final report

Project Code: A.COP.0034
Prepared by: <Name>
<Company>
Date published: November 2005

PUBLISHED BY
Meat and Livestock Australia Limited
Locked Bag 991
NORTH SYDNEY NSW 2059

EU regulatory and market access expert briefings

Meat & Livestock Australia acknowledges the matching funds provided by the Australian Government and contributions from the Australian Meat Processor Corporation to support the research and development detailed in this publication.

The co-products technology scanning in the EU required by MLA fits into the strategic scanning component of the MLA Co-products program. The purpose of strategic scanning is to help identify emerging and current threats to and recognise new opportunities for the co-products industry.

Scope

MLA recognises that co-products from pigs and poultry are significant aspects of the EU co-products scene. However technology scanning conducted for MLA concentrated on co-products derived from cattle and sheep. This does not exclude reporting on information about poultry and pig co-products where the information relates to or impacts on cattle and sheep co-products.

The technology scanning related mainly to rendered co-products or the materials that are traditionally rendered. If information on other co-products such as concentrated gall, pet food, edible offal, hair, is available it has been included in reports. It is not expected that technology scanning on issues related to hides and skins will be included.

Technology scanning related to the EU has four components. They are:

- Regulation
- Research and development activity
- Industry activity
- BSE status

Regulation

EU regulations are relevant to the Australian industry because Australian exporters have to comply with EU regulations when exporting to the EU, other third countries may partially adopt EU regulations and EU regulations affect the export of co-products from the EU and consequently affect the international trading environments.

MLA should be notified of potential changes in regulations that might affect exports of co-products to the EU or the international trading environment for co-products. It is not necessary to report all committee work leading up to regulations unless the preparatory work is expected to lead to regulations that have a major impact on co-product trade. Potential changes in regulation should only be reported if the changes are expected to have a significant impact or when the changes are close to being adopted.

It is expected that each report will include a comment on potential amendments to 1774/2002 and the regulatory status of feed bans.

Research and Development

R&D related to new uses for co-products is of particular interest to MLA. Where information on R&D projects is in the public domain it should be reported. Projects on new uses such as production of bone apatite move slowly and it is not necessary to

provide detailed updates of projects in each report. At the MLA workshop on expanding co-products business through R&D, Stephen Woodgate outlined nine co-products R&D projects being conducted through EU partnerships, national government and industry. It is expected that technology scanning reports will include updates on the status of these projects.

Industry activity

Technology scanning of industry activity should include reporting on how co-product are being processed and used. It should identify any growth in particular uses. Where possible it should provide statistics on the amount of material processed and the amount products produced. If possible it should also include data on the economics or cost of co-products production.

Developments in equipment and significant instillations of new equipment should be reported.

BSE Status

The technology scanning reports should include comment on BSE in the EU. It is not necessary to report numbers of cases but any unexpected cases or changes in trends in the number of cases should be reported along with any explanations for unexpected cases or trends. Developments in research on BSE including new information about the origin and transmission of BSE, infective dose, and diagnostic tests should be reported. New information on the safety of co-products with respect to BSE transmission should be reported.

Period of Report February 06 – May 06 to date inclusive

General items of interest:

1. ACREC dedication in the USA
Details of ACREC/ FPRF are described in the attached EFPRA newsletter just published (includes☆)
This new venture is worthy of a more detailed discussion I think (EU… Australia)

2. EFPRA Congress including the Technical Symposium☆ May 10-13 2006. www.efpra2006.org

Legislation:

1.Entries.
There have been no significant new entries into force. However it is worthwhile summarising the main points of Commission Regulation 2067/2005, introduced in December 2005, as an amendment to Commission Regulation 92/2005

The key points are that it:

- allows animal fat to be used in the production of bio-diesel
- allows the use of animal fat to be combusted in thermal boilers
- defines a process treatment for the animal fat thus used to be followed, but also to allow competent authorities to define safe processes
- exempts bio-diesel produced under laid down conditions, from the need to be marked

2. Proposals/Notices; None of any significance.

Technical Advances:

1. Markers for category 1 and 2.
Please see R&D report part 3 b

2. Species Identification of PAP in animal feeds

a. A new paper (attached) on the subject is noteworthy. Published in Journal of Food Protection, Vol. 69, No. 1, 2006, Pages 205–210. Title is "Validation of a PCR-Based Method for the Detection of Various Rendered Materials in Feedstuffs Using a Forensic DNA Extraction Kit" by Myers et al.
This paper reports on a trial to validate the use of a commercial DNA forensic kit to extract DNA from animal feed as part of a PCR-based method.
The results of this study demonstrated that the DNA forensic kit can be used to extract DNA from animal feed, which can then be used for PCR analysis to detect animal derived protein present in the feed sample, possibly at levels of as low as 0.1%.

b. Two unrelated projects in the UK are also working in areas that could eventually develop methods suitable for species ID.
1 is part of the "Apatite" project (2a) and the other is part of the "Biomark" project (2c).
In the latter project, this aims to use Mass Spectrometry to identify and quantify heat stable proteins/peptides from rendered MBM destined for animal feed.
Preliminary investigations have evaluated the potential of obtaining protein markers in MBM from bovine, porcine, avian and ovine sources.
The extent of protein degradation in MBM has been investigated by crude extraction, DEAE anion exchange chromatography and SDS PAGE.
Proteins have shown good separation by DEAE anion exchange and SDS Page. A protein of interest alpha-actinin has been identified by MALDI-TOF MS analysis. Direct crude extraction and SDS PAGE of MBM shows a characteristic smear of degraded protinaceous material, which could be masking low abundance intact proteins. Using DEAE anion exchange and SDS PAGE, the slurry of peptides and amino acids can be partially removed.
Silver stained bands from bovine MBM have been visualised on SDS PAGE in fractions eluted during DEAE anion exchange. Bands have been cut out, destained, enzymatically degraded and are currently waiting for analysis by MALDI-TOF MS.

c. The EU are continuing their efforts to find a method that will be validated by their Independent Scientific Research centre. There are 3 pcr candidates currently being studied, together with the Neogen dip stick method. Hopefully at least one will come up to the mark.
There will be an EU review at the end of May which will be reported to MLA in the next report.

Research and Development

1.EU Funded Projects

a. Stratfeed: MBM in Feed:
Technically this project has closed. A new project has been agreed, called SAFEED-PAP. I am on the management steering Group. I will review after our first meeting (expected within 1 month)

b. Hipermax: Protein matrices
The objective of the project is to evaluate the potential of using poultry fibres in the manufacture of new products which may include paper, structural materials, insulation, filters. The first phase of the project was to define equipment that both cleans and chops the feathers, to make a pulp on an industrial scale. This has been has been successfully completed.
The second phase of the project has been to make fibre material using this feather pulp. Fibre material consisting of 70% feather pulp/30% paper pulp, and 50% feather pulp/50% paper pulp have been made on a pilot plant scale.
Sheets of fibre material made from the 50/50 mix could be slit without tearing, but that made from the 70/30 mix was too weak to slit. However, both the materials could be braided and spun.
The third phase of the project will evaluate methods of improving the strength of the fibre materials made using the feather pulp.

c. BIODEPRO: Biodiesel (FAME).
An abstract of a paper to be given at the EFPRA Technical symposium is attached.
More details will be available in the next report

2.Nationally Funded Projects

a. APATITE: Uses for MBM apatite (UK)

A research project to study the structural and chemical changes of thermally treated bone apatite is underway. The study investigated the thermally induced changes occurring in the organic and mineral phases of bone in mammalian MBM.

Phase 1. The work has shown that the microstructure of the bone changes significantly when heated to a temperature greater than 500 deg C. This fundamental research suggests process conditions which would allow MBM to be used as agricultural soil enrichment, or for the immobilization of toxic heavy metals, or as a biomaterial for use in dentistry and orthopaedic medicine.

Phase 2 will move the work into a pilot scale reactor.

b. Biogas: Anaerobic Digestion of ABP (NL)

There has not been any reporting of work to date yet. Data is expected in quarter 3 2006.

c. Bio-mark: Markers in MR meat (UK)

The work in this project was delayed due to difficulties with recruitment. A project review will be held in June 2006and reported in the next MLA report

3. Business Funded Projects

a. AQUA (UK): use of ABP in Aqua (PhD)

The first phase of the research has tested selected animal by-products for use in the mediterranean fish species Gilthead sea bream, Sparus aurata. Trials have been run to define reliable digestibility coefficient data with respect to protein, lipid, energy and essential amino acids for sea bream.

The ABP tested were: standard heat treated feather meal, enzyme treated feather meal, poultry meat meal (PMM), spray dried haem (SDH),and blends of each feathermeal with SDH and PMM. The reference diet was based on a prime quality low temperature fishmeal.

The results show that both feather meals were not significantly different and were poorly digested. SDH and PMM were not significantly different in digestibility to each other and were well digested, though both performed worse than the benchmark fishmeal. When SDM was mixed with feather meal, the mixture gave a performance comparable to feathermeal. Mixtures of PMM and feathermeal gave a digestibility intermediate between the two components.

The next phase of the research is to use this data to define feeding mixtures that will be tested in long-term feeding and nutritional trials. PMM will be included at levels of up to 75% replacement for fishmeal, together with low inclusion levels of feather meal and SDH.

b. MARKERS (NL): The use of dyes and GTH as markers for ABP (Contract)

Different dyes were tested for their suitability as a marker of raw category 1 and 2 materials in the slaughterhouse. It was shown that the water soluble dyes Patent Blue V, Tartrazine and Methylene Blue are suitable to mark raw animal by-products. Patent Blue V and Methylene Blue are preferred because of a higher colour contrast between marker and substrate.

GTH was tested for a period of one week at different rendering plants as a marker for processed category 1 and 2 products. During the trial period GTH was added to the process and samples of meat and bone meal and fat were collected for GTH analysis.

The stability of GTH during storage of processed animal protein was tested for 40 weeks at room temperature. During this period GTH levels were constant.

A suggested method is the application of water soluble dyes for marking category 1 and 2 animal by-products in the slaughterhouse, at a dosage of 10 g (solved in 2 litre water) / MT raw material.

GTH is proposed as a marker for these products in the rendering plants. To guarantee the detection of the GTH marker, a dosage of 50 g GTH / MT raw material (or 250 g / MT on fat

basis) would be sufficient.

Work on the detection of GTH and C7 in animal feed and category 3 processed animal proteins has shown that GTH may be present in feed at levels that might falsely indicate contamination with category 1 and 2 products if GTH is used as a marker for these products.
Thus, when GTH is used as a marker for category 1 and 2 products, GTH should be determined in processed animal proteins (and fat), and not in feed, to assure that no category 1 and 2 products are used in feed production.

c. RENERGY (UK): Conversion of MBM to Energy

Since 2000, the PDM Group in UK has operated a biomass-fired CHP using Bubbling Fluidised Bed (BFB) technology. This integrated renewable energy and recycling plant is claimed to be the first of its kind in the world.
The primary raw materials are residues from poultry and livestock production.
260,000 tonnes of animal by-products are processed each year

These animal by-products then undergo a number of high temperature cooking and sterilization processes, which convert them into two highly calorific products; liquid tallow and solid meat and bone meal (MBM).The BFB combustion unit uses the MBM as fuel to generate steam and electricity to run the plant. The tallow is used to generate energy for export.

The plant exports 9MW of power. This will increase to 15MW by 2008. It also exports steam to an adjacent chemical company. Following the success of the first facility, PDM has received planning consent for a second CHP plant at another site, which will be on stream by late 2006.

Attachments

- EFPRA Technical Topics : Includes programme for EFPRA Technical symposium
- BIODEPRO Abstract
- Myers *et al* 2006. Journal Food Protection

Other Issues of note

BSE

- Incidence of confirmed cases of BSE in cattle in UK continue to decline, with a reported 225 cases in 2005, down from 343 in 2004, and the peak of 37000 in 1992. Other European countries also saw declines.

- The National CJD Surveillance Unit reported that onsets and deaths in humans due to vCJD in UK continued to decline in 2005. One onset case was reported in 2005 compared with 9 in 2004. Deaths declined from 9 in 2004 to 5 in 2005. The peak numbers for onset cases in a year was 29 in 1999 that for deaths was 28 in 2000.

- A European Commission ban on British beef exports has officially ended, 10 years after it was imposed. Live cattle born after 1 August 1996 can now be exported, as can beef from cattle slaughtered after 15 June 2005. Restrictions will remain for beef containing vertebral material and for beef sold on the bone. UK beef prices are expected to rise as a result of increased export trade.

- A study published by Lancet Neurology confirms that the likelihood of transmission from animal to human via infected meat is low, but suggests human-to-human transmission through infected blood products and surgical equipment is more likely than previously thought.

- Martin Jeffrey in the April issue of the *Journal of Pathology* reports that research by investigators in UK and Norway into the transmission route of the brain-wasting infection scrapie in sheep, a related prion-associated disease, has cast doubt on whether abnormal prion proteins are truly the infectious agents for vCJD disease infection in humans after all. They claim their work suggests that prion protein is merely a secondary marker of the presence of the scrapie agent.

- An enzyme that digests the agent that causes vCJD and BSE has been put on sale. It has been developed by scientists at Porton Down in UK to clean instruments and may also dispose of contaminated tissue, even digesting contaminated carcasses. The designer enzyme, originally conceived by Dr Neil Raven at Porton, is sold by Genencor International, branded as Prionzyme.

Avian Flu

- Avian Flu virus H5N1 has now been reported in domestic poultry in France and Germany. Strict measures to prevent a spread of the disease, including culling infected flocks and restrictions on movement in surrounding areas were imposed.
- Sales of poultry have seen a significant decline in some EU countries. The EU has agreed to compensate producers for half the value of the loss of sales.

Period of Report September 06 to date

General :

As expected the autumn months have been more active from a legislative point of view. The two key regulations directly affecting animal by-products (ABPR and TSER) are under discussion / review. The waste framework directive (WFD), which has an indirect relationship with animal by-products, is also under review. The EU now has a Community Reference Laboratory (CRL) dedicated to Animal Proteins. The CRL, situated in Gembloux, Belgium, was officially opened on November 8th 2006. This new initiative will further assist the efforts of EFPRA to gain re-entry of PAP's into farm animal feeds.

EFSA:

The Biohazard Panel opinion on the safety of "tallow" has not been recognised by the federal German risk committee (BfR) and a difference of opinion has ensued. This continuing lack of agreement has caused problems, in that was expected that EFSA would be the "ultimate" authority in matters such as scientific opinions on risk to human health. Nonetheless, a process of "conciliation" is now underway, and an agreement between the two bodies is expected in January 2007.

Legislation:

1.Review of the ABPR 1774/ 2002

This revision is now on draft no 9, and significant editing has occurred since draft no 5 was discussed by industry and the commission in September. The general consensus is that the new regulation will be a better regulation, placing a lower burden on industry when completed. The principles laid down in the ABPR will remain the same, however, but the layout and "user friendliness" will improve. Most of the working parts of the ABPR now found in the annexes, will be placed in an "implementing regulation", which will be flexible in the sense that it can be amended by comitology (Committee of member state representatives SCoFCAH), rather than by reference to the European Parliament (EP).

2.Review of the TSER 999/2001

This regulation is being amended in consultation with the EP. One of the main criteria that will be included in the amended TSER will be the recognition of a "tolerance level" in regard to PAP in animal feeds [as opposed to the current status of zero tolerance].

3.Tallow :WID

The independent report from Ecolas, commissioned by DG- Environment is now expected to be published in January 2007 !!, contrary to expectations. Meanwhile renderers in all member states who want to use tallow as a fuel, appear to be doing so without too many problems. UK industry is having to "show an intent" to comply with WID while

waiting for an outcome: In real terms this means an emissions monitoring programme at two sites (out of ~ 30)

Technical Advances:

1. Markers for category 1 and 2.

The principles discussed previously have now been incorporated into a draft regulation (amendment to ABPR 1774). This draft will be discussed in the SCoFCAH in early 2007 and it is expected that the regulation will be in place by the second quarter of 2007.

2.Species Identification of PAP in animal feeds

The SAFEED-PAP project will officially kick off in January 2007. The project will run for 3 years. This project will be coordinated by the CRA-W (the Agricultural Research centre in Gembloux) also the home of the new CRL Animal Proteins. As a result, a high level of coherence is expected in the area for the future. SLW is on the "advisory board", along with other international experts from USA, China, Japan. One particular area of interest is the intention to hold a series of "international workshops", with China already being proposed as a candidate for a workshop (in 2008).

3 EFPRA risk assessment
The DNV risk assessment conducted for EFPRA is now published (attached) and has been presented to DG-Sanco and EFSA. More detailed discussions with DG-Sanco will take place in early 2007 as regards mapping out a plan of action for PAP re-entry.

Research and Development

1.EU Funded Projects

d. Stratfeed: MBM in Feed: This project has closed
The new project is termed SAFEED-PAP. A report will be given after the kick off meeting in early 2007.

e. Hipermax: Protein matrices: The reviews in September (Europe) and in November (UK) indicated that the project would be extended by 3 months to May 2007. The main focus in the last 6 months is to get closer to commercialise some of the concept products produced so far. In particular, the feather part of the project has been a great success, when compared to wool and leather, where progress has not been so significant. The main ideas for using feather fibre is in moulded products, such as plant pots, packaging etc, as feather fibre sheeting which may be used to make braided fibres and in laminated products, which use feather fibre sheets between two layers of other materials to make composites.

f. BIODEPRO: Biodiesel (FAME). A final project report is awaited.

2.Nationally Funded Projects

c. APATITE: Uses for MBM apatite (UK) The most recent review in November, concluded that the differential of ~150 oC in combustion temperatures was potentially a big enough difference to detect different levels of apatite activity in ash derived from the combustion of MBM.
A trial has been set up to show the different level of heavy metal retention from contaminated mine water in 4 columns containing samples: ie two ash samples (~700oC and ~850oC), and two control samples, MBM and rock Apatite. Results from this trial should be available in the next 3 months.

d. Biogas: Anaerobic Digestion of ABP (NL). This project has been shelved, due to current lack of funds for this type of bio-energy project. The reason for no funding is that there has been an over-subscription to this type of "green" energy project, and federal government funding has been exhausted!! This may be temporary, but no new funds will be available in the foreseeable future.

c. Bio-mark: Markers in MR meat (UK). This is a two part project:

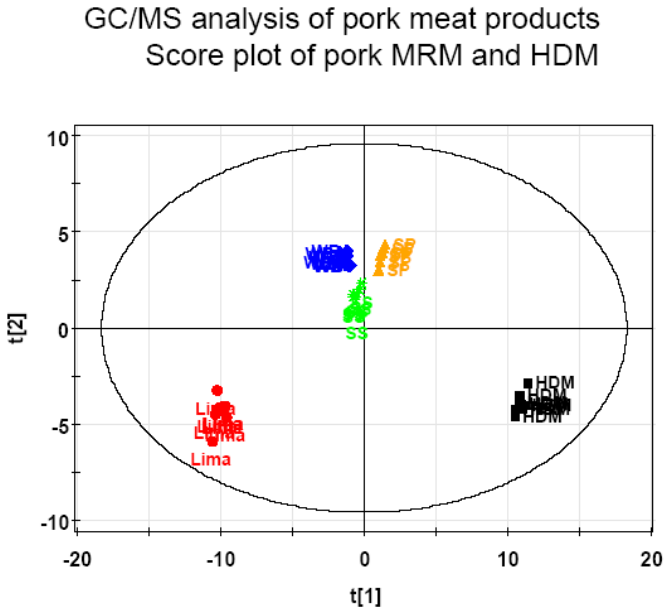
i. Detection of MRM in meat products

The project review in November indicated that the GS-MS screening of materials produced by a range of MSM machines did show differences between the control hand de-boned material and the 4 different machines, (see fig 1 below). Currently, attempts are being made to try and identify the unknown metabolites.

ii. Detection of different species in mixed meat products

This project is suspended temporarily due to loss of the post-doctoral researcher, who has returned to China. A new researcher is being sought.

Fig 1



3.Business Funded Projects

d. AQUA (UK): use of ABP in Aqua (PhD). This PhD is reaching completion, (January 2007), and the thesis will be published in due course. However, it is hoped that the research results will be presented in a technical format in a series of articles to be published in International Aquafeeds. The three related articles will consider the effect of inclusion of a) Poultry meat meal, b) hydrolysed feather meal and c) synergistic mixtures of animal by-products, in diets for trout, tilapia, sea bream, sea bass and turbot. Digestibility studies and growth-performance will be discussed in the 3 linked review articles.
A summary table taken from the poultry meat meal review is shown in table 1
This table indicates the recommended inclusion level of poultry meat meal in diets of a range of species and the reasoning for each recommendation.

Table 1

Species	Optimum replacement rates of fish meal proposed	Data used to estimate fish meal replacement rates
European sea bass	25%	digestibility data
turbot	10%	digestibility data
Gilthead sea bream	25%	digestibility & growth data
red tilapia	66%	growth data

rainbow trout	15%	digestibility & growth data

e. A new PhD proposal has been approved. The scope of this PhD will include studies on the health and performance in carnivorous fish, which use BP's in the diet. Comparisons will be made with other fishmeal replacers such as vegetable proteins.

Attachments

- DNV report for EFPRA (V3 final ...04/12/2006)
- Draft Sanco/10571/2006 (dated 29.11.2006)…. regarding markers

SANCO/10571/2006

As of: 29.11.2006

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2006) final

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards marking of animal by-products

(Text with EEA relevance)

(Communication from Mr. M. KYPRIANOU)

Draft

COMMISSION REGULATION

of

amending Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards marking of animal by-products

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,
Having regard to Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption[1], and in particular Article 32(1) thereof,
Whereas:

(1) Regulation (EC) No 1774/2002 lays down specific requirements for animal by-products not intended for human consumption.

(2) According to Articles 4(2)(b) and (c), 5(2)(b) and (c) and 6(2)(b) of Regulation (EC) No 1774/2002, permanent marking, in accordance with Annex VI Chapter I, is required for certain animal by-products.

(3) According to Annex VI Chapter I, marking is to be carried out in accordance with a system approved by the competent authority. So far, due to a lack of available scientific data on marking, no harmonised rules for such marking were laid down.

(4) On 17 October 2006, the Joint Research Centre of the European Commission issued an implementation study to evaluate Glyceroltriheptanoate (GHT) as a suitable marker for animal by-products in rendering systems[2].

(5) On the basis of this report, detailed requirements for the marking of animal by-products should be laid down. Annex VI Chapter I of Regulation (EC) No 1774/2002 is therefore amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

---

1 OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p. 25).

2 Available on the internet site of Directorate General … [http://www/ …].

HAS ADOPTED THIS REGULATION:

Article 1

Annex VI to Regulation (EC) No 1774/2002 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third day following that of its publication in the *Official Journal of the European Union*.
It shall apply from 1 July 2007.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Annex VI to Regulation (EC) No 1774/2002 is amended as follows:

(1) The title to Annex VI is replaced by the following:

'SPECIFIC REQUIREMENTS FOR THE PROCESSING OF CATEGORY 1 AND 2 MATERIAL, FOR BIOGAS AND COMPOSTING AND FOR THE MARKING OF ANIMAL BY-PRODUCTS'

(2) Chapter I is amended as follows:

(a) The title is replaced by the following:

'Specific requirements for the processing and marking of Category 1 and 2 animal by-products'

(b) Point (C) (8) is deleted.

(c) Point (C) (9) is renumbered as point (C) (8).

(d) The following points are added:

'D. Marking of animal by-products

(9) In slaughterhouses and, at any other points of first categorisation, the person who has the animal by-product under his control, including the producer, shall mark all surfaces of animal by-products with the following colouring agent:

(a) Category 1 materials by application of a 0,5 % weight/volume solution of patent blue (E131, 1971 colour index number 42051 (a)); and

(b) Category 2 material by application of a 0,5 % weight/ volume solution of methylene blue.

By way of derogation, Member States may decide to use other colour markers than those provided for in point (9) for material which is to be marked and further treated, used or disposed of within the same Member State.

(10) In processing plants approved in accordance with Article 13, the person who has the animal by-product under his control, including the producer, shall permanently mark the following animal by-products:

(a) Category 1 and 2 material destined for incineration, co-incineration, or landfill or, insofar as authorised in accordance with this Regulation or with Regulation (EC) No 92/2005, destined for transformation in a biogas plant or in a composting plant;

(b) Category 2 rendered fats destined for further processing or use in accordance with Article 5 (2) (b) (ii);

(c) Category 2 proteinaceous material destined for use as organic fertiliser or soil improver.

(11) Marking of animal by-products referred to in point (10) in a processing plant with the marking substance Glyceroltriheptanoate (GTH) shall take place after a first heating of the material to at least 80 °C in such a way that this substance will be distributed homogeneously in the material and in the end product with a minimum concentration of 250 mg GTH/kg fat in the end product.

(12) The operator of a processing plant shall put a system in place in order to demonstrate to the competent authority that the required homogeneous distribution and the end product concentration of the marking substance in the material are achieved. The competent authority shall carry out a performance check of this system before permanently approving the processing of material which is to be marked.

(13) At regular intervals and upon request of the competent authority, the operator shall analyse marking in the end products by way of a method based on the determination of GTH as triglyceride (intact GTH), in the samples. This determination shall be carried out as follows:

(a) GTH is extracted, with other fats, from the sample using petroleum ether 40-70.

(b) The extracted GTH is subsequently cleaned-up and its concentration is determined.

(c) Other methods for the extraction and determination of GTH with equivalent performance characteristics may be used.

(14) By way of derogation,

(a) marking as provided for in point (9) is not required for

(i) entire bodies of animals other than animals that died during transport to slaughter;

(ii) manure, digestive tract content separated from the digestive tract, milk and colostrums;

(b) marking as provided for in points (9) and (10) is not required for

(i) animal by-products transported between two establishments located on the same site and linked to each other by a conveyer system;

(ii) animal by-products intended for scientific use […].'

DNV CONSULTING

Assessment of the risk potential of reintroduction of certain processed animal proteins into animal feeds:

Final Report to the European Fat Processors and Renderers Association
Report No. 22514037, 4th December 2006

MANAGING RISK

Assessment of the risk potential of reintroduction of certain processed animal proteins into animal feeds for

The European Fat Processors and Renderers Association

DET NORSKE VERITAS LTD.
Palace House
3 Cathedral Street
SE19DE London
Tel: +44 (0)20 7357 6080
Fax: +44 (0)20 7357 6048
Registered in England
Company No. 1503799

Client ref:

Report No.: 22514037 v3
Final Report
Subject Group:

Indexing terms: Animal Feeds, Processed animal protein, MBM, TSE, Risk

Summary: The report presents an assessment of the potential increase in exposure to the BSE infective agent of the cattle population in the EU that could result from allowing non-ruminant processed animal protein (PAP) to be used as an ingredient in feed for non-ruminant farmed animals. The risk assessment model has been developed from the model used for the EFSA QRA Report (2004) *"Quantitative Assessment of the Residual BSE Risk in Bovine Derived Products"*. The study has indicated that allowing non-ruminant PAP to be used as an ingredient in non-ruminant animal feed would not result in any significant level of exposure of cattle to BSE infectivity.

Prepared by: *Name and position*
Philip Comer, Principal Consultant

Verified by: *Name and position*
Philip Comer, Principal Consultant

Approved by: *Name and position*
Philip Comer, Principal Consultant

Date of issue: 4th December 2006

Project No: 22514037

☐ No distribution without permission from the client or responsible organisational unit (however, free distribution for internal use within DNV after 3 years)

☑ No distribution without permission from the client or responsible organisational unit

☐ Strictly confidential

☐ Unrestricted distribution

Executive Summary

This report has been commissioned by the European Fat Processors and Renderers Association (EFPRA) as a contribution to the debate on possible changes to TSE controls in Europe as set out in the TSE Roadmap document. The report sets out to assess the potential increase in exposure to the BSE infective agent of the cattle population in the EU that could result from allowing non-ruminant processed animal protein (PAP) to be used as an ingredient in feed for non-ruminant farmed animals.

The risk assessment model has been developed from the model used for the EFSA QRA Report (2004) *"Quantitative Assessment of the Residual BSE Risk in Bovine Derived Products"*. The assumptions and data in the EFSA model have been used apart from assumptions about potential contamination with SRM of bovine by-products used to make MBM. The model has been run for a country with geographical BSE risk (GBR) status of III, as defined in the EFSA model. This is typical of EU countries at the present time. As the incidence of BSE cases in Europe continues to fall in future years then the risk potential will also reduce.

If non-ruminant PAP were to be allowed as an ingredient in non-ruminant animal feed it is assumed that the present restrictions on the use of restricted proteins such as fishmeal would remain in force to ensure that this material was not fed to ruminants. It is assumed that:

- The non-ruminant PAP would be produced in dedicated rendering facilities, not handling other animal species. This would minimise the risk of non non-ruminant material being included in the raw material.
- Dedicated transport would be used to transport the non-ruminant PAP from the rendering plant to the feed mill.
- The feed mill would either not produce any feedingstuffs for ruminants, or there would be complete physical separation of production lines from raw material reception through to product dispatch.
- Bulk product transport would also be in dedicated vehicles.

Non-ruminant PAP in itself would not represent a risk to ruminant animals. The risk potential is that by allowing non-ruminant PAPs to be used in some animal feeds then there is a greater chance that ruminant feeds would be contaminated. The study has not attempted to assess the likelihood of such contamination as this would require a detailed evaluation of production methods and controls across Europe. Instead, the study has estimated the amount of BSE infectivity, measured as cattle oral ID_{50} units ($CoID_{50}$), present in the total production of compound cattle feed in the EU (38 million tonnes in 2005), for assumed levels of contamination:

a. the contamination of non-ruminant PAP with bovine MBM (range from zero to 5%), and
b. the contamination of cattle feed with non-ruminant PAP (range 0.1% to 1%).

The controls in place for animal feed production would ensure that if such contamination were to occur it would be a rare event. The model assumes that the specified levels of contamination apply to ALL feed produced and does not take account of the likelihood that such contamination will occur. Thus the model results represent an absolute maximum value, and are not intended to be realistic estimates of possible exposures.

For the base case with 0.1% contamination of cattle feed and a uniform distribution of values for contamination of the non-ruminant PAP with bovine MBM, the mean exposure is estimated to be 0.0008 $CoID_{50}$ units per year with a 99 percentile value of 0.01. This is an extremely small potential exposure; and indicates that realistic exposures would be much less. For the

maximum assumed levels of contamination (5% ruminant MBM in non-ruminant PAP and 1% non-ruminant PAP in cattle feed) the predicted exposure is 0.01 $CoID_{50}$ units per year.

These results indicate that if there is a limit of detection as high as 5% ruminant PAP in non-ruminant PAP together with a limit of detection of 1% non-ruminant PAP in ruminant feed, and that these levels applied to all of the cattle feed produced in the EU, then the risk of additional BSE cases would be extremely low and significantly lower than the value reported in the EFSA "Opinion on the Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the residual BSE risk" (EFSA, 2005).

This initial study has indicated that allowing non-ruminant PAP to be used as an ingredient in non-ruminant animal feed would not result in any significant level of exposure of cattle to BSE infectivity. This would remain true even with higher levels of BSE prevalence than those used as a baseline, and certainly for the range of prevalence found in all EU countries. The overall levels of infectivity that may be present are so low that this conclusion is not sensitive to the sensitivity of the test for the presence of animal protein in ruminant feed.

TABLE OF CONTENTS

1.0 Introduction and Objectives

1.1 Background

Feed controls have been a key part of BSE control strategies in Europe and worldwide following the recognition that contaminated feed was the main mechanism for the spread of BSE in cattle. In the UK, the original feed ban was introduced in 1988 to prevent ruminant protein being fed to ruminants. This initial ban was extended in November 1994 to make it illegal to feed ruminants with all forms of mammalian protein (with some specific exceptions) and again in April 1996 to feed any farmed livestock with mammalian meat and bone meal.

Harmonised control measures were introduced in the European Union in 2001. These included a ban of the feeding of processed animal proteins to animals which are kept, fattened or bred for the production of food.

With the reduction in the numbers of BSE cases in the EU, it is now recognised that amendments to some of the control measures can be envisaged without endangering the health of the consumer or the policy of eradicating BSE. This new thinking on the BSE strategy in the EU was set out in The TSE Roadmap published in July 2005. One of the strategic goals set out in this document is *"A relaxation of certain measures of the current total feed ban when certain conditions are met."*

This report has been commissioned by the European Fat Processors and Renderers Association (EFPRA) as a contribution to this debate. EFPRA has fully supported the current feed controls in Europe, but is now keen to see the reintroduction of certain non-ruminant process animal proteins (PAP) in a controlled way.

1.2 Objectives

The objective of this study is to assess the risk potential, in terms of the possible exposure of the cattle population to the BSE infective agent that could result from allowing certain specified processed animal proteins to be used in certain animal feeds. The study should specifically examine the sensitivity of the risk estimate to the levels of PAP allowed in animal feeds.

1.3 Det Norske Veritas (DNV)

DNV is an independent foundation, established in 1864, with the objective of safeguarding life, property and the environment. DNV is among the world's leading companies in managing risks in areas of safety and the environment for today's industrial and societal settings. Throughout its history DNV has had a rule-setting function and/or determined conformance and compliance to Rules, Standards and Regulations. Being an independent, autonomous and self-owned foundation, DNV undertakes third party services requiring high technical expertise and the utmost integrity in all respects.

This study has been undertaken by DNV Consulting, the risk management consulting business of DNV.

2.0 Feed Production Scenarios

2.1 Current Feed Controls

Harmonised animal feeds controls were introduced in the European Union by Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 (Article 7 and Annex IV). Article IV of EC 999/2001 was subsequently replaced by Commission Regulation (EC) No 1292/2005 of 5 August 2005.

Essentially the legislation prohibits the feeding to ruminants of any animal protein or any feedingstuff which contains animal protein, apart from a short list of permitted proteins. The legislation also prohibits the feeding to non-ruminant farmed animals of any processed animal proteins or gelatine of ruminant origin, directly or in feedingstuffs. Prohibited processed animal proteins include mammalian meat and bonemeal, poultry meal, feather meal, etc.

Permitted proteins, which may be fed to ruminants, when sourced and processed in accordance with the Animal By-Product controls, include:

- Milk, milk based products and colostrums;
- Eggs & egg products;
- Gelatine from non-ruminants;
- Hydrolysed proteins derived from non-ruminants or from ruminant hides and skins.

Certain restricted proteins may be used for feeding to non-ruminant farmed animals. These restricted proteins are:

- Fishmeal;
- Blood products;
- Blood meal, only where fed to farmed fish;
- Dicalcium phosphate and tricalcium phosphate of animal origin.

There are various restrictions in place on the production and use of these restricted proteins aimed at ensuring that restricted proteins do not get into ruminant feeds. Feed mills, on-farm mixers and mobile mixers using any of these restricted proteins as feed material for non-ruminants must be authorised by the competent authority. Any farm using products containing restricted proteins, and where there are also ruminants present, must be registered.

In order to meet the authorisation standards, manufacture of feedingstuffs containing restricted proteins must either take place at premises which do not produce feedingstuffs for ruminants, or be able to demonstrate physical separation of the manufacturing process from reception through to dispatch.

2.2 Potential Changes to Feed Controls

The on going decline in the numbers of BSE cases in Europe has demonstrated that the control strategies put into place have been effective. The reduction in the numbers of cases, and hence the risk from BSE, has allowed the possibility that some of the control measures could be relaxed without endangering the health of the consumer or the policy of eradicating BSE. This was reflected in the TSE Roadmap, published by the European Commission in July 2005.

The TSE roadmap considers the range of TSE controls, sets out a strategic goal for each of the main areas and provides a framework for discussion in terms of potential changes. Section

2.2 refers to the feed ban and sets out the strategic goal as: *"A relaxation of certain measures of the current total feed ban when certain conditions are met."* It is noted that the starting point when revising current feed ban provisions should be risk based but at the same time taking into account the control tools in place to evaluate and ensure the proper implementation of this feed ban.

In Section 2.2.2.3 the TSE roadmap considers the potential for lifting some of the feed ban provisions for non-ruminants. Improvements in the ability of tests to differentiate animal proteins specific to certain species may allow consideration of the amendment of provisions with regard to the use in feedingstuffs of animal products, in particular non-ruminant proteins (e.g. poultry MBM to pigs).

2.3 Model Scenario

For the purposes of this study it will be assumed that the use of non-ruminant PAP (e.g. poultry MBM, feather meal and porcine PAP) would be allowed in feed for other non-ruminant farm animals. The details of this scenario are given in Section 3.4.

3.0 Risk Assessment Method

3.1 The Risk Question

The risk question to be assessed by this study is as follows:

> What is the expected increase in exposure of the cattle population in the EU to the BSE infective agent that could result from allowing non-ruminant PAP to be used in certain non-ruminant feed for farmed animals?
> and,
> How is this risk of exposure affected by the sensitivity of tests to determine the level of animal protein in ruminant feed?

3.2 Approach

From Section 2.3 it is clear that the potential for exposure will be largely determined by the processes and procedures used to produce the feed materials and the controls in place to minimise the risks from cross contamination. If non-ruminant PAP was being used in feeds for farm animals then a complete risk assessment to assess the potential for exposure would need to examine the production processes from initial raw material through to product use on farm to identify hazards and opportunities for cross contamination. This would need to cover the range of processes in use across Europe.

Such an assessment is not within the scope of this study and would be difficult to do at the present time before a detailed evaluation of production options had been carried out for different countries. Instead, the study will be based on assessing the potential exposure that could result from different assumed levels of cross contamination.

In 2004, EFSA published a Working Document “Quantitative Assessment of the Residual BSE Risk in Bovine Derived Products” (EFSA, 2004). This report was the culmination of work that had been started by the BSE/TSE ad hoc group of the EU’s Scientific Steering Committee in 2002, and included the results of a quantitative risk assessment carried out by DNV based on the assumptions agreed by the Working Group. This report included assessment of human exposure to BSE infectivity from tallow and gelatine, exposure of cattle to infectivity in milk replacers and Di-calcium phosphate and exposure of cattle to infectivity due to contamination of cattle feed with MBM. The working document was used as a reference for a range of updated opinions issued by EFSA.

This study will build on the EFSA risk assessment model and use the same assumptions as reviewed by the EFSA BIOHAZ panel where appropriate.

3.3 Infectivity of Bovine Tissues

3.3.1 Infectivity of brain tissues

In the EFSA (2004) risk assessment it was assumed that the infectivity titre in brain of a clinically BSE infected bovine could be represented by a log normal distribution with a median (50 percentile) value of 5 cattle oral ID_{50}/gram and a 99 percentile of 100 cattle oral ID_{50}/gram. This assumption was based primarily on results from the attack rate studies being carried out

by the UK Veterinary Laboratory Agency (VLA). The second attack rate study, using oral doses down to 1mg is still ongoing.

Since the EFSA report was published there have some new results from the second attack rate study, and a paper describing these updated results has been submitted for publication. The above infectivity distribution is still compatible with the new results.

3.3.2 Infectivity in a clinical case

The EFSA study provided estimates of the total quantity and infectious load of the various tissues in a typical adult beef animal. Table 1 from the EFSA report is reproduced here. The estimates given here are based on a typical beef animal at point of slaughter. The values will vary depending on age, breed and condition at slaughter, but minor variations were shown not to have a significant affect on the results (EFSA, 2004).

3.3.3 Infectivity at slaughter

The values given in the previous section refer to infectivity levels in an animal with clinical BSE. If control systems are working properly such an animal should never be slaughtered for human consumption. The available data on the development of infectivity through the incubation period suggests that infectivity in the CNS develops late and then rises rapidly. This has been modelled as an exponential increase with a 2 month doubling time (Comer, 2004). This is difficult to apply without a detailed model of infection and incubation stage for a national herd. In the EFSA study, this was handled by making the following assumptions:

In countries with reliable surveillance it is assumed that for 90% of infected animals the infective load at slaughter is less than 10% of the maximum load (this is modelled as a uniform distribution with range 1 – 10%). For the remaining 10% of animals the infectivity may be between 1 to 100% of the maximum load (modelled as a uniform distribution with range 1 – 100%). This was based on the performance of the rapid BSE tests.

For countries where the surveillance is not considered to be reliable it was assumed that for 50% of animals the infective load would be less than 10% of the maximum. This was based on the assumption that about half of all animals slaughtered for food would be below 24 months of age.

Table 1: Estimated tissue weights and infectivity levels from adult beef cattle, for an infectivity titre of 5 $CoID_{50}$ per gram in brain of a clinical case

Tissue	Total mass [1] (g)	Titre $CoID_{50}$/g	Total infective load
Brain	500	5	2500
Trigeminal Nerve Ganglia (TRG)	20	5	100
Spinal cord	200	5	1000
Dorsal Root Ganglia (DRG)	30	5	150
Ileum	800[3]	0.5	400
Spleen	800[2]	.0005	0.4
Rest of head, excl. skull and brain	6.500[4]		6.6
All bones, total:	**58.000**		
All bones, without skull	**50.000**		
Bones, excl. skull and vertebrae	**37.000**		
Bone marrow (10% ww)[5]	2.900	.0005	1.5
Bone adnexa (20% ww)[5]	5.800	.0005	2.9
Manure, gut content	80.000		
Hooves, hide, horns	50.000		
Other by-products / offals	**129.450**		
Consumed (excl. bones)	**215.000**		
Totals	**550.000******		**~4160 $CoID_{50}$**

Notes:

1. It should be noted that, in practice, these weights can vary greatly between different animals, depending on age, breed and condition at slaughter. There will also be differences between different counties.
2. No BSE infectivity has so far been found in the spleen of bovines. As a prudent view, bovine spleen is considered to be possibly infectious, but the infectivity level attributed corresponds to the current limit of detection.
3. 800g may be excessive for the anatomical region strictly termed ileum (without content), which in an adult bovine represents about 1 meter of bowel.
4. The rest of head is assumed to include the eyes (100g) and the tonsil (50g) both with an infectivity assumed to be 4 logs less than brain from the result for tonsil (0.0005 $CoID_{50}$/g) plus 1.3g of CNS contamination from captive bolt slaughter (Cooper & Bird 2002).
5. Estimates vary largely, but little measured data are available; The values given here are based on Koolmees et al (2002), who measured the weight of bones, bone marrow and adnexa of 20 sheep.

3.3.4 Numbers of infected animals

The prevalence of BSE infection in the model is selected by choosing the GBR status of the country being evaluated, together with the surveillance status (reliable or not).
This results in the following assumptions on prevalence:

GBR Status	Min	Mode	Max
BSE incidence per 10^6 over 2 year old cattle			
GBR I country, BSE highly unlikely, zero incidence	0	0	0
GBR II country, no BSE detected,	0	1	1
GBR III country, BSE possible,	1	30	99
GBR IV country, BSE confirmed,	100	300	1000
Number of non-detected pre clinical animals			
GBR II	2	3	4
GBR III	2	100	400
GBR IV	200	1000	4000

Most EU countries fall into the GBR III class and this is used as the basis for the assessment in this report.

3.3.5 Infectivity in bovine MBM

In the EFSA study, various levels of SRM removal were evaluated to cover different practices. In the EU there is strict separation of category 1 SRMs and it is not considered credible that this material could re-enter the feed chain. MBM produced from other by products, that may for example be used in pet food, may still have a low level of infective material present due to incomplete removal of SRMs. For this study it is assumed that all SRMs are removed, including the vertebral column, as per EU regulations for older cattle.

The working group that defined the assumptions for the EFSA study decided that contamination of the by products used to produce ruminant MBM should be represented by assuming that 10% of animals slaughtered have some level of contamination, due to incomplete removal of SRMs. This is represented by 5% of brain (25g) and the ileum (80g CNS equivalent). With the level of meat inspection and implementation of SRM controls in the EU this is a highly pessimistic assumption both in terms of the likelihood and amount of contamination. This was recognised in the report which stated that these assumptions represented a worst case scenario in a poorly regulated abattoir.

For this study it is proposed that the numbers of contaminated animals be represented by a distribution, with the 10% value as a maximum which should be more representative of the actual situation. It is suggested to model this as a log normal distribution with a 1 percentile value of 0.1% and a 99 percentile of 5%; this gives a mean value of 1% and a 99.9 percentile of about 10%. The amount of contamination has also been modelled as a log normal distribution with mean value of 10g of CNS tissue and a maximum of 105g.

3.4 Non-ruminant PAP Scenario

For this scenario it is assumed that non-ruminant PAP is being used as a feed material for non ruminant farm animal feed (e.g. in aquaculture). In the EU about 500,000 tonnes of poultry PAP is produced plus 250,000 tonnes of feather meal and about 225,000 tonnes of porcine PAP. The base assumption for this case is therefore a total production of 750,000 tonnes of poultry PAP plus 225,000 tonnes of porcine PAP going into non-ruminant feed. The total production of compound feeds for bovines in the EU in 2005 was 38 million tonnes (www.fefac.org).

It is assumed that the present restrictions on the use of restricted proteins such as fishmeal would remain in force to ensure that this material was not fed to ruminants. It is assumed that:

- The non-ruminant PAP would be produced in dedicated rendering facilities, not handling other animal species. This would minimise the risk of non non-ruminant material being included in the raw material.
- Dedicated transport would be used to transport the non-ruminant PAP from the rendering plant to the feed mill.
- The feed mill would either not produce any feedingstuffs for ruminants, or there would be complete physical separation of production lines from raw material reception through to product dispatch.
- Bulk product transport would also be in dedicated vehicles.

Non-ruminant PAP in itself would not represent a risk to ruminant animals. The risk potential is that by allowing some animal PAPs to be used in some animal feeds then there is a greater chance that ruminant feeds would be contaminated. In order for this scenario to result in cattle being exposed to the BSE agent it would be necessary that:

1. the non-ruminant PAP is contaminated with ruminant PAP (and that the ruminant PAP had been derived from a batch including an animal with BSE); with separation of rendering facilities and handling this is unlikely to occur. However, at the present time it is difficult to differentiate species in the processed material. For this study it is assumed that this contamination could range from zero to 5%; modelled both as a uniform distribution and in steps.
2. Ruminant feed is contaminated with non-ruminant PAP. Ruminant feed should contain no animal proteins, and will be routinely tested. A base case test sensitivity of 0.1% will be assumed (i.e. ruminant feed may contain up to 0.1% non-ruminant PAP without being detected), but values of 0.2, 0.5 and 1% will also be evaluated.

With the present arrangements and controls on the processing of animal by-products and production of animal feeds both these steps would be unlikely, and very unlikely to occur in any significant quantity. That they should occur together, i.e. that ruminant feed is contaminated with the non-ruminant PAP that was itself contaminated with ruminant PAP that had been derived from a batch including an animal with BSE, must be regarded as extremely improbable.

4.0 Model Results

The model developed for the EFSA risk assessment has been extended to assess the non-ruminant PAP scenario and assumptions adjusted as indicated in Section 3.0. The model has been set up to estimate the total quantity of infectious units ($CoID_{50}$) that could potentially be present in cattle feed in the EU as a consequence of allowing non-ruminant PAP to be used in non-ruminant animal feed, and given the specific assumptions on contamination. Note that the model assumes that the specified levels of contamination apply to ALL feed produced and does not take account of the likelihood that such contamination will occur.

4.1 EFSA opinion on residual risk from MBM

In 2005 EFSA published an "Opinion on the Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the residual BSE risk" (EFSA, 2005). The Opinion was based on the EFSA risk assessment and reported that for cattle fed compound feed containing 0.1% MBM with a 40% bovine origin in a GBR III country with reliable surveillance that the exposure would be 1.2×10^{-7} Co ID_{50} per animal per year in an intensive system (fed on average 8 kg/day) and 2.2×10^{-8} Co ID_{50} per animal per year in an extensive system (average 1.5 kg/day). (Note: there is an error in the Opinion which gives an incorrect value for the extensive system in the summary).

In the EFSA opinion the results are given as the estimated exposure per animal. This is in effect an "individual risk". In this report the results are given as the total exposure for all cattle feed produced in the EU. This is a "group risk". This gives a measure of the overall scale of the risk. Both are valid and represent different aspects of the risk.

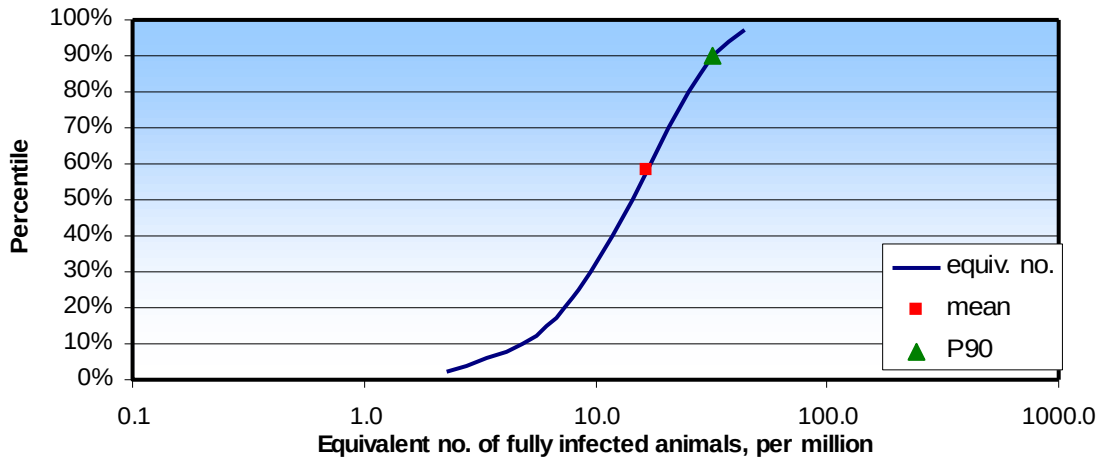
The EFSA individual risk estimate can be converted to a group risk estimate as follows. If the exposures were to apply across the European Union to all 43,200,000 adult cattle (European Commission, 2005) and it is assumed that 50% are intensively fed and 50% extensively and that there is a linear dose response relationship at low doses, this would be equivalent to 3 infections per year in the EU (i.e. that the total exposure to all adult cattle in the EU is 3 $CoID_{50}$ per year). This figure can be used as a baseline against which to compare the results from this assessment.

4.2 BSE prevalence and infectivity in MBM

The model has been run for the case of a GBR III country with a reliable surveillance system. This represents the present typical situation in EU countries. The assumptions result in a mean prevalence of 17 infected animals per million adult cattle with a distribution as shown in Figure 1. For the year to 30th October 2005, only 4 out of the 25 EU countries had a BSE prevalence greater than this (Portugal – 54 per million; UK – 40 per million; Spain – 25 per million; Ireland – 20 per million) (EC, 2005). The general incidence of BSE cases is reducing year on year in the EU so that in future years the general prevalence of BSE cases in the EU will be less than that assumed here.

When MBM is made from the by-products of animals slaughtered for human consumption from this population, and from which all SRM has been removed, small amounts of infectivity may be present due to incomplete SRM removal as discussed in Section 3.3.5. With this prevalence there will be an infected animal in about 1 in 20 batches. The mean level of infectivity in the MBM produced is predicted to be 7×10^{-7} $CoID_{50}$ per tonne of MBM, although most of the time the infectivity would be zero.

Figure 1: Prevalence of infection – GBR III Country



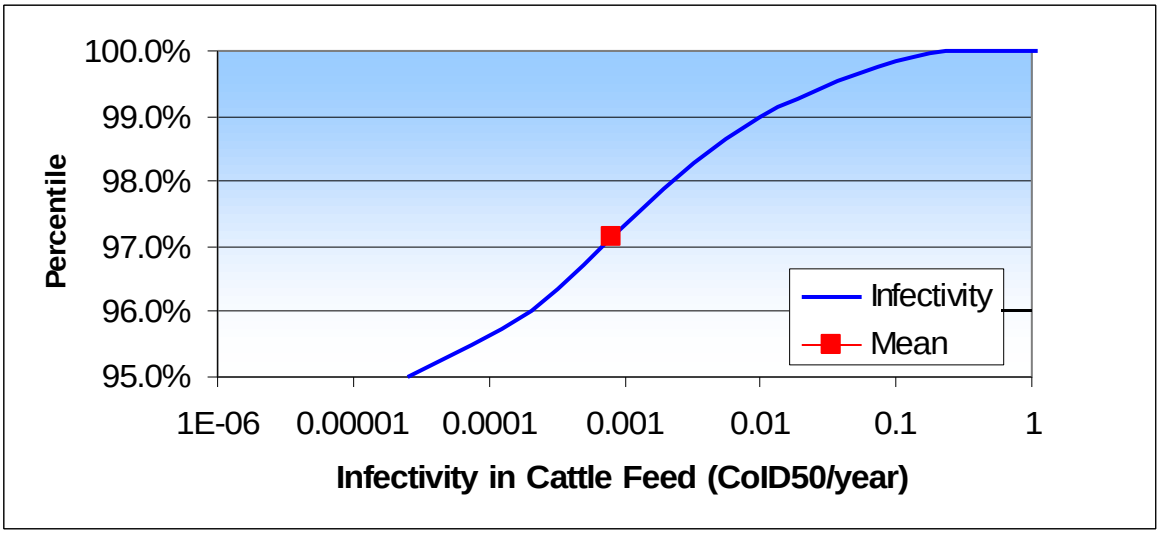
4.3 Infectivity in Cattle Feed

The total infectivity present in the cattle feed produced in the EU, assuming that non-ruminant PAP is contaminated with up to 5% ruminant MBM, and that the cattle feed is contaminated with 0.1% of the non-ruminant PAP, is estimated to be a mean value of 0.001 $CoID_{50}$ units per year; i.e. there is one thousandth of a $CoID_{50}$ unit present in a whole years production of feed.

This mean value hides a very skewed distribution, as the model predicts that the infectivity in the feed would be zero for up to 94% of the time. This is because with a low prevalence of BSE most of the time there will not be any infected animals present in a batch. The distribution for the range above 95% is shown in Figure 2. This shows a 99 percentile value of 0.01 $CoID_{50}$ units per year reaching an absolute maximum value of about 1 $CoID_{50}$ units per year. The mean value is also plotted, and is shown to occur at the 97%ile. Thus the mean value is not a typical value, as most of the time the infectivity present would be zero.

It must be stressed that these results assume that contamination is present at the levels specified. They do not take account of the actual likelihood that such contamination would occur. The combination of factors that result in the higher percentiles in Figure 2 would be very unusual and thus have a very low likelihood and would only apply to a very small fraction of the production.

Figure 2: Distribution of Infectivity in Cattle Feed



The results have also been estimated for a range of values for the two main factors, contamination of non-ruminant PAP with ruminant MBM (range from 0.5% to 5%) and contamination of cattle feed with non-ruminant PAP (0.1%, 0.2%, 0.5% and 1%). These results are shown in Figure 3 and Table 2.

The results in Figure 3 and Table 2, show that the mean exposure to infectivity may vary from 0.0001 $CoID_{50}$ units per year (0.5% ruminant MBM in non-ruminant PAP and 0.1% non-ruminant PAP in cattle feed) up to 0.01 $CoID_{50}$ units per year (5% ruminant MBM in non-ruminant PAP and 1% non-ruminant PAP in cattle feed). These values are all significantly less (by a factor of 300 or more) than the exposure given in the EFSA opinion summarised in Section 4.1 above.

It should be noted that the combination of the maximum values for ruminant PAP in non-ruminant PAP (5%) and non-ruminant PAP in cattle feed (1%) would result in a level of 0.05% ruminant PAP in feed. This is less than the limit of detection of 0.1%. Thus all combinations in Table 2 result in levels of ruminant PAP in feed that are less than 0.1%.

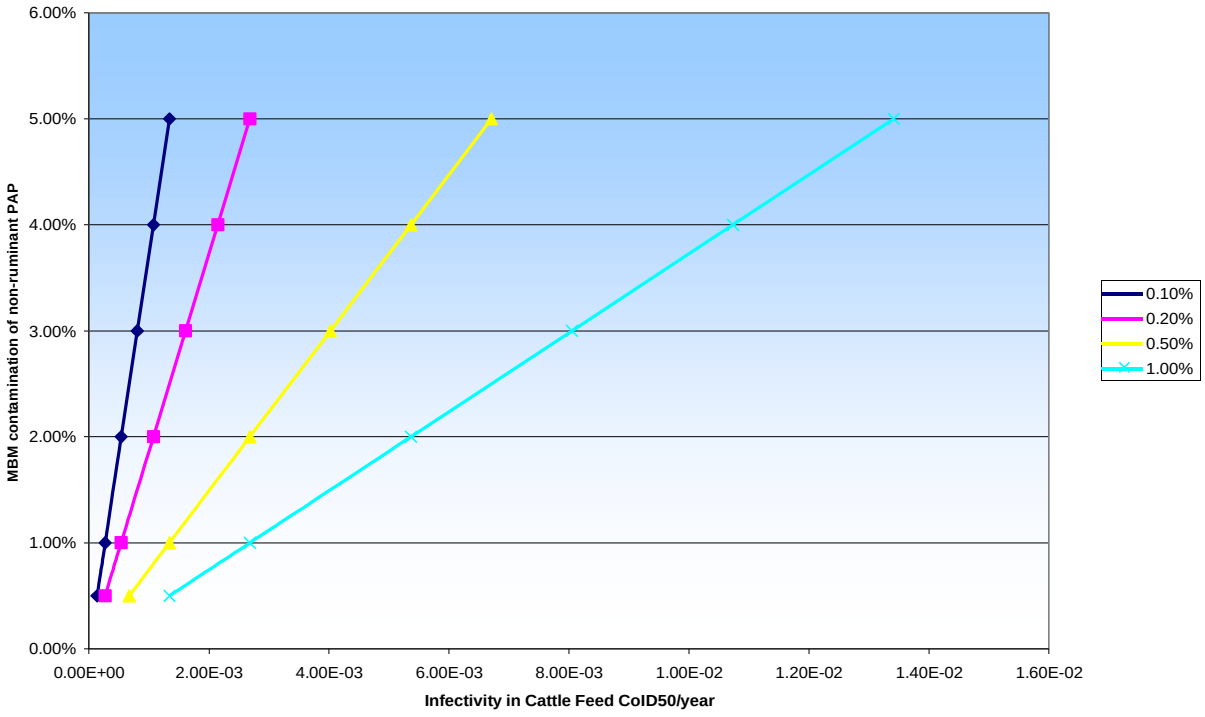
The top end of the range assumed for non-ruminant PAP in cattle feed (1%) would represent about 40% of the total non-ruminant PAP production if present in all the cattle feed produced in the EU. This is clearly not credible and demonstrates that the predicted values represent upper limits rather than representative values.

Table 2: Mean Infectivity in Cattle Feed by Contamination level
$CoID_{50}$ per year

Ruminant PAP in non-ruminant PAP		Ruminant feed contaminated by non-ruminant PAP			
	%	0.1	0.2	0.5	1.0
	0.5	0.0001	0.0003	0.0007	0.001
	1.0	0.0003	0.0005	0.001	0.003
	2.0	0.0005	0.001	0.003	0.005
	3.0	0.0008	0.002	0.004	0.008
	4.0	0.001	0.002	0.005	0.01
	5.0	0.001	0.003	0.007	0.01

Note:
The table gives the mean values of the total infectivity ($CoID_{50}$/year) estimated to be present in the cattle feed produced in the EU in one year
An example calculation is given in the box on the following page

Figure 3: Infectivity in Cattle Feed by Contamination level



Example Calculation

1. Infectivity in ruminant MBM is calculated using the EFSA model assuming a GBR III country with good surveillance, i.e. characteristic of most EU countries. The main assumptions are the same as in the EFSA opinion and are summarised in Section 3.3. The only significant differences from the EFSA opinion are as set out in section 3.3.5. These differences are:
    a) numbers of contaminated animals now represented as a distribution with a maximum value of 10% (99.9 percentile), rather than assuming that 10% of all animals have some level of contamination which was felt to be too pessimistic;
    b) Amount of contamination represented by a distribution with a mean value of 10g and a 99%ile of 105g of CNS tissue

2. These assumptions result in a calculated mean level of infectivity in ruminant PAP of 0.73 $CoID_{50}$ per million tonnes of PAP. (7.3×10^{-13} $CoID_{50}$/g).

3. Non ruminant PAP is assumed to be contaminated with (in this case) 5% ruminant PAP; so infectivity in non ruminant PAP is 5% of that in ruminant PAP.

4. Total production of compound feed for cattle is 38 million tonnes per year. It is sssumed that this may contain 0.1% of non ruminant PAP

5. So mean infectivity in total production of cattle feed is 38 (million tonnes) x 0.1/100 x .73 ($CoID_{50}$ per million tonnes) x 5/100 = .0014 $CoID_{50}$ / year

5.1 Findings

The risk assessment model developed for the EFSA (2004) "Quantitative Assessment of the Residual BSE Risk in Bovine Derived Products" has been used to estimate the potential exposure to BSE infectivity that could result from allowing non-ruminant PAP to be used as an ingredient in feed for non-ruminant farm animals. Non-ruminant PAP in itself would not represent a risk to ruminant animals. The risk potential is that by allowing non-ruminant PAPs to be used in some animal feeds then there is a greater chance that ruminant feeds would be contaminated.

The study has not attempted to assess the likelihood of such contamination as this would require a detailed evaluation of production methods and controls across Europe. Instead, the study has estimated the amount of BSE infectivity, measured as cattle oral ID_{50} units ($CoID_{50}$), present in the total production of compound cattle feed in the EU (38 million tonnes in 2005), for assumed levels of contamination:

a. the contamination of non-ruminant PAP with bovine MBM (range from zero to 5%), and
b. the contamination of cattle feed with non-ruminant PAP (range 0.1% to 1%).

The controls in place for animal feed production would ensure that if such contamination were to occur it would be a rare event. Thus the values presented here represent an absolute maximum value, and are not intended to be realistic estimates of possible exposures.

For the base case with 0.1% contamination of cattle feed and a uniform distribution of values for contamination of the non-ruminant PAP with bovine MBM, the mean exposure is estimated to be 0.0008 $CoID_{50}$ units per year with a 99 percentile value of 0.01. This is an extremely small potential exposure, and indicates that realistic exposures would be much less. For the maximum assumed levels of contamination (5% ruminant MBM in non-ruminant PAP and 1% non-ruminant PAP in cattle feed) the predicted exposure is 0.01 $CoID_{50}$ units per year.

These results indicate that if there is a limit of detection as high as 5% ruminant PAP in non-ruminant PAP together with a limit of detection of 1% non-ruminant PAP in ruminant feed, and that these levels applied to all of the cattle feed produced in the EU, then the risk of additional BSE cases would be extremely low and significantly lower than the value reported in the EFSA "Opinion on the Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the residual BSE risk" (EFSA, 2005).

Processing of animal by-products is closely controlled in EU countries and all SRM materials are removed, stained and disposed of separately. It is always possible that some SRM materials are not completely removed, but this is inspected routinely and levels of any contamination would be small. Together with the low prevalence of BSE infection in EU countries, the level of BSE infectivity in MBM produced from bovine by-products will be very low.

If non-ruminant PAP were to be allowed as an ingredient in feed for non-ruminant farm animals there would be strict controls on the production of the PAP, the transportation of bulk materials and the production and use of the animal feed aimed at minimising the potential for any contamination of ruminant feeds. These are likely to be similar to current controls on the use of fish meal that have been shown to be effective. These measures will not eliminate all possible sources of cross contamination, but they will ensure that it is infrequent and that the amounts of any contamination are small.

This study has assumed levels of infectivity for a GBR III country that are representative of the current prevalence of BSE cases. The general incidence of BSE cases is reducing year on

year in the EU so that in future years the general prevalence of BSE cases in the EU will be less than that assumed here.

This initial study has indicated that allowing non-ruminant PAP to be used as an ingredient in non-ruminant animal feed would not result in any significant level of exposure of cattle to BSE infectivity. This would remain true even with higher levels of BSE prevalence than those used as a baseline, and certainly for the range of prevalence found in all EU countries. The overall levels of infectivity that may be present are so low that this conclusion is not sensitive to the sensitivity of the test for the presence of animal protein in ruminant feed.

6.0 References

European Commission (2005) *"Report on the monitoring and testing of ruminants for the presence of transmissible spongiform encephalopathy (TSE) in the EU in 2004."* Health and Consumer Protection Directorate-General, 13 June 2005.

EFSA (2004) *"Quantitative Assessment of the Residual BSE Risk in Bovine Derived Products"*, The EFSA Journal (2005) 307, 1-135.

EFSA (2005) *"Opinion on the Quantitative risk assessment of the animal BSE risk posed by meat and bone meal with respect to the residual BSE risk*", The EFSA Journal (2005) 257, 1-30.

Comer, P.J. and Huntly, P.J. (2004) *Exposure of the human population to BSE infectivity over the course of the BSE epidemic in Great Britain and the impact of changes to the Over Thirty Month Rule.* Journal of Risk Research, **7,** (5) 523-543.

Cooper, J.D. and Bird, S.M. (2002-b) *UK dietary exposure to BSE in head meat: by birth-cohort and gender.* J. of Cancer Epidemiology and Prevention, Vol 7, No. 2, 71-83.

Koolmees, P.A., Barends, B.R., and Tersteeg, M.H.G., (2002) *Risk Assessment of the use of sheep natural casings and legs of lamb.* Pilot research for ENSCA, INSCA and NANCA. VVDO Report No. H0204, July 2002, Utrecht.

DNV Consulting:

is a different kind of consulting firm, offering advanced cross-disciplinary competence within management and technology. Our consulting approach reflects the new risk agenda in high-risk and capital-intensive industries. We have a firm base in DNV's strong technological competencies, international experience and unique independence as a foundation. Our consultants serve international clients from locations in Norway, UK, Germany, Benelux and the USA.

DNV CONSULTING
Veritasveien 1 N-
1322 Hovik
Norway
Phone: +47 67 57 99 00

DNV CONSULTING
Johan Berentsenvei
109-111
N-5020 Bergen
Norway
Phone: +47 55 94 36 00

DNV CONSULTING
Bjergstedveien 1
N-4002 Stavanger
Norway
Phone: +47 51 50 60 00

DNV CONSULTING
Ingvald Ystgaardsvei 15
N-7496 Trondheim
Norway
Phone: +47 73 90 3500

DNV CONSULTING
Businesspark
Essen - Nord
Schnieringshof 14
45329 Essen
Germany
Phone: +49 201 7296 412

DNV CONSULTING
Duboisstraat 39 – Bus 1
B-2060 Antwerp
Belgium
Phone: +32 (0) 3 206 65 40

DNV CONSULTING
Palace House
3 Cathedral Street
London SE1 9DE
United Kingdom
Phone: +44 20 7357 6080

DNV CONSULTING
Highbank House
Exchange Street
Stockport
Cheshire SK3 0ET
United Kingdom
Phone: +44 161 477 3818

DNV CONSULTING
Cromarty House
67-72 Regent Quay
Aberdeen AB11 5AR
United Kingdom
Phone: +44 1224 335000

DNV CONSULTING
16340 Park Ten Place
Suite 100
Houston, TX 77084
USA
Phone: +1 281 721 6600

a different approach for a new reality:

DNV CONSULTING

MANAGING RISK