some parts of Europe, consumed on special occasions and in low quantities. On the other hand, there is also a lack of information on the safety of these products from countries that have regular consumption, like in some parts of Africa and Asia, or from Australia, which is one of the main exporters of skin-on goat meat. Production of smoked/singed, skin-on meat and singed cattle hides in West Africa is often performed on a non-regulated basis and lacks control. This often leads to the lack of awareness of the options for delivering a safe and hygienic process for the production of smoked, skin-on meat. It is clear from the published studies on the presence of chemical hazards in these products (heavy metals and PAHs) that singeing process as performed, significantly contributes to the chemical contamination of these products. No microbiological data were available for these products. Also, extrapolation of these results to the production of smoked, skin-on sheep in the UK is not possible since the processes significantly differ, but could be useful to highlight possible risks.

Overall, there is not sufficient evidence in the available literature sources to conclude that smoked, skin-on sheep/goat/cattle meat poses a greater or lower risk to consumers when compared to conventionally produced skin-off carcasses. So, further studies are necessary to address the gaps in knowledge and to enable safe production of this product.

4 Critical Review on the smoked, skin-on sheep meat production

4.1 Summary

A comprehensive critical review was performed to evaluate the available evidence on a proposed production method for smoked, skin-on sheep meat and to identify appropriate research required to fill gaps in scientific knowledge regarding this production. The main aspects covered were to identify the relevant public health hazards arising from this production and the possible effects of the smoked, skin-on sheep meat production process on these hazards, as well as its effects on official controls. Animal welfare and occupational health implications were briefly discussed. Some alternative methods for production of smoked, skin-on sheep meat were then proposed.

Different sheep variables were considered, especially in cull ewes, which are thought to be the main source of animals for smoked, skin-on meat production. The review identifies four bacterial hazards relevant for consideration for assessment of the safety of smoked, skin-on sheep meat: *Bacillus cereus*, *Clostridium perfringens*, pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) and *Salmonella* spp. The primary chemical hazards that may be formed during the production of skin-on sheep meat are dioxins, PAHs and heterocyclic aromatic amines. Also provided is the list of veterinary medicines currently authorised in the UK for use in sheep and considered as most likely to represent an increased hazard for skin-on sheep meat production due to the risk of, and lack of data regarding, skin residues.

A range of relevant pathological conditions in smoked, skin-on sheep carcasses were reviewed and discussed. It was concluded that the change in sheep carcass dressing process will affect official control procedures that will need to be evaluated and amended. Also, some of the practices will likely have positive or negative effect on animal welfare, so these implications should also be considered when developing SOPs for this production.

Further research requirements were identified, including laboratory based experiments and those needed for validation purpose in commercial settings.

4.2 Introduction

Systematic review of previous FSA commissioned studies on smoked, skin-on sheep meat described in chapter 3 found that the evidence gathered from these studies do not provide conclusive answer regarding the microbiological and chemical safety of smoked, skin-on sheep meat nor about its relation to conventionally produced skin-off carcasses. Also, the information reviewed from other studies on similar smoked, skin-on meat products found that there were insufficient data to assess microbiological safety.

The results of this systematic review outlined gaps in current knowledge about this product that need to be addressed in further research: (i) the effect of the smoked, skin-on process on public health hazards; (ii) the microbiological profile of smoked, skin-on sheep meat, and (iii) the effect of the smoked, skin-on production and changes in the dressing process of the carcass on official controls.

Therefore, the main aim of this critical review was to identify all relevant aspects for safe and hygienic production of smoked, skin-on sheep meat, and gather available information from the literature to identify areas of research that need to be addressed before making a case to legalise this production in the UK and EU. Specifically, this chapter reviews available scientific information pertinent to smoked, skin-on sheep meat production that relates to:

(i) animal variables;

(ii) identification of relevant public health hazards arising from this production and possible effects that this process could have on these hazards;

(iii) implications on official controls;

(iv) implications on animal welfare and occupational health.

Also, some alternative methods for production of smoked, skin-on sheep meat to the one described in abovementioned FSA commissioned studies are reviewed and proposed.

4.3 Animal variables

The proposed source of animals for smoked, skin-on sheep meat production is cull ewes. There is an interest in providing a higher value market for these animals and their body condition score, meat flavour and tenderness more closely matches that of goat that would be the preferred species for the potential initial market than lamb. Once the market is established it is conceivable that lambs may also be included to meet expectations from new consumers who require more tender meat but with a smoked flavour.

4.3.1 Sheep production variables

Animals may be sourced from a variety of breeds and farming systems. The greatest density of ewes are in North and mid Wales but the greatest number are in England and the majority of cull ewes pas through English live markets[5]. The ethnic market purchases 94% of cull ewes currently[6].

The main reasons for culling ewes in the UK are: (i) body condition score; (ii) mastitis; (iii) failure to conceive; (iv) condition of teeth (prevention of poor body condition in next season); and, (v) lameness. Ewes are examined to ensure they are in suitable condition for mating and to carry and rear lambs before rams are introduced to the flock. At this point animals will be sent for slaughter due to body condition, teeth, lameness, and mastitis / udder and teat condition. Animals that have failed to conceive will be selected for culling. The exact timing of these events depends on the target lambing time. Cull ewes may be retained to improve condition prior to sale. This may be achieved by a combination of the fact lambs have been weaned reducing metabolic load and increasing pasture/feed quality and quantity. Diseases such as liver fluke and blow fly strike have seasonal incidence carcass lesions or the risk of residues for medicines administered to treat or prevent the conditions also occur seasonally. Thus the risks of a carcass having specific issues may vary through the year and slightly between geographical locations.

Wool is composed of keratin fibres (protein), lanolin (fat) and suint (the aqueous soluble portion from sweat and other debris in the fleece). Sweat glands themselves secrete both stored and newly synthesised sweat (Johnson, 1973). The ratio of these components depends on fleece type, and thus breed of sheep, and ambient temperature. Modern proteomic approaches have been used to identify the range of protein present in wool, the predominant being keratin and that is divided into two broad classes. Studies on breed variation have chiefly focused on the Merino compared to a selection of other breeds common in the Southern Hemisphere, however, they have identified large within breed and flock variations (Plowman et al., 2012). The variation in high sulphur containing amino acids

---

[5] http://www.eblex.org.uk/wp/wp-content/uploads/2014/07/UK-Yearbook-2014-Sheep-240714.pdf
[6] http://beefandlamb.ahdb.org.uk/wp/wp-content/uploads/2014/08/brp-manual-4-Managing-ewes080814.pdf

by breed and due to seasonal and reproduction associated changes in nutrition and wool growth have been reported (Flanagan, Plowman, & Bryson, 2002). Feed restriction to simulate seasonal reduction in feed availability results in significant reduction in the fibre diameter of wool and significant increases in the expression of the high sulphur protein KAP13.1 and proteins from the high glycine–tyrosine protein KAP6 family in the wools from the animals on the restricted diet were also detected (Almeida et al., 2014). As a possible source of flavour and residues variation in these amino-acids may be relevant to smoked, skin-on sheep meat production.

Early studies suggest length and crimp of wool are affected by the type of forage that has been consumed by sheep (Patil, Jones, & Hughes, 1969). Only one study appears to have taken place using Welsh Mountain ewes and that focussed on the relationship between cadmium and zinc and pollutant and ameliorant rather than composition after normal farming practice. It does, however, highlight the possibility of toxic minerals being present in the wool from past exposure (Phillips, Omed, & Chiy, 2004). This could be factored into the consideration of Wool harvest interval dates to determine when wool is free of residues when burnt (see residue section for further discussion).

Rate of incorporation of isotopes in wool is related to overall growth rate and is not different with age suggesting changes in diet will have a similar effect regardless of age of animal (Zazzo et al., 2015). Maternal nutrition during pregnancy influences offspring wool production and wool follicle development particularly maternal selenium intake (Magolski et al., 2011). Isotope measurements suggest significant changes in composition of wool between seasons in Ireland. Similar changes may occur in Welsh sheep given the geographical closeness of the locations (Zazzo et al., 2015). The exact compounds in the wool were not studied in this publication but suggest that seasonal influences on wool composition. Effects seem relatively small.

The protein composition of sheep skin varies with diet and genetic potential for wool growth in Merinos but similar data do not appear to be available for breeds more common in the UK (Magnusson, Walters, & Roberts, 2001). Skin from the high producing sheep and from the sheep with greater intake had lower concentrations of collagen per unit mass of skin, but similar collagen per unit area of skin. Further studies suggest nutrition influences skin thickness (Li, Oddy, Nolan, Godwin, & Liu, 2006). Detailed studies of sheep skin composition from studies using them as models for human allergy and skin healing may provide further information but were outside the scope of the present study. Further information on skin composition is likely to become available from the SheepGENOMICS project in the coming years (White et al., 2012).

There are little specific data on animal variables affecting skin and wool composition in the breeds likely to be used for smoked, skin-on sheep meat production in the UK. Differences observed in other breeds and geographical locations are relatively small. Further investigation of differences in sulphur containing amino-acids may be warranted if these contribute to the taste of the final product.

4.3.2 Sheep skin diseases

The following sheep skin diseases are considered to require specific consideration in animals intended for use in smoked, skin-on sheep meat production.

Blow Fly Strike

Blowfly strike is tissue damage caused by migration (myiasis) of green bottle larvae (*Lucilia sericata).* A survey has suggested that 80% of flocks experience some blow fly strikes occurring between May and September, although this range is increasing due to climate change. The female flies lay eggs on the dorsal spine and breech area above the tail attracted by the odour of wounds or faeces soiled fleece. Eggs hatch in 3 days and feed on the exudate but may burrow into muscle and damage deeper structures leading to shock and death. The odour from this damage attracts other flies. Other skin diseases and loose faeces due to gastrointestinal parasites predisposes to strike. In mild cases wool discolouration and loss will be seen and fetid, moist exudate from damaged skin will be present on animals and their carcasses. More extensive lesions can result in skin scaring and deeper wounds may granulate and lead to deeper areas of scar tissue into the dermis and underlying muscle. Medical treatment may occur at any time between May and September but preventative treatments tend to be used before shearing only during high risk years or in response to early cases using short acting products and longer acting products are used after shearing (June) as most products are contra-indicated immediately before shearing to limit residue exposure to shearing staff[7].

Oestrus ovis

Sheep bot flies deposit larvae around the nasal cavity of sheep which migrate into the nasal cavity. They may cause myiasis around the head and eyes and tissue damage and scarring due to irritation and rubbing. Clinical signs are most common in May but can range from March to late October depending on the weather. It is not a national problem but can be a major problem in individual flocks in the year following a very warm summer (Peter Bates, 2007). Larvae present in carcasses may drop out the nose during carcass handling or die in situ. Their response to heating/singeing is not known. This organism is unlikely to be a major concern in smoked, skin-on sheep meat production.

[7] http://www.scops.org.uk/ectoparasites-sheep-blowfly.html

Sheep Scab

Sheep scab is an allergic dermatitis caused by the faeces of the Sheep scab mite *Psoroptes ovis*. Clinical signs are mostly seen between September and April but can occur in the summer especially in animals in poorly or unshorn animals. Sheep with early or sub-clinical scab can show no signs or milk restlessness and rubbing. Later stages contain high mite numbers and scabbing, wool loss and rubbing leading to open wounds may occur. Secondary fly strike may occur. Skin thickening and scabbing in active disease, scarring from healed disease and risk of residues after prevention or treatment need to be considered in smoked, skin-on sheep meat production.

Bacterial infections

Dermatophilus congolensis or lumpy wool disease is a skin infection in sheep which can lead to scabs and scaring on the dorsal aspect of the carcass skin. It is most common in warm wet conditions. The effect of this on the aesthetic quality of the skin colour after singeing needs to be considered. However, it is also an important attractant for blow flies to cause fly strike and thus may precipitate use of ectoparasiticides and risk of residues (Gherardi, Johnson, Monzu, & Sutherland, 1983)[8].

Caseous lymphadenitis is a chronic systemic infection caused by *Corynebacterium pseudotuberculosis*. It was imported into the UK in the 1990s and spread through pedigree flocks but has less penetration into commercial flocks. The organism gains access via skin or other epithelium and forms an abscess in the local draining lymph node such as the parotid, submandibular, prefemoral, prescapular, popliteal or mammary or abscesses in the lungs and associated thoracic (bronchial and mediastinal) lymph nodes (O'Reilly, Green, Malone, & Medley, 2008). Large superficial swellings will be visible but smaller swellings may be missed after smoking. Cases of human lymphadenitis have been described previously (Peel, Gregory, Ann, & Trevor, 1997), although transmitted via occupational exposure and not through consumption of meat (EFSA, 2013).

Footrot is an infection of the foot leading to damage to the hoof caused by *Dichelobacter nodosus*. In itself it does not pose a risk but vaccination is a very effective form of control. The authorised vaccine in the UK may cause injection site abscesses, usually in the neck. These may be present on carcasses. They tend to be hard and inactive but could be missed at inspection after singeing.

Several diseases could alter the aesthetic quality of the final product due to associated skin damage, scarring or subcutaneous abscess formation. Treatment of these diseases may pose a risk of skin residues. Stringent anti-mortem inspection may allow selection of animals for smoked, skin-on sheep meat production without these risk factors.

[8] http://www.nadis.org.uk/bulletins/non-parasitic-skin-conditions-in-sheep.aspx

4.4 Identification of public health hazards associated with skin-on sheep meat

4.4.1 Biological hazards

4.4.1.1 Methodology

For the purpose of the hazard identification carried out in this report, only biological hazards with the public health relevance (i.e. transmitted to humans via any possible route) and present in the sheep population in the EU and UK were considered as relevant. Subsequently, their occurrence on the skin/fleece, in meat and viscera (internal organs) was assessed. Then, using a combination of literature review and the expertise within the project team, hazards were assessed by considering the possibility and the existing evidence of the transmission to humans through handling, preparation and/or consumption of sheep meat (meat-borne route). In the context of this report, handling and preparation relates to these activities immediately prior to consumption (EFSA, 2013). However, it should be taken with precautions that, meat-borne transmission route described in available literature considers only the consumption of skin-off sheep meat, as this is currently permitted to be produced under current EU legislation. There is a lack of data in available literature of transmission of any of these public health meat-borne hazards to humans through consumption of smoked, skin-on sheep meat, apart from one short study that briefly mentioned several outbreaks of food poisoning in humans that had occurred in Iceland in 1995, and had been traced back to salmonella contamination of singed sheep heads (Hjartardottir et al., 2002). However, it can be speculated that the same scenario of transmission can occur with the most of these meat-borne hazards, particularly with those which presence is often associated with sheep skin and/or older animals.

The final criterion that was assessed was whether carcass meat contamination/infestation is considered as being the main risk factor for human foodborne exposure to this hazard. This relates to the fact that it is often not possible to identify the original source of the contamination or foodstuff implicated in foodborne disease outbreaks. Some biological hazards are often associated with live animals as the original source (bacteria shed by healthy animals and/or meat infestation with certain parasites) and contamination events during slaughter and dressing. On the other hand, some other hazards (for example *Staphylococcus aureus* and *Listeria monocytogenes*) are considered as ubiquitous and hence meat contamination often occurs in the later stages of the meat chain (production of meat products, distribution, preparation and handling of meat) and might not be associated with their presence in animal or on carcass. Relative relevance of the source of contamination of skin-on sheep meat with these hazards to human exposure to them is not known.

This comprehensive list of public health hazards that could be associated with skin-on sheep meat was created in line with recent EFSA Opinion on the public health hazards to be covered by inspection of meat from sheep and goats (EFSA, 2013) and by collating information and evidence found in peer-reviewed literature, textbooks, through reported data from EFSA and ECDC summary reports on zoonoses, previous assessments and other EFSA opinions. Also, comparisons with hazard identification performed in the context of recent FSA research projects (Alonso et al., 2011; Hill et al., 2013) revealed that there were no additional hazards related specifically to epidemiological situation in the UK that should have been selected for further assessment.

The final list of identified hazards included in the further assessment of their relevance for the smoked, skin-on sheep meat production in the UK, consisted of ten hazards (nine bacteria and one parasite) occurring in the UK and for which there is evidence of foodborne transmission through handling, preparation and/or consumption of sheep meat (meat-borne route). Based on this list, four bacterial hazards relevant to the assessment of the safety of smoked, skin-on sheep meat were identified, taking into consideration criteria such as: (i) reported occurrence and prevalence on sheep fleece and in sheep carcass meat (primarily in the UK); (ii) evidence for sheep meat as an important risk factor for human disease (based on the assessment from EFSA (2013) and other sources); (iii) evidence of carcass meat contamination as the main risk factor for human foodborne exposure to the respective hazard; and, (iv) potential association with the skin-on sheep meat products due to specific nature of this production process (arbitrarily decided).

4.4.1.2 Results

Based on the methodology described, a long list of potentially zoonotic biological hazards occurring in sheep was created (Table 4.1). The majority of these hazards (bacteria, fungi, parasites and viruses) were considered not to be sheep meat-borne pathogens, as no evidence for this was found in the literature. Some of these pathogens were considered as not relevant as they are not currently present in the sheep population in the UK (like *Brucella* or *Trichinella*). For *Linguatula serrata*, even though evidence of transmission via consumption of sheep meat were described in the literature, it is considered that contact with the final host (canids) is the source for the human cases in Europe, so consumption of sheep meat is not considered as a significant source of infection. There is a lack of data regarding potential sheep meat-borne route for transmission of extended-spectrum β-lactamase- (ESBL-)/AmpC-carrying *Escherichia coli* to humans, despite their presence in the animal reservoir.

Table 4.1: Preliminary long list of **potentially zoonotic biological hazards occurring in sheep** categorised by whether they are present in the sheep population in the EU and UK and whether they are meat-borne

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Bacteria								
Aeromonas spp.	Yes	Yes	Yes	Yes	Yes	No. Contaminated water, contact infection. Food-borne transmission not established	NA[2]	(Daskalov, 2006; Sierra, Gonzalez-Fandos, García-López, Fernandez, & Prieto, 1995)
Anaplasma phagocytophilum, Panola Mountain *Ehrlichia* spp.	No	Yes	Yes	Yes	Yes	No. Vector-borne (ticks)	NA	(Scharf et al., 2011; Stuen, 2013; Woldehiwet, 2006)
Arcanobacterium pyogenes	Yes	Yes	Yes	Yes	Yes	No. Contact infection, isolated from abscesses	NA	EFSA (2004); (Jost & Billington, 2005)
Arcobacter spp.	Yes	Yes	Yes	Yes	Yes	No. Rarely human pathogen. Food-borne transmission not established	NA	(De Smet, De Zutter, & Houf, 2011; Houf, 2009; Merga et al., 2013)
Bacillus anthracis	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**No. Pulmonary, gastrointestinal or cutaneous infection.**	**(Fasanella et al., 2010; Popescu et al., 2011)**

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Bacillus cereus	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**No. Toxicoinfection (diarrheal) including meat-borne; intoxication (emetic) due to starchy foods**	**(Bhandare, Paturkar, Waskar, & Zende, 2010; EFSA, 2005a; Lyness, Pinnock, & Cooper, 1994; Meyer, Neurand, & Tanyolaç, 2001; Willayat, Sheikh, & Misgar, 2007)**
Borrelia burdogferi sensu lato	No	Yes	Yes	Yes	Yes	No. Vector-borne (ticks)	NA	(Bettridge, Renard, Zhao, Bown, & Birtles, 2013; Mannelli, Bertolotti, Gern, & Gray, 2012; Stuen, 2013)
Brucella abortus, B. melitensis	No	Yes	Yes	Yes	No	No. Contact infection; can be food-borne (primarily milk)	NA	(EFSA, 2004; EFSA & ECDC, 2015)
***Campylobacter* spp. (thermophilic)**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**(Bilei et al., 2012); EFSA and ECDC (2015); (Garcia, Steele, & Taylor, 2010; Milnes et al., 2008; Sproston et al., 2011; Stanley, Wallace, Currie, Diggle, & Jones, 1998; Zweifel, Zychowska, & Stephan, 2004)**

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Chlamydophila abortus	No	No	Yes	Yes	Yes	No. Contact infection.	NA	(Longbottom & Coulter, 2003; Michalopolou, Leigh, & Cordoba, 2007)
Clostridium botulinum	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**No. Intoxication after multiplication in foods (non-infant)**	**(EFSA, 2005b; EFSA & ECDC, 2015)**
Clostridium difficile	Yes	Yes	Yes	Yes	Yes	No. Nosocomial infection. Present in meat; meat-borne transmission not established	NA	(Knight & Riley, 2013; Koene et al., 2012; Saif & Brazier, 1996)
***Clostridium perfringens* type A**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**No. Toxicoinfection after multiplication in foods**	**(Bilei et al., 2012; EFSA, 2005b; EFSA & ECDC, 2015; Guran, Vural, & Erkan, 2014)**
Corynebacterium pseudotuberculosis	Yes	Yes	Yes	Yes	Yes	No. Contact infection, food-borne via milk	NA	(Baird & Fontaine, 2007; Hill et al., 2013; Meyer et al., 2001; Nuttall, 1988; Peel et al., 1997)
Coxiella burnetii	Yes	Yes	Yes	Yes	Yes	No. Aerosols; shed in milk but not considered food-borne	NA	(Donaghy, Prempeh, & Macdonald, 2006; EFSA & ECDC, 2015; Gale, Kelly, Mearns, Duggan, & Snary, 2015; Georgiev et al., 2013)

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Pathogenic verocytotoxin-producing *Escherichia coli* (VTEC)	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**(Brandal et al., 2012; Chapman, Malo, Ellin, Ashton, & Harkin, 2001; L. L. Duffy, Small, & Fegan, 2010; Edrington et al., 2009; EFSA & ECDC, 2015; Kalchayanand et al., 2007; Lenahan, O'Brien, Kinsella, Sweeney, & Sheridan, 2007; Long et al., 2004; Milnes et al., 2008; Ogden, MacRae, & Strachan, 2005; Prendergast et al., 2011; Pritchard, Smith, Ellis-Iversen, Cheasty, & Willshaw, 2009; A. Small et al., 2002; Zweifel et al., 2004)**
Erysipelothrix rhusiopathiae	Yes	Yes	Yes	Yes	Yes	No. Contact infection	NA	(EFSA, 2004; Ersdal, Jørgensen, & Lie, 2015; Wang, Fidalgo, Chang, Mee, & Riley, 2002)

Hazard	**Occurrence in sheep**			**Present in sheep population in the EU?**	**Present in sheep population in the UK?**	**Is there evidence of transmission via consumption of sheep meat?**	**Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?**[1]	**Examples of recent supporting evidence for inclusion**
	skin/ fleece	**meat**	**viscera**					
ESBL/AmpC carrying bacteria	Yes	Yes	Yes	Yes	Yes	No. No evidence of transmission via consumption of sheep meat	NA	(EFSA, 2011b; Geser, Stephan, & Hächler, 2012; Snow, Wearing, Stephenson, Coldham, & Teale, 2011)
Helicobacter pylori	No	No	Yes	Yes	Yes	No. Food not identified as a source, no evidence of meat-borne transmission.	NA	(Momtaz, Dabiri, Souod, & Gholami, 2014; Quaglia et al., 2008)
Klebsiella pneumoniae	No	Yes	Yes	Yes	Yes	No. No evidence of meat-borne transmission	NA	(Gundogan, Citak, & Yalcin, 2011)
Leptospira spiralis	No	Yes	Yes	Yes	Yes	No. No evidence of meat-borne transmission	NA	(Dreyfus et al., 2014; Melo, de Castro, Leite, Moreira, & de Melo, 2010; Tonin et al., 2015)
***Listeria* spp.**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**No. Invasive infection after post-processing introduction and multiplication in ready-to-eat foods**	**(Antoniollo, Bandeira, Jantzen, Duval, & Silva, 2003; EFSA & ECDC, 2015; Sheridan, Blair, McDowell, & Duffy, 1994)**

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Mycobacterium avium subspecies *paratuberculosis*	Yes	Yes	Yes	Yes	Yes	No. Food-borne transmission not confirmed	NA	(Biet, Boschiroli, Thorel, & Guilloteau, 2005; Eltholth, Marsh, Van Winden, & Guitian, 2009; Hill et al., 2013; NACMCF, 2010; Waddell et al., 2008)
Mycobacterium bovis	No	Yes	Yes	Yes	Yes	No. Aerosols, food-borne via milk; no evidence of meat-borne transmission in the EU	NA	**(EFSA & ECDC, 2015; Hill et al., 2013; Marianelli et al., 2010; Muñoz Mendoza et al., 2012; van der Burgt, Drummond, Crawshaw, & Morris, 2013)**
***Salmonella* spp.**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**(Bilei et al., 2012; Bonke et al., 2012; L. L. Duffy et al., 2010; Edrington et al., 2009; Kalchayanand et al., 2007; Long et al., 2004; Sierra et al., 1995; A. Small et al., 2002; Zweifel et al., 2004)**

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Staphylococcus aureus **(toxin producing)**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**Yes**	**No. Intoxication after multiplication and toxin formation in foods**	**(Bhandare et al., 2010; Meyer et al., 2001; Mørk, Kvitle, & Jørgensen, 2012; Smith, Needs, Manley, & Green, 2014; Vitale et al., 2015)**
Methicillin resistant *Staphylococcus aureus*	Yes	Yes	Yes	Yes	Yes	No. Contact infection. Currently no evidence of transmission via consumption of sheep meat	NA	(Boer et al., 2009; EFSA, 2009)
Streptococcus suis, Streptococcus equi subspecies *zooepidemicus*	Yes	Yes	Yes	Yes	Yes	No. Contact infection mainly. No evidence of meat-borne transmission	NA	(EFSA, 2004; Las Heras et al., 2002; Muckle et al., 2014; Poulin & Boivin, 2009)
Yersinia pseudotuberculosis/ enterocolitica	Yes	Yes	Yes	Yes	Yes	No. Food-borne, including milk. Currently no evidence of transmission via consumption of sheep meat	NA	(EFSA & ECDC, 2015; Fredriksson-Ahomaa, Stolle, & Korkeala, 2006; McNally et al., 2004; Milnes et al., 2008; Sierra et al., 1995; Söderqvist, Boqvist, Wauters, Vågsholm, & Thisted-Lambertz, 2012)
Fungi								
Candida albicans	Yes	No	Yes	Yes	Yes	No	NA	(EFSA, 2013)

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Cryptococcus neoformans var. *neoformans*	Yes	No	Yes	No	No	No	NA	(EFSA, 2013)
Encephalitozoon cuniculi	Yes	No	No	Yes	Yes	No	NA	(EFSA, 2013)
Enterocytozoon bieneusi	Yes	No	Yes	Yes	Yes	No	NA	(EFSA, 2013)
Parasites								
Ascaris lumbricoides	Yes	No	Yes	Yes	Yes	No. Ingestion of material containing contaminated faeces	NA	(EFSA, 2013)
Babesia divergens, B. microti	No	Yes	No	Yes	Yes	No. Vector-borne (ticks)	NA	(EFSA, 2013)
Coenurus cerebralis	No	No	No	Yes	Yes	No. Ingestion of material containing contaminated canine faeces	NA	(EFSA, 2013)
Cryptosporidium parvum	Yes	Yes	Yes	Yes	Yes	No. Food and water-borne, sheep meat-borne transmission not established	NA	(EFSA, 2013)
Dicrocoelium dendriticum	No	No	Yes	Yes	Yes	No. Ingestion from contaminated environment	NA	(EFSA, 2013)
Echinococcus granulosus	No	No	Yes	Yes	Yes	No. Ingestion of material containing contaminated canine faeces	NA	(EFSA & ECDC, 2015)
Fasciola hepatica	No	No	Yes	Yes	Yes	No. Ingestion from contaminated environment	NA	(EFSA, 2013)
Giardia intestinalis	Yes	Yes	Yes	Yes	Yes	No. Food and water-borne, sheep meat-borne transmission not established	NA	(EFSA, 2013)
Gongylonema pulchrum (“gullet worm”)	No	No	Yes	Yes	No	No. Ingestion of infected vectors	NA	(EFSA, 2013)

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Linguatula serrata	No	No	Yes	Yes	Yes	Yes	Yes. However, contact with the final host (canids) is the source for the human cases described in Europe	(Kheirabadi, Azizi, Fallah, Samani, & Dehkordi, 2015; Koehsler et al., 2011; Sinclair, 1954; Tappe et al., 2006)
Moniezia expansa	No	No	Yes	Yes	Yes	No. Ingestion from contaminated environment	NA	(EFSA, 2013)
Sarcocystis spp.	No	Yes	No	Yes	Yes	No. Only meat from pigs and bovine animals	NA	(EFSA, 2013)
Toxoplasma gondii	**No**	**Yes**	**No**	**Yes**	**Yes**	**Yes**	**Yes**	**(Dubey, 2009; Dumètre, Ajzenberg, Rozette, Mercier, & Dardé, 2006; EFSA, 2007; EFSA & ECDC, 2015)**
Trichinella spp.	No	Yes	No	No	No	Yes	Yes	(EFSA, 2013)
Trichophyton verrucosum	Yes	No	No	Yes	Yes	No. Contact infection.	NA	(EFSA, 2004)
Trichostrongylus spp.	No	No	Yes	Yes	Yes	No. Ingestion of material containing contaminated faeces	NA	(EFSA, 2013)
Viruses								
Astroviruses	No	No	Yes	Yes	Yes	No	NA	(EFSA, 2013)
Borna disease virus	No	No	No	Yes	Yes	No	NA	(EFSA, 2013)
Bovine enterovirus type 1 (BEV-1)	No	No	Yes	Yes	No	No	NA	(EFSA, 2013)
Chandipura virus	No	No	No	No	No	No	NA	(EFSA, 2013)

Hazard	Occurrence in sheep			Present in sheep population in the EU?	Present in sheep population in the UK?	Is there evidence of transmission via consumption of sheep meat?	Is carcass meat contamination / infestation considered as being the main risk factor for human foodborne exposure to this hazard?[1]	Examples of recent supporting evidence for inclusion
	skin/ fleece	meat	viscera					
Crimean-Congo Haemorrhagic Fever Virus (CCHFV)	No	Yes	No	No	No	No	NA	(EFSA, 2013)
Hepatitis E virus	No	Yes	Yes	Yes	Yes	No. Currently no evidence of transmission via consumption of sheep meat	NA	(EFSA, 2013)
Influenza virus	No	Yes	Yes	Yes	No	No	NA	(EFSA, 2013)
Orfvirus	Yes	No	No	Yes	Yes	No. Contact infection.	NA	(EFSA, 2013)
Rabies	No	No	No	Yes	No	No. Contact infection, mainly through animal bites	NA	(EFSA, 2013)
Rift Valley Fever virus	No	Yes	Yes	No	No	Yes	No. Mainly transmitted through mosquito vectors	(EFSA, 2013)
Rotavirus	No	No	Yes	Yes	Yes	No	NA	(EFSA, 2013)
Tick-borne encephalitis	No	No	No	Yes	No	No. Vector-borne (ticks), milk borne	NA	(EFSA, 2013)

[1]This addresses hazards often associated with meat contamination in the later stages of the meat chain (production of meat products, distribution, preparation and handling of meat) that might not originate from animals and/or carcass meat in abattoir. In many cases, it is not possible to identify the original source of the contamination or implicated foodstuff
[2]NA = not applicable, as the hazard already does not comply with the sheep meat-borne transmission criterion

The selected ten biological hazards (nine bacteria and one parasite) occurring in sheep in the UK and for which there are evidence of foodborne transmission through handling, preparation and/or consumption of sheep meat (meat-borne route) were subjected to further assessment of their relevance for the smoked, skin-on sheep meat production in the UK. A brief overview of this assessment is presented in Table 4.2.

Bacillus anthracis

The spores of this organism are present in the soil in some enzootic areas, like in Greece, Spain, France and Italy (Fasanella et al., 2010). Anthrax is now considered as very rare in livestock in EU. The human exposure routes to anthrax spores are usually through handling infected animals or through contact with animal products such as hides, wool and hair. Therefore, respiratory infections through inhalation of aerosols contaminated with spores and cutaneous infections through contact with materials contaminated with spores are the most common form. Cases of gastrointestinal anthrax that have resulted from the ingestion of raw, undercooked or well cooked beef, sheep or goat meat are described in literature, but are usually consequence of the lack of official controls during slaughter of animals showing clinical signs of anthrax. However, the risk of acquiring this disease through consumption of meat from sheep slaughtered in a licenced slaughterhouses subjected to official control can be considered very low. Due to all these factors, *Bacillus anthracis* is a hazard classified as of low priority for meat inspection of sheep in recent EFSA opinion on the public health hazards to be covered by inspection of meat from sheep and goats (EFSA, 2013). It is also unlikely that this hazard is relevant for skin-on sheep meat production since this would be subjected also to official controls and clear HACCP based procedures developed would take into account the sourcing of animals (i.e. sheep for skin-on production would originate from areas not known as enzootic for anthrax).

Bacillus cereus

The spores of *Bacillus cereus* are very ubiquitous in the nature and soil is the primary source of contamination of foods with this spores. *B. cereus* has been isolated in almost all the categories of foodstuffs and it seems that its presence in most raw foods appears as inevitable (EFSA, 2005a). It is considered as regularly present on animal coats including fleece (Lyness et al., 1994), and carcass meat contamination during slaughtering process is therefore possible. However, carcass meat contamination appears not to be the main risk factor for human foodborne exposure to this hazard due to its very ubiquitous nature (EFSA, 2005a). Common scenario of human toxicoinfection (with diarrhoeal type) or intoxication (with emetic type) with this pathogen is that raw food has been contaminated with *B. cereus* spores from unknown source and then improper food storage allows the proliferation to vegetative forms and growth to concentration levels of relevance for production of toxins in guts after ingestion (or in food in the case of emetic type). However, due to its regular presence on sheep skin and fleece and specific nature of skin-on sheep meat production, further evaluation of its fate during this production seems necessary.

***Campylobacter* spp. (thermophilic)**

Human campylobacteriosis is the most frequently reported zoonotic illness in the EU and UK (EFSA & ECDC, 2015). *Campylobacter* spp. is commonly found in sheep intestines and on sheep fleece (Garcia et al., 2010), as well as on carcass meat surface during slaughter as a result of carcass contamination from the skin (Garcia et al., 2010). However, consumption of sheep meat has not been found as an important risk factor for human disease (EFSA, 2013). This might be due to the fact that there is a significant reduction of *Campylobacter* following chilling, probably due to the low temperature and drying of the carcass surface, so prevalence in fresh sheep meat often falls to 0%. Human infection with sheep strains is most likely through waterborne transmission or direct contact with animals, produce, or raw milk. Due to all these factors, *Campylobacter* spp. is a hazard classified as of low priority for meat inspection of sheep (EFSA, 2013). Therefore, it could be assumed that it is highly unlikely that this hazard could survive heat treatments and subsequent desiccation and chilling of carcass surface during skin-on sheep meat production.

Clostridium botulinum

The spores of *Clostridium botulinum* are ubiquitous and widely distributed in the soil. They also occur in the intestinal tracts of fish and animals (EFSA, 2005b). There is a lack of information of their presence in the foodstuffs, including sheep meat (and fleece). Considering its ubiquitous nature small numbers of spores of that organism may be present in all types of raw food materials (EFSA, 2005b), so carcass meat contamination appears not to be the main risk factor for human foodborne exposure to this hazard. The initial contamination of raw foods with this hazard is difficult to control and appears that presence of the spores in not sufficient to cause human disease (EFSA, 2005b). Growth of this organism under appropriate conditions, accompanied by toxin production in the food, is the main risk factor which leads to human intoxication. Due to all these factors, it seems unlikely that this hazard is relevant for the smoked, skin-on sheep meat production.

***Clostridium perfringens* (type A)**

The spores of this organism are ubiquitous and widely distributed in soil, dust, vegetation and raw foods. It is commonly found in the intestinal tract of man and animals (EFSA, 2005b). There is a lack of information of its presence on sheep fleece, but considering its ubiquitous nature and presence in guts, the prevalence on fleece could be similar to that of *Bacillus cereus* and the carcass meat contamination during slaughtering process seems likely. Like with *B. cereus*, carcass meat contamination appears not to be the main risk factor for human foodborne exposure to this hazard and sheep meat is not considered as an important risk factor for human disease. Common scenario of human toxicoinfection is similar to those from Bacillus cereus (diarrhoeal type), so its growth in the food as a consequence of inadequate food preparation/storage/handling leads to human poisoning. However, due to its likely presence on sheep skin and fleece, the skin and meat from skin-on products might represent important source for human infection if these products are not handled properly in post-processing stage. Therefore, further evaluation of its fate during the production process of smoked, skin-on sheep meat seems necessary.

Pathogenic verocytotoxin-producing *Escherichia coli* (VTEC)

The VTEC group of bacteria are characterised by the ability to produce potent cytotoxins and other virulent factors which lead to severe clinical symptoms, sometimes even death. Consumption of sheep meat has been considered as being an important risk factor for human VTEC infections (EFSA, 2013). Reported prevalence on sheep fleece varies significantly and has been found to be 5.5% and 6% in UK and Ireland, respectively (Lenahan et al., 2007; A. Small et al., 2002). Also, it has been found on sheep carcasses usually in low prevalence during slaughter process (Chapman et al., 2001), but carcass contamination is considered as important risk factor for human foodborne exposure to this hazard. Therefore, it was classified as of high priority for meat inspection of sheep (EFSA, 2013). Due to all these factors, it seems highly likely that this hazard is also relevant for the smoked, skin-on sheep meat production.

Listeria monocytogenes

Listeria monocytogenes is considered as being a foodborne pathogen very ubiquitous in the environment, including animal feed, food processing plants, refrigerators, drains, soil, water, sewage and dust. It is also often carried asymptomatically in the guts of livestock including sheep. There is a lack of data of its occurrence and numbers in sheep fleece and meat, but this can be considered as very common. Human foodborne illness caused by *L. monocytogenes* is usually associated with ready-to-eat products of different origin, in which contamination has occurred before or during processing (often from unknown source), followed by its growth during storage at refrigeration temperatures. Therefore, it has not been exclusively attributed to sheep meat and it is considered that the risk of disease is not correlated with its occurrence in raw meat contaminated in the primary stage (including sheep meat). It seems unlikely that this hazard is relevant for the control in smoked, skin-on sheep meat production.

***Salmonella* spp.**

The common source of *Salmonella* spp. is the intestinal tract of many animal species, including sheep. Therefore, presence of *Salmonella* in sheep meat as a consequence of carcass meat contamination during slaughter is considered as being the risk factor for human foodborne exposure to this hazard, as compared to some other sources of sheep meat contamination. However, it is more common in poultry, pigs and bovine than in sheep.

Also, data from epidemiological or source attribution studies suggest that the role of sheep meat as a vehicle for *Salmonella* spp. infection is limited (EFSA, 2013). Reported prevalence on sheep fleece varies significantly and has been found to be 8% in the UK (A. Small et al., 2002). Also, it has been found on sheep carcasses usually in low prevalence during slaughter process. It was considered as of low priority for meat inspection of sheep (EFSA, 2013) due to these reasons. However, since it is common hazard arising from sheep and introduced to a carcass meat during primary stage, it should be considered also as relevant for the smoked, skin-on sheep meat production.

***Staphylococcus aureus* (toxin producing)**

Staphylococcus aureus is a common environmental contaminant found in dust, air, water, vegetation and on environmental surfaces. The illness due to this hazard is associated with the ingestion of its enterotoxin, which is produced after growth of the pathogen in food as a consequence of poor hygiene during food handling. There is a lack of data of its occurrence and numbers in sheep fleece and meat, but this can be considered as very common since the hazard itself is very ubiquitous. Human foodborne intoxication caused by staphylococcal enterotoxin is usually associated with food products of different origin, in which contamination (often from unknown source) has occurred before, during or after processing, followed by its growth and toxin production during storage. Once produced, enterotoxins are extremely heat stable and hard to destroy by cooking treatments. Therefore, it has not been exclusively attributed to sheep meat and it is considered that the risk of disease is not correlated with its occurrence in raw meat contaminated in the primary stage (including sheep meat). It seems unlikely that this hazard is relevant for the control in smoked, skin-on sheep meat production.

Toxoplasma gondii

This protozoan parasite is a common inhabitant of most animals, including sheep. It has been commonly found in sheep muscles, with 65% seroprevalence determined in the UK sheep (EFSA & ECDC, 2015). The proportion of human toxoplasmosis attributable to the consumption of sheep meat is unknown. Raw or undercooked lamb and sheep meat is considered as being the main risk factor for human infection. Due to these reasons, it was classified as of high priority for meat inspection of sheep (EFSA, 2013). With respect to its relevance for skin-on sheep meat production, its control would be similar to that in conventional skin-off sheep meat production, so based on risk categorisation of batches and animals according to detailed FCI and post-processing intervention applied to inactivate *T. gondii*.

Table 4.2: Short list of selected sheep meat-borne biological hazards occurring in sheep in the UK subjected to assessment of their relevance for the smoked, skin-on sheep meat production

Hazard	Occurrence and prevalence in sheep			Evidence of sheep meat as an important risk factor for human disease	Evidence of carcass meat contamination / infestation as the main risk factor for human foodborne exposure to this hazard[1]	Potentially relevant for the smoked, skin-on sheep meat production
	skin/fleece	**carcass meat**	**viscera**			
Bacillus anthracis	n.a.[2]	n.a.	n.a.	No	No	No
Bacillus cereus	100%[3]	10%[3]	Yes	No	No	**Yes**
Campylobacter spp. (thermophilic)	up to 95%	up to 90%	Yes	No	Yes	No[4]
Clostridium botulinum	n.a.	n.a	Yes	No	No	No
Clostridium perfringens (type A)	n.a.[5]	4%[3]	Yes	No	No	**Yes**
Pathogenic verocytotoxin-producing *Escherichia coli* (VTEC)	5.5%	0.7%, 3%[3]	Yes	Yes	Yes	**Yes**
Listeria monocytogenes	n.a.	4%[3]	Yes	No	No	No
Salmonella spp.	8%	0.5%	Yes	No	Yes	**Yes**
Staphylococcus aureus (toxin producing)	n.a.	n.a.	Yes	No	No	No
Toxoplasma gondii	No	65%	No	Yes	Yes	No

[1]This addresses hazards often associated with meat contamination in the later stages of the meat chain (production of meat products, distribution, preparation and handling of meat) that might not originate from animals and/or carcass meat in abattoir. In many cases, it is not possible to identify the original source of the contamination or implicated foodstuff
[2]No current surveillance data available
[3]Data not from UK, given as an indication
[4]Additional aspects considered beside reported occurrence on the sheep skin were adverse effect of the conventional skin-off process to *Campylobacter* spp. and very low prevalence after chilling process and likely more adverse effect of skin-on production process
[5]Occurence on sheep skin likely to be regular

4.4.1.3 Effect of the skin-on sheep meat processing on biological hazards

The protocol for production of smoked, skin-on sheep meat developed in study of Fisher et al. (2006) included the sequence of processing steps as follows: (i) removal of the feet after bleeding; (ii) singeing of the carcass with gas burners; (iii) high pressure water washing to remove burnt wool; (iv) evisceration; (v) removal of head; (vi) splitting of the carcass; (vii) carcass inspection; and, (viii) singeing or "toasting" of the carcass. For all trials, old female sheep from the Shetland breed over 12 months of age were used. Only clean animals were used and they were shorn within a week of slaughter so to have the wool length of approximately 5 mm. It can be assumed that the critical steps in this process that could have significant effect on biological hazards would be animal sourcing, shearing, singeing, high pressure water washing, toasting and chilling.

4.4.1.3.1 Sourcing of animals

It is expected that cull ewes would predominantly be used for the production of smoked, skin-on sheep meat. The main source of these sheep in the UK is usually Wales, Northern England and Scotland. Older sheep are known to be at increased risk of having different pathological conditions which may or may not be observed during ante and post mortem inspection. This aspect can be addressed in Food Chain Information and subjected to official controls and envisaged in HACCP based procedures. Furthermore, sheep are also known to be the important source of human health hazards which can be: a) shed by healthy animals and contaminating carcasses during slaughter, b) causing disease in animals that can be transmitted to humans via food, and c) causing disease in animals that can be transmitted to humans via direct contact (EFSA, 2004). It is also likely that, even when best hygiene practices are applied during slaughter and dressing, some microbial contamination will be introduced to carcass meat surface, including with foodborne pathogens (Antic, Blagojevic, Ducic, Mitrovic, et al., 2010). Contamination usually originates from the animal coats, viscera, equipment, slaughterhouse environment, people handling carcass meat, etc. (J. Sofos, 2005).

Animal coats (skin, hide, fleece) can carry high number of microorganisms, including normal microbiota of the skin (staphylococci, micrococci, pseudomonads, yeasts and moulds) as well as organisms of soil, water and faecal origin, some of them that could be human pathogens (Koutsoumanis & Sofos, 2004; Meyer et al., 2001). The total number of microorganisms on the animal coat (fleece, hide) can reach 10^{10} colony forming units (CFU)/cm^{-2} (Antic, Blagojevic, Ducic, Mitrovic, et al., 2010; Jackson, Pearson, Young, Armstrong, & O'Callaghan, 2002; Koutsoumanis & Sofos, 2004). Bacterial pathogens previously reported on sheep fleece include *Salmonella* spp. (A. Small et al., 2002), *E. coli* O157 (Lenahan et al., 2007; A. Small et al., 2002), *Campylobacter* spp. (Garcia et al., 2010) and *Bacillus cereus* (Lyness et al., 1994). Also, presence of some common ubiquitous foodborne pathogens on sheep fleece like *Listeria monocytogenes*, *Staphylococcus aureus* and *Clostridium perfringens* cannot be excluded. Therefore, microbial contamination of animal coat is recognised as the main source of microbial contamination of the abattoir and the carcass meat surface (Antic, Blagojevic, Ducic, Mitrovic, et al., 2010; Koohmaraie et al., 2005). Some bacterial and parasitic pathogens can also be found in muscles and consequently in meat (like *Toxoplasma*, *Trichinella*) and internal organs (MAP, Cysticerci, *Echinococcus*).

The composition of fleece microbiota could depend on several factors. Usually, fleece microbiota originates from sheep faeces and/or their environment. Therefore, it could be influenced by the production system as animals raised on pastures may carry more bacteria of soil origin, whilst animals from feedlots carry more of enteric origin since they are kept more closely. It is likely that fleeces may become contaminated with enteric bacteria quickly after entering contaminated animal pens and the fleece contamination increases with holding time/degree of pen floor contamination (A Small & Buncic, 2009). Transport and lairaging are known to have significant influence on fleece microbial contamination since frequent contact between animals and heavily contaminated environment increase possibility for cross contamination (Arthur et al., 2008; A Small & Buncic, 2009). It can be speculated that wool structure could have an influence on “vertical” distribution of fleece microbiota along the wool/hair and therefore increase the potential for subsequent carcass contamination. Namely, longer fleeces with a lower crimp appear to be more likely to become faecally soiled (McClain, Wohlt, McKeever, & Ward, 1997). On cattle hair however, ‘‘vertical” distribution (i.e. bacterial distribution along the hair tip-to-root), seems to be uniform (Antic, Blagojevic, Ducic, Nastasijevic, et al., 2010).

Visual cleanliness of the fleece is also well recognised as significant factor for carcass meat contamination. Wet and dirty fleeces pose significant risk for carcass contamination since water droplets serve as vector for microbial contamination transferred from the fleece (Hadley et al., 1997). It has been widely assumed that the ‘dirtier hide/fleece’ leads to the ‘dirtier carcass’; therefore, hide/fleece cleanliness is considered important in meat hygiene of the ruminants (Blagojevic et al., 2012). Several studies found positive relationship between the degree of fleece/hide dirtiness and microbiological contamination of sheep (B. Byrne, Dunne, Lyng, & Bolton, 2007; Hadley et al., 1997) and beef carcasses (Blagojevic et al., 2012; Hauge et al., 2012). The dirt on fleeces is usually composed of dry or wet faeces, mud and bedding, firmly or loosely attached to the wool and covering larger or smaller areas usually accumulated on the belly and/or legs (M. E. Biss & Hathaway, 1995). This dirt, particularly if it is predominantly composed of faeces, is significant source of enteric bacterial pathogens, like *E. coli* O157, *Salmonella* and *Campylobacter* (J. N. Sofos et al., 1999). Preslaughter washing of sheep has traditionally been employed to improve the visual appearance of the carcasses in New Zealand, but in two studies appeared to have no effect on microbiological contamination on wool, but even increased microbiological contamination on carcass meat surface after dressing (M. Biss & Hathaway, 1996; M. E. Biss & Hathaway, 1995). Similar results were obtained also in the study that examined goats washing procedures (Kannan, Jenkins, Eega, Kouakou, & McCommon, 2007). In principle, the antimicrobial efficacy of all washing treatments applied by hosing/spraying is influenced by water temperature and amount, as well as the angle of application of the spray and the pressure at which the solution is delivered. However, there is a concern that high pressure washing may enhance penetration of bacterial cell deeper into tissue (J. N. Sofos & Smith, 1998) and generate aerosols contaminated with bacteria leading to air-borne cross contamination.

4.4.1.3.2 Shearing

Sheep fleece shearing is a common practice in slaughterhouses when sheep are not presented in clean status and is predominantly done on the belly and/or legs. This practice is useful for removal of visual dirtiness from the skin (Davies, Hadley, Stosic, & Webster, 2000) but has no significant effect in the reduction of microbiota on the skin (A Small, Wells-Burr, & Buncic, 2005). However, it was shown that carcasses derived from woolly lambs had generally higher microbial contamination that than those derived from shorn lambs (M. Biss & Hathaway, 1996).

Furthermore, it is well known that air can act as an important source of carcass contamination, including during mechanical fleece pulling (Burfoot et al., 2006). Clipping/shearing dirty animals before slaughter generate significant amount of bacterial aerosols, which could facilitate cross contamination of the slaughterline and the final product (Okraszewska-Lasica et al., 2012), including with *Salmonella* and *Listeria monocytogenes* (Okraszewska-Lasica et al., 2014). Therefore, shearing if performed in the slaughterhouse, should be done in separate area to minimise air-borne contamination. Also, the potential application of clipping/shearing animals in slaughterhouses to remove dirt remains unclear, since the EU Hygiene Regulation 853⁄2004 (EC, 2004) requires that all animals should be clean before being accepted into the slaughterhouse. Therefore, shearing on the farm will have several benefits, including avoiding unnecessary stress to the animal prior to slaughter and keeping clean shorn sheep on clean bedding several days prior to slaughter. Obviously, the need for including this step in HACCP based procedures setting clear limits, monitoring procedures and corrective actions could not be more emphasized considering its importance for the safety of the final product.

4.4.1.3.3 Singeing

The singeing step was proposed by Fisher et al. (2006) as a technological process designed to remove wool efficiently from the skin and to impart a desired smoked flavour to the meat, and also to act as a decontamination step against any potentially present microbiota on the fleece. The immediate antimicrobial effect of singeing was not explored in this study, rather only of the second singeing step (toasting), with around 2 log units of TVC reduction achieved. There is a lack of data in literature regarding singeing sheep wool, or other similar substrates. In the study of (A Small et al., 2005), around 2 log units reduction of TVC was found after clipping and singeing of cattle hide's hair. There are several reports on singeing efficiency in reduction pig skin microbiota, but predominantly with quantitative results from indicator bacteria. Hence, reductions of TVC and *Enterobacteriaceae* similar to previously mentioned, of 2 to 3 log_{10} cfu/cm^2 were found by Gill and Bryant (1993), Bolton et al. (2002) and Pearce et al. (2004). Also, *Salmonella* was not detected following singeing, as opposed to after bleeding, dehairing and evisceration in the study of Pearce et al. (2004). Obviously, these results cannot be extrapolated to sheep wool singeing, since pig carcasses are usually scalded and largely dehaired by the time they reach the singeing stage.

Such reductions are not unexpected as the surface temperature of the pig carcass may increase to 100^oC after 10 seconds of the singeing process, which is usually performed at 800-1000°C for 10-15 sec. (Borch, Nesbakken, & Christensen, 1996). The carcass surface temperature achieved during singeing in the study of Fisher et al. (2006) was 70-85^oC, but a temperature profile of sheep skin-on carcasses' surface after singeing and toasting was not performed. The singeing process is expected not be long enough for the meat to begin cooking. However, even heating of the skin during singeing is essentially impossible, so large numbers of bacteria may persist on some parts of the carcass (Gill & Sofos, 2005). Of particular concern are some areas that receive lower heat treatment ("cold spots"), like beneath the forelegs, or around anus, but this will obviously depend on the singeing system used. This non uniformity of singeing can enhance bacterial survival in cold spots, especially spores that are known to survive temperatures below 100^oC. Pearce et al. (2004) found significantly lower TVC on the neck, compared to the ham and belly, which may have been related to the singeing system used in that study. In that study, a single gas flame from the base of the singeing machine was used, resulting in the neck receiving a more severe heat treatment. In other study, where multiple heat source singeing was used, such differences between sites were not observed (Yu et al., 1999).

It could be expected that heating treatments like singeing would have significant effect on of eliminating vegetative forms of bacteria present on the skin (like VTEC, *Salmonella* and others), but spores of other foodborne pathogens likely present on the fleece (such as *Bacillus cereus* and *Clostridium perfringens*) could survive this treatment since they are more heat resistant. The extent of reduction for a specific bacterial species depends on the heat resistance of the bacterium and the time/temperature combinations used. In general, numbers of bacterial cells in a uniformly heated, homogeneous substrate will decrease exponentially with time over many orders of magnitude. The rate of this inactivation is defined as the D-value, also called the decimal reduction time, or the time required to destroy 90% of the population (i.e. one log cycle). D-values are known for many foodborne pathogenic bacteria at different temperature regimes (including the ones expected for singeing process) and are available from literature (Table 4.3). However, they are only approximate and indicative since combinations of environmental factors could have a big influence on bacterial growth and survival. Also, most of these data were obtained in controlled laboratory conditions, from different heating system or substrate so might not be representative for singeing process in real commercial conditions in slaughterhouses.

Table 4.3: Heat resistance and growth range for selected pathogenic bacteria

Bacteria	**Heat resistance (D-value)**	**Growth range**	
		Temperature (°C)	**pH**
Bacillus anthracis (spores)	D_{90} = 2.5-7.5 min	max 43	5-8
Bacillus cereus (spores)	D_{100} = 6-27 min	4-55	4.5-9.3
Campylobacter spp.	D_{60} = 12-24 s	28-45	5.5-7.5
Clostridium botulinum[1] (spores)	D_{82} = 0.25-42.4 min D_{110} = 0.61-2.48 min	10-50	4.7-8.9
Clostridium perfringens (spores)	D_{90} = 0.015-8.7 min D_{100} = 0.31-13 min	12-50	5-8.5
Escherichia coli O157	D_{65} = 0.4 min	8-42	min 4.5
Listeria monocytogenes	D_{60} = 40-190 s	-0.7-45	4.1-8
Salmonella spp.	D_{60} = 33 s – 9.5 min	4-47	4-8.2
Staphylococcus aureus	D_{55} = 55 s	7-48	4-10

[1]depending on the group (i.e. proteolytic group is more, while non-proteolytic group is less heat resistant)

4.4.1.3.4 High pressure water washing

This step was used in study by Fisher et al. (2006) to remove charred wool residues and to yield a golden skin colour on the smoked, skin-on sheep carcasses. It was indicated that the water temperature was at 60°C, so it was likely to also have a mild heating reduction effect in addition to the physical removal of any microbiota that were potentially present on the skin. The antimicrobial efficacy of washing treatments applied by hosing/spraying is influenced by water temperature and amount, as well as the angle of application of the spray and the pressure at which the solution is delivered. Spraying/washing of animal carcasses with water (at temperatures that do not injure or kill bacteria) has been extensively researched, and on average, provides approximately 1 log unit physical reduction of microbial populations (Byelashov & Sofos, 2009). There is a concern that high pressure washing may enhance any penetration of bacterial cells deeper into tissue (J. N. Sofos & Smith, 1998), and also there is the possibility that aerosols contaminated with bacteria may be generated leading to air-borne cross contamination on the slaughterline. Some other suggested negative effects of spray-washing carcasses with water include: (i) increasing carcass surface moisture resulting in increased proliferation of microorganisms; (ii) entrapment, embedding, or driving bacteria into tissues, thereby providing a physical barrier against subsequent decontamination applications (or desiccation during chilling); and, (iii) redistribution or spreading of a localized microbiological population over a much larger area on carcasses (Bacon & Sofos, 2005). Indeed, it was determined by scanning electron microscopy that *Salmonella* cells remain on the poultry skin surface even after rinsing and were mostly located in crevices and skin cracks (Kim, Frank, & Craven, 1996). Some modifications of washing equipment (e.g., nozzle numbers, configuration, and type), several operating parameters (e.g., water temperature, pressure, and flow rate, and carcass surface distance and exposure or dwell time) can be adjusted to increase or optimize spray-washing system performance (Bacon & Sofos, 2005).

4.4.1.3.5 Toasting

The toasting step was proposed by Fisher et al. (2006) as a decontamination step to reduce or eliminate microbiological contamination introduced to the carcass surface in the previous steps (i.e. evisceration, meat inspection and carcass splitting) but also to improve carcass sensory properties by additional "browning" of insufficiently singed carcass areas. The principles described in the section about singeing are applicable to toasting process as well.

Heating processes such as singeing and toasting are also known to affect bacterial cell viability and recoverability, sometimes resulting in sub-lethally injured bacterial cells which are at the time of sampling and laboratory processing unable to multiply, leading to lower counts or false negative results (Wu, 2008). Sub-lethally injured cells have the capability to repair themselves under favourable conditions and return to a normal physiological state with growth and multiplication. Therefore, the detection of sub-lethally injured pathogens is critical as they have the potential to cause illness (Sheridan et al., 1994). Severely injured/stressed microorganisms, however, may fail to recover and grow in selective enrichment media containing agents that prevent the growth of the competing microbiota, or they may be out-competed by other bacteria present in the sample. Thus, to detect injured target organisms, it is often necessary to allow the bacteria to repair from injury in a non-selective medium prior to selective enrichment (Fratamico, Gehring, Karns, & van Kessel, 2005). Potential problem with sub-lethally injured bacteria is that the bacterial exposure to sub-lethal levels of a physical or chemical stress can result in habituation or adaptation, which may subsequently confer cross-protection against otherwise lethal levels of the same stress or other stresses (Samelis & Sofos, 2005). Such adaptive stress-hardening responses of food-borne pathogens resulting in virulence enhancement are readily expressed in laboratory studies (Buncic & Avery, 1998).

The toasting step, envisaged to serve as a decontamination treatment as such, should be subject to regulatory approval following risk assessment. EU Hygiene Regulation 853⁄2004 (EC, 2004) allows, in principle, the use of decontamination treatments on the slaughterline, following appropriate consideration and approval of the treatments by the regulatory authorities (Antic, Blagojevic, Ducic, Mitrovic, et al., 2010).

4.4.1.3.6 Chilling

Normal chilling procedures are generally rapid chilling where the carcass surface temperature rapidly falls, followed by slower chilling. The chilling parameters may vary from slaughterhouse to slaughterhouse. Normal chilling procedures comprise blast chilling (-30°C to -10°C air, 1-1.5 h) followed by cold room storage (1-5°C, overnight to 3 days). Important criteria for chilling carcasses are usually preventing microbial proliferation, minimizing carcass mass loss and minimizing chilling time to increase throughput. The effect of chilling on the potential growth of pathogenic bacteria may be predicted using models. The critical limit set in EU Hygiene Regulation 853/2004 (EC, 2004) is that the temperature achieved throughout the meat should be of not more than 3°C for offal and 7°C for other meat. Therefore, it is expected that the chilling process of smoked, skin-on sheep carcasses would be subjected to the same regimes, and to achieve the same limits set by regulation and specific HACCP based procedures.

4.4.1.4 Final product (Skin-on sheep meat)

The shelf life of skin-on meat compared to conventional carcass meat was one of the aspects investigated in the study by Fisher et al. (2006). It was reported that levels of monitored spoilage bacteria (lactic acid bacteria, *Pseudomonas* spp., yeasts and moulds and TVC) after several days of chilling were similar or slightly higher for skin-on meat (particularly for yeasts and moulds). They reported that difference carcass sites also affected carcass contamination.

Bacterial growth will occur during storage of the carcass meat, predominantly with psychrotrophic bacteria such as *Pseudomonas* spp. or *Listeria monocytogenes*. The growth rate is dependent on environmental factors such as temperature, pH-value and gaseous atmosphere. It could be assumed that, if most of background microbiota is eliminated during previous heat treatments and additional contamination is introduced, then the safety of this product could be more compromised compared to conventional skin-off sheep meat. Testing by food business operators might be necessary to determine the adequate shelf life of this product, whenever it is likely that it would support the growth of potential hazards. The effect of anticipated conditions of storage and handling after production in slaughterhouses on the potential growth of pathogenic bacteria may be predicted using models. Considering that smoked, skin-on sheep meat is the product of unique properties, additional requirement could be envisaged, such as: (i) storage in separate designated chilling rooms to prevent potential cross contamination with conventionally produced skin-off carcasses and to prevent smoked flavour transfer; (ii) specifically designed packaging, according to expected presence of certain microbiota; and, (iii) advice on handling and preparation at home, based on evidence about expected microbiological profile of the final product.

4.4.2 Chemical hazards

There are two major classes of chemical hazards; residues of chemical that have been deliberately used in the production of the food product, namely pesticides or veterinary medicines, and contaminants which can be either natural in origin (e.g. mycotoxins) or are a result of anthropogenic activity or processing (e.g. dioxins and PAHs). It is those contaminants that may arise specifically as a result of production of skin-on sheep meat that we focus on here since other classes of contaminants are not likely to be different than those associated with other sheep products.

All chemicals that may be present have the potential to produce transformation or breakdown products as a result of metabolism or other process (e.g. photolysis if they are present in an area exposed to light). The production of skin-on sheep meat involves heat and other treatments that give rise to the potential of additional sources of contamination or potential to produce transformation products (or conversely to reduce the amount of contaminants present).

4.4.2.1 Veterinary medicine residues

4.4.2.1.1 Veterinary residues risks from smoked, skin-on sheep meat

To meet the data requirements to obtain a marketing authorisation the constituents must have a maximum residue in Table 1 of Commission Regulation (EU) No 37/2010 (EC, 2010). This states the maximum residue limit in tissues (and milk) considered edible obtained from type of animal for which authorisation has been requested. The system is market driven, so if no pharmaceutical company requests and provides data for a specific species then an MRL will not be set. For example not all products have an MRL for milk. Skin may be included as a residue site for chicken, pigs and fish but not sheep, goat, cattle or equidae. If skin is designated as an edible part of a sheep carcass it may be added to the list of sites for which residues information are required to support applications for Marketing Authorisations of new veterinary products, and existing ones when they are periodically reviewed (VMD personal communication 2015). The options for a pharmaceutical company may be: (i) perform extra studies to determine skin concentrations and provide residues information; (ii) request that the product be excluded from use in animals intended for production of skin-on sheep meat; (iii) not re/apply for an indication for use in sheep; and, (iv) no specific extra residue information is required but meat and fat residue data are used to produce a withhold period that covered the whole carcass.

Option (i) will have cost implications and may delay application for a short period compared to the current situation. Veterinary Medicines Directorate and European Medicines Agency (VMD/EMA) have approved software for calculation of withhold times from residue information which may need to be extended to include calculations for skin. This may require additional underpinning research on Pharmacokinetic/ Pharmacodynamic (PK/PD) with skin as a specific compartment in (aged) sheep.

Option (ii) is analogous to the present situation for milk production in sheep for many authorised products, where the label excludes use in animal producing milk for human consumption. However, milk production is from specific breeds of sheep and farm business operations. Sheep are unlikely to be bred for smoked, skin-on sheep meat production and it will require purchasers of cull ewes to view the FCI prior to purchase to ensure no animals are purchased that have EVER been treated with any product with this exclusion. This is similar to the current situation with horses intended for human consumption and use of phenylbutazone. Surveillance in the UK suggests 3.5% of horse carcasses have phenylbutazone residues suggesting that this type of exclusion is difficult to police in practice (EFSA & EMA, 2013).

Option (iii) would result in a loss of new and possible existing treatment options for sheep compromising welfare. If products were then used under the prescribing cascade, similar residues risks could occur if skin residue information was not known[9].

Option (iv) would not require any further cost or data to be produced. It is the current situation with residues in sheep skin-on feet. The information below regarding macrolide antibiotics suggests that this may not be a safe option for all compounds without further research and scientific opinion.

VMD currently carry out residue surveillance sampling of carcasses at abattoirs and final product at the point of sale. If smoked, skin on sheep meat were to become legal, skin and finished product may need to be added to surveillance sampling frames including all carcasses and not just those designated to be used for this type of food production (VMD 2015 personal communication). The financial costs of this will need to be included in any cost / benefit calculation.

Some farmers use fleece dyes sprayed on the sheep, via a hose over the group, knapsack or hand sprayer or added to a dip, to produce a more homogenous looking group of animals before showing or sale. This is termed “Bloom” and is associated with a better sale price than pens with variable fleece colour etc. The nature of these dyes has not been investigated due to the limited scope of this project. We believe them to be water soluble and in general to be on the outside of the fleece so probably removed if the shearing step to create a small covering of wool for singeing is followed. As these products are not authorised in the same way as medicines assessment of a range of products on the market would be required before their safety and residues for skin on sheep meat production could be determined.

[9] http://www.vmd.defra.gov.uk/pdf/vmgn/vmgnote13.pdf

4.4.2.1.2 Residues from systemically administered compounds

There is very little information regarding skin residues of systemically administered compounds as skin is not currently considered an edible component of the carcass and residue depletion studies are not required to include skin when obtaining a marketing authorisation for a veterinary medicine. Most medicines authorised for sheep do not claim efficacy for skin infections specifically so no skin concentration and duration of efficacy information have been published. However a recent study specifically measured skin concentrations of an, as yet, unauthorised antibiotic, Gamithromycin, and found them to be much higher than plasma concentrations resulting in skin/plasma concentration ratios of approximately 21, 58, and 138 at two, five and ten days after subcutaneous injection, demonstrating extensive and selective distribution to skin tissue (Kellermann, Huang, Forbes, & Rehbein, 2014). This was not due to injection site residues as the injection was given in the neck and skin tissue sampled from the front legs. This study provided information of prolonged duration of action at the site required for possible treatment of footrot (Strobel, Lauseker, & Forbes, 2014). However, Gamithromycin has also been shown to have activity against the organisms that are associated with Contagious Ovine Digital Dermatitis (CODD) (Angell et al., 2015; Evans, Brown, Hartley, Smith, & Carter, 2012). This is an emerging disease of great potential importance to the sheep industry. It is possible that a marketing authorisation will be applied for and this compound with prolonged skin activity may be present in the potential slaughter population for smoked, skin-on sheep meat in the future. Another member of the same class of antimicrobial (macrolides) Tilmicosin, is currently authorised in the UK. Tilmicosin has a shorter duration of action in cattle pneumonia than Gamithromycin, but published pharmacokinetics data do not include skin concentrations (Modric, Webb, & Derendorf, 1998). As both compounds are alkaline and skin is acidic it is possible that Tilmicosin will show similar plasma to skin partitioning to that observed in the above paper for Gamithromycin. This warrants further investigation before the residue limits and withhold periods for other tissues are extrapolated to skin for this class of compound. It is possible that plasma or muscle to milk partition ratios could be used to indicate if skin residues will follow meat residues. Milk, like skin, is acidic relative to plasma and large differences in elimination times from muscle verses milk may indicate similar differences in muscle to skin elimination times. It cannot be assumed that skin residues will follow those in muscle or other edible tissues without further research.

Sheep feet, including skin from the lower leg, are currently considered edible. Residue information for this tissue is not required in support of a marketing authorisation. FSA commissioned study (P. Bates, 2006) assessed the available information regarding the consumption of skin-on sheep meat treated with veterinary medicines. This was a comprehensive review but the core assumption that skin and fat residues in pigs and poultry can be extrapolated to sheep skin if the sheep fat residue limit is similar is called into question by the study on Gamithromycin cited above. Also the assumption that skin and fat will be consumed in equal or “natural” proportions when cull ewes with minimal subcutaneous fat are being selected for the production of smoked, skin-on sheep meat is open to question. The report makes the final conclusion that “It is important that these assumptions are confirmed by the CVMP” (Committee for Medicinal Products for Veterinary Use who advise the European medicines Agency). VMD would need to ask EMA a specific question, on which CVMP would give an opinion.

Another study commissioned by the FSA (Anon., 2009) investigated the prevalence of veterinary medicines residues in “skin-on” sheep feet. Residues of a wide range of compounds were analysed in 300 sheep feet. The sampling strategy is not stated, other than that they were obtained from a number of abattoirs over the period of a year. It is thus difficult to assess how the finds of low residues (1/300 samples over EU MRL for Diazinon) would relate to the type of animal, geographical location and time of year animals would be sourced for smoked, skin of sheep meat production. Treatment and thus risk of residues may be focused on specific groups and times of year. The study also reported residue findings from a small study where 3 animals per group were treated with cypermethrin and slaughtered three days later (compared to 12-18 days recommended withhold). Half the animals were foot-bathed prior to slaughter and one front and back foot from each animal underwent laboratory simulated shearing and singeing prior to residue sampling. High concentrations of cypermethrin were detected with no statistically significant differences in residues detected between treatments. There were numerical differences but also wide individual variation with the data range for all groups overlapping. The main conclusion we would make is that cypermethrin residues are detectable at some time after dosing in feet skin and that washing and simulated smoked, skin-on sheep meat production does not remove them. Detailed studies at the time of authorised withhold will be needed to determine if such treatments alter residues at the time when animals can currently be slaughtered after treatment.

The compounds listed in Table 4.4 below are those currently authorised in UK to administer via a pour on route in sheep or pour on versions of products authorised in their injectable form in sheep that we consider may be used off licence in sheep by farmers. These are the veterinary medicines we consider are most likely to represent an increased hazard for skin-on sheep meat production due to the risk of residues at the site of application. Compounds in the systemic circulation may also be incorporated in hair or wool. For example measurement of hormones in hair is being developed as a welfare and drug doping indicator in many species. Incorporation occurs at the time of hair / wool synthesis and growth rate and measurement of residue location along the hair allows timing of exposure to the substance. This provides a route for residues when wool and hair are singed. Further research is needed to evaluate the full range of compounds that can be incorporated into hair and be present for longer periods than in the rest of the body.

Table 4.4 below contains information on skin and wool residues extracted from European Medicines Agency (EMA), UN FAO and published data. Review of the detailed dossier data submitted to the VMD or EMA for each product will be required to confirm which data are directly comparable to current authorised products. These are not in the public domain but some pharmaceutical company study data are referred to in the FAO publications referenced below and official requests for VMD or FSA to the marketing authorisation holders are required to obtain those data.

Table 4.4: Authorised pour-on products for sheep in UK

Compound[1]	EMA Marker residue	Product	Meat withhold	Milk withhold sheep	Skin residues on MA data sheet?	Skin residue data for sheep or goat in EMEA Summary Opinion.	Other data
Cyromazine	Cyromazine May be metabolised to melamine (FAO)	Vetrazin 6% w/v Pour-On Solution Novartis Animal Health UK Ltd	28 days	Not permitted for use in lactating animals producing milk for human consumption	No	None for skin 300 µg/kg Muscle 300 µg/kg Fat 300 µg/kg Liver 300 µg/kg Kidney 33000mg/kg at the pour on treatment site 10 days later. No data after 28 day meat withhold Inconsistent residue distribution. Organ residues dependent on wool length.	Water soluble and does not associate with wool wax. Residue of 24 mg/kg in wool after 6 months. Other studies 150 mg/kg wool at 16 weeks.
Dicyclanil Water and Polyethylene glycol according to patent EP2262368A1	Sum of Dicyclanil (most in fat) and 2,4,6,-triamino-pyrimidine-5-carbonitrile (most in meat)	CLiKZiN and CLiK (Elanco) 01256 353131 elancovets@elanco.com	7 days (CLiKZiN) 40 days (CLik)	Not permitted for use in lactating animals producing milk for human consumption	Do not shear sheep in the 3 months after treatment. Handle sheep as little as possible after treatment as residues remain on the fleece for some weeks.	None for skin 200 µg/kg Muscle 50 µg/kg Fat 400 µg/kg Liver 400 µg/kg Kidney Sub cut fat residue peaked at 14 days, higher than 7 days. Only 2% absorbed via skin. Fleece residues high	Additionally, the wool must not be shorn from treated sheep, for subsequent use in clothing and textiles, for 2 or 3 months after application according to patent EP2262368A1 AFBNI developed IHC assay to detect in tissue.
Cypermethrin	Cypermethrin. (sum of isomers)	Crovect (Elanco) Molecto	8 days (49 days for	Not to be administered to animals		Skin+fat 400ug/kg day 1 100ug/kg day 8.	ftp://ftp.fao.org/ag/agn/jecfa/vetdrug/41-9-alphacypermethrin.pdf Table 6 and other FAO docs. 14 days skin when pour on 150 ug/kg, dip 300ug/kg.

Compound[1]	EMA Marker residue	Product	Meat withhold	Milk withhold sheep	Skin residues on MA data sheet?	Skin residue data for sheep or goat in EMEA Summary Opinion.	Other data
		(Molevalley Farmers) Ectofly (Bimeda). Dysect Sheep 12.5 g/l Pour-On Solution (alpha isomer only)(Zoetis)	Dysect)	producing milk for human consumption, nor in pregnant dairy ewes within 2 weeks prior to parturition.		20 µg/kg Muscle 200 µg/kg Fat 20 µg/kg Liver 20 µg/kg Kidney	No MRL given for skin. Other data on sub cut vs omental fat concs after pour on suggest higher concs in omental fat and urine than back fat at 14 days suggesting ongoing distribution and excretion. Unchanged cypermethrin is major residue in ^{14}C studies. Two male sheep were topically treated (21.9 mg/kg BW) while a third was orally dosed (3.9 mg/kg BW) with labelled in the cyclopropyl and benzyl positions, see Table 3 (Crawford and Hutson, 1977b). Cypermethrin was slowly absorbed and eliminated when applied topically to sheep. Less than 0.5% of the dose was excreted in urine within 24 h and only 2 % over a six day period. Faecal elimination was also slow, 0.5 % of the dose being eliminated in six days. Approximately 30% of the applied dose was recovered from the application areas of both sheep. Additionally, With some pour-on formulations 95—98% of the applied active ingredient remains at the site of application bound to the animal's fleece or hair. (http://www.google.co.uk/patents/US6955818).
Diazinon	Diazinon. Pyrimidinyl metabolites have toxicity comparted to the parent compound	Osmonds Gold Fleece Sheep Dip Bimeda Paracide 62, Animax	49 days. (Osmonds) 70 days (Paracide)	Not to be used on animals producing milk for human consumption	Owing to their lipid solubility, they are rapidly absorbed into the oily secretions on wool and the skin surface and persists at concentrations	None for skin 20 µg/kg Muscle 700 µg/kg Fat 20 µg/kg Liver 20 µg/kg Kidney	3110 ppm in wool when first batch dipped at commercial dose in the inner layers of wool close to skin (Aust Vet J (1968) 44 344). Breed (fleece type) associated with differences in drug concentration. Diazinon is the major residue in omental and perirenal fat. Hydroxypyrimidine is the major residue in muscle. http://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/Evaluation96/diazinon.pdf Sheep are likely to incur the highest

Compound[1]	EMA Marker residue	Product	Meat withhold	Milk withhold sheep	Skin residues on MA data sheet?	Skin residue data for sheep or goat in EMEA Summary Opinion.	Other data
					effective against mites, lice and blowfly for at least 60 days. In the 3 month period after dipping you are advised not to shear sheep.		residues because of their wool coat and the high solubility of residues in wool grease (lanolin). Cites Roberts and MacDonald, 1989 SC and omental fat concs 35 days after treatment of 0.7 mg/kg. Subcutaneous max fat residue Dip 4.3(1.3) Spray 0.3(0.14). All mg/kg fat Other places in document quote subcutaneous fat 1.4 mg/kg max and median residue from a single dipping. Conc in wool at different depths depends on breed of sheep. Australian Veterinary Journal (1968) 44 344-349
Deltamethrin	Deltamethrin	Deltanil (Virbac) Fly & Lice Spot On Insecticide 1% w/v Cutaneous Solution (Formerly Pfizer Spot On) Zoetis	35 day	0 hours (Deltanil). Not for use in sheep producing milk for human consumption	After dermal application, deltamethrin is slightly absorbed through skin of cattle and sheep	None for skin Ovine 10 µg/kg Muscle 50 µg/kg Fat 10 µg/kg Liver 10 µg/kg Kidney	Conc in greasy wool over time plunge dip vs Pour on. Less dispersion that after pour on. Kettle, Watson and White. New Zealand Journal of Experimental Agriculture (1983) 11 321 – 324. No FAO skin residue data. 41-12 contains info on several small scale trials. None reported sc fat or skin concs. Perirenal and omental fat concs highest deltamethrin (in 1% miglyol) was applied topically to the mid-point of the shoulder of each animal, the fleece being parted to ensure skin contact. Groups of 3 animals were slaughtered at 3, 7 and 14 days. In the perirenal and omental fat, the mean concentrations were equal to or below the limit of quantification (10 µg/kg) EMEA2004 opinion. Deltamethrin skin conc after pour on depletion study Johnson, et al International Journal for Parasitology (1995) 25 471-482. Not Xylene base. Note transfer from treated to untreated animals re lairage mixing

Compound[1]	EMA Marker residue	Product	Meat withhold	Milk withhold sheep	Skin residues on MA data sheet?	Skin residue data for sheep or goat in EMEA Summary Opinion.	Other data
12.5% closantel and 0.5% w/v ivermectin 20% closantel and 0.5% w/v ivermectin		Closamectin injection in sheep (Norbrook) Closamectin Pour on in cattle	28 days	Not for use in sheep producing milk for human consumption		Closantel 1500 µg/kg Muscle 2000 µg/kg Fat 1500 µg/kg Liver 5000 µg/kg Kidney	ftp://ftp.fao.org/ag/agn/jecfa/vetdrug/41-3-closantel.pdf Kidney residue highest after I.m. or oral. Fat low conc. Sub Cut dosing in steers resulted in sub cut fat residues lower than liver, kidney muscle or perirenal fat. No skin data.
200mg/ml levamisole		Levicide Pour-on (possible off label use in sheep)	28 days	Not for use in cattle producing milk for human consumption		Levamisole 10 µg/kg Muscle 10 µg/kg Fat 100 µg/kg Liver 10 µg/kg Kidney	

[1]Cattle pour-on products that may be used off-licence are listed here for completeness

Notes:

The metabolic pathways of dicyclanil in sheep treated topically are essentially the same as those in rats. (http://www.inchem.org/documents/jecfa/jecmono/v45je04.htm)

Other compounds not yet authorised in UK:

Spinosad – Sheep in Australia. UK only in dogs and cats orally for fleas.

Diflubenzuron - Sheep in Australia. UK only in Salmonidae.

Triflumuron - Sheep in Australia. Not animals in EU.

Imidacloprid - Sheep in Australia. UK only in dogs and cats orally for fleas

Temephos - Sheep in Australia. Not animals in EU.

In addition to residues in meat there are maximum residue limits for pesticides in wool to be awarded the EU Ecolabel table 2 for ectoparasiticideds[10]. These limits were determined to meet environmental residue limits in effluent water from wool washing plants in the EU from home produced and imported greasy wool. These limits are thus not defined by safety for human consumption but to avoid accumulation in the environment. However, after singeing the burnt fleece residue will be washed and if the parent compound is present then the effluent wash water will carry similar residue risks to wool wash water. To ensure that exported fleeces meet the compliance with these limits Australia sets Wool harvesting intervals (WHI) for each authorised ectoparasiticide. A detailed review of sheep ectoparasiticides authorised in Australia has recently been completed by the Australian Pesticides and Veterinary Medicines Agency[11]. This report gives useful background to each compound, not all of which are authorised in the UK. Australia Meat withhold periods for animals to be consumed in the country and an Export Slaughter Interval (ESI) specifically for those that may be exported are also specified[12]. These are set by the highest residue limit in a possible export market (often Russia). An on-line database allows searching for these periods by generic and trade name[13]. This may provide useful guidance for wool residues and thus possible maximum residues on carcases due to singeing the wool rather than removing the hide. The WHI specified in Australia could be adopted to ensure environmental residues limits from wash water are met.
The proportion of ewes or lambs treated with ectoparasiticides, to indicate the likely risk of residues, is not readily available. Many companies obtain market analysis from GfK[14] (Donal Murphy, National Office of Animal Health (NOAH) personal communication). This could be used as a source of information or an official request to the Marketing Authorisation holders via the Veterinary Medicines Directorate could be made.

The residue data available for veterinary medicines has not been produced with the aim of determining residue limits and withhold periods for the safe human consumption of skin. Any extrapolation from these data must be made with caution. PK/PD modelling of measured skin concentrations from the available studies would give some indication of residue depletion. Reviewing the detailed technical dossiers submitted for marketing authorisation approval to obtain any data not in the public domain would help to determine what further work was required before a safety assessment could be made. Consultation with EMA and CVMP are advised.

[10] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014D0350&from=EN
[11] http://apvma.gov.au/node/14876
[12] http://apvma.gov.au/sites/default/files/docs/esi-sheep-8-september-2014.pdf
[13] https://portal.apvma.gov.au/pubcris
[14] http://www.gfk.com/uk

4.4.2.2 Environmental and process contaminants

4.4.2.2.1 Contaminants as a result of environmental factors

Contaminants such as dioxins, PCBs, PAH and heavy metals are present as airborne pollutants from industrial and other sources. They can contaminate soils on which sheep graze and can be absorbed into the lanolin which is a waxy substance present in sheep wool. The amounts present will depend on the geographical location of where the sheep are raised; of special interest are any localised sources of pollution in the vicinity of sheep farms. The amounts of these compounds present as a result of environmental contamination in skin-on sheep meat will be no different to those found in other sheep meat products.

4.4.2.2.2 Special considerations in relation to the composition of the sheep fleece

Sheep wool contains lanolin, a complex mixture of mainly waxes which is produced by the sebaceous glands in the skin. The amount produced is dependent on the sheep breed. While the main purpose of lanolin is to protect the sheep against climate, the EFSA Opinion discusses the lipophilic properties that may facilitate the absorption of airborne environmental contaminants, such as PAH, heavy metals, dioxins and polychlorinated biphenyls (PCBs) on the sheep wool. The EFSA Opinion goes on to say that levels absorbed will mainly differ on the location where the sheep are bred. Of special importance would be such “hot spots” where the respective contaminants are emitted in high concentrations. Other parameters that might influence the levels in sheep wool are length and amount of wool (EFSA, 2011a).

The EFSA opinion also suggests that another potential source for contamination of sheep wool might be adherence of soil particles which could contain considerable amounts of chemicals. Of special importance are sediment particles in flooding areas where sheep are often grazed to avoid vegetation encroachment at the waterside in order to minimise undesired effects after flooding events. Earlier investigations have shown that sediment particles settled on riverbanks after flooding may carry high concentrations of contaminants, such as dioxins and PCBs.

The potential risks relating to the issues discussed in the above paragraphs would be minimised by the removal of most of the wool before treatment and the fact that the animals must be subsequently kept clean. However, due to the production process, and temperatures reached, the possibility of formation of dioxins cannot be excluded and this should be investigated (see below).

4.4.2.2.3 Contaminants as a result of processing

There are several stages in the production process that may result in the presence of process contaminants. These processes include singeing and de-fleecing, washing and toasting (or burning). The temperature during the defleecing singe process reaches 515°C at incandescent glowing sections of fleece directly under the burner and around 70-85°C on the carcass surface. Although primarily undertaken to remove the wool, this singeing process also produces a smoked flavour. These processes may result in uneven formation and distribution of any contaminants that are formed. Dioxins and PAHs are discussed above as being environmental contaminants as a result of industrial sources. There is also the possibility that these compounds can be formed during the production process where there is a source of heat or smoke. Regulations are in place for dioxins and for PAHs and it will be important for industry to demonstrate compliance with these regulations before a product can be place on the market. It will be important to bear in mind that formation of these contaminants may not be even due to the way in which the product is made, and to design studies that are sufficiently robust to take this into account.

Other compounds that can be formed during cooking and processing include N-Nitroso compounds which can be formed if there is a presence of nitrite, often used as a preservative during the curing process, and heterocyclic amines that can be formed during the cooking process from precursors that are naturally present in foods including meat.

4.4.2.2.4 Temperatures and cooking conditions associated with the production of skin-on sheep meat

There exists a possibility that over time or during processing, that breakdown or transformation products may be formed. Given the range of storage, processing and cooking methods that are already in wide use for sheep meat products, it is not envisaged that any of the conditions used in the production of skin-on meat products would result in the formation of any different products, or any greater yield of known breakdown products. Hence there is not likely to be any additional risk with respect to transformation products when compared with consumption of other commonly available sheep meat products.

This is on the assumption that some cooking methods, for example barbecue, will result in higher temperatures and more harsh conditions than those involved in the production of skin-on sheep meat, and cooking methods such as roasting would involve longer times.

4.4.2.2.5 Polycyclic Aromatic Hydrocarbons (PAHs)

Polycyclic Aromatic Hydrocarbons (PAHs) are a complex group of chemicals with two or more aromatic rings. The occurrence of PAHs in the environment, and in food, is of concern as a number of them have proved to be carcinogenic in animal feeding studies. Foodstuffs usually represent the major source of exposure for non-smokers although a few instances of direct exposure due to combustion processes are found. Smokers may receive a level of exposure resulting from inhalation of smoke similar to average dietary intake. The presence of PAHs in food is usually a consequence of the ubiquitous nature of these compounds in the environment, formation during a cooking process or as a result of a manufacturing process.

Studies on the formation of PAHs during cooking have shown that the amounts formed can depend on a variety of factors. These include temperature, distance from heat-source, nature of fuel used, cooking time etc. It is therefore important to establish the uniformity of formation and presence of PAHs over the treated carcasses and between carcasses, and to ensure that quantities of PAH present are always within regulatory limits.

Initial work conducted for the FSA took 36 samples (6 samples from each of 6 sheep) which were analysed for a total of 27 different PAHs, including the 16 priority compounds identified by EFSA. The levels found ranged from <0.09-0.76 and <0.5-10.74 µg/kg wet weight for benzo[a]pyrene and PAH4 (sum of benzo[a]pyrene, chrysene, benz[a]anthracene and benzo[b]fluoranthene), respectively. The occurrence data indicated that all concentrations measured for benzo[a]pyrene were well below the current and proposed maximum levels for smoked meat and meat products. The concentrations for PAH4 were in most cases below 3 µg/kg wet weight. The contribution to the samples with elevated concentrations of PAH4 was in two cases benz[a]anthracene with values of 6.85 and 8.83 µg/kg wet weight measured in leg and shoulder of one carcass. The highest level for PAH4 of 10.74 µg/kg almost reached the maximum level of 12.0 µg/kg.

The two samples with elevated concentrations from one carcass considerably differed from the concentrations determined in the remaining samples. While the left side shoulder and the right side leg gave concentrations for benz[a]anthracene of 8.83 and 6.85 µg/kg, respectively, the right side shoulder (0.65 µg/kg) and the left side leg (0.82 µg/kg) from the same carcass were found to contain considerably lower concentrations for benz[a]anthracene. As this PAH is normally not present at these high concentrations in fresh meat, it is reasonable to conclude that it must have been introduced as a result of the singeing process.

Monitoring should be put in place to check for consistency in production methods and to ensure that production over time does not change with respect to meeting regulatory limits. The ratio of skin to muscle meat normally consumed for skin-on sheep meat products should be established. Variations of PAH content for different ratios should be established and either a standard ratio or a worst case (precautionary) ratio should be used as standard for further investigations.

Some of the practices used in traditional environments such as in rural Africa where skin-on sheep meat is widely consumed include using old tyres as a fuel source and putting the sheep carcass in direct contact with the material as it burns. This may give rise to higher levels of PAHs than more controlled production methods proposed for Europe where flames from blow-torches using clean gas such as propane as fuel is proposed. There is evidence that PAHs formed in the production of singed cattle hides in Africa under un-controlled conditions is greater when used tyres are used as a source of fuel, but the concentrations can be reduced to a large extent when the treated hides were washed (Essumang et al., 2011).

There are European Limits in place for PAHs in food and any producer would need to ensure compliance with these limits in order to ensure food safety.

4.4.2.2.6 Dioxins

Polychlorinated dibenzo-p-dioxins and polychlorinated dibenzofurans (PCDD/Fs, or 'dioxins') can be formed as a result of uncontrolled combustion and there is therefore a risk of formation of these compounds during the production of skin-on sheep meat. Once formed, PCDD/Fs are non-volatile and are stable to high temperatures and will not therefore decompose during normal cooking procedures.

To date, no studies have been conducted to investigate the formation of dioxins during the production of skin-on sheep meat. There are a limited number of studies in the published literature on the effects of other commonly used cooking methods. For most conventional cooking practices, changes in concentration of dioxins can be explained as a result of loss of water and elimination of dioxins within fat that is released during some cooking methods.

As for PAHs, there are regulatory limits that apply for dioxins in food within Europe. It is important to establish whether or not dioxins can be formed in the production of skin-on sheep meat, and if so, the uniformity of formation and presence of dioxins over the treated carcasses and between carcasses, and to ensure that quantities of dioxins present are always within regulatory limits. In the same way as for PAHs, the ratio of skin to muscle meat normally consumed for skin-on sheep meat products should be established. Variations of dioxins content for different ratios should be established and either a standard ratio or a worst case (precautionary) ratio should be used as standard for further investigations.

4.4.2.2.7 Heterocyclic aromatic amines

Heterocyclic aromatic amines (HAAs) can be formed during the cooking process from precursors that are naturally present in foods including meat. High-temperature cooking processes such as pan-frying, grilling and barbecuing produce greater amounts than poaching, boiling and steaming, and hence the production of skin-on sheep meat is likely to present a risk in terms of their formation. HAA formation depends on both the temperature and time of cooking, and their concentration is strongly influenced by the extent of cooking, i.e. the degree of doneness. Meat and fish represent the predominant sources of exposure for the majority of the population, and 2-amino-1-methyl-6-phenylimidazo(4,5-b)-pyridine (PhIP) is a major HAA in terms of dietary intake (Augustsson, Skog, Jägerstad, & Steineck, 1997; Rohrmann, Zoller, Hermann, & Linseisen, 2007; Sinha et al., 2000; Zimmerli, Rhyn, Zoller, & Schlatter, 2001).

Although meat below the surface of the skin is not cooked during the preparation of skin-on sheep meat, the singeing and toasting process can result in temperatures of over 500°C on the surface of the skin, which is not common in food production. Due to the manner of production, the temperatures and duration of heating are not likely to be uniform across the surface of the whole carcass, and so any formation of HAA is also not likely to be uniform. Individual parts of the carcass may need to be scorched for longer or shorter times, e.g. if there are areas of rough wool still present on the animal after shearing. As a result, local overheating may result potentially affecting not only skin surfaces but also some inner tissues of the carcass, particularly in the cut/split areas such as the neck, the legs and along the median line where meat could be directly exposed to the torch. Because heterocyclic amines can be generated under these conditions, EFSA concluded that analyses for these carcinogenic compounds would be useful at least to give an indication of their potential formation.

4.4.2.2.8 Nitrosamines

N-Nitroso compounds can be formed if there is a presence of nitrite, often used as a preservative during the curing process. Since nitrites are not used during the production of skin-on sheep meat, it is unlikely to be a significant risk from this route. Nitrate can be reduced to nitrite by some bacterial / mammalian enzyme systems and so this may also be a potential source of nitrosamine formation, and gas phase oxides of nitrogen, which may be present in direct-fired gas burners such as those used for drying grain are also a potential source.

Foods that give most significant intake from the diet include alcoholic beverages (mainly beer), fish, cured meats and cheese. It is therefore not likely that large quantities of nitrosamines will be formed since nitrite is not used in the production process.

It may be possible to issue guidance or to stipulate that nitrite should not be used in the process, or to authorise only processes that do not involve the use of nitrites in production.

4.5 Summary of hazards

Based on the final list of identified biological sheep meat-borne hazards, four bacterial hazards relevant for consideration for assessment of the safety of smoked, skin-on sheep meat were identified as follows:

1. *Bacillus cereus*

2. *Clostridium perfringens*

3. Pathogenic verocytotoxin-producing *Escherichia coli* (VTEC)

4. *Salmonella* spp.

The assessment was done according to several parameters: (i) reported occurrence and prevalence on sheep fleece and in sheep carcass meat (primarily in the UK); (ii) evidence for sheep meat as an important risk factor for human disease (based on the assessment from (EFSA, 2013) and other sources); (iii) evidence of carcass meat contamination as the main risk factor for human foodborne exposure to the respective hazard; and, (iv) potential association with the skin-on sheep meat products due to specific nature of this production process (arbitrarily decided).

The primary chemical hazards that may be formed during the production of skin-on sheep meat are dioxins, PAHs and heterocyclic aromatic amines. The uniformity of these contaminants across the treated carcass should be established, and dioxins and PAHs should comply with regulated limits. If HAAs are found to be formed by the production of skin-on sheep meat, the quantities produced should be compared with other meat products.

Several diseases could alter the aesthetic quality of the final product due to associated skin damage, scarring or subcutaneous abscess formation. Treatment of these diseases may pose a risk of skin residues. Stringent anti-mortem inspection may allow selection of animals for smoked, skin-on sheep meat production without these risk factors.

The compounds listed in Table 4.4 are those currently authorised in UK to administer via a pour on route in sheep or pour on versions of products authorised in their injectable form in sheep that we consider may be used off licence in sheep by farmers. These are the veterinary medicines we consider are most likely to represent an increased hazard for skin-on sheep meat production due to the risk of residues at the site of application.

4.6 Official controls in relation to skin-on sheep meat production

The changes in the dressing process of the carcass will need to be evaluated for the effect they may have in the inspection protocols for official controls and on the design and application of HACCP principles. We are examining the process while at the same time highlighting areas of change and uncertainty that may have an impact on both the above processes. Where appropriate, practical suggestions are included in the report though it is anticipated that both laboratory and field based research will also be needed to identify an appropriate process.

4.6.1 Ante-mortem inspection including pre-requisites, monitoring of animal welfare and lairage maintenance

Ante-mortem inspection, as performed by the FSA Official, includes the evaluation of the Food Chain Information (FCI) and the on-site assessment of animal identification, health and welfare and any conditions, including the cleanliness/dryness state, which may affect Public Health.

4.6.1.1 Evaluation of the Food Chain Information (FCI)

The FCI is of particular interest because it provides information both about the health status of the animals and the use of veterinary medicines. In addition information on previous rejection conditions can inform the FBOs and the Official Veterinarian (OV) about the possible risks associated with the farm of origin. Based on current information on the use of adult sheep for the illegal production of smoked, skin-on sheep meat, “cull” ewes are the preferred animals for such a production. The health status of such animals is more likely to be not of the standard of lambs or hoggets. An element that may complicate the evaluation of the FCI is that the vast majority of adult animal originate from livestock markets and collection centres with large batches of animals being presented for slaughter according to the market and not the farm of origin. Further investigation would be required for the establishment of adequate systems for animal presentation at ante-mortem which secures identification and traceability.

4.6.1.2 Ante-mortem assessment of animal health

In the current legislative requirements all animals submitted for slaughter have to be clinically inspected. In practical terms this is a brief overview whilst the animals are in groups aimed at detection of major abnormalities such as locomotor and/or systemic conditions that would have implications on the animal health or welfare. The suitability of this brief examination bears in mind that further in the process there is going to be detailed post-mortem inspection of carcasses. Systemic conditions include septicaemia which ideally would be diagnosed on the farm and/or during AM inspection at the abattoir. However, depending on the clinical signs of the animals and given the large numbers of animals examined in the context of an abattoir, septicaemic conditions can potentially be missed by visual only ante-mortem inspection. Post-mortem inspection aids in further detection of septicaemic conditions since these conditions are associated with generalized congestion of subcutaneous tissues and muscles despite adequate exsanguination technique, petechial haemorrhages and incomplete of rigor mortis. However in the setting of skin-on and flamed sheep carcasses the aforementioned post-mortem characteristics of septicaemic carcasses are likely not going to be as perceivable (discussed ahead further). Other lesions that are possible to be missed on brief examination unless severe are abscesses, traumatic lesions and or mastitis, the latter particularly frequent in older animals, which are most likely to be used by the current target market for this product.

Therefore, in the context of the amended processing, the need for a more detailed ante-mortem inspection and its protocol may be evaluated as part of the field application of the process. Aspects in this evaluation could include:

- Stocking density: To enable a more detailed inspection of the animals the stocking densities of pens to maintain animals should be considered.
- Detection of systemic conditions: Further equipment, such as infrared thermometers could be used peri-mortem, either in the lairage or immediately after death which would allow the detection of increased body temperature. The heightened temperature could be detected throughout the carcass when animals present fever or could be localised to tissues including that of the mammary gland in case of mastitis.

The alternative remains of ante-mortem inspection being conducted on farm by a veterinarian coupled with health certification that could be included in the FCI. Being performed on farm would be beneficial to the animal's welfare since it would avoid a further stressor at the abattoir. This on farm examination could include palpation of neck, head, legs and mammary gland. The health certificate could constitute part of the ante-mortem inspection of the animal and thus the ante-mortem at abattoir would be less extensive and would target mostly the cleanliness and dryness state of the animals. Given though the structure of the cull ewe market and it reliance on markets this may not be easy to instigate.

4.6.1.3 Assessment of cleanliness/dryness state

Aspects to be evaluated in the assessment of the cleanliness/ dryness of the carcass include:

- The areas of fleece contamination: In current settings, when processing skin-off sheep carcasses, the areas most relevant in the evaluation of the cleanliness/dryness of the animals submitted for slaughter, are the ones where during dressing the first knife-cuts are done through the skin. The sites of main interest in the animals intended to be processed with the skin off are the brisket, the *linea alba*, the perineal and perianal areas. However in the production of smoked, skin-on sheep meat the full skin is left on, so the overall cleanliness of the animal is likely to affect the microbiological quality of the final product. Such an effect could be examined when comparing the difference between traditional and skin-on meat processing.

- Contamination in the lairage: According to the FSA studies, to allow adequate and uniform flaming of the hair, the sheep wool should be shorn to approximately 5 mm prior to flaying. The shearing of the skin however means that the skin will be more exposed to contamination and so the maintenance of the live animal following shearing should be considered when performing ante-mortem inspection. Without further studies it cannot be stipulated which are the most adequate conditions for the keeping of sheared sheep intended to be processed as skin-on, nonetheless there are foreseeable requirements that would benefit a hygienic dressing. *E. coli* O157, *Salmonella* spp. and *Campylobacter* spp*.* are some examples of resilient foodborne pathogen that can be harboured in the skin of sheep and which are thought to survive for long periods in common slaughterhouse lairage surfaces (A. Small et al., 2002). The evaluation should include the effect of equipment such as conveyor belts, the type of bedding used.

4.6.2 Logistics of slaughter

The effect of slaughtering both skin-on and skin-off animals in the same space and time in commercial settings has not been evaluated. Ideally animals to be processed as smoked, skin–on carcasses would be processed in separate areas on the same site, or in separate establishments, within as to avoid potential cross-contamination. Aspects of the process that would need to be evaluated (often site by site) include:

- The effect of using a blowtorch/rig in relation to temperature and ventilation;
- The use of a pressure washer or any other devise that will be used to remove the burned wool residue and the “behaviour” of such residue in the slaughterhall;
- The possible smoke taint of the remaining or production;

- The logistics of using the “toasting” stage before refrigeration, particularly where automated lines are involved.

There are several systems of logistic slaughter that may be implemented to address the above aspects including time and/or space separation but the requirements will need to be assessed in real slaughter conditions.

Animal Welfare considerations are discussed in section 4.7.1

4.6.3 Potential effects of the production of smoked, skin-on sheep carcasses on regulatory controls - Hazards associated with the changing physical characteristics of carcass

4.6.3.1 Developing and evaluating Standard Operating Procedures (SOP) and HACCP

The development of SOPs for the processes involved in the smoked, skin-on sheep meat production will be based on hazards identified from current and future studies, the particular requirements of individual production settings as well as risk assessment of individual steps of the process. Some of the aspects included may not be of public health significance. Given the changes from the traditional process the following should be included in the evaluation:

- The existence of skin and subcutaneous lesions, including abscesses and the effect that the flaming process may have on them;
- The uniformity of the flaming process;
- The level of handling required during the flaming and washing process;
- The effect of the washing/scraping process both on the treated carcass and the environmental contamination;
- The positioning of the inspection points both official and quality control ones;
- The effect of the treatment on the efficiency of the evisceration/ effect on organs given the change in the shape of the carcass and particularly when applied in automated lines;
- The appropriate points for microbiological testing;

- The appropriate tests based on the identification of the relevant microorganism including factors affecting their growth such as Aw, pH etc.;
- The effect on the chilling process, particularly in automated lines where carcasses are led in the chiller after the "toasting" stage;
- The effect of contact between skin-on and skin-off carcass surfaces;
- The organoleptic changes and their transmissibility to skin-off product.

4.6.3.2 Adequacy of dressed carcass for final inspection

4.6.3.2.1 Possible effects on the inspection process

Part of the operators' responsibility is to provide appropriately dressed carcasses and facilities to enable an efficient inspection. Aspects that could be evaluated include:

1. <u>*Effect on visibility of internal surfaces*</u>: The effect of the heat induced tightening of musculature is on the adequacy of inspection process if maintained as it is currently. In routine slaughter of skin-off sheep carcasses, the general condition of the carcass is generally inspected once the skin is removed because it allows a better overview of the carcass. In the production of skin-on sheep meat the skin is not allowing the observation of the conformation and general appearance and colouring of subcutaneous tissues including musculature of the limbs. Sheep carcasses are relatively narrow. Where animals are split as part of the process the inspection is facilitated. The dressing of lambs, generally is done by opening only the abdominal wall via an incision of the *linea alba* and sawing of the sternum. Considering the narrowing of the carcass with heat tightening and normal ovine anatomy, there is likely little visibility of the inside of the carcass including lack of light coming inside to enable adequate inspection unless heavily manipulated. In order to address this and the inability to inspect subcutaneous tissues and underlying musculature including that of the limbs, the need for the carcasses to be split lengthways, irrespective of the animals age, should be evaluated.
2. <u>*Masking of smells*</u>: Based on the FSA the smell associated with the carcass is not intense. However the representative of the target market did not share the same opinion and said that the smell was detectable. Without further research the possibility that the odour released during the smoking will not mask other smells including that of urea, pyogenic processes or for example the sweet smell associated with ketosis cannot be ruled out.
3. <u>*Masking of skin lesions*</u>: Following the flaming, according to the FSA preliminary studies on the processing of smoked, skin-on sheep carcass, there is a change in skin appearance with findings including loss of continuity "cracks" at overheated areas of

skin and diffuse yellowing of the skin. Potentially these changes to the appearance could mask lesions present in the skin such as injection sites or scar tissue in the mammary gland associated with chronic mastitis. Furthermore the smoking leads to an overall yellow discolouration of the skin which can make certain lesions inconspicuous. Conversely, during the current slaughter process, the skin is not examined after ante-mortem inspection when it is usually covered by wool. In the skin-on sheep production, though following the flaming process which is expected to alter its characteristics, the skin will be visible in much more detail. The skin is the organ exposed to the environment more than any other and likely to show signs of such exposure. It also reflects internal systemic and local conditions. This presents a challenge since we have no experience or knowledge of the effect of the skin-on sheep production process to such cases but also the possibility to develop an inspection process that takes advantage of the exposure of skin. The need to train staff in any such process should be considered.

4. *Changing carcass shape*: The FSA report indicates that the singeing made carcasses appear smaller and fatter due to heat tightening and deformed the shape of the spine in some cases. EFSA suggests that singeing and toasting might interfere with rigor mortis and so the assessment for septicaemia and/or exhaustion (EFSA, 2011a).

5. *Changes in tissue humidity*: If the tissues are dried there is a potential that tissues affected by effusions such as observed in serous atrophy associated with cachexia or other oedematous conditions will become less apparent. The recognition of serous atrophy is particularly important in the differentiation between emaciation and age related muscular atrophy commonly seen in older ewes, likely the standard choice for the current target market of this product. The current guidelines on post mortem inspection are that an emaciated carcass is unfit for human consumption whilst age related muscular atrophy in older animals is not.

6. *Subcutis and underlying musculature including that of the limbs unavailable for inspection*. The absence of skinning means that the subcutis and underlying musculature cannot be visually assessed. The skin is still present but is altered in colour and appearance by the processing thus likely affecting its full assessment. Potential lesions missed include those stated below.

7. *Traumatic lesions* including those occurring secondary to foreign body penetration and/or site of drug administration and/or occurring during shearing, docking and castrations - If these lesion types are not detected there is a potential for repercussions in the monitoring animal welfare;

    (i) Secondary infections of traumatic lesions including caused by *Erysipelothrix rhusiopathiae*;

    (ii) Arthritis;

(iii) Generalised oedema - when less severe oedema is often restricted and/or visible to the naked eye in the subcutaneous tissue.

8. Discolouration of subcutaneous tissues, including that associated with jaundice or septicaemic processes: Jaundice is a yellow discoloration of tissues associated with increase haemoglobin degradation. Examples of the worst case scenario in terms of the origin of jaundice aetiology include haemolytic infectious agents such as in leptospirosis, cirrhosis or post hepatic impediment of bile circulation due to compression by a tumour. Examples of septicaemic conditions include Salmonella sp. infection. Ideally septicaemia would be diagnosed on the farm and/or during AM inspection at the abattoir. However, depending on the clinical signs of the animals and given the large numbers of animals examined in the context of an abattoir, septicaemic conditions can potentially be missed by visual only ante-mortem inspection. Post-mortem inspection aids in further detection of septicaemic conditions since these conditions are associated with generalized congestion of subcutaneous tissues and muscles despite adequate exsanguination technique, petechial haemorrhages and incomplete of rigor mortis.

9. *Presence of foreign bodies*: Foreign bodies, for example broken needles, besides posing as a potential physical hazard to the final consumer can be sources of contaminants including *Clostridium chauvoei* (causing Blackleg in sheep) or other highly resilient foodborne zoonotic agents including *E. coli*, *Salmonella* spp. and *Campylobacter spp.* frequently present in most farming environments and/or the fleece (Alonso et al., 2011).

10. *Drug administration sites* (legal/illegal including implants). These are of particular concern if skin is left on neck and the legs where most intramuscular injections are given. Areas of inflammatory reaction secondary to drug administration can go unnoticed if the skin is left on and depending on the substance administered affected areas can act as a potential chemical hazard.

11. *Lesions with infectious and non-zoonotic aetiology including Cysticercus ovis*: *C. ovis* is usually detected due to the presence of cysts in skeletal muscle. Meat containing viable cysts is a source of infection of canids. If not detected the infection cycle can potentially be maintained if the contaminated meat is given to canids. Furthermore even though not zoonotic the customer would unlikely appreciate the consumption of such cysts on aesthetics and gustatory perception grounds.

12. *Mastitis*: If the live animal presents with severe mastitis, it will likely be identified on ante-mortem inspection of the shorn sheep. However if this mastitis is mild to moderate and the mammary gland is not severely enlarged as a result of it, it will be unlikely to be detected at ante-mortem inspection. Mastitis due to *Pasteurella* spp. is a common reason for farmers to cull ewes. Given the current target market for smoked, skin-on sheep meat and its preference for the use of ewes, there is an increased risk of sheep

with mastitis being used. Other foodborne agents that are possible to be present in the mammary gland include *Yersinia pseudotubercul*osis.

4.6.3.2.2 Possible inspection stages of benefit if the skin-on sheep process is adopted

- Palpation of head, neck, legs including rump and joints prior to flaming: In order to address the lack of inspection of the subcutaneous tissues it would be useful if all carcasses produced in this manner were thoroughly palpated on the head, neck and legs to detect any area of crepitance (subcutaneous or intramuscular emphysema for instance due to *C. chauvoei*), crackly consistency (evidence of broken bones), or arthritis. The palpation in order to avoid cross-contamination of the final product would be best done prior to flaming but following the death of animal considering that if done whilst the animal alive would cause undue stress. Any carcass where a change was noticed could be highlighted so that at a later point of the dressing when further inspection of the carcass is performed, further incisions could be made hygienically in order to investigate the change. The presence of broken bones, even if processing related can have an impact on the health of the consumer since it could lead to traumatic lesions due to foreign bodies. If the broken bones originated ante-mortem it is important to assess when, in order to stipulate how the animal was managed and if its welfare was seriously compromised.
- Palpation of udder prior to flaming: In order to address the lack of inspection of the udder, it would be useful if all carcasses from female sheep dressed in this manner were thoroughly palpated on the udder to detect any area of crepitance and/or swelling and/or increased temperature suggestive of mastitis. The palpation in order to avoid cross-contamination of the final product would be best done prior to flaming but following the death of animal considering that if done whilst the animal alive would cause undue stress. Any carcass where a change was noticed could be highlighted so that at a later point in the dressing when further inspection of the carcass is performed, further incisions could be made hygienically in order to investigate the change and remove the udder. Mastitis can be of several origins including Brucellosis, a zoonotic agent which has not been reported in the UK.

4.6.3.2.3 Further suggestions on prerequisites if smoking is adapted as a dressing process

These are suggestions in terms of the safety of the final product but these do not take into account the practicality and financial implications on live animal management

- No use of intramuscular only subcutaneous injections during the life of the animal: This measure is to decrease the likelihood of intramuscular lesions including abscesses (Alonso et al., 2011) following drug administration's due to local reaction to the drug or broken needles. Given the fact the skin would be kept on the legs of skin-on sheep carcasses, if local lesions were present these would likely be missed. If the administration of injectable substances were restricted to the subcutaneous tissue, the reaction would likely be more localised in this area and if palpation was used as aid to inspection, detection of any changes secondary to the administration would be easily detected.

- Use of flocks vaccinated against *Clostridia* and/or inclusion of microbial examination for clostridia in the routine microbiological testing to assess the efficiency of processing.

4.6.4 TSE controls

4.6.4.1 TSE testing

TSE testing in sheep requires the collection of the brainstem and cerebellum of overaged sheep at specific slaughterhouses or on clinical suspicion. If the head of the animal is removed prior to the flaming process this step will not interfere with the testing. Without further studies it cannot be ascertained if the high temperature during flaming and its effect on the contraction of the musculature will affect the sampling technique and the sampled tissue if the head is left on during smoking. The effect of scorching on TSE sampling could be evaluated in field or experimental studies.

4.6.4.2 Removal of SRM

SRM includes in sheep of all ages spleen and the ileum and in sheep of over 12 months or with permanent incisors, tonsils, spinal cord, skull including the brain and eyes. If in the skin-on sheep meat production, the head is removed prior to the flaming process this step will not interfere with the head removal. According to the FSA studies into skin-on sheep meat production singeing made carcasses appear smaller and fatter due to heat tightening and deformed the shape of the spine in some cases (Fisher et al., 2006). The change in the spine linearity might affect the removal of the spinal cord but without further studies this cannot be ascertained.

4.6.5 National monitoring of drug residues

The possibility for additional drug residues cannot be ruled out and should be considered when determining sites to sample and drugs to be tested in the national drug residue surveillance scheme. Potential drug residues are discussed elsewhere in this report.

4.6.6 Health marking

The colour of the stamp is similar to the golden brown colour of flamed skin but according to the FSA study (Anon., 2010) singeing did not affect the visibility stamp. EFSA feedback on this finding is that the number of animals was few and further research would be needed to confirm this. Alternative measures to ensure the visibility of the health mark could be the application of extra stamps on the inner, non-flamed side of the carcass. The type of labelling and characterisation of the product will also require clarification (fresh meat/ meat preparation) and the type of labelling that would indicate the legal status against the possible derogation.

4.6.7 Recommendations regarding official controls in relation to skin-on sheep meat production

The smoking of sheep carcasses that will be maintaining skin will undoubtedly give rise to different practices and consequently different potential hazards. Consequently official controls should be adapted to the amended processing method and final product and not be based on the current routine processing of sheep.

Very briefly recommendations include:

- Evaluation of the FCI requirements for the new process (see section 4.6.1.1);
- Evaluation of the ante-mortem inspection requirements (see section 4.6.1.2);
- Evaluation of operational/structural requirements as part of a risk assessment for the development of SOPs and HACCP (see sections 4.6.2 and 4.6.3.1.1);
- Evaluation of the effects on meat inspection practices (see section 4.6.3.2);
- Additional application of on carcass health mark stamps, including a specific stamp for this process;
- Evaluation of the effect of the process on official controls for TSEs, drug residues and health marking (see sections 4.6.4, 4.6.5 and 4.6.6).

4.7 Other aspects in the context of public health

4.7.1 Animal welfare implications of the legalisation of the smoked, skin-on meat production

Any immediate welfare implications for sheep following the legalisation of the smoked, skin-on meat production process would likely be limited to those associated with increased handling necessary to shear the sheep before slaughter and processing, either on-farm or in the lairage. Many sheep that are currently slaughtered and processed in a conventional manner are also shorn in order to increase cleanliness. However, this tends to be limited to heavily contaminated areas of fleece, especially around the incision sites. The complete shearing that would be required for the production of smoked, skin-on meat would, therefore, represent a potential welfare issue. Shearing may impact on animal welfare as a result of:

(i) increased stress associated with handling and shearing;

(ii) potential traumatic lesions such as cuts from the shearing equipment and subcutaneous bruising associated with potential poor handling techniques;

(iii) cold stress associated with shearing on-farm during cold weather;

(iv) and potential secondary infections of skin cuts and abrasions if shearing takes place on-farm several days before slaughter.

Many of these problems could be eliminated if sheep were only shorn after killing. However, such a process would inevitably generate considerable aerosols in the dressing area which would cause increased contamination of surrounding carcasses. The provision of an isolated area for post-slaughter shearing would likely be prohibitively difficult to implement for many abattoirs.

In the longer term there are several potential issues that may impact on the welfare of animals depending on commercial decisions of pharmaceutical companies and on how the market for a legally-produced smoked, skin-on meat develops in the future. In the first case, it is likely that withdrawal periods for pharmaceutical products will need to be reassessed in the event of the legalisation of smoked, skin-on meat. Consequently, it is possible that pharmaceutical companies may make the commercial decision not to license their products for use in sheep that will enter the smoked, skin-on meat market. As a result, the clinical benefit associated with the use of such products will be lost and may, therefore, impact on the welfare of the animals.

In the second case, the market for legal smoked, skin-on meat may develop in such a way that it promotes the production of lower welfare animals. For example, the current preference for smoked, skin-on meat is older, leaner – and, hence, potentially malnourished

– sheep. If the smoked, skin-on meat market were to grow and such preferences dominated, it is feasible that the welfare of animals destined for this market could be compromised. At this stage, however, it is impossible to predict how such markets will develop and it is, perhaps, equally likely that the preference will be for small, younger animals.

Finally, it is worth pointing out that there could be potential welfare benefits associated with the legalisation of the smoked, skin-on meat process. Preliminary results from the questionnaire suggest that many FBOs anticipate that the production of smoked, skin-on meat will likely be the province of small- to medium-sized abattoirs, perhaps as a 'cottage industry'. If such a situation arose, it is likely that transporting animals to one of many small abattoirs – rather than transporting them to one of only a few large abattoirs – would ultimately lead to shorter journey times for the affects animals.

In addition, if the market for smoked, skin-on meat develops in such a way that the preferred animal is an older ewe (as described above) then it may actually result in an increased demand and market value for such animals and, consequently, may be associated with improved welfare. Of course, legalisation of the production of smoked, skin-on sheep meat would certainly lead to improved animal welfare by ceasing illegal, non-controlled production.

4.7.2 Environmental / Occupational Health (by-products)

Although outside the scope of this report, it is clear that operators involved in the production of skin-on sheep meat would need to comply with all usual health and safety procedures in order to minimise risks associated with production. These include the physical risks associated with the use of naked flames and also other health risks that may be associated with fumes and vapours produced as part of the process. Good ventilation and appropriate personal protective equipment should be provided.

4.7.2.1 Heat and smoke

The initial studies conducted on behalf of the FSA used propane as fuel for the singeing process. Other relatively clean sources of fuel such as butane or other hydrocarbon gas mixtures are unlikely to pose any additional risk. The use of waste materials such as old tyres for fuel as used in some rural locations in Africa should not be done without a risk assessment.

4.7.2.2 Effluents

Depending on size and resources slaughterhouse effluent may be treated on site or treated as Trade Effluent by the local waste company. It is uncertain what effect the burning of the wool may have on the characteristics of the effluent which could also depend on the size of the smoked skin on product throughput relative to the standard product throughput at the premises. As part of the evaluation of the process it is recommended that each local Waste Water Company is informed as the effluent may require adaptation of the treatment system both for on-site and for public sewage works.

4.7.2.3 Biological occupational hazards

Some of the hazards explained more in detail in sections 4.4.1 and 4.6.3.2 are associated with different pathological conditions in sheep (such as septicaemia and conditions associated with foci of infection in tissue such as arthritis, bronchopneumonia, mastitis, pleuritis or abscesses) and might have zoonotic implications. Those are particularly related to *Staphylococcus aureus*, *Mycobacterium bovis*, *Arcanobacterium pyogenes*, *Corynebacterium pseudotuberculosis*, *Erysipelothrix rhusiopathiae, Coxiella burnetii* and *Streptococcus* spp. Although rare, human occupational infections with these pathogens have been recorded amongst farm and abattoir workers handling sheep and/or sheep carcasses. Reduced handling of the meat on the slaughterline, including the omission of some laborious meat inspection procedures (such as incision and palpation), is assumed to reduce the likelihood of occupational exposure (EFSA, 2013). However, meat inspection procedures in the context of smoked, skin-on meat are described in more detail in chapter 4.6.

4.8 Alternative production

4.8.1 General considerations

The current production method involves uncontrolled burning of a chemically undefined substrate of wool using variable, possibly high, temperatures. This makes the formation of contaminants' such as PAHs and fate of residues such as pesticides difficult to predict. The aim of alternative production methods would be to create a smoked flavour under controlled conditions with a temperature assured to be below 500^{o}C to minimise formation of toxic contaminants and to allow standard PM carcass inspection. Finally, it must be acceptable to the potential market otherwise it will not displace current illegal production methods.

4.8.2 Production of smoked skin separately from carcass meat

Removal of the skin prior to singeing will allow normal inspection of the carcass and assessment of subcutaneous lesions. The skin could then be singed, toasted flat with dry heat or flavoured with liquid smoke flavour before recombining with cut up sections (joints) of meat. Freezing may aid the skin to stick to the meat again or a knitted material could be used, as is common to add fat around beef joints before sale. The meat could then be smoked in a variety of ways from cold smoke to liquid smoking. Toasting skin flat on a conveyor would allow an even distance from the heat source so a very uniform and predictable heat and subsequent colour could be obtained. It may be possible to control singing of wool in a similar way. Animals could be handled in a conventional slaughter hall and the skin treated elsewhere and reunited in a cutting hall.

Furthermore, a skin on product could be produced and then the individual sides or cuts could be smoked. The consumer in the FSA smoked, skin-on sheep meat production video suggests she is already using this technique but the market prefers the smoking to occur before evisceration, as is undertaken in small ruminants in Nigeria. However, parts of the cattle carcass are smoked separately after dressing of the carcass in parts of Nigeria so these methods can be acceptable. It may be that if this method is used and the product becomes widely available from legitimate sources it would displace illegal production.

4.8.3 Skin-on goat meat produced in Australia

The Australian meat industry now utilises a new automated method to dehair feral goats, which includes scalding in hot water at 65^{o}C and subsequent automated dehairing, with some slaughterhouses using singeing in addition. Wool removal by scalding and dehairing prior to singeing could be beneficial to allow for the uniformity of subsequent singeing, which in turn will make formation and presence of PAHs over the treated carcasses and between carcasses more uniform and easier to control, to ensure that quantities of PAH present are always within regulatory limits. However, due to the difficulties in goat hair removal during dehairing, a new automated method had to be developed to de-hair goat carcasses in Australia. It could be assumed that that would be the case with sheep as well. Therefore, considering that commercial dehairing processes already exist for pigs, goats and sheep feet, investigation into hot water scalding and automated dehairing for sheep merits further attention.

4.8.4 Modifications of the process proposed in the FSA studies

4.8.4.1 Hot air singeing

Hot air at a controlled temperature could cause browning of skin without uncontrolled combustion and formation of unpredictable amounts PHA etc. This was attempted in the University of Bristol work and the main problem was the time taken and removal of the fleece. Very fine sheering and a system used after evisceration, like a chicken rotisserie, may address some of these issues, though the smoked flavour may be different from that of the singed product.

4.8.4.2 Rotating singeing frame vs hand torch

A rotating frame either moving the flame source over the carcass or the carcass moving round would remove some variability. Holding the tail up and limbs out to avoid cold spots for part of the process could also be considered. Uncontrolled combustion of surface wool would still occur but the distance of the flame source and strength could be altered in response to surface temperature measurements. Such a rig could be portable and produced off site with control systems. It would be much more expensive initially than hand held burners but if it produced a consistent product the variability that concerned EFSA may be removed.

4.8.4.3 Washing step

High pressure water washing, as it was used in the FSA studies, could be modified using different process parameters. Angle of jets to over 45 degrees from the perpendicular could be used to reduce the force of water on the skin and wash off from the skin rather than force bacteria and other contaminants into the carcass.

Cuts in the skin at shearing may cause combustion debris and other contaminants to be forced into the subcutaneous connective tissue. This needs to be monitored and these sites specifically sampled in any development project.

Also, there is a possibility to use washing combined with some chemical decontaminant, to eliminate bacteria present on carcass surface. However, any meat decontamination treatment to be used in the food industry should be subjected to regulatory approval following risk assessment. EU Hygiene Regulation 853/2004 (EC, 2004) allows, in principle, the use of decontamination treatments on the slaughterline, following appropriate consideration and approval of the treatments by the regulatory authorities (Antic, Blagojevic, Ducic, Mitrovic, et al., 2010).

4.9 Conclusions

This comprehensive critical review was performed to evaluate available evidence on a proposed production method for smoked, skin-on sheep meat and to identify appropriate research required to fill the gaps in scientific knowledge regarding this production. The objective was to identify the relevant public health hazards arising from this production and the possible effects of the smoked, skin-on sheep meat production process on these hazards, as well as its effects on official controls.

Different sheep variables were considered. The main source of animals for smoked, skin-on meat production is expected to be cull ewes with these animals likely to have specific health problems when identified for culling and sent for slaughter. Different sheep diseases might affect the skin, particularly Blow Fly strike, sheep scab and others, and these should be considered in Food Chain Information and/or when developing Standard Operating Procedures for this production. Treatment of these diseases may pose a risk of skin residues at the time of slaughter. Also, sheep wool and skin composition could be a significant factor for this production since the meat is consumed with the skin left on. However, there are little specific data on animal variables affecting skin and wool composition.

Furthermore, a comprehensive list of biological and chemical hazards of public health relevance was created, taking into account different criteria. Bacterial hazards relevant for consideration for assessment of the safety of smoked, skin-on sheep meat were identified as *Bacillus cereus*, *Clostridium perfringens*, pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) and *Salmonella* spp. The assessment of their relevance for this production was done based on the likely occurrence in sheep (particularly on skin) and the evidence that sheep carcass meat is an important source for human exposure to that particular pathogen. Furthermore, the likely effects of this production process on these biological hazards were reviewed. Hence, sourcing of animals, shearing, singeing, high pressure water washing, toasting and chilling appear to be the steps that could have significant effect on pathogen fate, by decreasing or increasing their number. However, further research is needed to determine the microbiological profile of smoked, skin-on sheep meat and the true effect of the process on the most relevant bacterial pathogens.

The primary chemical hazards that may be formed during the production of smoked, skin-on sheep meat are dioxins, Polycyclic Aromatic Hydrocarbons (PAHs) and heterocyclic aromatic amines (HAAs). The uniformity of these contaminants across the treated carcass should be established, and dioxins and PAHs should comply with regulated limits. If HAAs are found to be formed by the production of skin-on sheep meat, the quantities produced should be compared with other meat products.

Several sheep skin diseases could alter the aesthetic quality of the final product due to associated skin damage, scarring or subcutaneous abscess formation. Treatment of these diseases may pose a risk of skin residues. The list of veterinary medicines currently authorised in the UK for use in sheep and considered as most likely to represent an increased hazard for skin-on sheep meat production due to the risk of residues, is provided. The levels of chemical residues from these veterinary medicines in sheep skin should be assessed following treatment with them (especially, with 'pour-on' products). Also, the effect of smoked, skin-on production process on these residues at the time of authorised withhold and slaughter should be evaluated. If skin is designated as an edible part of a sheep carcass it may be added to the list of sites for which residues information are required to support applications for Marketing Authorisations of new veterinary products. VMD and EMEA views on this and any requirement for adding sheep skin to the residues surveillance system will be needed.

The official controls are informed by both statutory requirements and the risk assessment of the regulated processes. Their application and modification will depend on the results of research on identified hazards and the practical observation and application of the process during production. All aspects of official controls, from ante-mortem inspection to HACCP verification, post-mortem inspection, TSE, residue, and chemical contaminant controls should be evaluated on public health, animal health and welfare grounds. A range of relevant conditions for smoked, skin-on sheep carcasses were reviewed and discussed. The change in the sheep carcass dressing process will undoubtedly affect official control procedures that will need to be evaluated and amended. Also, some of the practices will likely have a positive or negative effect on animal welfare, so these implications should also be considered when developing SOPs for this production.

Alongside all abovementioned aspects, further research requirements were identified, including laboratory based experiments and those needed for validation purposes in commercial settings. These are all listed under the recommendations section.

The current proposed production method for smoked, skin-on sheep meat involves a singeing process that aims to efficiently remove wool and impart smoked colour and odour to the carcass. However, some other alternative production methods could also be investigated. These could be used to create a smoked flavour under controlled conditions with a temperature assured to be below 500^{o}C (to minimise formation of toxic contaminants), and/or facilitate standard post-mortem carcass inspection. The production of smoked skin separately from carcass meat and sheep wool removal by scalding and dehairing prior to singeing are alternative methods that merit further attention.

Overall, this critical review included all relevant aspects for delivering a safe and hygienic process for the production of smoked, skin-on sheep meat, including the identification of relevant public health hazards associated with this production, possible effects that this process could have on these hazards and also possible implications on official controls and animal welfare. Furthermore, the results of this review have highlighted areas of research that need to be addressed before making a case to legalise the production of smoked, skin-on sheep meat in the UK and EU.

5 Survey of slaughterhouse operators’ attitudes towards the legalisation of skin-on sheep meat production

5.1 Summary

The attitudes of slaughterhouse operator’s towards the legalisation of skin-on sheep meat production were examined using semi-structured telephone interviews. 10% of all operators slaughtering sheep, in addition to all operators slaughtering high numbers of adult sheep, in England and Wales were targeted (28,9% of all slaughterhouses approved for the slaughter of sheep). Twenty interviews were completed over a period of 3 weeks during October/November 2015. Only 50% of the responders indicated medium or high interest for the application of the process in their premises. It is concluded that their interest is driven by business considerations supported by interest from existing clients and the prospect of new markets (including exports). Concerns were expressed regarding the structural and operational requirements and the effect that the process would have on the safety, aesthetic and organoleptic characteristics of the product.

5.2 Introduction

The survey focussed on slaughterhouse operators who specialise in the slaughter of adult ewes. Its aim was to gauge the slaughterhouse operator’s position on the possible legalisation of skin-on sheep meat production. The objective was to explore the anticipated risks and benefits of the process for the meat industry and the questions/suggestions that the industry has in relation to the implementation of the process.

5.3 Survey structure

The survey took the form of anonymised semi-structured telephone interviews (Annex 1) and was approved by the University’s Research Ethics’ Committee. The questionnaire was agreed by the FSA and was subsequently piloted in 5 premises. The list of slaughterhouses specialising in adult ewes and of all slaughterhouses approved to slaughter sheep in England and Wales was obtained from the FSA. All the slaughterhouses specialising in adult sheep and 10% of the remaining slaughterhouses, approved to slaughter sheep, selected randomly within each country of the UK were the designated sample. Contact details were obtained either from the FSA or from internet searches. Food Business Operators (FBOs) were contacted by phone in order to establish initial interest. If they were interested, information regarding the process and the research (Annex 2) was sent to them either by e-mail, fax or by post. The FBOs were contacted again to confirm they were interested in taking part in the research and at that stage an appointment was booked for the interview. Consent was recorded as part of the interview. On one occasion consent was recorded but the interview was conducted by taking notes.

Responders' attitudes were recorded using scales (1 to 5) for concerns regarding the implementation of the process with 1 representing a low and 5 representing a high level of concern or difficulty. The responders' attitudes were analysed against region, throughput of adult sheep, their concerns regarding structural, operational and administrative requirements and the anticipated disruption in the plant using analysis of variance and Fisher's exact test (stata® 13). Reported means and associated confidence intervals were calculated using bootstrapping (1000 iterations) at a 95% level of confidence.

5.4 Results

5.4.1 Sample characteristics

39 Slaughterhouses specialising in the slaughter of adult sheep in addition to 15 slaughterhouses approved to slaughter sheep were included in the sample (n=54). Forty nine FBOs were contacted. We have been unable to contact five FBOs. Information regarding the process was sent to 35 FBOs. Interviews were completed with 20 FBOs. The regional distribution of the responders is summarised in Table 5.1.

Table 5.1: Regional distribution of the sample of premises included in the study

Region	Total No of premises (%*)	No of premises contacted	No of premises that were sent information	Number of interviews
East	3 (12.5%)	3	2	1
South	9 (17.3%)	8	5	1
North	21 (42.0%)	20	12	6
Wales	12 (54.5%)	10	8	6
Midlands	9 (23.1%)	8	8	6
Total	54 (28.9%)	49	35	20

** Percent of total No of slaughterhouses in the region*

There is overrepresentation of Wales and the North. This may be the result of a large number of slaughterhouses specialising in adult sheep in these areas. 39 of the 54 slaughterhouses were included in the list of premises that specialise in cull ewes. The overall response rate was 37.04%. The higher response rate by slaughterhouses specialising in adult ewes may be the result of the higher interest by this part of the trade but may also be attributed to the fact such premises were given priority when contacted for the interviews. Table 5.2 summarises the distribution of premises according to production.

Table 5.2: Distribution of responders according to production type

	Premises in sample	No of premises contacted	No of premises that were sent information	Number of interviews (%*)
Specialising in ewes	39	37	30	16 (41.02%)
Licenced to slaughter sheep	15	12	5	4 (26.66%)
Total	54	49	35	20 (37.04%)

** Response rate as a percentage of the sample*

From the responders 4 are slaughtering sheep only, eight are slaughtering cattle and sheep and eight slaughter cattle, sheep and pigs. Six of the premises also slaughter goats and 2 slaughter alpacas. The throughput for each species is summarised in Table 5.3.

Table 5.3: Weekly throughput distribution by species

	Average* Throughput (kg)	Max Throughput (Kg)	Low (No of premises)		Medium (No of premises)		High (No of premises)	
Cattle	199.64	1500	0-20	10	21-100	3	>101	5
Lambs	2481.58	15000	0-500	9	501-1000	4	>1001	5
Sheep	428.29	2000	0-100	6	101-500	7	>501	5
Pigs	205.71	1000	0	10	1-500	6	>501	1

* The average of those plants producing the relevant species
One responder did not provide information about throughput

The total weekly throughput of adult sheep for the responders is 7281 animals of which 81.44% are supplied by markets and collection centres. The remaining adult sheep are supplied by local farmers. The destination of the meat from such sheep is predominantly butchers (65%) though most of the responders did not appear to have detailed information during the interviews and the figure is an approximation.

5.4.2 Interest and concerns for the process, the data

Seven of the responders were adamant they did not want to be involved in the process, three considered their involvement unlikely, six expressed an interest and four were very interested. Table 5.4 summarises the interest for the process against characteristics of the responders.

Table 5.4: Interest distribution according to throughput and region

	"No way"	"Not Likely"	"Possible"	"Very"	Total
*Adult sheep throughput**					
0-100	4		2	1	7
101-500	2		3	1	6
>500	1	3	1	1	6
Region					
North	3		1	2	6
Wales	2		3	1	6
Midlands	1	3	1	1	6
South and East	1		1		2

*One responder did not provide information about throughput

When evaluating the difficulty of different aspects of the production responders were more concerned about structural requirements (14 out of 17 responders, average score 3.16 (95% CI: 2.43-3.82)). Operational requirements were the second most important concern (10 out of 17 responders, average score 3.07 (95% CI: 2.19-3.34)) with administrative ones being less of a concern (7 out of 18, average score 2.43 (95% CI: 1.51-3.34)), though the differences are not statistically significant.

When the levels of expected disruption were examined against the interest for the process no significant differences were established between different levels of interest. There is though, a trend of expecting higher level of disruption by those less likely to undertake the process. Table 5.5 summarises the anticipated disruption scores (1 to 5) according to level of interest. Table 5.6 summarises the expectations of the responders across the different interest levels. Analysis of Variance identified levels of "General disruption" as significantly associated with the expressed interest to the process ($p<0.01$). There are no other statistically significant associations between interest for the process and any of the rest of the factors.

Table 5.5: Scores (%CI) of anticipated levels of disruption acording to level of interest tor the process

	"No way"	"Not Likely"	"Possible"	"Very"
General disruption	4.4 (3.67-5.13)	4.33 (2.62-6.04)	1.6 (1.09-2.11)	2 (0.11-3.88)
Separation of processes	4.2 (2.59-5.8)	5 (3.16-6.84)	2 (0.51-3.49)	4.25(3.78-4.72)
Separation of storage	3.6 (1.88-5.32)	5 (3.16-6.84)	2.6 (0.68-4.52)	4.25 (2.89-5.60)
HACCP & SOPs	3.6 (2.34-4.86)	2.67 (0.38-4.95)	1.4 (0.9-1.9)	2.5 (0.65-4.34)
Staff Training	3.6 (2.35-4.85)	2.67 (0.38-4.95)	2 (1.1-2.9)	2.5 (0.65-4.34)
ABP	1 (0.88-1.12	2 (0.75-3.25)	1 (0.89-1.11)	1.5 (0.6-2.4)
H&S	2.8 (1.45-4.15)	3.67 (1.62-5.71)	2 (1.13-2.87)	2 (0.11-3.89)

Table 5.6: Responders' expectations according to level of interest to the process*

Expectations / Interest	Demand from existing clients		Creation of new markets [a]		Exports		Increase of cost of labour		Damage to reputation [a]	
	Yes	No	Yes	No	Yes	No	Yes	No	Yes	No
"No way"	2	5	4	3	3	4	5	2	3	3
"Not Likely"	1	2	0	3	2	1	3	0	2	1
"Possible"	1	5	4	1	4	2	3	4	1	5
"Very"	4	0	4	0	3	1	1	2	1	3
Total	8	12	12	7	12	8	12	8	7	12
Fisher's Exact	p=0.052		p<0.05		p=0.798		p=1.47		p=47	

* Risks and benefits put into context…
[a] Not all responders answered the questions

5.4.3 Insight and opinion

The factors presented above do not individually explain the interest or lack thereof for the process. Some trends may be obvious but the sample size may not have been large enough to provide statistical significance. The only factor providing a significant association with the interest in the production is the creation of new markets ($p<0.05$) and the level of general disruption ($p<0.01$). The insight provided by the interviews is more eloquent in identifying the responders' approach to the process.

Interest to the process is "begrudgingly" or enthusiastically driven by the creation of a new product whether it responds to the demand of existing clients or the prospect of new ones.

> *"…If it was legalised I suppose we would have to be [interested], for commercial reasons. Very interested but begrudgingly."*

> *"…As to wanting to do it, it's all about economics depending on what the suggested numbers of the markets and the whole economics, pricing and stuff, if it's like the stuff we're doing at the moment, if it generates some profit then we would be interested and we would look at it."*

> *"…Within what they call ethnic communities, people want this thing and as long as it's done properly I can't see any problems."*

> *"As a business we would look at anything and I think a piece that is totally unknown is what the export market for this could be. If we can smoke it freeze it and ship it out that is a whole different ballgame."*

Where new or existing markets do not take priority responders were less likely to show interest for the process. This may also reflect the understanding of different cultural culinary practices including possible prejudice.

> *"Not much [interested] to be honest. Abattoir of our size we already have enough sheep going through. As I said if there was a demand we would be receiving enquiries every month at least and we do not get this."*

> *"I think there is information about how many people would want it if [it] were legal but you see, people that can't have things say that they want them and when they can have them they don't want them [any more]… I don't think there will be a massive trade for it, certainly not enough trade to pay back the costs involved in setting it up."*

When identifying possible risks and benefits most responders identify profits from new markets, national or international, as a possible benefit. Even amongst those not interested in the process there is recognition of this as a positive effect, though the fact that this new market will be affecting the existing market is recognised by some though not all of the responders.

> *"We can sell them we can make three phone calls and we can sell about 10000. But of course the problem is, you would sell them "smokies" but of course on the same contract you wouldn't sell your other thing. We sell this product into this community now because they can't; well they're supposed not to be able to get hold of "smokies", so they buy the skin-off. So if you get to the situation where you can sell "smokies", without question we would sell "smokies" but we wouldn't sell the skin-off.*

The reduction in illegal provision is an additional expected benefit.

> *"…usually in my experience when things are not allowed to take place they're always done secretly or illegally so then you get more problems. So if there is a demand for that kind of thing then better that it is done in places where it can be monitored rather than in back yards."*

The possible risks are identified in the areas of profit, health and safety, the quality and the hygiene of the product and process:

> *"[The risk is]…losing money, staff may be put off, people working on the line, they don't like any change"*

> *"The only benefit will be giving the West African and Jamaican people a product which they are used to eating, which they have no problem eating. The problem is I don't believe it could be done hygienically and the first person who dies of E. coli, there will be a bad reflection on the meat trade as a whole again…"*

“The bigger risk I see is the contamination side of it, the process as looking at it, to me, it looks a bit of a minefield with all this cross contamination and stuff so I think it would have to be very heavily regulated

I can’t see the risk as a business thing because there probably is a demand for that kind of thing because obviously it has been done underground for a long time so I wouldn’t say there is a risk as a business. I don’t think it would alienate people that you have already on board, well our client base, wouldn’t be their kind of thing.”

Business risks no because we would only do it if we know that there is a customer base whether at home or abroad, but if there is then you do it. And in business there is always a risk in everything we do.”

“The only thing that I would be concerned about is abscesses in the skin. There will be no risk to the business. If they were legal I would do them to order.”

“The risks: first of all is using the flamethrower, in any abattoir it would increase the insurance dramatically and probably they would find it very difficult to get cover. The other thing is storage of the carcasses and obviously the smell in production which may go into the rest of the meat in the abattoir. And also there is the risk to staff of using that equipment. So basically it is a job that should have to be done in a specific area in a high production abattoir. “

“The biggest thing would be the price of the process when it is done legally compared to what illegally what it is costing and how easily it could be done legally because if it can compete with the illegal trade it’s not going to work”

“The risk to staff during processing, obviously with the scorching, I do not like the pressure washing, the burned hair,[…] it would just be a dirty process, I wouldn’t want that to be happening in my plant. Although I am sure they have looked into it and they know the risks, still no matter what you tell me, seen from a hygienic point of view it is very risky and I don’t think I would like to be selling that product.”

The perceived effect on reputation depends on the position in the market and the client base profile:

“I think if we went down the road…, because our reputation here is for all locally sourced animals and sort of minimum transportation all that sort of thing and I think if we went into different type of product which people wouldn’t really understand around here it might not do our reputation, it wouldn’t be good for our reputation.”

“No, No, No, because we would never do such an operation without licencing, permits and we would never do it unprofessionally so, no if there is a demand for it and it can be done in a professional hygienic manner then that would be good for us for our reputation that we are doing something which is needed by a community or

communities and we are doing it professionally so it would enhance our reputation I would imagine."

Though the need for regulation has been identified by some responders others considered supervision and regulation as part of the risks to the business: Asked on the risks one of the responders suggested that…

"Depends, if the vet starts saying they want this, that or the other, it won't be worth doing it."

"I would like to know what FSA expect of us and their rules and regulations because unless until we read that you can't do anything because, it's all very well saying we're going to set it up but there is so many rules and regulations, the FSA, the more money you spend the happier they are, they can't do simple."

5.4.4 Information and consultation

FBOs have indicated they would need to have additional information before deciding to undertake the process. Information regarding the market dynamics and technical applications is considered predominantly as a business responsibility. The FSA is tasked with providing information on the legal requirements and establishing consistent standards of supervision.

"… Information on the production methods, on the implications of the production methods on carcass hygiene or carcass quality, the sort of relevant procedures that we should put in place on how to segregate the product, how to label the product. Information on that we would have to research as a company and obviously the cost implications…"

It is also tasked with assessing the risks to hygiene and public health.

"*Product risks, I can't assess these risks. It will be done by the likes of the FSA, DEFRA and so on, so you know the professional bodies out there would be the ones to advise on that. There is obviously a risk of some sort and it has to be evaluated, I wouldn't know.* Those FBOs more likely to be involved with the process also expressed the desire to be involved in a consultation.

5.5 Conclusions

There is interest in the production of skin-on sheep meat amongst FBOs, particularly those who have an established client base within the community that traditionally consume this type of product. Those FBOs who have prior experience in the production process through participation or observation of the previous experiments have also indicated an interest. For others, the decision will be based on a combination of factors including financial criteria and the level of disruption it may cause in established practices and client bases. Most of the practical aspects including separation of processes and equipment will probably be decided on financial grounds. The size of the businesses that may undertake the process varies and will probably continue to do so until the demand for the product is stabilised after legalisation. A further factor in this process will be the effect of international trade, both of exports and imports, an aspect for which there is limited information regarding supply and demand at this stage.

Public health risks including both specific hazards associated with the carcass (abscesses) and the process (cross contamination) remain a concern for the responders and inform their decision as part of an informal "risk assessment". Meat quality aspects such as tainting of the "normal" meat as a result of the process provide an additional cause for concern.

Respondents believe that regulatory requirements are providing both security against the Illegal trade and an additional business burden.

6 A review and update of Hybu Cig Cymru's (HCC) report "Appraisal of the Opportunities in the Skin on Sheep Meat Market for Wales"

6.1 Summary

The original HCC report (2008) can be updated using the contents of the current report. In addition, using information from the Office of National Statistics, the potential UK consumer population was determined and an increase of 133,000 (85.25%) was identified between 2008 and 2014. The number of carcasses needed to meet this demand was calculated using the ONS estimates for West African born population in the UK. It is estimated that, based on these calculations, the proportion of carcasses to be used for skin-on sheep meat production ranges between 1.89 and 3.81% of the UK adult sheep slaughtered in 2014. Considerations should also be given to possible changes in legislation regarding the official meat controls.

6.2 Introduction

The review of the HCC report will be based on the information included in the current report. Specifically, this will include aspects or summarised information from:

- The review of biological and chemical hazards
- The review of the official controls in relation to the implementation of the process
- The animal welfare considerations
- The conclusions of the slaughterhouse operators' survey
- The recommendations for future research

In additions to the above, two more sections are included here which update the report in relation to changes in legislation and population associated demand.

6.3 Consumer demands according to the production of smoked, skin-on meat in West Africa

6.3.1 Changes in UK population of West African Origin between 2008 and 2014

The report commissioned by the HCC in 2008, estimated the number of West Africa born people living in the UK in 2008 at 155,000 to 240,000. In order to establish the level of change that occurred between 2008 and 2015 information provided by the Office of National Statistics in their "Population by Country of Birth and Nationality" data sets for 2008[15] and 2014[16] was used.

Since these datasets are producing population estimates using the Annual Population Survey (APS), which is the Labour Force Survey (LFS) plus various sample boosts, we also included the data collected during the 2011 Census regarding Country of birth[17] and self-declared national identity[18] for England and Wales. There is no information on National identity, currently, for Scotland and Northern Ireland.

Table 6.1: Comparison of population estimates for UK residents born in West African countries known to consume skin-on sheep meat between 2008 and 2014

Country	2008		2014	
	Estimate	CI** +/-	Estimate	CI** +/-
The Gambia	6	3	11	5
Ghana	54	10	92	13
Ivory Coast	5	3	6	4
Nigeria	90	12	178	19
Togo	1	1	2	2
Total	156	29	289	43

* Figures in Thousands
** CI+/- is the upper (+) and lower (-) 95% confidence limits. It is defined as: 1.96 x standard error

According to the United Nations[19] (UN) the West Africa Regions includes Benin, Burkina Faso, Cabo Verde, Cote d'Ivoire, Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Mauritania, Niger, Nigeria, Saint Helena, Senegal, Sierra Leone and Togo. The 2009 HCC report only included Benin, Togo, Ghana, Mali, Liberia and Cote d'Ivoire in the list of

[15] ONS Population of the United Kingdom by Country of Birth and Nationality underlying datasheets, 2008 http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-405714 Accessed 10/11/2015

[16] ONS Population of the United Kingdom by Country of Birth and Nationality underlying datasheets, January 2014 to December 2014 http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-376534 Accessed 10/11/2015

[17] ONS 2011 Census: QS203UK Country of birth, local authorities in the United Kingdom http://www.ons.gov.uk/ons/rel/census/2011-census/key-statistics-and-quick-statistics-for-local-authorities-in-the-united-kingdom---part-1/rft-qs203uk.xls Accessed 10/11/2015

[18] ONS2011 Census: QS214EW National identity (detailed), local authorities in England and Wales http://www.ons.gov.uk/ons/rel/census/2011-census/quick-statistics-for-england-and-wales-on-national-identity--passports-held-and-country-of-birth/rft---qs214ew.xls Accessed 10/11/2015

[19] UN Composition of macro geographical (continental) regions, geographical sub-regions, and selected economic and other groupings http://millenniumindicators.un.org/unsd/methods/m49/m49regin.htm#africa Accessed 10/11/2015

countries where it was a culinary custom for skin-on sheep and goat meat to be prepared/ consumed (research at that time indicated that it was not a culinary custom for individuals from Guinea-Bissau; Guinea; Burkina Faso; Senegal; Sierra Leone; and other African nations not listed as well as Afro-Caribbean's to eat 'skin-on goat/ sheep meat'). In the ONS reports on Population by Country of Birth and Nationality there was no information allowing us to compare all these countries between 2008 and 2014. Consequently, in the comparison are included those countries where information is available for both years (Table 6.1). These include: The Gambia, Ghana, Ivory Coast, Nigeria and Togo. More detailed information is available through the ONS data files listed as original references.

The overall estimated increase in West Africa born population between 2008 and 2014 is 133,000 (85.26%).

According to the 2011 Census 412,553 UK residents were born in West and Central African countries of which 201,184 were born in Nigeria. There is no detailed information about the remaining West African countries. Of the above 397,068/191,183 respectively live in England and Wales. Census information on identity indicates that 222,252 residents in England and Wales consider their identity as West or Central African of which 41,195 are Ghanaian and 93,506 Nigerian. The ONS information does not allow the cross-reference the two datasets and those identifying themselves as having West/Central African identity may include people that were not born in these countries. Table 6.2 summarises the above figures.

Table 6.2: 2011 Census information regarding country of birth and national identity for West/Central Africa

Country	Born		National Identity		
	West/Central Africa	Nigeria	West/ Central Africa	Nigeria	Ghana
UK	412,553	201,184			
England and Wales	397,068	191,183	222,252	93,506	41,195

6.3.2 Calculation of demand

According to information from DEFRA Slaughter statistics[20] 1,805,300 ewes and rams were slaughtered in 2014. The same data were used to calculate the average weight of adult sheep carcasses between 1987 and 2014 at 20kg/head based on a 75% conversion of carcass to meat cuts.

[20] DEFRA, UK home-killed livestock slaughterings and dressed carcase weights – monthly dataset, https://www.gov.uk/government/statistics/cattle-sheep-and-pig-slaughter Accessed 12/01/2016

Using one of the methods ("Method 3: Estimate the number of individual consumers"[21]) used for the preparation of the 2009 HCC report and assuming a 50% and 75% reversion from mutton to skin-on sheep meat the projected consumption based on the above population figures were calculated. Table 6.3 summarises the calculations. For the purposes of the comparison between 2008 and 2014 the estimates of the APS were used.

With a 50% reversion to skin-on sheep meat and based on an estimated population for 2014 of 289,000 (+/-43,000) consumers, the consumption of skin-on sheep meat is calculated at 1,083.8 (+/-161.3) tons and corresponds to 40,139 (+/-5,972) carcasses. This represents 2.22% (+/-0.33%) of the ewe and ram carcasses slaughtered in 2014.

With a 75% reversion to skin-on sheep meat the consumption of skin-on sheep meat is calculated at 1,618,4 (+/-240.8) tons and corresponds to 59,941 (+/-8,919) carcasses. This represents 3.32% (+/-0.49%) of the ewe and ram carcasses slaughtered in 2014.

This represents an increase of 85.26% compared to 2008 but differs in absolute numbers with the calculations in the 2009 HCC report which were predicting 70,000 carcasses for a 50% reversion and 100,000 carcasses for a 75% reversion. These differences are caused by the different consumer population numbers as the 2009 report calculations are based on earlier ONS data available at the time the report was prepared. In addition, in the 2009 report the carcass weight was calculated for welsh ewes at 18.1kg while for this report an average of 27kg was used based on the national average weight for adult sheep. The same (75%) carcass to meat conversion rate was used for both reports. Regardless of the difference in the calculations of the number of carcasses the data presented here can be used to identify the relative increase in population and subsequent skin-on sheep meat consumption.

Table 6.3: Quantities of skin-on sheep meat consumption and carcasses based on the ONS estimates of the Population by Country of Birth and Nationality report

Country	Population	Meat weight at 50% reversion	No of carcasses	Meat weight at 75% reversion	No of carcasses
West African population estimate					
2008	156 (+/- 29)	585 (+/- 108.8)	29.3 (+/- 5.4)	873.6 (+/- 162.4)	43.7 (+/- 8.1)
2014	289 (+/- 43)	1,083.8 (+/- 161.3)	54.2 (+/- 8.1)	1,618.4 (+/- 240.8)	80.9 (+/- 12.4)

Numbers in thousands and rounded to the closest hundred
Upper and lower limits can be calculated using the numbers in brackets and are based on the population 95% CIs

[21] In the HCC report it was estimated that 155,000 to 240,000 West Africa-born people living in the UK in 2008 were from West African 'skin-on goat/ sheep meat' eating countries. The report used a base consumption of 7.5kg of sheep meat per capita and assumed two options: one where consumers would revert by 50% (3.75kg) to consumption of skin-on sheep meat and one of 75% (5.6kg) reversion.

Census information, as opposed to the estimates used for the above comparisons, provides additional insight in the possible consumption. Two different population measures are being presented: the UK population of those born in West/Central African countries with specific reference to Nigeria and Ghana and the UK population of those identifying themselves as having West/Central African (Nigerian/Ghanaian) identity. Table 6.4 presents the calculations based on the 2011 census data. The census data do not include the details for the remaining West African countries that have a tradition in the consumption of skin-on sheep meat and do not include the growth in population since 2011. In addition, the ONS data do not include short term non-UK born residents (3 to 12 months) or, naturally, non-documented residents. As a result, it is probably an underestimation of the possible total consumption and proportion of the national throughput.

Table 6.4: Quantities of skin-on sheep meat consumption and carcasses based on the 2011 Census

Country	Population	Meat weight 50% reversion	No of carcasses	Meat weight 75% reversion	No of carcasses
2011 Census data on country of birth					
UK West/Central African born population	412,553	1,547,074	77,354	2,310,297	115,515
UK Nigeria born population	201,184	754,440	37,722	1,126,630	56,332
E&W West/Central African born population	397,068	1,489,005	74,450	2,223,581	111,179
E&W Nigeria born population	191,183	716,936	35,847	1,070,625	53,531
2011 Census data on identity					
E&W West/Central African identity	222,252	833,445	41,672	1,244,611	62,231
E&W Nigeria identity	93,506	350,648	17,532	523,634	26,182
E&W Ghana identity	41,195	154,481	7,724	230,692	11,535

6.4 Changes in legislation

There have been no major changes in legislation, since 2008, affecting directly the requirements of the skin-on sheep meat production. There have been changes in TSE controls[22], which remain under review[23]. New Welfare at slaughter legislation[24],[25],[26] was

[22]The Transmissible Spongiform Encephalopathies (England) Regulations 2010 SI. 801/2010

introduced to comply with EU legislation[27] General food law saw the addition of The Food Safety and Hygiene (England) Regulations 2013[28].

More significant for regulatory controls are the anticipated further changes in official controls as a result of the revision of both general food law[29] and more specifically the changes in meat inspection. Though such changes do not impact yet on sheep inspection requirements, any further research or application for the legalisation of the skin-on sheep meat production process would need to take into account their possible effect both in the public health, animal health and animal welfare aspects of the production process and the regulatory burden. For example, skin-on sheep meat production, if approved or on achieving a derogation, would remain at an exploratory level since practical application will ultimately provide the evidence for its merits. As such it would possibly be unlikely to benefit, at least at the early stages, form reduced inspection rates.

An additional aspect, though still related to the review of general food law, is the further emphasis given to the enforcement of legal provisions, particularly in relation to food fraud and food related crime. The illegal production of skin on sheep meat has not achieved the level of prominence of the horse meat scandal but has had its ten minutes of fame, with successful prosecutions and media exposure. The Elliot review[30] has led to a series of initiatives for better organisation, coordination and transparency of food related enforcement including new guidance on food law[31]. A legalised and regulated production of skin-on sheep meat is anticipated to help towards a reduction in illegal trade.

6.5 Conclusions

There is an increase in the number of potential consumers of skin-on sheep meat of 85% between 2008 and 2014. Further research on the public health hazards, as identified in the current report can inform a new submission to EFSA and facilitate the legalisation process at a time when a drive exists for risk based statutory meat controls.

[23] Scientific Opinion on BSE/TSE infectivity in small ruminant tissues, EFSA Journal 2010;8(12):1875, Accessed 11/11/2015 http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/1875.pdf
[24] The Welfare of Animals at the Time of Killing (England) Regulations 2015, SI. 1782/2015
[25] The Welfare of Animals at the Time of Killing (Scotland) Regulations 2012 (As Amended) SI.321/2012
[26] The Welfare of Animals at the Time of Killing (Wales) Regulations 2014 (As amended) SI. 951(W92)/2014
[27] Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing
[28] The Food Safety and Hygiene (England) Regulations 2013, SI2996/2013
[29] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 2013, COM(2013) 265 final
[30] Elliott Review into the Integrity and Assurance of Food Supply Networks – Final, July 2014, Accessed 11/11/2015 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/350726/elliot-review-final-report-july2014.pdf
[31] Food Law Practice Guidance (England) (Issued October 2015) Accessed 11/11/2015 http://www.food.gov.uk/sites/default/files/Food%20Law%20Practice%20Guidance%20October%202015%20-%20FINAL%20.pdf

7 Conclusions and recommendations

7.1 Conclusions

- Systematic review of the FSA commissioned studies on smoked, skin-on sheep meat found that the evidence gathered from these studies were incomplete in respect of the microbiological and chemical safety of smoked, skin-on sheep meat and did not explore comparison to conventionally produced skin-off carcasses.
- Furthermore, there is not sufficient evidence in the available literature sources to conclude that smoked, skin-on sheep/goat/cattle meat poses a greater or lower risk to consumers when compared to conventionally produced skin-off carcasses.
- Systematic review also outlined gaps in current knowledge about this product that need to be addressed in further research: (i) the effect of the smoked, skin-on process on public health hazards; (ii) on the microbiological profile of smoked, skin-on sheep meat, and (iii) the effect of the smoked, skin-on production and changes in the dressing process of the carcass on official controls.
- The evidence gathered, and the production protocol developed, in the FSA studies provide a solid basis for further development of the process for safe production of smoked, skin-on meat.
- Critical review included all relevant aspects for delivering a safe and hygienic process for the production of smoked, skin-on sheep meat, including the identification of relevant public health hazards associated with this production, possible effects that this process could have on these hazards and also possible implications on official controls and animal welfare.
- Four bacterial hazards relevant for consideration for assessment of the safety of smoked, skin-on sheep meat were identified: *Bacillus cereus*, *Clostridium perfringens*, pathogenic verocytotoxin-producing *Escherichia coli* (VTEC) and *Salmonella* spp.
- The primary chemical hazards that may be formed during the production of skin-on sheep meat are dioxins, PAHs and heterocyclic aromatic amines. Also the list of veterinary medicines currently authorised in the UK for use in sheep and considered as most likely to represent an increased hazard for skin-on sheep meat production due to the risk of, and lack of data regarding, skin residues was provided.
- Sourcing of animals, shearing, singeing, high pressure water washing, toasting and chilling appear to be the steps that could have significant effect on public health hazards, by decreasing or increasing their number (biological hazards) and presence/quantities (chemical hazards).
- A range of relevant pathological conditions in smoked, skin-on sheep carcasses were reviewed and discussed. The change in sheep carcass dressing process will inevitably

affect official control procedures that will need to be evaluated and amended, on public health, animal health and welfare grounds.

- Some other alternative production methods for smoked, skin-on sheep meat, to the one proposed could also be investigated. These could be used to create a smoked flavour under controlled conditions with a temperature assured to be below 500^{o}C (to minimise formation of toxic contaminants), and/or facilitate standard post-mortem carcass inspection. Production of smoked skin separately from carcass meat and sheep wool removal by scalding and dehairing prior to singeing are some options that merit further attention.
- The survey of food business operators (FBOs) indicates that 50% of the responders are inclined to undertake the process, particularly those who have an established client base within the community that traditionally consume this type of product. Also, their interest is driven by business considerations supported by interest from existing clients and the prospect of new markets (including exports).
- There is an increase in the number of potential consumers of skin-on sheep meat of 85% between 2008 and 2014. The proportion of carcasses that may be used for skin-on sheep meat production ranges between 1.89 and 3.81% of the UK adult sheep slaughtered in 2014.

7.2 Recommendations

On the basis of the work undertaken during this study, the options for delivering a safe and hygienic production of smoked, skin-on sheep meat have been identified and following recommendations on areas that merit further research suggested.

7.2.1 Recommendations on biological hazards

1. An assessment of individual steps in the production of smoked, skin-on sheep meat on their effect on four identified important biological hazards (VTEC, *Salmonella* spp., *Bacillus cereus* and *Clostridium perfringens*) should be performed taking into account different variables.

2. Microbiological methods, including those for sampling and laboratory investigation, aimed to be used for trials in this specific smoked, skin-on sheep meat production, should be validated in experimental conditions prior to use.

3. The effects of the process on microbiological safety of derived carcasses should be evaluated both in low and high production speed settings, under varied conditions.

4. Based on this assessment, clear production protocols should be developed based on HACCP principles, with indication of critical control points, clear set limits, monitoring procedures and corrective actions.

7.2.2 Recommendations on chemical hazards

5. Establish the uniformity of formation and presence of PAHs over the treated carcasses and between carcasses, and to ensure that quantities of PAH present are always within regulatory limits.

6. Establish whether or not dioxins can be formed in the production of smoked, skin-on sheep meat, and if so, the uniformity of formation and presence of dioxins over the treated carcasses and between carcasses, and to ensure that quantities of dioxins present comply with regulatory limits.

7. Because heterocyclic amines can be generated under conditions that may occur during the production of smoked, skin-on sheep meat, analyses for these compounds should be undertaken to give an indication of their potential formation.

8. An assessment of the levels of chemical residues in sheep skin following treatment with pharmaceutical products (especially, ‘pour-on’ products) should be performed along with the evaluation of the effect of smoked, skin-on production process on these residues at the time of authorised withhold and slaughter.

7.2.3 Recommendations on official controls

9. It is important to evaluate the information that should be included in the FCI given both the nature of the process and that of the source of animal supply.

10. Ante-mortem inspection requirements and associated facilities should be examined in the light of the changes in the post mortem inspection and the risk assessment of the process.

11. Both research and practical application should be used for the evaluation of operational/structural requirements as part of a risk assessment for the development of SOPs and HACCP.

12. Animal welfare implications should be taken into account when developing SOPs for smoked, skin-on meat production.

13. The effects of the process on meat inspection practices and protocols should be evaluated both in low and high production speed settings.

14. The labelling, packaging, legal characterisation and health marking requirements should be investigated.

15. The effect of the process on the application and validity of official controls for TSEs, drug residues should be evaluated;

16. If smoked, skin of sheep meat were to become legal, skin and finished product may need to be added to surveillance sampling frames including all carcasses and not just those designated to be used for this type of food production;

17. Products should be tested to ensure compliance with regulations for dioxins and PAHs.

18. In order to minimise occupational health and safety risks for the staff involved in the production of smoked, skin-on sheep meat, FBOs will need to comply with all related procedures.

19. If skin is designated as an edible part of a sheep carcass it may be added to the list of sites for which residues information are required to support applications for Marketing Authorisations of new veterinary products. VMD and EMEA views on this and any requirement for adding sheep skin to the residues surveillance system will be needed.

8 Further research requirements identified

The results of this report, together with the scientific opinion of EFSA regarding studies conducted on behalf of the FSA (EFSA, 2011a, 2012) have highlighted areas of research that need to be addressed before making a case to legalise the production of smoked, skin-on sheep meat in the UK and EU. Broadly speaking, the necessary studies can be categorised as follows:

1. Evaluation of laboratory techniques and development of standard operating procedures to enable the microbiological safety of skin-on sheep meat to be routinely assessed

1.1 Validation of microbiological methods

As described later, evaluating the microbiological impacts and implications of the skin-on sheep meat production process will require seeding pelts and carcasses with a known cocktail of specific pathogens and the subsequent enumeration of sampled bacteria. As a result, it will be necessary to develop and validate: standard culture procedures to produce bacterial suspensions containing known numbers of bacteria; a standard method to inoculate fleeces with a known number of bacteria per area; an optimised process to enable re-isolation of bacteria from fleeces using swabbing and/or excision methods; and the culture, identification and enumeration of isolated bacteria (recommendation 2).

1.2 Effect of combustion products on microbiological culture techniques

EFSA suggested that the effects of combustion products (produced during the singeing and toasting of the fleece/skin) on the ability to culture pathogens and indicators of hygiene had not been evaluated and, therefore, studies were required to explicit assess the effects of combustion products on laboratory-based culture methods.

The effect of combustion products on bacterial culture could be assessed in the laboratory. Pelts would be obtained from a licenced abattoir and would be divided into sample areas. The areas would have the wool removed either mechanically, without the use of singeing (controls) or using singeing at various temperatures to generate potential toxic combustion products. Then, each sample site would be seeded with a known bacterial cocktail. The sites would be sampled and the number of bacteria isolated from singed samples would be compared with bacteria isolated from unsinged controls. Any differences would not be due to heat but would be due to the consequences of heating such as the presence of combustion products or changes in the skin structure due to heating (recommendation 2).

1.3 Identifying the most appropriate sampling sites for microbiological and toxicological sampling

The use of hand-held burners or a specifically designed “burner rig” are unlikely to heat the surface of the carcass evenly all over. Instead, it is likely that ‘hot’ and ‘cold’ spots may occur and, as a result, ‘cold’ sites may be more likely to harbour potential pathogens. Consequently, it is likely that the sites currently used for microbiological testing of conventional, skin-off sheep meat will not be the most appropriate sampling sites for future skin-on sheep products based on the temperatures achieved during the singeing and toasting processes. It will, therefore, be necessary to determine whether there are any ‘typical’ patterns of hot and cold areas following singeing and toasting. In order to reduce unpredictable variation due to the use of hand-held burners, it would be preferable to use a specially-designed burner rig. The identification of ‘hot’ and ‘cold’ spots would likely represent the areas most likely to have increased toxic compounds and most likely to harbour potential pathogens, respectively. Therefore, the identification of such sites would allow the development of standard operating procedures for microbiological and toxicological sampling of skin-on sheep meat (recommendations 2 and 4).

2. Toxicological potential of singeing and toasting processes

2.1 Monitoring toxic combustion products on skin-on sheep carcasses

The burning of wool during the singeing and toasting phases is associated with the production of potential toxic chemicals. EFSA concluded that studies conducted on behalf of the FSA did not address the complete range of important compounds, had only a small sample size and sampled carcasses prepared at a single abattoir. Nevertheless, these preliminary studies provide extremely valuable pilot data (included mean values and variability) that can be used to design more detailed studies.

In order to provide data that can be extrapolated to a wider population, samples should be collected from a range of abattoirs, each implementing a typical process to produce skin-on sheep meat. For each carcass, replicated samples should be collected from a range of pre-defined sites, especially any areas commonly identified as reaching very high temperatures as determined in chapter 1.3 above. Samples should be normalized concerning skin to muscle meat ratio and tested for a range of compounds including PAH, dioxins and heterocyclic amines (recommendations 5, 6, 7 and 17).

- It is important to establish the uniformity of formation and presence of PAHs over the treated carcasses and between carcasses, and to ensure that quantities of PAH present are always within regulatory limits.

- It is important to establish whether or not dioxins can be formed in the production of skin-on sheep meat, and if so, the uniformity of formation and presence of dioxins over the treated carcasses and between carcasses, and to ensure that quantities of dioxins present comply with regulatory limits.
- Because heterocyclic amines can be generated under conditions that may occur during the production of skin-on sheep meat, analyses for these compounds would be useful at least to give an indication of their potential formation.

2.2 Assessing the levels of chemical residues in sheep skin following treatment with pharmaceutical products (especially, 'pour-on' products)

Monitoring concentration of skin residues of pharmaceutical products

A large number of pour-on products are authorised for use in sheep and these have been discuss in previous sections of this report. Each product has meat and milk withdrawal periods and these are different for each product. However, to date, the production of skin-on sheep meat has been illegal and, as a result, pharmaceutical products (especially, pour-on products) have not required a skin withdrawal period. Consequently, the concentration of drug residues in the skin of sheep at various times after application is unknown. Studies should be designed to determine how residues reduce over time, taking into account age, breed, fleece characteristics and season. In parallel with the experimental examination pharmacokinetic/pharmacodynamic modelling to predict skin concentration may also be applied where there is available data (recommendations 8 and 19).

Example study design

Several study designs could be implemented to answer these questions with the exact design being heavily influenced by available resources. An example of a potential study design is illustrated below:

- Sheep are purchased and kept on pasture at field station.
- After a suitable period of acclimatization, animals are treated with a pour-on pharmaceutical product in accordance with manufacturer's instructions.
- After various time points appropriate to the meat withhold period and other published data, animals are culled and skin samples collected post-mortem to evaluate drug residues.

- Laboratory assessment conducted using EMA approved techniques for marker residues of each compound.

- The process should be repeated at different times of year to evaluate seasonal and climatic affects.

Advantages

- Animals can be purchased and treated as part of a flock that could be maintained at a farm facility.

- Each data point would be considered as an independent data point and would not be influenced or affected by other samples. Induced changes resulting from inflammation associated with repeat biopsy sampling would be avoided.

- Sample size calculations are straightforward.

Disadvantages

- Samples could only be taken from each animal at a single time point. This would mean that longitudinal changes within individual animals could not be determined. Each animal could not act as its own control and, as a result, variation at each time point would be greater, thereby necessitating larger sample sizes.

- Larger sample sizes would require increased resources to purchase and maintain the animals.

Sample size calculations

- The sample size required to estimate a population mean is given by:

$$n = \frac{\left(z_{\alpha/2}\right)^2 \sigma^2}{E^2}$$

Where: n = required sample size

$z_{\alpha/2}$ = desired percentile of standard normal distribution

σ = standard deviation

E = margin of error

- So, for example, if the standard deviation of a drug residue on carcasses is estimated to be 20ng/cm^2, then a sample size of 62 would be required to estimate the mean value with a 5ng/cm^2 margin of error at 95% confidence level[32].

The compatibility of the protocols for calculation of resides and withhold limits adapted for skin residues with approved EMA requirements should also be established[33].

3. Microbiology and risk based official controls

3.1 EFSA Requirements

In response to studies conducted on behalf of FSA to characterise the microbiological safety of skin-on sheep meat, EFSA identified some weaknesses and highlighted some issues that should be addressed in future studies. The primary issues that EFSA recommended that future studies should address were:

i. The studies conducted on behalf of the FSA used total viable counts (TVC) and *Enterobacteriaceae* as indicators of carcass hygiene. However, EFSA recognised that a much wider range of organisms and potential pathogens (including spore-forming pathogens) would likely be present on fleeces and the effects of each stage of the process on these organisms should be evaluated. It is proposed that future studies should – in addition to *Enterobacteriaceae* and TVC – evaluate the impact of processing on two non-spore-forming pathogens (verocytotoxin-producing *Escherichia coli* (VTEC) and *Salmonella enterica subsp. enterica* serotypes) and two spore-forming pathogens (*Bacillus cereus* and *Clostridium perfringens* (type A)). Justification for use of these four bacterial species is given elsewhere (See section 4.4.1).

ii. The individual processes involved in the production of skin-on sheep meat – namely shearing, singeing, washing and toasting – are likely to have different effects on the microbiological contamination of carcasses. It is possible, for example that singeing and toasting reduce contamination due to the heat being involved, whilst shearing and washing may increase the bacterial burden. EFSA proposed that the effects of each process should be evaluated.

[32] Sampling of a population mean, http://www.r-tutor.com/elementary-statistics/interval-estimation/sampling-size-population-mean, Accessed 12/11/2015

[33] VICH GL54: Studies to evaluate the safety of residues of 5 veterinary drugs in human food: General approach to 6 establish an acute reference dose (ARfD), Accessed 12/11/2015, http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2015/03/WC500184530.pdf

iii. For each microbiological measure, it is important to compare the results of the skin-on process with the results in conventional skin-off controls.

iv. Samples should be collected from multiple sites on each carcass because it is likely that there is variation in the temperatures attained at different anatomical sites (as described in chapter 1.3 above).

v. The studies conducted on behalf of the FSA used small samples sizes collected from a single abattoir. This was considered to represent a 'best-case scenario' but did not represent the variation that would likely be seen in multiple sites. It was recognised, therefore, that samples should be collected from a range of abattoirs to simulate real-world variability in distribution of potential organisms on skin-on sheep products.

vi. It is likely that bacterial contamination is related to climate, season, geography, transport, holding conditions and production system. The effects of these variables on microbiological safety of carcasses should be evaluated.

There are several research approaches that could be used to address the specific issues identified by EFSA. It is proposed that these issues are addressed using a combination of laboratory-based and abattoir-based studies.

<u>3.1.1 Laboratory-based analysis using pelts to evaluate the effects of fleece type, cleanliness, shorn length and scorching at various temperatures and duration on isolation of bacterial spp.</u> (recommendations 1 and 4)

- Pelts of high and low grades would be collected from a licenced abattoir and graded as clean or dirty.
- Pelts would be shorn to 3 mm or 10 mm.
- Areas of each pelt would be randomly allocated to specific heat treatments.
- Pelts would be inoculated with a bacterial cocktail containing VTEC, *Salmonella*, *Bacillus cereus* and *Clostridium perfringens*.
- Sample areas would be scorched with a blow-torch to various specified temperatures, distances and durations.
- Areas would be sampled using excision and swabbing methods and previously-evaluated culture techniques would be used to isolate inoculated organisms.

3.1.2 The effects of each stage of the smoked, skin-on sheep meat production process – singeing, washing and toasting – on the isolation of specific pathogen bacterial species (recommendations 1 and 4)

- This experiment would need to be run at an experimental abattoir (rather than a commercial abattoir) because the fleeces will be seeded with a bacterial cocktail containing high numbers of specific pathogens. The experimental abattoir will have a burner rig installed to standardise the singeing and toasting processes. The stunning, slaughter and skin-on sheep meat processing will be carried out by experienced slaughtermen using standardised method developed by the University of Bristol.
- Cull ewes will be purchased and shorn to a length determined as desirable in the previous experiment.
- The shorn fleeces will be seeded with a bacterial culture (see previously) in typical 'hot' and 'cold' spots (as identified previously) and areas used for routine sampling in traditional skin-off sheep production. These areas will form the sampling sites for this experiment.
- Sheep will be processed and, after each stage, excision samples will be collected from each of the labelled sample areas.
- Quantitative microbiological methods (as validated previously) will be employed to determine the impact of each stage of the process on bacterial burden of the carcasses.

Sample size calculation

The number of organisms present at a specific anatomical sampling site on carcasses is likely to be log-normally distributed with a standard deviation of 0.5 $\log_{10}$ organisms.

The sample size required to identify a difference of 0.5 $\log_{10}$ bacteria before and after treatment (i.e. paired samples) with = 0.05% and 80% power was calculated using pwr.t.test function in R.

The effect size (required for the sample size calculation) was calculated as Cohen's *d* using the formula:

$$d = \frac{\text{Difference between means}}{\text{Pooled SD}} = \frac{\left(\bar{X}_1 - \bar{X}_2\right)}{\sqrt{\left(\frac{SD_1^2 + SD_2^2}{2}\right)}} = \frac{0.5}{0.5} = 1$$

The required sample size is 10.

3.1.3 Real-world observations studies to compare skin-on with traditional skin-off sheep meat production and to provide preliminary evaluation of the variation between different abattoirs carrying out the same defined procedures and the effect of the new process in the official control requirements (recommendations 4 and 13)

- In order to compare the microbiological safety of skin-on sheep meet with traditional skin-on sheep production, it is proposed that several small commercial abattoirs who have indicated a desire to pursue production of skin-on sheep meat (see results of questionnaire) are recruited to the study.
- In order to participate in the study, abattoirs will require permission from Government to produce skin-on sheep meat in a licenced abattoir.
- Cull ewes will be purchased and randomly allocated to either skin-on or skin-off treatment groups.
- Animals will be slaughtered in the usual manner and processed in accordance with either the traditional skin-off method currently performed routinely, or the skin-on method described by the University of Bristol, using a specially designed burner rig for singeing and toasting.
- Samples will be taken from hot and cold spots (as identified previously) and from sites routinely used for routine hygiene assessment.
- Samples will be cultured as validated previously. *Enterobacteriaceae* and TVC will be the main indicators of whether carcasses have been produced hygienically.
- As these animals will NOT be seeded with a bacterial cocktail, it is likely that specific pathogens will only be identified on a very small number of carcasses. Consequently, very large sample sizes would be required to identify differences in the presence of specific pathogens.
- The information collected during the previous studies will provide the basis for the risk assessment and the development of the SOPs for plant operations, inspection processes and the HACCP. Their application will be assessed and verified as part of these studies.
- This approach will enable skin-on and skin-off procedures to be compared.
- This experimental design could be conducted at different times of year, in different weather conditions, etc. to assess the effects of season, climate and other variables.

9 References

Akwetey, W. Y., Eremong, D. C., & Donkoh, A. (2013). Chemical and Nutrient Composition of Cattle Hide (“Welle”) Using Different Processing Methods. *Journal of Animal Science Advances, 3*(4), 176-180.

Almeida, A. M., Plowman, J. E., Harland, D. P., Thomas, A., Kilminster, T., Scanlon, T., Milton, J., Greeff, J., Oldham, C., & Clerens, S. (2014). Influence of feed restriction on the wool proteome: a combined iTRAQ and fiber structural study. *Journal of Proteomics, 103*, 170-177.

Alonso, S., Dadios, N., Gregory, N., Stärk, K. D. C., Nigsch, A., & Blagojevic, B. (2011). Outcomes and Value of Current Ante and Post-Mortem Meat Inspection Tasks Including Green Offal Inspection Activities: Project MC1003 report. Food Standards Agency, London, UK.

Amfo-Otu, R., Agyenim, J. B., & Adzraku, S. (2014). Meat contamination through singeing with scrap tyres in Akropong-Akuapem abattoir, Ghana. *Applied Research Journal, 1*(1), 12-19.

Angell, J. W., Clegg, S. R., Sullivan, L. E., Duncan, J. S., Grove-White, D. H., Carter, S. D., & Evans, N. J. (2015). In vitro susceptibility of contagious ovine digital dermatitis associated *Treponema* spp. isolates to antimicrobial agents in the UK. *Veterinary Dermatology, 26*(6), 484-e115.

Anon. (2001). Research to improve the processing efficiency of skin on goat meat.Submitted by Norvic Food Processing Pty Ltd & DNRE Victoria: MLA Project PSHIP.051B report. Meat & Livestock Australia.

Anon. (2009). A detailed study of the prevalence of veterinary medicine residues (e.g. parasiticides) in “skin-on” sheep feet: Project M01048 report. Food Standards Agency, London, UK.

Anon. (2010). Report on research into the production of smoked skin-on sheep meat (Vol. 10/01/04): Food Standards Agency, London, UK.

Anon. (2011). Automated “Skin-on” goat meat processing. Submitted by Norvic Food Processing PTY LTD & DPI Victoria: MLA Project P.PIP.0065 report. Meat & Livestock Australia.

Antic, D., Blagojevic, B., & Buncic, S. (2011). Treatment of cattle hides with Shellac solution to reduce hide-to-beef microbial transfer. *Meat science, 88*(3), 498-502.

Antic, D., Blagojevic, B., Ducic, M., Mitrovic, R., Nastasijevic, I., & Buncic, S. (2010). Treatment of cattle hides with Shellac-in-ethanol solution to reduce bacterial transferability – A preliminary study. *Meat Science, 85*, 77-81.

Antic, D., Blagojevic, B., Ducic, M., Nastasijevic, I., Mitrovic, R., & Buncic, S. (2010). Distribution of microflora on cattle hides and its transmission to meat via direct contact. *Food control, 21*(7), 1025-1029.

Antoniollo, P. C., Bandeira, F. D. S., Jantzen, M. M., Duval, E. H., & Silva, W. P. D. (2003). Prevalence of *Listeria* spp. in Feces and Carcasses at a Lamb Packing Plant in Brazil. *Journal of Food Protection, 66*(2), 328-330.

Arthur, T. M., Bosilevac, J. M., Brichta-Harhay, D. M., Kalchayanand, N., King, D. A., Shackelford, S. D., Wheeler, T. L., & Koohmaraie, M. (2008). Source tracking of *Escherichia coli* O157:H7 and *Salmonella* contamination in the lairage environment at commercial US beef processing plants and identification of an effective intervention. *Journal of Food Protection, 71*, 1752-1760.

Augustsson, K., Skog, K., Jägerstad, M., & Steineck, G. (1997). Assessment of the human exposure to heterocyclic amines. *Carcinogenesis, 18*(10), 1931-1935.

Awosanya, A. E. J., & Cole, B. O. (2011). Comparative assessment of lead and cadmium contaminants in singed hides, skin and muscle from cattle and goats in Nigeria. *Tropical Veterinarian, 29*(2), 41-48.

Bacon, R., & Sofos, J. (2005). Physical decontamination strategies for meat. In J. Sofos (Ed.), *Improving the safety of fresh meat* (pp. 318-349): Woodhead Publishing Ltd, Cambridge, England.

Baird, G. J., & Fontaine, M. C. (2007). *Corynebacterium pseudotuberculosis* and its Role in Ovine Caseous Lymphadenitis. *Journal of Comparative Pathology, 137*(4), 179-210.

Bates, P. (2006). An assessment of the available information regarding the consumption of “skin-on” sheep meat treated with veterinary medicines: Project ZM0112 report. Food Standards Agency, London, UK.

Bates, P. (2007). Sheep nasal bot fly and differential diagnosis of bluetongue. *The Veterinary Record, 160*(19), 671-671.

Bettridge, J., Renard, M., Zhao, F., Bown, K. J., & Birtles, R. J. (2013). Distribution of Borrelia burgdorferi sensu lato in Ixodes ricinus populations across central Britain. *Vector Borne Zoonotic Diseases, 13*(3), 139-146.

Bhandare, S. G., Paturkar, A. M., Waskar, V. S., & Zende, R. J. (2010). Prevalence of microorganisms of hygienic interest in an organized abattoir in Mumbai, India. *Journal of Infection in Developing Countries, 4*(7), 454-458.

Biet, F., Boschiroli, M. L., Thorel, M. F., & Guilloteau, L. A. (2005). Zoonotic aspects of *Mycobacterium bovis* and *Mycobacterium avium*-intracellulare complex (MAC). *Veterinary Research, 36*(3), 411-436.

Bilei, S., Rodas, E. M. F., Tolli, R., De Santis, P., Di Domenico, I., Del Frate, S., Palmieri, P., & Condoleo, R. (2012). Prevalence of major pathogens on sheep carcasses slaughtered in Italy. *Italian Journal of Food Science, 24*(1), 9-18.

Biss, M., & Hathaway, S. (1996). Effect of pre-slaughter washing of lambs on the microbiological and visible contamination of the carcases. *The Veterinary Record, 138*(4), 82-86.

Biss, M. E., & Hathaway, S. C. (1995). Microbiological and visible contamination of lamb carcasses according to preslaughter presentation status: implications for HACCP. *Journal of Food Protection, 58*(7), 776-783.

Blagojevic, B., Antic, D., Ducic, M., & Buncic, S. (2011). Ratio between carcass-and skin-microflora as an abattoir process hygiene indicator. *Food Control, 22*(2), 186-190.

Blagojevic, B., Antic, D., Ducic, M., & Buncic, S. (2012). Visual cleanliness scores of cattle at slaughter and microbial loads on the hides and the carcases. *The Veterinary record, 170*(22), 563-563.

Boer, E. d., Zwartkruis-Nahuis, J. T. M., Wit, B., Huijsdens, X. W., Neeling, A. J. d., Bosch, T., Oosterom, R. A. A. v., Vila, A., & Heuvelink, A. E. (2009). Prevalence of methicillin-resistant *Staphylococcus aureus* in meat. *International Journal of Food Microbiology, 134*(1/2), 52-56.

Bolton, D., Pearce, R., Sheridan, J., Blair, I., McDowell, D., & Harrington, D. (2002). Washing and chilling as critical control points in pork slaughter hazard analysis and critical control point (HACCP) systems. *Journal of Applied Microbiology, 92*(5), 893-902.

Bonke, R., Wacheck, S., Bumann, C., Thum, C., Stüber, E., König, M., Stephan, R., & Fredriksson-Ahomaa, M. (2012). High prevalence of *Salmonella enterica* subsp. *diarizonae* in tonsils of sheep at slaughter. *Food Research International, 45*, 880-884.

Borch, E., Nesbakken, T., & Christensen, H. (1996). Hazard identification in swine slaughter with respect to foodborne bacteria. *International journal of food microbiology, 30*(1), 9-25.

Bosilevac, J. M., Wheeler, T. L., Rivera-Betancourt, M., Nou, X., Arthur, T. M., Shackelford, S. D., Kent, M. P., Jaroni, D., Rossman, M., & Reagan, J. O. (2004). Protocol for evaluating the efficacy of cetylpyridinium chloride as a beef hide intervention. *Journal of Food Protection, 67*, 303-309.

Brandal, L. T., Sekse, C., Lindstedt, B. A., Sunde, M., Løbersli, I., Urdahl, A. M., & Kapperud, G. (2012). Norwegian sheep are an important reservoir for human-pathogenic *Escherichia coli* O26:H11. *Applied and Environmental Microbiology, 78*(12), 4083-4091.

Buncic, S., & Avery, S. (1998). Effects of cold storage and heat–acid shocks on growth and verotoxin 2 production of *Escherichia coli* O157:H7. *Food microbiology, 15*(3), 319-328.

Burfoot, D., Whyte, R., Tinker, D., Howell, M., Hall, K., Holah, J., Smith, D., White, R., Baker, D., & McIntosh, J. (2006). Importance of airborne contamination during dressing of beef and lamb carcasses. *Journal of Food Protection, 69*(12), 2828-2836.

Byelashov, O. A., & Sofos, J. N. (2009). Strategies for on-line decontamination of carcasses. In F. Todra (Ed.), *Safety of meat and processed meat* (pp. 149-182): Springer, New York, USA.

Byrne, B., Dunne, G., Lyng, J., & Bolton, D. (2007). The development of a 'clean sheep policy'in compliance with the new Hygiene Regulation (EC) 853/2004 (Hygiene 2). *Food microbiology, 24*(3), 301-304.

Byrne, C., Bolton, D., Sheridan, J., McDowell, D., & Blair, I. (2000). The effects of preslaughter washing on the reduction of *Escherichia coli* O157:H7 transfer from cattle hides to carcasses during slaughter. *Letters in Applied Microbiology, 30*(2), 142-145.

Chapman, P., Malo, A. C., Ellin, M., Ashton, R., & Harkin, M. (2001). *Escherichia coli* O157 in cattle and sheep at slaughter, on beef and lamb carcasses and in raw beef and lamb products in South Yorkshire, UK. *International journal of food microbiology, 64*(1), 139-150.

Daskalov, H. (2006). The importance of *Aeromonas hydrophila* in food safety. *Food Control, 17*, 474-483.

Davies, M., Hadley, P., Stosic, P., & Webster, S. (2000). Production factors that influence the hygienic condition of finished beef cattle. *The Veterinary Record, 146*(7), 179-183.

De Smet, S., De Zutter, L., & Houf, K. (2011). Small ruminants as carriers of the emerging foodborne pathogen *Arcobacter* on small and medium farms. *Small Ruminant Research, 97*, 124-129.

Donaghy, M., Prempeh, H., & Macdonald, N. (2006). Outbreak of Q fever in workers at a meat processing plant in Scotland, July 2006. *Euro surveillance: bulletin européen sur les maladies transmissibles, 11*(8), E060824.060822.

Dreyfus, A., Benschop, J., Collins-Emerson, J., Wilson, P., Baker, M. G., & Heuer, C. (2014). Sero-prevalence and risk factors for leptospirosis in abattoir workers in New Zealand. *International Journal Of Environmental Research And Public Health, 11*(2), 1756-1775.

Dubey, J. P. (2009). Review: Toxoplasmosis in sheep—The last 20 years. *Veterinary Parasitology, 163*, 1-14.

Duffy, L., Barlow, R., Fegan, N., & Vanderlinde, P. (2009). Prevalence and serotypes of *Salmonella* associated with goats at two Australian abattoirs. *Letters in applied microbiology, 48*(2), 193-197.

Duffy, L. L., Small, A., & Fegan, N. (2010). Concentration and prevalence of *Escherichia coli* O157 and *Salmonella* serotypes in sheep during slaughter at two Australian abattoirs. *Australian Veterinary Journal, 88*(10), 399-404.

Dumètre, A., Ajzenberg, D., Rozette, L., Mercier, A., & Dardé, M. L. (2006). *Toxoplasma gondii* infection in sheep from Haute-Vienne, France: seroprevalence and isolate genotyping by microsatellite analysis. *Veterinary Parasitology, 142*(3/4), 376-379.

EC. (2001). Commission Decision No 471/2001 of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultry meat. *Official Journal of the European Union L, 165/48*.

EC. (2004). Commission regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for on the hygiene of foodstuffs. *Official Journal of the European Union L, 47*, 55-205.

EC. (2005). Commission regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. *Official Journal of the European Union L, 338/26*.

EC. (2010). Commission regulation (EC) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. *Official Journal of the European Union L, 15*(1).

Edrington, T. S., Long, M., Ross, T. T., Thomas, J. D., Callaway, T. R., Anderson, R. C., Craddock, F., Salisbury, M. W., & Nisbet, D. J. (2009). Prevalence and antimicrobial resistance profiles of *Escherichia coli* O157:H7 and *Salmonella* isolated from feedlot lambs. *Journal of Food Protection, 72*(8), 1713-1717.

EFSA. (2004). Opinion of the Scientific Panel on Biological Hazards on the request from the Commission on meat inspection procedures for lambs and goats. *The EFSA Journal, 54*, 1-49.

EFSA. (2005a). Opinion of the Scientific Panel on Biological Hazards on *Bacillus cereus* and other *Bacillus* spp. in foodstuffs. *The EFSA Journal, 175*, 1-48.

EFSA. (2005b). Opinion of the Scientific Panel on Biological Hazards on the request from the Commission related to *Clostridium* spp. in foodstuffs. *The EFSA Journal, 199*, 1-65.

EFSA. (2007). Scientific Opinion of the Panel on Biological Hazards on a request from EFSA on Surveillance and monitoring of *Toxoplasma* in humans, foods and animals. *The EFSA Journal, 583*, 1-64.

EFSA. (2008). Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Polycyclic Aromatic Hydrocarbons in Food. *The EFSA Journal, 724*, 1-114.

EFSA. (2009). Assessment of the Public Health significance of methicillin resistant *Staphylococcus aureus* (MRSA) in animals and foods. *The EFSA Journal, 993*, 1-73.

EFSA. (2010). Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA guidance for those carrying out systematic reviews. *The EFSA Journal, 8*(6), 1637.

EFSA. (2011a). Scientific Opinion on a summary of scientific studies undertaken by the UK Food Standards Agency to support a proposed production method for smoked “skin-on” sheep meat. *The EFSA Journal, 9*(6), 2191.

EFSA. (2011b). Scientific Opinion on the public health risks of bacterial strains producing extended-spectrum β-lactamases and/or AmpC β-lactamases in food and food-producing animals. *The EFSA Journal, 9*(8), 2322-2322.

EFSA. (2012). Clarifications on the interpretation of technical issues about the Scientific Opinion on a summary of scientific studies undertaken by the UK Food Standards Agency (FSA) to support a proposed production method for smoked “skin-on” sheep meat. *The EFSA Journal, 10*(10), 2937.

EFSA. (2013). Scientific opinion on the public health hazards to be covered by inspection of meat from sheep and goats. *The EFSA Journal, 11*(6), 3265-3265.

EFSA, & ECDC. (2015). The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2013. *The EFSA Journal, 13*(1), 3991-3991.

EFSA, & EMA. (2013). Joint Statement of EFSA and EMA on the presence of residues of phenylbutazone in horse meat. *The EFSA Journal, 11*(4), 3190.

Ekenma, K., Anelon, N. J., & Ottah, A. A. (2015). Determination of the presence and concentration of heavy metal in cattle hides singed in Nsukka abattoir. *Journal of Veterinary Medicine and Animal Health, 7*(1), 9-17.

Eltholth, M. M., Marsh, V. R., Van Winden, S., & Guitian, F. J. (2009). Contamination of food products with *Mycobacterium avium paratuberculosis*: a systematic review. *Journal of Applied Microbiology, 107*(4), 1061-1071.

Ersdal, C., Jørgensen, H. J., & Lie, K. I. (2015). Acute and Chronic *Erysipelothrix rhusiopathiae* Infection in Lambs. *Veterinary Pathology, 52*(4), 635-643.

Essumang, D. K., Dodoo, D. K., & Hadzi, G. (2011). Distribution, Levels, and Risk Assessment of Polycyclic Aromatic Hydrocarbons (PAHs) in Singed Cattle Hide. *Human and Ecological Risk Assessment: An International Journal, 17*(5), 1018-1038.

Evans, N. J., Brown, J. M., Hartley, C., Smith, R. F., & Carter, S. D. (2012). Antimicrobial susceptibility testing of bovine digital dermatitis treponemes identifies macrolides for in vivo efficacy testing. *Veterinary Microbiology, 160*(3/4), 496-500.

Fasanella, A., Garofolo, G., Galante, D., Quaranta, V., Palazzo, L., Lista, F., Adone, R., & Jones, M. H. (2010). Severe anthrax outbreaks in Italy in 2004: considerations on factors involved in the spread of infection. *New Microbiologica, 33*, 83-86.

Fisher, A., Wilkin, C.-A., & Purnell, G. (2006). A practical investigation into the hygienic production of 'skin-on' sheep carcasses and cattle and sheep feet.: Project MO1027 report. Food Standards Agency, London, UK.
Fisher, A., Wilkin, C.-A., & Purnell, G. (2007). The production and microbiological status of skin-on sheep carcasses. *Meat Science, 77*(4), 467-473.
Flanagan, L. M., Plowman, J. E., & Bryson, W. G. (2002). The high sulphur proteins of wool: Towards an understanding of sheep breed diversity. *Proteomics, 2*(9), 1240-1246.
Fratamico, P., Gehring, A., Karns, J., & van Kessel, J. (2005). Detecting pathogens in cattle and meat. In J. Sofos (Ed.), *Improving the Safety of Fresh Meat* (pp. 24-55): Woodhead Publishing Ltd, Cambridge, England.
Fredriksson-Ahomaa, M., Stolle, A., & Korkeala, H. (2006). Molecular epidemiology of *Yersinia enterocolitica* infections. *FEMS Immunology And Medical Microbiology, 47*(3), 315-329.
Gale, P., Kelly, L., Mearns, R., Duggan, J., & Snary, E. L. (2015). Q fever through consumption of unpasteurised milk and milk products - a risk profile and exposure assessment. *Journal of Applied Microbiology, 118*(5), 1083-1095.
Garcia, A. B., Steele, W. B., & Taylor, D. J. (2010). Prevalence and carcass contamination with *Campylobacter* in sheep sent for slaughter in Scotland. *Journal of Food Safety, 30*, 237-250.
Georgiev, M., Afonso, A., Neubauer, H., Needham, H., Thiéry, R., Rodolakis, A., Roest, H. J., Stärk, K. D., Stegeman, J. A., Vellema, P., Hoek, W. v. d., & More, S. J. (2013). Q fever in humans and farm animals in four European countries, 1982 to 2010. *Eurosurveillance, 18*(8).
Geser, N., Stephan, R., & Hächler, H. (2012). Occurrence and characteristics of extended-spectrum β-lactamase (ESBL) producing *Enterobacteriaceae* in food producing animals, minced meat and raw milk. *BMC Veterinary Research, 8*(21).
Gherardi, S. G., Johnson, K. G., Monzu, N., & Sutherland, S. S. (1983). Field observations on body strike in sheep affected with dermatophilosis and fleece-rot. *Australian veterinary journal, 60*(1), 27-28.
Gill, C., & Bryant, J. (1993). The presence of *Escherichia coli*, *Salmonella* and *Campylobacter* in pig carcass dehairing equipment. *Food Microbiology, 10*(4), 337-344.
Gill, C., & Sofos, J. (2005). HACCP in the processing of fresh meat. In J. Sofos (Ed.), *Improving the safety of fresh meat* (pp. 630-672): Woodhead Publishing Ltd, Cambridge, England.
Gundogan, N., Citak, S., & Yalcin, E. (2011). Virulence properties of Extended Spectrum beta-Lactamase-producing *Klebsiella* species in meat samples. *Journal of Food Protection, 74*(4), 559-564.
Guran, H. S., Vural, A., & Erkan, M. E. (2014). The prevalence and molecular typing of *Clostridium perfringens* in ground beef and sheep meats. *Journal für Verbraucherschutz und Lebensmittelsicherheit, 9*(2), 121-128.
Hadley, P., Holder, J., & Hinton, M. (1997). Effects of fleece soiling and skinning method on the microbiology of sheep carcases. *The Veterinary Record, 140*(22), 570-574.
Hauge, S. J., Nafstad, O., Røtterud, O.-J., & Nesbakken, T. (2012). The hygienic impact of categorisation of cattle by hide cleanliness in the abattoir. *Food Control, 27*(1), 100-107.
Hill, A. A., Horigan, V. H., Buncic, S., Staerk, K. D. C., O'Brien, S. O., & Clarke, K. (2013). A qualitative risk and benefit assessment for visual-only post-mortem meat inspection of cattle, sheep, goats and farmed/wild deer.: Project report. Food Standards Agency, London, UK.
Hjartardottir, S., Gunnarsson, E., & Sigvaldadóttir, J. (2002). *Salmonella* in sheep in Iceland. *Acta Veterinaria Scandinavica, 43*(1), 43-48.
Houf, K. (2009). *Arcobacter* in a food safety perspective. *Archiv Fur Lebensmittelhygiene, 60*, 73-76.
Jackson, T. A., Pearson, J. F., Young, S. D., Armstrong, J., & O'Callaghan, M. (2002). Abundance and distribution of microbial populations in sheep fleece. *New Zealand Journal of Agricultural Research, 45*(1), 49-55.
Johnson, K. G. (1973). Sweat storage as a factor influencing sweat discharge in sheep. *The Journal of Physiology, 235*(2), 523-534.

Jost, B. H., & Billington, S. J. (2005). *Arcanobacterium pyogenes*: molecular pathogenesis of an animal opportunist. *Antonie van Leeuwenhoek International Journal of General and Molecular Microbiology, 88*(2), 87-102.

Kalchayanand, N., Arthur, T. M., Bosilevac, J. M., Brichta-Harhay, D. M., Guerini, M. N., Shackelford, S. D., Wheeler, T. L., & Koohmaraie, M. (2007). Microbiological Characterization of Lamb Carcasses at Commercial Processing Plants in the United States. *Journal of Food Protection, 70*(8), 1811-1819.

Kannan, G., Jenkins, A., Eega, K., Kouakou, B., & McCommon, G. (2007). Preslaughter spray-washing effects on physiological stress responses and skin and carcass microbial counts in goats. *Small Ruminant Research, 67*(1), 14-19.

Kellermann, M., Huang, R. A., Forbes, A. B., & Rehbein, S. (2014). Gamithromycin plasma and skin pharmacokinetics in sheep. *Research in Veterinary Science, 97*(2), 199-203.

Kheirabadi, K. P., Azizi, H., Fallah, A. A., Samani, A. D., & Dehkordi, S. D. (2015). Prevalence of *Linguatula serrata* nymphs in slaughtered sheeps in Isfahan province, southwest of Iran. *Journal of Parasitic Diseases, 39*(3), 518-521.

Kim, K., Frank, J., & Craven, S. (1996). Three-dimensional visualization of *Salmonella* attachment to poultry skin using confocal scanning laser microscopy. *Letters in applied microbiology, 22*(4), 280-282.

Knight, D. R., & Riley, T. V. (2013). Prevalence of gastrointestinal *Clostridium difficile* carriage in Australian sheep and lambs. *Applied and Environmental Microbiology, 79*(18), 5689-5692.

Koehsler, M., Walochnik, J., Georgopoulos, M., Pruente, C., Boeckeler, W., Auer, H., & Barisani-Asenbauer, T. (2011). *Linguatula serrata* tongue worm in human eye, Austria. *Emerging Infectious Diseases, 17*(5), 870-872.

Koene, M. G. J., Mevius, D., Wagenaar, J. A., Harmanus, C., Hensgens, M. P. M., Meetsma, A. M., Putirulan, F. F., van Bergen, M. A. P., & Kuijper, E. J. (2012). *Clostridium difficile* in Dutch animals: their presence, characteristics and similarities with human isolates. *Clinical Microbiology & Infection, 18*(8), 778-784.

Koohmaraie, M., Shackelford, S. D., Wheeler, T. L., Guerini, M., Arthur, T. M., & Bosilevac, J. M. (2005). Post-harvest interventions to reduce/eliminate pathogens in beef. *Meat science, 71*(1), 79-91.

Koutsoumanis, K., & Sofos, J. N. (2004). Microbial contamination. In C. Devine & M. Dikeman (Eds.), *Encyclopedia of Meat Sciences, Three-Volume Set* (pp. 727-737): Elsevier Ltd.

Las Heras, A., Vela, A. I., Fernández, E., Legaz, E., Domínguez, L., & Fernández-Garayzábal, J. F. (2002). Unusual outbreak of clinical mastitis in dairy sheep caused by *Streptococcus equi* subsp. *zooepidemicus*. *Journal of Clinical Microbiology, 40*(3), 1106-1108.

Lenahan, M., O'Brien, S., Kinsella, K., Sweeney, T., & Sheridan, J. J. (2007). Prevalence and molecular characterization of *Escherichia coli* O157:H7 on Irish lamb carcasses, fleece and in faeces samples. *Journal of Applied Microbiology, 103*(6), 2401-2409.

Li, L., Oddy, V. H., Nolan, J. V., Godwin, I., & Liu, S. (2006). Skin characteristics and skin protein composition of Merinos differing in estimated breeding values for wool growth and fed at above and below maintenance. *Australian journal of experimental agriculture, 46*, 937-941.

Long, M., Ross, T. T., Edrington, T. S., Craddock, B. F., Salisbury, M., & Christensen, K. L. (2004). Incidence of *Escherichia coli* and *Salmonella*, in fecal, wool, and carcass samples in feedlot lambs. *Journal of Animal Science, 82*, 114-114.

Longbottom, D., & Coulter, L. J. (2003). Animal chlamydioses and zoonotic implications. *Journal of Comparative Pathology, 128*(4), 217-244.

Lyness, E. W., Pinnock, D. E., & Cooper, D. J. (1994). Microbial ecology of sheep fleece. *Agriculture, Ecosystems and Environment, 49*(1), 103-112.

Magnusson, B. M., Walters, K. A., & Roberts, M. S. (2001). Veterinary drug delivery: Potential for skin penetration enhancement. *Advanced Drug Delivery Reviews, 50*(3), 205-227.

Magolski, J. D., Luther, J. S., Neville, T. L., Redmer, D. A., Reynolds, L. P., Caton, J. S., & Vonnahme, K. A. (2011). Maternal nutrition during pregnancy influences offspring wool production and wool follicle development. *Journal of animal science, 89*(11), 3819-3823.

Mannelli, A., Bertolotti, L., Gern, L., & Gray, J. (2012). Ecology of *Borrelia burgdorferi sensu lato* in Europe: transmission dynamics in multi-host systems, influence of molecular processes and effects of climate change. *FEMS Microbiology Reviews, 36*(4), 837-861.

Marianelli, C., Cifani, N., Pasquali, P., Capucchio, M. T., Fiasconaro, M., Russo, M., di Marco, V., & la Mancusa, F. (2010). A case of generalized bovine tuberculosis in a sheep. *Journal of Veterinary Diagnostic Investigation, 22*(3), 445-448.

McClain, J., Wohlt, J., McKeever, K., & Ward, P. (1997). Horse hair coat cleanliness is affected by bedding material: A comparison of clean and used wheat straw, wood shavings and pelleted newspaper. *Journal of Equine Veterinary Science, 17*(3), 156-160.

McNally, A., Cheasty, T., Fearnley, C., Dalziel, R. W., Paiba, G. A., Manning, G., & Newell, D. G. (2004). Comparison of the biotypes of *Yersinia enterocolitica* isolated from pigs, cattle and sheep at slaughter and from humans with yersiniosis in Great Britain during 1999–2000. *Letters in Applied Microbiology, 39*(1), 103-108.

Melo, L. D. S., de Castro, M. B., Leite, R. C., Moreira, E. C., & de Melo, C. B. (2010). Main aspects of *Leptospira* spp. infection in sheep. *Ciencia Rural, 40*(5), 1235-1241.

Merga, J. Y., Williams, N. J., Miller, W. G., Leatherbarrow, A. J. H., Bennett, M., Hall, N., Ashelford, K. E., & Winstanley, C. (2013). Exploring the Diversity of *Arcobacter butzleri* from Cattle in the UK Using MLST and Whole Genome Sequencing. *PLoS ONE, 8*(2), 1-12.

Meyer, W., Neurand, K., & Tanyolaç, A. (2001). General anti-microbial properties of the integument in fleece producing sheep and goats. *Small Ruminant Research, 41*, 181-190.

Michalopolou, E., Leigh, A. J., & Cordoba, L. G. (2007). Detection of the genome of *Chlamydophila abortus* in samples taken from the uteri of 304 sheep at an abattoir. *Veterinary Record, 161*(5), 153-155.

Milnes, A. S., Stewart, I., Clifton-Hadley, F. A., Davies, R. H., Newell, D. G., Sayers, A. R., Cheasty, T., Cassar, C., Ridley, A., Cook, A. J. C., Evans, S. J., Teale, C. J., Smith, R. P., McNnally, A., Toszeghy, M., Futter, R., Kay, A., & Paiba, G. (2008). Intestinal carriage of verocytotoxigenic *Escherichia coli* O157, *Salmonella*, thermophilic *Campylobacter* and *Yersinia enterocolitica*, in cattle, sheep and pigs at slaughter in Great Britain during 2003. *Epidemiology and Infection, 136*, 739-751.

Modric, S., Webb, A., & Derendorf, H. (1998). Pharmacokinetics and pharmacodynamics of tilmicosin in sheep and cattle. *Journal of Veterinary Pharmacology & Therapeutics, 21*(6), 444-452.

Mohammed, B. R., Jegede, O. C., Malang, S. K., Obeta., S. S., Ejiofor, C. E., Onyekanihu, L. N., Farimoyo, B. T., & Onah, D. N. (2015). Awareness of the Public Health Importance of Singeing of Slaughtered Goats Using Spent Tyres at Gwagwalada Abattoir, Abuja - Nigeria. *Journal of Foodborne and Zoonotic Diseases, 3*(3), 34-38.

Momtaz, H., Dabiri, H., Souod, N., & Gholami, M. (2014). Study of *Helicobacter pylori* genotype status in cows, sheep, goats and human beings. *BMC Gastroenterology, 14*, 61-61.

Mørk, T., Kvitle, B., & Jørgensen, H. J. (2012). Reservoirs of *Staphylococcus aureus* in meat sheep and dairy cattle. *Veterinary Microbiology, 155*, 81-87.

Muckle, A., López, A., Gottschalk, M., López-Méndez, C., Giles, J., Lund, L., & Saab, M. (2014). Isolation of Streptococcus suis from 2 lambs with a history of lameness. *The Canadian Veterinary Journal. La Revue Vétérinaire Canadienne, 55*(10), 946-949.

Muñoz Mendoza, M., Juan, L. d., Menéndez, S., Ocampo, A., Mourelo, J., Sáez, J. L., Domínguez, L., Gortázar, C., García Marín, J. F., & Balseiro, A. (2012). Tuberculosis due to *Mycobacterium bovis* and *Mycobacterium caprae* in sheep. *Veterinary Journal, 191*(2), 267-269.

NACMCF. (2010). Assessment of food as a source of exposure to *Mycobacterium avium* subspecies *paratuberculosis* (MAP). *Journal Of Food Protection, 73*(7), 1357-1397.

Nuttall, W. O. (1988). *Caseous lymphadenitis in sheep and goats in New Zealand* (Vol. 15): Ministry for Primary Industries.

Nwosu, C. O., Iwuoha, C. L., Torru, C., & Mohammed, A. (2006). Prevalence Of Caprine Strongyle Infection And The Diagnostic Efficacy Of Some Media For Faecal Culture And Nematode Larval Recovery From Goat Faeces. *Animal Research International, 3*(1), 419-421.

O'Reilly, K. M., Green, L. E., Malone, F. E., & Medley, G. F. (2008). Parameter estimation and simulations of a mathematical model of *Corynebacterium pseudotuberculosis* transmission in sheep. *Preventive Veterinary Medicine, 83*, 242-259.

Obiri-Danso, K., Hogarh, J., & Antwi-Agyei, P. (2008). Assessment of contamination of singed hides from cattle and goats by heavy metals in Ghana. *African Journal of Environmental Science and Technology, 2*(8), 217-221.

Ogden, I. D., MacRae, M., & Strachan, N. J. C. (2005). Concentration and prevalence of *Escherichia coli* O157 in sheep faeces at pasture in Scotland. *Journal of Applied Microbiology, 98*, 646-651.

Okiei, W., Ogunlesi, M., Alabi, F., Osiughwu, B., & Sojinrin, A. (2009). Determination of toxic metal concentrations in flame-treated meat products, ponmo. *African Journal of Biochemistry Research, 3*(10), 332-339.

Okraszewska-Lasica, W., Bolton, D., Sheridan, J., & McDowell, D. (2012). Comparison of aerial counts at different sites in beef and sheep abattoirs and the relationship between aerial and beef carcass contamination. *Food microbiology, 32*(2), 325-331.

Okraszewska-Lasica, W., Bolton, D., Sheridan, J., & McDowell, D. (2014). Airborne *Salmonella* and *Listeria* associated with Irish commercial beef, sheep and pig plants. *Meat science, 97*, 255-261.

Patil, B. D., Jones, D. I. H., & Hughes, R. (1969). Wool characteristics as an indication of nutritive attributes in herbage varieties. *Nature, 223*, 1072-1073.

Pearce, R., Bolton, D., Sheridan, J., McDowell, D., Blair, I., & Harrington, D. (2004). Studies to determine the critical control points in pork slaughter hazard analysis and critical control point systems. *International Journal of Food Microbiology, 90*(3), 331-339.

Peel, M., M, Gregory, G. P., Ann, M. S., & Trevor, G. K. (1997). Human Lymphadenitis Due to *Corynebacterium pseudotuberculosis*: Report of Ten Cases from Australia and Review. *Clinical Infection and Disease, 24*(2), 185-191.

Phillips, C. J., Omed, H. M., & Chiy, P. C. (2004). The effects of cadmium in feed, and its amelioration with zinc, on element balances in sheep. *Journal of animal science, 82*(8), 2489-2502.

Plowman, J. E., Deb-Choudhury, S., Clerens, S., Thomas, A., Cornellison, C. D., & Dyer, J. M. (2012). Unravelling the proteome of wool: towards markers of wool quality traits. *Journal of Proteomics, 75*(14), 4315-4324.

Popescu, R., Pistol, A., Miltaru, L., Caplan, D., Cucuiu, R., & Popovici, F. (2011). Two cases of infection with *Bacillus anthracis*, Romania, October 2011. *Eurosurveillance, 16*(45).

Poulin, M. F., & Boivin, G. (2009). A case of disseminated infection caused by *Streptococcus equi* subspecies *zooepidemicus*. *Canadian Journal of Infectious Diseases & Medical Microbiology, 20*(2), 59-61.

Prendergast, D. M., Lendrum, L., Pearce, R., Ball, C., McLernon, J., O'Grady, D., Scott, L., Fanning, S., Egan, J., & Gutierrez, M. (2011). Verocytotoxigenic *Escherichia coli* O157 in beef and sheep abattoirs in Ireland and characterisation of isolates by Pulsed-Field Gel Electrophoresis and Multi-Locus Variable Number of Tandem Repeat Analysis. *International Journal of Food Microbiology, 144*(3), 519-527.

Pritchard, G. C., Smith, R., Ellis-Iversen, J., Cheasty, T., & Willshaw, G. A. (2009). Verocytotoxigenic *Escherichia coli* O157 in animals on public amenity premises in England and Wales, 1997 to 2007. *The Veterinary Record, 164*(18), 545-549.

Quaglia, N. C., Dambrosio, A., Normanno, G., Parisi, A., Patrono, R., Ranieri, G., Rella, A., & Celano, G. V. (2008). High occurrence of *Helicobacter pylori* in raw goat, sheep and cow milk inferred by

glmM gene: a risk of food-borne infection? *International Journal of Food Microbiology, 124*(1), 43-47.
Rohrmann, S., Zoller, D., Hermann, S., & Linseisen, J. (2007). Intake of heterocyclic aromatic amines from meat in the European Prospective Investigation into Cancer and Nutrition (EPIC)-Heidelberg cohort. *British Journal of Nutrition, 98*(06), 1112-1115.
Saif, N. A., & Brazier, J. S. (1996). The distribution of *Clostridium difficile* in the environment of South Wales. *Journal of Medical Microbiology, 45*(2), 133-137.
Samelis, J., & Sofos, J. (2005). Meat decontamination and pathogen stress adaptation. In J. Sofos (Ed.), *Improving the safety of fresh meat* (pp. 562-591): Woodhead Publishing Ltd, Cambridge, England.
Scharf, W., Schauer, S., Freyburger, F., Petrovec, M., Schaarschmidt-Kiener, D., Liebisch, G., Runge, M., Ganter, M., Kehl, A., Dumler, J. S., Garcia-Perez, A. L., Jensen, J., Fingerle, V., Meli, M. L., Ensser, A., Stuen, S., & von Loewenich, F. D. (2011). Distinct Host Species Correlate with *Anaplasma phagocytophilum* ankA Gene Clusters. *Journal of Clinical Microbiology, 49*(3), 790-796.
Sheridan, J. J., Blair, I. S., McDowell, D. A., & Duffy, G. (1994). The occurrence and initial numbers of *Listeria* in Irish meat and fish products and the recovery of injured cells from frozen products. *International journal of food microbiology, 22*(2/3), 105-113.
Sierra, M.-L., Gonzalez-Fandos, E., García-López, M.-L., Fernandez, M. C. G., & Prieto, M. (1995). Prevalence of *Salmonella*, *Yersinia*, *Aeromonas*, *Campylobacter* and cold-growing *Escherichia coli* on freshly dressed lamb carcasses. *Journal of Food Protection, 58*(11), 1183-1185.
Sinclair, K. B. (1954). The incidence and life cycle of *Linguatula serrata* (Frohlich 1789) in Great Britain. *Journal of Comparative Pathology and Therapeutics, 64*, 371-383.
Sinha, R., Gustafson, D. R., Kulldorff, M., Wen, W.-Q., Cerhan, J. R., & Zheng, W. (2000). 2-Amino-1-methyl-6-phenylimidazo [4, 5-b] pyridine, a carcinogen in high-temperature-cooked meat, and breast cancer risk. *Journal of the National Cancer Institute, 92*(16), 1352-1354.
Small, A., & Buncic, S. (2009). Potential for the cross-contamination of the hides of cattle while they are held in lairage. *The Veterinary Record, 164*(9), 260-265.
Small, A., Reid, C. A., Avery, S. M., Karabasil, N., Crowley, C., & Buncic, S. (2002). Potential for the Spread of *Escherichia coli* O157, *Salmonella* and *Campylobacter* in the Lairage Environment at Abattoirs. *Journal of Food Protection, 65*(6), 931-936.
Small, A., Wells-Burr, B., & Buncic, S. (2005). An evaluation of selected methods for the decontamination of cattle hides prior to skinning. *Meat Science, 69*(2), 263-268.
Smith, E. M., Needs, P. F., Manley, G., & Green, L. E. (2014). Global distribution and diversity of ovine-associated *Staphylococcus aureus*. *Infection, Genetics and Evolution, 22*, 208-215.
Snow, L. C., Wearing, H., Stephenson, B., Coldham, N. G., & Teale, C. J. (2011). Investigation of the presence of ESBL-producing *Escherichia coli* in the North Wales and West Midlands areas of the UK in 2007 to 2008 using scanning surveillance. *Veterinary Record, 169*(25), 656.
Söderqvist, K., Boqvist, S., Wauters, G., Vågsholm, I., & Thisted-Lambertz, S. (2012). *Yersinia enterocolitica* in sheep - a high frequency of biotype 1A. *Acta Veterinaria Scandinavica, 54*(39), 1-7.
Sofos, J. (2005). *Improving the safety of fresh meat*: Woodhead Publishing Ltd, Cambridge, England.
Sofos, J. N., Kochevar, S. L., Bellinger, G. R., Buege, D. R., Hancock, D. D., Ingham, S. C., Morgan, J. B., Reagan, J. O., & Smith, G. C. (1999). Sources and extent of microbiological contamination of beef carcasses in seven United States slaughtering plants. *Journal of Food Protection, 62*(2), 140-145.
Sofos, J. N., & Smith, G. C. (1998). Nonacid meat decontamination technologies: Model studies and commercial applications. *International Journal of Food Microbiology, 44*(3), 171-188.
Sproston, E. L., Ogden, I. D., MacRae, M., Dallas, J. F., Sheppard, S. K., Cody, A. J., Colles, F. M., Wilson, M. J., Forbes, K. J., & Strachan, N. J. C. (2011). Temporal Variation and Host

Association in the *Campylobacter* Population in a Longitudinal Ruminant Farm Study. *Applied and Environmental Microbiology, 77*(18), 6579-6586.

Stanley, K. N., Wallace, J. S., Currie, J. E., Diggle, P. J., & Jones, K. (1998). Seasonal variation of thermophilic campylobacters in lambs at slaughter. *Journal of Applied Microbiology, 84*(6), 1111-1116.

Strobel, H., Lauseker, M., & Forbes, A. B. (2014). Targeted antibiotic treatment of lame sheep with footrot using either oxytetracycline or gamithromycin. *Veterinary Record, 174*(2), 46.

Stuen, S. (2013). Tick-borne infections in small ruminants in northern Europe. *Small Ruminant Research, 110*(2/3), 142-144.

Tappe, D., Winzer, R., Büttner, D. W., Ströbel, P., Stich, A., Klinker, H., & Frosch, M. (2006). Linguatuliasis in Germany. *Emerging Infectious Diseases, 12*, 1034-1036.

Tonin, A. A., Martins, B., Zago, R. V. M. S., Tochetto, C., Azenha, N. P., Schaefer, P. C., Martins, J. L. R., & Badke, M. R. T. (2015). Outbreak of leptospirosis: reproductive losses in sheep. *Comparative Clinical Pathology, 24*(4), 961-965.

van der Burgt, G. M., Drummond, F., Crawshaw, T., & Morris, S. (2013). An outbreak of tuberculosis in Lleyn sheep in the UK associated with clinical signs. *The Veterinary Record, 172*(3), 69-69.

Vitale, M., Scatassa, M. L., Cardamone, C., Oliveri, G., Piraino, C., Alduina, R., & Napoli, C. (2015). Staphylococcal food poisoning case and molecular analysis of toxin genes in *Staphylococcus aureus* strains isolated from food in Sicily, Italy. *Foodborne Pathogens and Disease, 12*, 21-23.

Waddell, L. A., Rajić, A., Sargeant, J., Harris, J., Amezcua, R., Downey, L., Read, S., & McEwen, S. A. (2008). The Zoonotic Potential of *Mycobacterium avium* spp. *paratuberculosis*: A Systematic Review. *Canadian Journal of Public Health, 99*(2), 145-155.

Wang, Q., Fidalgo, S., Chang, B. J., Mee, B. J., & Riley, T. V. (2002). The detection and recovery of *Erysipelothrix* spp. in meat and abattoir samples in Western Australia. *Journal of Applied Microbiology, 92*(5), 844-850.

White, J. D., Allingham, P. G., Gorman, C. M., Emery, D. L., Hynd, P., Owens, J., Bell, A., Siddell, J., Harper, G., Hayes, B. J., Daetwyler, H. D., Usmar, J., Goddard, M. E., Henshall, J. M., Dominik, S., Brewer, H., van der Werf, J. H. J., Nicholas, F. W., Warner, R., Hofmyer, C., Longhurst, T., Fisher, T., Swan, P., Forage, R., & Oddy, V. H. (2012). Design and phenotyping procedures for recording wool, skin, parasite resistance, growth, carcass yield and quality traits of the SheepGENOMICS mapping flock. *Animal Production Science, 52*(2-3), 157-171.

Willayat, M. M., Sheikh, G. N., & Misgar, G. R. (2007). Prevalence of *Bacillus cereus* biotypes in raw and cooked mutton. *Journal of Veterinary Public Health, 5*(2), 123-125.

Woldehiwet, Z. (2006). *Anaplasma phagocytophilum* in Ruminants in Europe. *Annals of the New York Academy of Sciences, 1078*(1), 446-460.

Wu, V. (2008). A review of microbial injury and recovery methods in food. *Food microbiology, 25*(6), 735-744.

Yu, S.-L., Bolton, D., Laubach, C., Kline, P., Oser, A., & Palumbo, S. A. (1999). Effect of dehairing operations on microbiological quality of swine carcasses. *Journal of Food Protection, 62*(12), 1478-1481.

Zazzo, A., Cerling, T. E., Ehleringer, J. R., Moloney, A. P., Monahan, F. J., & Schmidt, O. (2015). Isotopic composition of sheep wool records seasonality of climate and diet. *Rapid Communications in Mass Spectrometry, 29*(15), 1357-1369.

Zimmerli, B., Rhyn, P., Zoller, O., & Schlatter, J. (2001). Occurrence of heterocyclic aromatic amines in the Swiss diet: analytical method, exposure estimation and risk assessment. *Food Additives & Contaminants, 18*(6), 533-551.

Zweifel, C., Zychowska, M. A., & Stephan, R. (2004). Prevalence and characteristics of Shiga toxin-producing *Escherichia coli, Salmonella* spp. and *Campylobacter* spp. isolated from slaughtered sheep in Switzerland. *International Journal of Food Microbiology, 92*, 45-53.

ANNEXES

Annex 1. Survey of slaughterhouse operator attitudes towards the legalisation of the production of skin-on sheep meat

Interview Script

Part A._ Information on the premises

1. Date/Time__________________
2. Name and address____
3. Name of Person interviewed____

Hello, my name is [_____________] and I am calling from the University of Liverpool regarding the skin-on sheep meat interview.
Do you agree for the interview to be recorded? Yes ☐ No ☐
If yes we will continue with the interview if not we will wait for the written consent form to arrive and book the appointment for a different time.

Have you had time to review the information we sent regarding the production process?
Yes ☐ No ☐

If not the appointment will be booked again within 1hour.

4. Position of the person responding to the survey (owner, production manager, Public relations etc.)

Could you please let me know what your position in the slaughterhouse is?
Owner ☐ production manager ☐ public relations ☐ other ☐ ___________ NA ☐

5. Throughput by species?

What species do you slaughter at your premises?
Cattle ☐ Lambs ☐ Adult sheep ☐ Pigs ☐ other ☐___________ NA ☐
Could you please let me know what the monthly average throughput is by species?
Cattle _______ Lambs _______ Adult sheep _________ Pigs _________ other _____________ NA ☐

6. Origin of the ewes.

• *What proportion of adult sheep slaughtered at your premises originates from livestock markets?*
____________________________ *NA ☐*
• *Which livestock markets are you buying adult sheep from?*

NA ☐

• *In cases that adult animals are sourced directly from the farm what proportion of these farms originates from one of the following regions:*					
East of England		*North Wales*		*South Wales*	
East Midlands		*North West*		*South West*	
London		*Scotland*		*West Midlands*	
North East		*South East*		*Yorkshire and the Humber*	
NA ☐					

7. Clients they supply including type, size and location

• *What is your average monthly production of adult sheep meat for the last calendar year?*
______________________ *NA ☐*
• *What proportion is going to?*
butchers, ___________ for further processing ___________ or large retailers ___________ NA ☐

Part B._ Awareness of the skin-on sheep meat process

This next part of the interview aims to establish a preliminary understanding of your approach to the process and the questions need mainly Yes/No answers. There will be an opportunity to get into more detail a bit later.

1. If the production of skin-on sheep meat were legalised, how interested would you be in applying the process to your plant?					
Very ☐	*a bit ☐*	*possible ☐*	*not likely ☐*	*no way ☐*	
2. Which of the following areas has informed your decision above?					
i) Structural requirements?	*Yes ☐*	*No☐*	*NA ☐*		
If yes, in a scale from 1 to 5, how easy would it be to implement required structural changes with 1 being very easy and 5 very difficult?					
1 ☐	*2 ☐*	*3 ☐*	*4 ☐*	*5 ☐*	*NA ☐*
ii) Operational requirements?	*Yes ☐*	*No☐*			
If yes, in a scale from 1 to 5, how easy would it be to implement operational changes with 1 being very easy and 5 very difficult?					
1 ☐	*2 ☐*	*3 ☐*	*4 ☐*	*5 ☐*	*NA ☐*

iii) Administrative requirements?	*Yes ☐*	*No☐*	*NA ☐*

If yes, in a scale from 1 to 5, how easy would it be to implement operational changes with 1 being very easy and 5 very difficult?					
1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	NA ☐

Part C._ Risks and Benefits of the process

1. What benefits do you expect from undertaking the process?
i) *Do you expect that there will be demand for skin-on sheep meat from existing clients?*
Yes ☐, No ☐, NA ☐
ii) *Do you expect that the production of skin-on sheep meat may open new markets creating new clients?*
Yes ☐, No ☐, NA ☐
iii) *Would you be interested in exporting skin-on sheep meat?*
Yes ☐, No ☐, NA ☐
iv) *In addition to customer satisfaction do you expect that undertaking the process may be profitable?*
Yes ☐, No ☐, NA ☐
2. What are the risks you believe are involved in the production of skin-on sheep meat?
i) How long do you expect it would take for the cost of installations and structural requirements to be "repaid"?
ii) In a scale from 1 to 5 how much disruption to the plant's operations do you anticipate the new process cause?
1 ☐   2 ☐   3 ☐   4 ☐   5 ☐   NA ☐

In particular:					
a. The separation of the processes during operations					
1 ☐	*2* ☐	*3* ☐	*4* ☐	*5* ☐	*NA* ☐
b. The separation of the processes during storage					
1 ☐	*2* ☐	*3* ☐	*4* ☐	*5* ☐	*NA* ☐
c. The creation and implementation of new SOPs and HACCP					
1 ☐	*2* ☐	*3* ☐	*4* ☐	*5* ☐	*NA* ☐
d. The training of staff					
1 ☐	*2* ☐	*3* ☐	*4* ☐	*5* ☐	*NA* ☐
e. Handling and disposal of animal by-products generated during this production process					
1 ☐	*2* ☐	*3* ☐	*4* ☐	*5* ☐	*NA* ☐
f. Implementing new Health and Safety procedures					
1 ☐	*2* ☐	*3* ☐	*4* ☐	*5* ☐	*NA* ☐
iii) Do you expect the process to affect the cost of labour?					
Yes ☐, *No* ☐, *NA* ☐					
How? Increase ☐ Reduce☐					
iv) Do you expect the process to affect the regular supply of ewes?					
Yes ☐, *No* ☐, *NA* ☐					
How? Increase ☐ Reduce☐					
v) Do you expect that undertaking the process may affect your reputation?					
Yes ☐, *No* ☐, *NA* ☐					
How? Positive ☐ Negative ☐					
vi) How do you believe the fleece market will be affected by the legalisation of skin-on sheep meat?					

vii) Do you anticipate there will be competition from foreign imports?
Yes ☐, No ☐, NA ☐

Part D._ Additional information

○ What is the anticipated effect of the process to the marketing of the adult sheep meat?
○ What additional information would you like to have in order to decide whether to undertake the process?
○ Do you have any specific comment/recommendation on how the process should look like considering practicalities for the production of smoked skin-on sheep meat?
○ Are you aware if there will be competition from the illegal production in your area?
Yes ☐, No ☐, NA ☐

○ Are you aware if there will be competition from the illegal trade in your area?
Yes ☐, No ☐, NA ☐

Thank you for your time and cooperation. Though we hope it will not be necessary would it be OK if we return to you with any additional questions?

Yes ☐, No ☐, NA ☐

Annex 2. A description of skin-on sheep meat processing

I. In a study, commissioned by the FSA (*The production and microbiological status of skin-on sheep carcasses, Alan Fisher, Carol-Ann Wilkin, Graham Purnell Meat Science 77 (2007) 467–473),* the researchers tried different methods for the production of skin-on sheep meat and concluded that the best method involved the following steps:

- Singeing, occurring after stunning and bleeding and the removal of the hind feet.
  The researchers used purpose built equipment which they describe:

  "…this consisted of a ring of eight inwardly directed gas burners attached to a supporting octagonal ring that moved up and down around a sus-pended carcass. The burner ring was chain driven by a DC motor controlled by a small programmable logic controller. Adjustable micro-switches on the support structure controlled the stroke end positions. A single skinned hood was built above the rig to collect rising heat and fumes and was connected to a large displacement extractor fan (600 mm diameter) using flexible ducting. A satisfactory degree of wool singeing was achieved by three complete cycles of burner ring travel, i.e. three down-up passes (the parked, home position of the ring is at the top of its travel)."

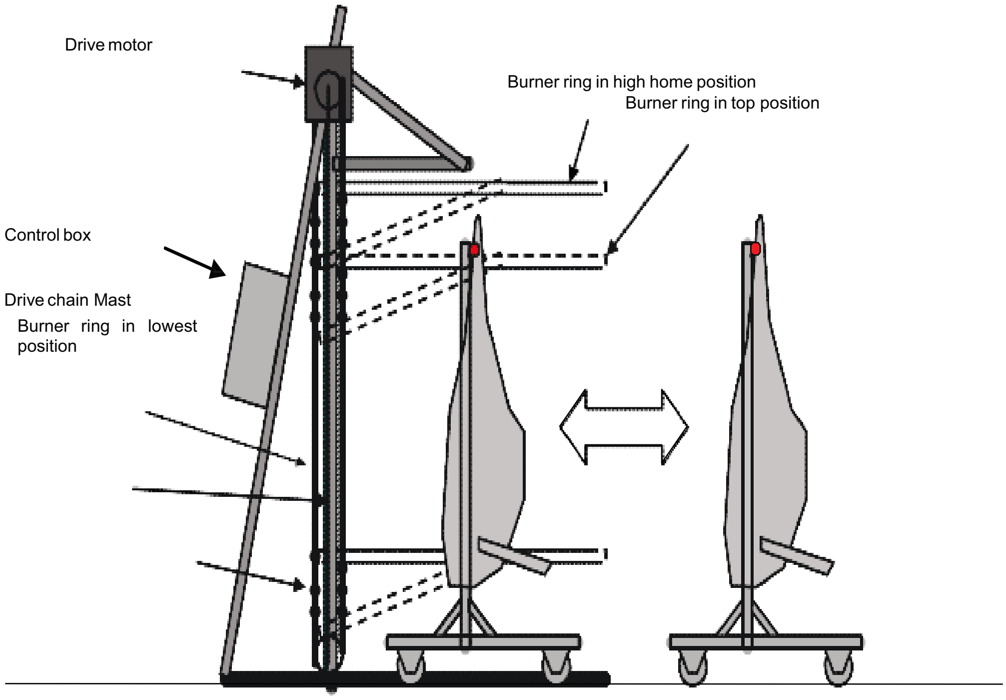
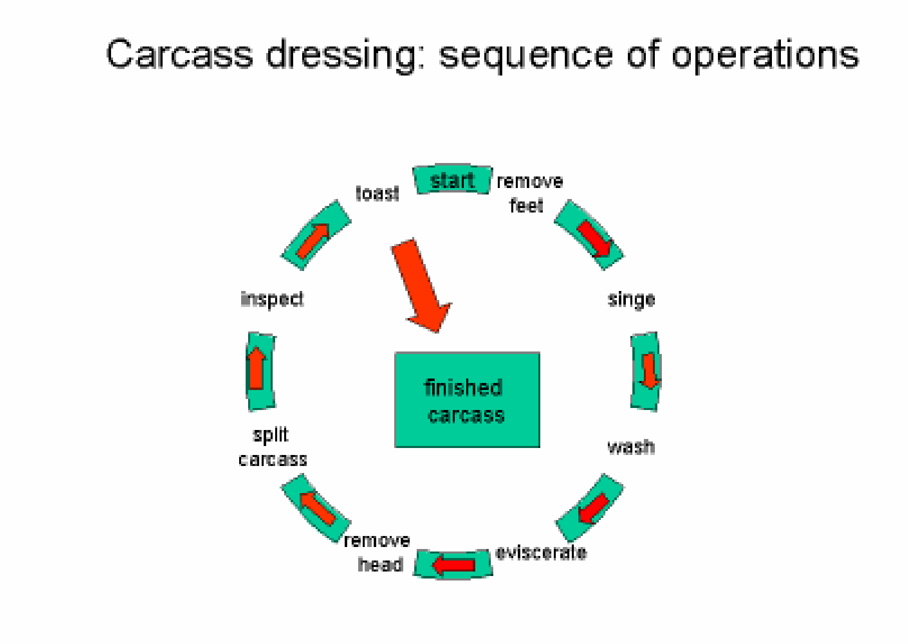


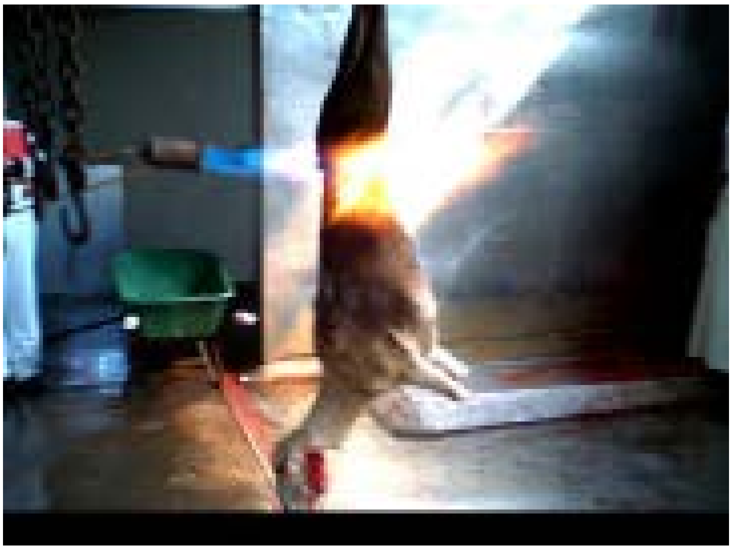
Fig. 1. A schematic diagram of the singeing equipment, viewed from the side.

- Washing in order to remove the wool remains, using a pressure washer with water at 50^{o}C and occurring directly after singeing
- "Toasting" is recommended by the researchers of the above project and consists of a single passage through the burners. In their opinion this step should take place after inspection.



Sequence of steps in the best practice protocol for the production of smoked, skin-on sheep carcasses.

II. An alternative simplified method was used during different trials and involved the use of a propane coupled blow torch.



Though we cannot exclude the development of alternative methods, current knowledge on the microbiological validation of the skin-on sheep meat production is based on the above processes. We would be grateful if you could consider these methods as the basis of for your answers to our interview.

A full copy of the paper describing the 1st method is attached (will need to establish copyright issues). The illegal process was also investigated by journalists (http://munchies.vice.com/articles/the-complicated-case-of-smokies), and the link below is for a video which includes a presentation of the process: https://www.youtube.com/watch?v=voTkc49dODQ