

A Thesis Submitted for the Degree of Doctor of Philosophy at Harper Adams University

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HARPER ADAMS UNIVERSITY

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The role of rendering in the bovine spongiform encephalopathy (BSE) epidemic, the development of EU animal by-product legislation and new markets for rendered products

Submitted in fulfilment of the requirements of the degree of Doctor of Philosophy by publications

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Declaration

I declare that the work published herein is my own.

Acknowledgements

I would like to express my gratitude to my Director of Studies, Dr. Robert Wilkinson who, in addition to guiding and encouraging me through the process of preparing this thesis, has shown enduring patience in what has seemed to be an unending process.

Also to Dr Simon Davies, my supervisor, who initially encouraged me to start down the path of producing a thesis by publications to ensure that the published papers were recognized as a complete body of work.

To all my colleagues in the global rendering industry, past and present, who have by their advice and encouragement made me feel that this thesis was worthy of being published as a record of the events of the last forty years.

Finally, to my family without whose support, I could not have completed the work necessary to finalise all the publications and this thesis.

Dedication

To Anne

Curriculum Vitae

Employment

Stephen Woodgate was employed by Unilever Research as a senior research assistant between 1970 and 1984. He joined Prosper deMulder (PdM) as a product development manager in 1984. In 1990 he established Beacon Research as an international consultancy focussing on the role of rendering in the livestock food chain. He re-joined PdM as their Technical Director in 1999, and subsequently joined the European Fat Processors and Renderers Association (EFPRA) in 2004 as their Technical Director. In 2010 he became the Chief Executive of the Foodchain and Biomass Renewable Association (FABRA), leaving in 2015 to become Managing Director of Beacon Research, a position he still holds.

Industry representation and leadership

The author has held several UK, European and World roles during his career. He was firstly a member of the United Kingdom Renderers Association (UKRA) Technical Committee between 1991 and 2004, before becoming Chairman, a position he held from 2001 to 2004.

Concurrently, he was a member of the EFPRA Technical Committee between 1999 and 2004, holding the position of Technical Committee Chairman between 2001 and 2004. Subsequently the role of Technical Director was created by EFPRA which he held from 2004 until 2010.

FABRA was created in 2010 and Stephen was appointed Chief Executive a position he held until 2015.

He was a member of the World Renderers Organisation (WRO) Scientific Advisory Panel between 2004 and 2010, then WRO first Vice President between 2011 and 2013 then WRO President between 2013 and 2015.

Industry: Government roles and Research

The author has held various key roles at the interface between industry and government (UK/ EU/World) over his career. Initially he was the rendering industry coordinator for the EU transmissible spongiform encephalopathies (TSE) Research programme between 1988 and 1993. He also held a position on the Standing Veterinary Committee (SVC) rendering sub-committee between 1992 and 1995. Later, he was a key member of the project management team responsible for research on species identification and quantification in processed animal proteins (PAPs). Initially, Stratfeed between 2001 and 2004 followed by Safeed-PAP from 2006 to 2009.

Abbreviations

ABP: Animal By-Product

BSE: Bovine spongiform encephalopathy

CJD; Creutzfeldt Jacob Disease

DEFRA: Department of Environment Food and Rural Affairs

EU: European Union

EFPRA: European Fat Processors and Renderers Association

FABRA: Foodchain and Biomass Renewable Association

FAO: Food and Agriculture Organisation (UN)

LCA: Life Cycle Analysis

MBM; Meat and Bone Meal

MAFF: Ministry of Agriculture Fisheries and Food

OIE: World Organisation for Animal Health

PAP: Processed Animal Protein

SCoPAFF: Standing Committee on Plants Animals Food and Feed (EU)

SVC: Scientific Veterinary Committee (EU)

TSE: Transmissible spongiform encephalopathy

UKRA: United Kingdom Renderers Association

UN: United Nations

WRO: World Renderers Organisation

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1. Introduction.

This narrative covers a timeline from 1985 to date and describes the evolution of the animal by-product and rendering industries throughout this period. The dominating feature and focal point of this period was the Bovine Spongiform Encephalopathy (BSE) epidemic, which began in the UK in 1987, but subsequently impacted the World over following years. Even now, in 2021, the impact of the BSE epidemic can be seen in Europe and further afield.

These papers chart the role and impact of the author in both understanding the issues involved from the rendering perspective and thereafter seeking solutions that would allow the rendering industry to regain a vital role in the livestock food chain.

This series of published papers describes the context and actions taken by the author within the rendering industry during this period. The initiatives taken and their consequences are described in a group of 11 papers, published between 1994 and 2021. The final paper (paper 10) adds more detail of the author's contribution, by way of previously unpublished research

2. Inactivation of TSE agents by rendering (papers 1a, 1b)

Taylor D.M., Woodgate S. L., Atkinson M.J. (1995). Inactivation of the bovine spongiform encephalopathy agent by rendering procedures. Veterinary Record 137, p605-610.

Taylor D.M., Woodgate S. L., Fleetwood A.J., Cawthorne R.J.G. (1997). Effect of rendering procedures on the scrapie agent. Veterinary Record 141, p643-649.

Note: these two papers are considered together, as they have identical objectives, in relation to the inactivation of two different Transmissible Spongiform Encephalopathy (TSE) agents, i.e., BSE and scrapie. Although the test material for the experiments was different, the design of the inactivation trials was identical. However, the experiments were conducted two years apart and as a consequence, there were minor differences to the implementation of the test protocols and the experimental conclusions.

Impact factor; 2.05

Citations; Paper 1: 188, Paper 2: 102.

Background

The emergence of BSE in 1987 and the subsequent epidemiology studies led to a focus on animal by-products (ABPs), rendering and the use of rendered products in animal feeds. However, the supposition that ABPs and rendering processes were directly involved in the aetiology and amplification of BSE was hypothetical. Research was required to test this hypothesis and, if confirmed, adjust the use of ABPs and rendering processes by legislative changes.

Summary

The paper details the research into inactivation of BSE (experiment 1) and scrapie (experiment 2) agents by rendering procedures that were considered to be accurate facsimiles of industrial processes. The samples produced were assayed by mouse bioassay and the results of the bioassay and the recorded data were used to inform the conclusions of the papers.

Author's contribution

The author was responsible for conducting all aspects of the inactivation trials, including the preparation of the raw material for rendering, operation of the processes and sampling for all experiments. Prior to the inactivation experiments, three preliminary objectives were completed by the author (described in paper 10). As it was not feasible to conduct research into BSE inactivation in an industrial size processing plant, the first objective was to design and build suitable pilot scale equipment that was able to replicate the dynamics of the processes in operation within UK and Europe. The second objective was to prepare a suitable raw material complex that both represented the typical raw material mixture for rendering and which contained infectious cattle brain material. This mixture represented the reference (untreated) sample which was subjected to the range of processing conditions. The third objective was to ensure that the pilot plant produced a product that could be identified as MBM (by both compositional and microbiological standards), such that industry and regulators accepted the validity of the inactivation trials. Further details of the preliminary and experimental research are described in paper 10.

Implications

Legislation defining the process conditions required for the safe processing of ABPs was introduced for the first time in the EU. In practice, the inactivation trial data was directly transposed into the EU regulations published in 1994 (EU Commission Decision 94/382) and 1996 (EU Commission Decision 96/449). Although the regulations have subsequently been amended, the findings from the inactivation trials are still incorporated into the current regulatory requirements (EU Regulation 1069/2009 and EU Commission Regulation 142/2011).

3. Rendering systems in the EU (paper 2)

Woodgate S. L., Van der Veen J. T. (2004) The use of fat processing and rendering in the

European Union animal production industry. Biotechnology, Agronomy, Society and

Environment, 8, 283-294.

Impact factor: 1.23

Citations:75

Background

The EU regulations approved in 2002 (EU Regulation 1774/2002) were not yet fully

understood by the rendering industry and regulators by 2004. This paper presents a

summary of the new regulations in a practical environment for all interested parties.

Summary

This paper reviews the status of the ABP and rendering industries up to and including

2004 and includes details of the regulatory changes made in 2002. The paper also

introduces the concept of re-introducing certain rendered products back into animal feeds

according to risk and processing standards. In particular, the need for rendering systems

to incorporate HACCP systems (formerly limited to human foods) into their approval

requirements are introduced. Additionally, research proposed to achieve the goal of re-

introduction into animal feeds was highlighted (see paper 5) together with prospective

timescales.

Author's contribution

The author's experience and knowledge regarding the development of the EU rendering

regulations was used to write this authoritative paper that explains the role of ABP

processing in the EU livestock industry. The initial development of HACCP as a safety

system within the UK rendering industry by the author, formed a key aspect of explaining

the importance of HACCP systems for rendering (Woodgate & Smith, 1993).

Implications

This paper has been recognized as a definitive reference document for the operation and

regulations relating to the EU fat processing and rendering industries from 2004 to date.

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4. Alternatives to rendering (paper 3)

Woodgate S. L. (2006). What would a world without rendering look like? in Essential

Rendering: All about the animal by-products industries.

Ed. D. Meeker p277. ISBN: 0-9654660-3-5

Impact factor; n/a

Citations: 9

Background.

As a result of the BSE epidemic in the EU, the rendering industry had lost traditional markets and as a result was becoming economically unviable. With no obvious viable alternative, this paper addressed the question: 'Is there an alternative to rendering?'

Summary.

This paper was conceived when the rendering industry was under considerable pressure to maintain its traditional position in the livestock supply chain. The fact that animal proteins were banned from use in animal feeds in Europe meant that the normal level of income for the products reduced and, in some cases, became negative. This situation led to widespread concerns that the rendering industry might be on the point of collapse. However, for the meat supply industry to be able to continue, animal by-products needed to be treated. If not rendering, then what? This paper reviewed several process options as alternatives to rendering. Particular emphasis was placed on processes that did not produce standard products but ensured high biosecurity standards and the potential to produce renewable energy. Such systems were identified and discussed in relation to the prevailing circumstances at the time of writing.

Author's contribution

This was the first and (possibly) only paper to address the question about economically viable alternatives to rendering and used the author's research into any prospective alternatives that might achieve key criteria; safety, sustainability and economy.

Implications.

This paper prompted considerable debate amongst and between the rendering industry and regulators. However, with the progress of time, together with the research aimed at reauthorizing the use of animal proteins for use in animal feeds (see paper 5), the postulated alternative processes were never fully adopted as a complete replacement for

rendering. Although some alternative processes, such as combustion, anaerobic digestion and composting have been developed and approved for the processing of ABPs, they have become complementary processes that are limited by their ability to process only some categories of ABP.

5. Thermal treatment of meat and bone meal (paper 4)

Etok S.E., Valsami-Jones E., Wess T. J., Hiller J. C., Maxwell C. A., Rogers K.D., Manning D. A. C., White M. L., Lopez-Capel E., Collins M.J., Buckley M., Penkman K. E. H., Woodgate S. L. (2007). Structural and chemical changes of thermally treated bone apatite. J Material Sci 42:9807–9816 DOI 10.1007/s10853-007-1993-z

Impact factor; 3.44

Citations: 117

Background.

As a result of the EU regulations in 2001/2, up to 50% of ABPs (Category 1 and 2) were required to be disposed of. The chosen method of disposal was to firstly render the ABP and then dispose of the rendered fat and MBM separately. Accordingly, a new combustion technology was developed for the disposal of MBM and production of energy in the form of heat. One consequence of the process was the production of significant quantities of ash (inorganic material), comprising ~ 25% of the dry weight of the input MBM. As there were no immediate uses for the ash, the material was disposed as a waste to landfill at considerable cost burden to the business. The objective of the research was to investigate the properties of the MBM ash, with the objective of investigating the properties of the inorganic fraction and exploring the potential for developing new products.

Summary.

The paper considers how the chemical structure of bone is affected by combustion of the organic component. The effect of different combustion temperatures on the crystalline nature of hydroxyapatite (a component in the bone residue) was determined. The possibility of new applications for MBM ash are discussed in relation to the results.

Author's contribution

The author's study of the literature and analysis of the chemical constituents of MBM ash led to the hypothesis that novel active components could be present in the mineral residue from the combustion of MBM. Thereafter, the author was part of a research project team that was tasked with establishing if the MBM ash contained components that might be of value in non-animal feed applications. The author had specific responsibility for the industrial plant where monitoring and adjustment of temperature and time criteria was possible. Ensuring that representative samples of combusted MBM taken accorded with the processing conditions, was also the responsibility of the author.

Implications.

The research project identified specific chemical components that could have interesting and valuable properties. These included phosphate compounds such as hydroxyapatite and tri-calcium phosphate. Properties of the inorganic components of MBM ash were subsequently investigated in depth and the research published (paper 7).

6. Detection of animal proteins in animal feeds (paper 5)

Woodgate S.L., van den Hoven S., Vaessen J., Margry R. (2009). Control tools to detect processed animal proteins in feed and in animal by-products: specificity and challenges

Biotechnology, Agronomy, Society and Environment, 13, 9–13.

Impact factor: 1.23

Citations: 14

Background.

Following EU regulatory changes, ruminant proteins were banned for use in animal feed

for farmed animals. Furthermore, the potential to use non-ruminant proteins in animal

feeds was limited by the intra-species recycling prohibition. Therefore, there was an

urgent requirement to develop tests that could identify the species origin of processed

animal proteins (PAPs) The main problem was that PAPs are heat treated as part of the

process to ensure sterility and this heat treatment could denature the protein such that it

might be difficult to assay accurately or reproducibly.

Summary.

This paper relates to the research initiated to determine the species identity of PAPs, a

pre-requisite for their approval in animal feeds. Specifically, the need to ensure a) no

ruminant protein is present in any animal feed and b) no porcine PAP is present in porcine

feed or no poultry PAP is present in poultry feed. The first research challenge was the

preparation of standardised species-specific PAP products by rendering. Thereafter a

series of experimental test methods were assessed to determine the most appropriate

method to detect a target species protein within a mixture. The criteria included the

accuracy, sensitivity and replicability.

Author's contribution.

The author had prime responsibility for the production of the species-specific PAPs to be

used as reference material for the method evaluations. This required the author to design

the process and sampling protocol to ensure that pure species ABP were processed

according to validated methods, into pure species PAP. Subsequently, the author was a

member of the research team that designed and completed the EU projects STRATFEED

(Dardenne, 2005) and SAFEED-PAP (Jorgensen & Baeten, 2013).

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Implications.

The results of this project resulted in greater focus on PCR techniques which appeared to be more suitable for the detection of low levels of potentially heat denatured proteins in PAPs. Subsequent work by co-authors and others resulted in the EU regulatory approval of PCR methods for the detection of ruminant protein in mixtures of PAPs and animal feeds (EU 2013a).

7. Nutritional evaluation of animal proteins in aqua species (paper 6)

Davies S.J., Gouveia A., Laporte J., Woodgate S.L. Nates S. (2009). Nutrient digestibility

profile of premium animal protein by-products for temperate marine fish species

(European sea bass, gilthead sea bream and turbot). Aquaculture Research 06/2009; 40

(15):1759 - 1769

Impact factor: 1.75

Citations: 52

Background.

The BSE epidemic and subsequent feed ban in 2001 led to the cessation of animal

nutrition research on the utilization of animal proteins in animal feeds. Nonetheless, the

author considered that the feed ban would be lifted in future and, in his opinion, it was

likely that the first approval would be for poultry derived PAP for use in aquafeeds. Based

on this consideration, research commenced on studying the potential benefits of using

poultry derived PAP, produced under validated and characterised conditions.

Summary.

The utilisation of processed animal proteins (PAPs) in several marine fish species were

studied in this paper. The PAPs evaluated were produced under characterised process

conditions which enabled the nutritional data to be more meaningfully interpreted. The

investigation produced valuable data for the digestibility coefficients of essential amino

acids such that these can be used in feed formulations that include specification limits for

digestible amino acids

Author's contribution

The author was responsible for the production of the PAP samples under characterised

process conditions. The important step of reporting the characterisation of samples under

evaluation allows realistic comparisons between different PAPs rather than previously,

when generic samples were compared.

Implications.

In addition to the nutritional data yielded, this paper was included as evidence in

information provided to the European Commission to show the efficacy of PAPs in

aquafeed. This evidence supported the aquafeed industry request to approve the use of

non-ruminant PAP in feeds for aquatic species (paper 5). Accordingly, a regulation giving

effect to this was adopted in 2013 (EU 2013b).

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8. Evaluation of active minerals in meat and bone meal ash (paper 7)

Dybowska A., Manning D.A.C., Collins M.J., Wess T., Woodgate S.L., Valsami-Jones E.

(2009). An evaluation of the reactivity of synthetic and natural apatites in the presence of

aqueous metals. Science of The Total Environment 02/2009; 407(8):2953-65.

Impact factor; 6.55

Citations:72

Background.

This paper follows on from paper 4, where data published provided an insight into the

properties of MBM ash. Nonetheless, no specific applications were identified in the former

paper, so research was initiated to evaluate the potential for MBM ash to be used as an

adsorption medium for water contaminated by aqueous metals.

Summary.

On the basis of previous research (paper 4), it was hypothesised that the hydroxyapatite

content of MBM ash might have a role to play in reducing the levels of aqueous mineral

contaminants in mine water effluent. Experiments were designed to evaluate the removal

of high concentrations of minerals such as Lead, Cadmium, Copper and Zinc from

aqueous solutions by MBM ash and other forms of hydroxyapatite. MBM ash was very

effective (100%) in the removal of lead and moderately effective (50-60%) in the removal

of the other metals tested. Higher combustion temperatures for the MBM ash reduced the

surface area by re-crystallisation and as such reduced its reactivity.

Author's contribution.

The author had key responsibility for the management and sampling from the process that

produced characterised MBM ash samples. He was a member of the research team that

directed the research into the use of hydroxyapatite as a potential component in filters to

adsorb heavy metals from contaminated waters.

Implications.

The findings of this paper have been used to inform further research into the unique

properties of bone ash, (Modin et al., 2011, Lei et al., 2019).

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9. Life Cycle Analysis in rendering systems (paper 8)

Ramirez A. D., Humphries A. C., Woodgate S. L., Wilkinson R. G. (2012) Greenhouse gas life cycle assessment of products arising from the rendering of mammalian animal by-products in the UK. Environmental Science and Technology, 46, 447–453.

Impact factor: 7.86

Citations: 16

Background.

Prior to the formal launching of the Food and Agriculture Organisation (FAO) Livestock Environmental Assessment and Performance (LEAP) programme (FAO 2012), members of the animal feed industry were beginning to discuss how 'Carbon footprint' data using life cycle assessment (LCA) could be determined for animal products such as meat, milk and eggs. Although LCA determinations of primary products had begun, the author recognised that no LCA data had been published regarding the rendering industry processes or its products. Therefore, research in this sector offered the possibility to satisfy the demand for LCA data in the rendering industry, where none existed previously. With such data, it was hypothesised that the rendering industry would be able to participate in a debate regarding 'Carbon footprint' armed with knowledge. It was also recognised by the author that there was potential for the EU regulatory regime for separating ABP by risk, to deliver an opportunity for producing low carbon impact rendered products.

Summary.

The main focus of this paper was to assess the energy consumption by the UK rendering industry and to quantify the level of greenhouse gases produced using LCA. System boundaries were described that recognised the state of the current ABP categorization i.e. Category 1 ABP rendered and products used as carbon neutral fuel and Category 3 ABP rendered (using Category 1 products as fuels) into animal feed grade products. The results of this study illustrated the potential of the rendering industry to provide fats and protein sources with a lower global warming potential than traditional vegetable-based alternatives such as palm oil and soyameal.

Author's contribution

The author instigated this research programme (in the form of PhD research) as he recognised the increased interest and importance of LCA studies by society in general and in the animal feed industry in particular. Accordingly, a project to investigate the LCA

impact of rendering was proposed by the author and he acted as a co-supervisor for the PhD student. In particular, the author's role in the development of rendering post 2002 was used to inform the project scope such that there was a twin focus on both the production of renewable energy and production of animal proteins and fats for use in animal feeds.

Implications.

Data from this paper (and the PhD thesis) is currently being used in LCA assessment projects that are considering the impact of all types of feed ingredient used in livestock production. The recently operational Global Feed LCA Institute (GFLI) is the product of an international consortium that was formed to establish a "global gold standard" for calculating the carbon impact of feed ingredients for animal feeds, (GLFI, 2021). The ability to include data on rendered products in the GFLI database represents a very positive outcome for this research.

10. Safe animal proteins and fats in animal feeds (paper 9)

Woodgate S.L. (2012). 'Ensuring the safe supply of animal-derived ingredients for animal

feed' in Animal feed contamination: Effects on Livestock and Food Safety.

Ed. J. Fink-Gremmels, p 589 ISBN: 978-1-84569-725-9

Impact factor: n/a

Citations: 3

Background.

Although EU regulations were in place to ensure that animal proteins and fats were safe

to use in certain animal feeds, many in the feed industry considered that rendered

products were stigmatised following the BSE crisis in the EU. This paper attempted to lay

out the detailed safety measures in place to allay the concerns of the feed industry,

retailers and consumers.

Summary.

This paper is in the form of a book chapter by the author that reviews all of the

overarching regulatory developments and improvements in product safety since the

1980s. This paper updates the progress made to ensure that PAPs are safe to use in

animal feeds. Specifically, the security standards cited include the categorization of ABPs,

the use of validated rendering processes together with the use of HACCP principles to

enhance the safety credentials of rendered products, (Woodgate 2010). Furthermore, the

production of species-specific PAPs, together with the necessary control tools, ensures

that the safety requirement of the intra-species prohibition can be met.

Author's contribution.

The author used his extensive knowledge and experience to set out the facts about safety

of animal proteins and fats in feeds for farmed animals for human food.

Implications.

This paper is regarded as a valuable reference for the rendering and feed industries

respectively. However, due to limited progress with the re-introduction of PAPs into animal

feed since the publication of this chapter, the number of citations has been relatively low.

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11. Rendering processes pre and post BSE (paper 10)

Woodgate S.L. Wilkinson R.G. (2021). The role of rendering in relation to the BSE epidemic, the development of EU animal by-product legislation and the reintroduction of rendered products into animal feeds. Annals of Applied Biology. 2021;178:430–441

Impact assessment n/a

Citations n/a

Background.

No publications have considered the BSE epidemic from the perspective of the rendering industry over such an extended period of time. This paper covers the period 1985 to date and is an extensive and detailed review of the rendering industry and its role in the development of regulations following the BSE epidemic. This paper includes previously unpublished research from the authors work on i) the inactivation of BSE and scrapie agents by rendering (papers 1a,1b) and ii) the development of a validation method for rendering processes.

Summary.

The development of the animal by-product (ABP) processing industry, known as rendering, is charted from its earliest days through to the industrial processing systems that became established throughout the world in the 1970s.

BSE emerged in the UK in 1986 and the subsequent epidemiological study in 1988 confirmed that the protein meal (MBM) produced by rendering of ABP had a causal role in the origin and amplification of BSE.

Following location of a focal point for the start of the epidemic, some 5-6 years earlier, research conducted by the author and others revealed considerable knowledge gaps with respect to the actual rendering processes.

The author recommended a generic characterization of different processes which in turn highlighted the limited understanding of the process dynamics, particularly within continuous processes. These knowledge gaps informed the direction of the research completed by the author and others.

The imperative to devise a research protocol for the inactivation of TSE agents required that key criteria in continuous systems, such as particle size, transit time and temperature profiles were able to be quantified. Development of the methods by the author, for use in

the inactivation trials revealed significant differences in transit times for the continuous systems. Subsequently, a validation process was developed by the author in conjunction with UK and EU regulators, based on the minimum transit time and temperature profiles applied to the process criteria from the inactivation studies.

The immediate impact of the finding that BSE in cattle was linked to variant Creutzfeldt Jacob Disease (vCJD) in humans for the rendering industry was the ban on the use of animal proteins in feeds for farmed animals. Thereafter, much of the author's research was centered on meeting the challenge of ensuring the safety of rendered products (papers 2 and 3).

As a result of the legislative focus on risk reduction, a pre-requisite that some ABP categories were required to be disposed of, if low risk ABPs were able to be used in animal feeds in future. This requirement led to the development of a dual-stream rendering industry with one stream producing fuel products and an inorganic ash residue (papers 4 and 7). The second stream produced proteins and fats suitable for animal feeds and in anticipation of the authorization of non-ruminant PAP for aquafeed research on the use of poultry PAP in some aquafeed species began, (paper 6). The key feature of this two-stream business is that it offered an opportunity to produce carbon neutral fuels, which could be used in the rendering process to produce low carbon PAPs, (paper 8).

In order to meet the requirements of the intra-species recycling ban, production of species pure PAPs became a focus. Consequently, research by the author and others (paper 5) led to the development of a method to determine the species identity of PAPs, which eventually led to non-ruminant PAPs being approved for aquafeeds in 2013 (EU 2013b).

Footnote: The acronym EFSA stands for the European Food Safety Authority (and not the European Food Safety Agency- as stated incorrectly in published paper number 10)

Author's contribution

The author was primarily responsible for five research areas which directly led to the development of a modern (post BSE) rendering industry;

- Proposal of the set of criteria to use to characterise rendering systems.
 The grouping of the processes into generic processes, made the development of a research protocol possible.
- 2) Characterisation of rendering systems. The key criteria for continuous systems, were considered to include the particle size, transit time and temperature of the ABP particles achieved at various points in the process.
- 3) Development of a technique to determine transit time in continuous systems. The author developed a manganese dioxide 'briquette' to determine the minimum transit time in rendering processes. This step was considered to be an essential factor in characterizing the different process systems, understanding their role in the development of BSE and establishment of appropriate processing regulations.
- 4) Completion of transit time studies and interpretation of data. The transit time research revealed very significant differences in the minimum times taken for the ABP to travel through the four systems being evaluated and led to an early hypothesis for cause and amplification of the BSE epidemic by the use of non-inactivated MBM in animal feeds.
- 5) Development of a protocol to validate rendering systems. The EU regulation of 2002 required that the continuous rendering processes described needed to meet stringent process criteria. These conditions required validation. Accordingly, the EU validation process was developed by the author, in conjunction with UK and EU regulators, based on the minimum transit time and temperature profiles applied to the process criteria from the inactivation studies.

Implications.

This recently published paper offers the first complete narrative of the progress of the BSE epidemic from the perspective of the rendering industry. As such, it is expected that the paper will be used as a valuable reference document for stakeholders, policy makers and regulators in future.

12. Additional Information

In addition to the published papers by the author he has made significant impact in a range of developments related to the improved security and sustainability of rendered products for use in animal feeds.

In his capacity as President of the World Renderers Organisation (WRO) 2013-2015 the author initiated the development and publication of a model HACCP plan for rendering (WRO, 2013). This guide emphasises the role of the author in securing high biosecurity standards for rendering by the use of HACCP principles. In this same period, the author initiated WRO involvement in the development of LCA calculations to illustrate the sustainability credentials of rendered products

The current state of play of rendered animal proteins has been described in a paper by the author and colleagues titled 'Advances in the utilisation of processed animal proteins for aquafeeds' which has been submitted to 'Reviews in Aquaculture'. This paper considers the progress made since the re-authorisation of non-ruminant PAPs in aquaculture in 2013. In addition to the legislation cited in paper 10, this paper also refers to key EU regulations that, i) approved the export of non-ruminant PAPs to be used in animal feeds (EU, 2016) and ii) that acknowledged PAPs as an ingredient for use in animal feeds in the EU Catalogue of Feed materials. (EU, 2017). This global review puts the production of safe and low carbon PAPs from Europe into a global context and compares and contrasts them with other sources of global animal proteins in a wide range of aquafeeds.

13. Conclusions

The research outlined has contributed towards the eradication of BSE in England, with no cases in cattle born after 2010. An application to the World Organisation for Animal Health (OIE) for recognition as a 'negligible risk' status, the lowest BSE risk status possible, has been made. This submission will be considered by the OIE at their general assembly in 2022 and if approved, will place England in a negligible risk zone, such that trade in many animal by-product commodities can re-commence.

To bring the BSE story up to date, the use of poultry and porcine PAPs in feed for non-ruminant animals has recently been approved by the EU. Accordingly, Commission Regulation 2021/1372 was published in the EU Official Journal (OJ) on the 17th August 2021 (EU, 2021).

In summary, the research included in this submission highlights the author's contribution to our understanding of the aetiology, control and eradication of BSE. In addition, the submission illustrates the original thinking of the author in the development of new markets for rendered products. The safety and sustainability credentials of rendering and rendered products are such that modern rendering is now considered to be a technically competent and responsible sector within the livestock food chain industry.

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