



CONSIDERATION OF VARIOUS OPTIONS RELATING TO A RELAXATION OF THE TOTAL FEED BAN

ISSUE

1. The Department for Environment, Food and Rural Affairs (Defra) the devolved Rural Affairs Departments and the Food Standards Agency (FSA) have asked SEAC to consider, in qualitative terms, the potential for further transmissible spongiform encephalopathy (TSE) infections and epidemics to arise as a result of possible implementation of various future options for relaxing the TSE-related feed controls. This paper, prepared by Defra, provides an overview of European Union (EU) proposals and relevant science.

BACKGROUND

2. In 2001, the EU extended the ban on feeding mammalian meat and bone meal (MBM) to ruminants¹ to a ban (with certain exceptions²) on feeding animal protein to ruminants and feeding processed animal protein (PAP) to all animals farmed for food production³.
3. At SEAC 89 (September 2005) Defra and the FSA sought advice from SEAC on the issues outlined in the EU TSE Roadmap⁴, which was published in July 2005. The TSE Roadmap sought to ensure that any relaxation of the bovine spongiform encephalopathy (BSE) controls, such as specified risk material (SRM) controls, TSE surveillance and feed controls, as a result of the decline in the BSE epidemic, would be science-based and would not endanger either public health or the policy of eradicating BSE.
4. In relation to the feed ban, the TSE Roadmap noted that, with certain exceptions, there was zero-tolerance of PAP in farmed animal feed and that any revision of the feed ban should be risk-based and take into account the control tools available. Unavoidable environmental contamination of sugar beet pulp with soil-borne bone fragments had posed problems in some Member States (e.g. Germany) which could be

¹ Commission Decision 94/381/EC

² Further information on the current scope of the feed ban is available at <http://www.defra.gov.uk/animalh/bse/animal-health/feedbanguide.pdf>

³ Council Decision 2000/766/EC

⁴ http://ec.europa.eu/food/food/biosafety/bse/roadmap_en.pdf

addressed by a risk-based tolerance. Similarly, a more risk-based tolerance of a small presence of fish meal in ruminant feed, arising from cross-contamination, could be introduced. In addition, further improvements in analytical methods to differentiate animal proteins of different species may allow a relaxation of the feed ban in relation to non-ruminants, taking into account the prohibition on intra-species recycling. In summary, in relation to TSE feed controls, the TSE Roadmap proposed the following:

- i. the introduction of a tolerance of the presence of bone fragments in sugar beet pulp and other feed due to environmental contamination, where a robust risk assessment demonstrated the absence of cross contamination or the fraudulent incorporation of MBM. In September 2005⁵, the Commission and Member States adopted this risk-based approach for the detection of bone spicules in tuber and root crops and feed containing such products.
 - ii. the introduction of a tolerance for the presence of fish meal in ruminant feed, e.g. where there is cross contamination during manufacture, distribution or use; and
 - iii. a relaxation of the feed ban for non-ruminants, e.g. allowing the feeding of poultry PAP to pigs and vice versa.
5. SEAC welcomed the TSE Roadmap and made a number of recommendations. SEAC considered that
- *“appropriate feed controls are fundamental to prevent recycling of potentially infectious material in animal feed and re-emergence of a BSE epidemic. Any potential changes to feed controls should therefore be considered very carefully. Consideration should be given to assessment of the risks associated with the use of fishmeal in animal feed as it was unclear whether fish material would be sufficiently contaminated with BSE to present a risk. Since there is a great deal of movement of substances used in animal feed both within and into the EU, potential risks could arise from contaminated materials used in animal feed imported from outside the EU. This might also be an area that required further examination and risk assessment. The committee considered it important to examine carefully all the constituents of animal feed, the sources of those materials and then assess the potential TSE risk.”*

⁵ Regulation (EC) No. 1292/2005 amending Annex IV of Regulation (EC) No.999/2001 allowed Member States to permit the feeding to farmed animals of tuber and root crops and feedingstuffs containing such products following the detection of bone spicules if there has been a favourable risk assessment which takes into account the amount and the possible source of the contamination and the final destination of the consignment.

- *“appropriate surveillance is essential to monitor the potential impact of other changes to control measures. It was considered that effective surveillance to ascertain infection prevalence was very important as a public health measure and an effective surveillance system should be maintained. Surveillance programmes should be capable of monitoring potential changes to TSE prevalence, and of identifying new TSEs or other similar diseases. There should also be mechanisms in place to deal with any changes detected.”*
- *“changes to legislation in any one of the strategic areas [of the TSE Roadmap] might impact on other areas, therefore no single strategic area should be considered in isolation.”*
- *“there should be a watching brief on emerging science that may impact on any of the measures under consideration.”*
- *“in the event of any changes to TSE legislation it would be important to communicate effectively to customers, the reasons for change.”*

Defra and FSA undertook to seek advice from SEAC on specific proposals as the European Union discussions developed.

6. In September 2005 the European Food Safety Authority (EFSA) published an opinion on a “quantitative risk assessment of the animal BSE risk posed by MBM with respect to residual BSE risk”. In 2007, EFSA published an opinion on the “health risks of feeding ruminants with fishmeal in relation to the risks of TSE”. *[Hard copies of both reports have been provided – see Annex 7 References]*. The European Parliament has also tasked EFSA with a mandate to provide an opinion on the risks of feeding non-ruminant MBM to pigs and poultry.
7. In September 2006, the European Economic and Social (EESC) Committee published an opinion⁶ on the disposal of animal carcasses and the use of animal by-products. The EESC recommended that the European Commission “*pursue and step up as quickly as possible, the studies currently under way which clearly show that the use of meat meal from non-ruminants can be used in pig and poultry feed without posing any danger to human health*”. Following adverse media coverage in June 2007, the EESC issued a press release⁷ in which it clarified that its recommendation only applied to non-ruminants.
8. Following extensive consultation with Member States, the European Parliament and stakeholders, the European Commission produced a

⁶ http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/c_318/c_31820061223en01090113.pdf

⁷ <http://www.eesc.europa.eu/activities/press/cp/docs/2007/communique-presse-eesc-051-2007-en.doc>

Work Programme⁸ on TSEs in November 2006. In relation to the feed ban, the document proposed discussions on:

- i. Permitting a tolerance of “*insignificant amounts*” of animal protein, including fish meal in feed, arising as a result of “*adventitious*” (e.g. rodent/avian) or “*technically unavoidable*” (e.g. fish meal) contamination.
- ii. The use of fish meal in feed for young ruminants on the basis of a scientific assessment of their dietary needs and following an assessment of the control aspects.
- iii. Permitting a general tolerance level with regard to the “*small presence*” of mammalian MBM in feed for farmed animals.

Currently it is not possible to expand on the terms “insignificant amount” or “small presence”. Any future tolerance level would be determined to a large extent by the sensitivity and specificity of the quantitative tests available. Quantitative risk assessments (e.g. EFSA quantitative risk assessment of animal BSE risk posed by mammalian MBM 2005) may also be taken into account. Also it is not clear exactly what is envisaged under (iii) but the UK Government’s current understanding is that it is a variation on (i) in that an accepted “tolerance” level would be agreed below which the Member State would not be obliged to investigate and assess the individual risk.

9. In January 2007, the TSE Regulation was amended by co-decision. This provided a legal basis for the future options of (i) feeding fishmeal to *young* ruminants only – a political compromise between the European Commission which wanted the option of permitting the feeding of fish meal to ruminants and the European Parliament which opposed the feeding of such animal protein to herbivores on “ethical” grounds, but conceded to allowing the option of feeding fish meal to young ruminants based on a scientific assessment of their dietary needs – and (ii) the introduction of a risk-based tolerance level for the presence of “*insignificant*” amounts of animal protein in feed “*caused through adventitious and technically unavoidable contamination*”. Apart from the circumstances outlined above (and existing exemptions), the ban on feeding animal protein to ruminants remained. The TSE Regulation required that rules for the prevention of cross contamination and methods of sampling and analysis to check compliance, should be based upon a European Commission report covering the sourcing, processing, control and traceability of feedingstuffs of animal origin. The recitals of the TSE Regulation were also amended to propose that “*the feeding to non-ruminants of certain PAP originating from non-ruminants should be allowed taking into account the prohibition on intra-species recycling...*”

⁸ http://ec.europa.eu/food/food/biosafety/bse/work_prog_tse_en.pdf

and the control aspects in particular linked to differentiation of PAP specific to certain species”: this proposal could be agreed by the European Commission and EU Member States.

10. At SEAC 98 (July 2007) following the media coverage referred to in paragraph 7, SEAC “*considered it important that Defra should seek the views of SEAC should such a policy [of feeding non-ruminant MBM to non-ruminants] be proposed as part of the TSE Roadmap*”.
11. In July 2007, the European Parliament adopted a report⁹, which called on the European Commission and the European Council to “*lift the ban on feeding fish meal and fish oil to ruminants*” (although there is no ban on feeding fish oil to ruminants). The report stressed that “*there is no scientific evidence to support a total ban on fish meal on the grounds that it may transmit BSE or other TSEs*”.
12. In September 2007, the European Commission tabled a proposal (SANCO/2017/2007) to permit the use of fish meal in milk replacers for feeding to young ruminants *before weaning*, while maintaining strict controls on the feeding of fish meal to adult ruminants, in line with the requirements of the TSE Regulation. In November 2007, the European Commission discussed an amended proposal (SANCO/2017/2007rev.1) to permit the use of fish meal in milk replacers for feeding to young ruminants, with Member States. The amended proposal indicated that it applied to milk replacers administered in either dry or liquid form, provided to young ruminants as a supplement or milk substitute before the completion of weaning. The Commission explained that the European Food Safety Authority had advised that a scientific assessment of the dietary needs of young ruminants was outside its remit. Consequently, the Commission was considering establishing a group of animal nutrition experts to carry out this task. The European Commission indicated following additional training, the qualitative performance of National Reference Laboratories had improved beyond the position reported from the 2006 inter-laboratory trial. However, no further progress could be made on tolerance proposals (e.g. an agreed tolerance level for the presence of fish meal in adult ruminant feed) until there had been a significant improvement in the performance of quantitative tests and this could take at least a year. The European Commission undertook to make data relating to the assessment of dietary needs (EFSA) and the assessment of control aspects (further report from Community Reference Laboratory for Animal Proteins) available to Member States in due course.

⁹ European Parliament (2007) European Parliament resolution of 10 July 2007 on industrial fisheries and the production of fishmeal and fish oil. P6_TA-PROV(2007)0327

http://www.europarl.europa.eu/news/expert/infopress_page/033-9006-190-07-28-904-20070709IPR08984-09-07-2007-2007-false/default_en.htm

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0327+0+DOC+XML+V0//EN&language=EN>

CONSIDERATION

13. The TSE risks associated with animal feed can potentially be mitigated by a number of means including (i) restrictions on the constituents of feed and their origin to exclude the inclusion of risk materials; (ii) prevention of intra-species recycling of PAP; and (iii) processing of animal-derived feed constituents to reduce any TSE infectivity present. Annex 1 provides a glossary of terms relating to animal feed.
14. The EU is exploring relaxation of the total ban on feeding animal protein to ruminants and feeding processed animal protein (PAP) to all animals farmed for food production, to allow (i) the introduction of tolerance levels for certain types of PAP in feed, although the magnitude of these levels has not yet been agreed and largely depends on further development of quantitative tests; (ii) the inclusion of fish meal in young ruminant diets; and (iii) feeding non-ruminant PAP to non-ruminants of a different species. The current position of the UK Government with respect to these proposals is at Annex 2.
15. Control of proposed tolerance levels for PAP, to prevent both the feeding of ruminant PAP to ruminants and the intra-species recycling of PAP, depends upon the availability of robust assays that permit the detection and quantification of PAP in feed and, in some cases, permit the origin (e.g. species/risk category) of PAP to be assessed. Details on the performance of such assays as well as other considerations that inform consideration of the introduction of tolerance levels such as the prevalence of TSEs and data on infective doses are given at Annex 3. Information relating to the feeding of fish meal, non-ruminant derived MBM and ruminant-derived MBM is provided at Annexes 4, 5 and 6 respectively. A bibliography is provided at Annex 7. Key references have been provided to SEAC members with the hard copy of this paper. Annex 8 gives a summary of the presentation to be given at the meeting by VLA on the standard analytical methods used to qualitatively and quantitatively assess MBM and fishmeal in animal feeds.

ADVICE SOUGHT FROM THE COMMITTEE

16. The Committee is invited to consider, in qualitative terms, the potential for (i) new TSE infections; and (ii) new TSE epidemics, to arise as a result of the following proposals:
 - a. Permitting a tolerance of the presence of animal proteins or PAP in feed, where this arises as a result of adventitious (e.g. wild rodent or avian protein) or technically unavoidable (e.g. during manufacture or supply) contamination;
 - b. Permitting the feeding of fish meal to young ruminants (e.g. before weaning); and

- c. Permitting the feeding of non-ruminant PAP to non-ruminants (e.g. poultry to pig) taking into account the prohibition on intra-species recycling of PAP.
17. Where appropriate, the Committee is also invited to consider, in qualitative terms, the impact of the following control measures, or any other measures, in reducing the potential for new TSE infections or epidemics to occur with each of the options above:
- a. Ensuring that source material derives from “low risk” Category 3 material – by definition, PAP is derived from Category 3 material;
 - b. Processing mammalian¹⁰ source material by Method 1¹¹ (50mm particle size, 133°C and absolute pressure of 3 bar for 20 minutes);
 - c. Preventing intra-species recycling;
 - d. Chemical marking of higher risk material; and
 - e. The sensitivity and specificity of qualitative and quantitative tests available to detect animal protein/PAP in feed.

¹⁰ Under Regulation (EC) No.1774/2002 non-mammalian PAP may be derived by processing Methods 1-5 or Method 7. Fish meal may be derived by processing Methods 1-7 or other methods which ensure that it complies with the required microbiological criteria.

¹¹ As defined in Regulation (EC) No.1774/2002.

ANNEX 1 – GLOSSARY

Animal By-Products

Entire bodies, or parts of animals, or products of animal origin, not intended for human consumption.

Category 1 Material

“High risk” animal by-products, including specified risk material (SRM).

Category 2 Material

“Medium risk” animal by-products, including fallen stock.

Category 3 Material

“Low risk” animal by-products, including parts of carcasses which were otherwise fit for human consumption, former foodstuffs and catering waste.

[*Note:* BSE infectivity has been detected in tissues which are not categorised as SRM. However, the combination of the very low prevalence of BSE and the current post-mortem testing of over-thirty month cattle reduce the risk of infective tissues being disposed of as Category 3 material].

Fish Meal

PAP derived from fish.

Meat and Bone Meal (MBM)

This is a generic term for protein-rich product of processing.

Poultry Meal

PAP derived from poultry.

Processing (Rendering)

The treatment of animal by-products by specified processes which generally involve reduction (mincing), application of heat and, in some cases, application of pressure.

Processed Animal Protein (PAP)

This is the protein-rich product of processing Category 3 material.

ANNEX 2 – CURRENT UK POLICY ON CHANGES TO FEED CONTROLS

Mammalian MBM Ban

Feed controls form a key part of the BSE control measures. The most important aspect of the feed controls is the ban on the feeding of mammalian MBM to farmed livestock, which has proved highly effective in preventing the recycling of the BSE agent in ruminant feed. We would not wish to see this ban relaxed, other than the possible future use of porcine PAP for poultry feed (see below). It is unlikely that the use of ruminant protein in livestock feed will be proposed in the foreseeable future.

General Tolerances of Animal Protein in Livestock Feed

In general, we do not support the principle of allowing general tolerances (i.e. an acceptable level of cross-contamination) for animal protein (other than fish meal) as a contaminant of livestock feed. Current tests and sampling arrangements are not absolute. Thus there should be an investigation of each individual case where there is evidence of contamination (e.g. where there is a positive test result), and suitable action taken in the light of the findings of the investigation.

Fish Meal and Poultry Meal Feed Ban

There is no evidence that fish meal and poultry meal present a TSE risk (unless these are contaminated with mammalian MBM). Controlling the use of such products involves enforcement resources that would be more productively directed at activities which present a far higher risk to public and animal health. Providing any change is based on robust tests, is itself enforceable and does not hinder the application and enforcement of the ban on the feeding of mammalian MBM to livestock, we would support a relaxation of the restrictions on these products (although there have not yet been any proposals to feed poultry meal to ruminants).

Feeding Non-Ruminant Protein to Non-Ruminants

We support the development and EU-validation of improved tests. If through an improvement in marking and detection methods, porcine PAP could in the future be fed to poultry and vice versa, without compromising the public and animal health aims of the ban on feeding ruminant MBM to ruminants, we would support this development.

ANNEX 3 - GENERAL CONSIDERATIONS RELATING TO THE RELAXATION OF THE CURRENT FEED BAN

1. Origin of BSE

The precise origin of BSE is unknown and there are various hypotheses. The two leading hypotheses are:

- Arising as the consequence of a mutation in the prion protein gene of cattle or possibly of other TSE-susceptible species.
- Derived in some way from scrapie in sheep.

2. Incidence and Prevalence of TSE

The incidence of BSE in cattle has declined steadily in the EU (and the UK) in recent years. However the feed industry is a global market.

Year	Bovines Tested in EU	BSE Cases in EU
2001	8,516,277	2,153
2006	9,999,867	320

i. Prevalence of BSE in Cattle in Great Britain

- Born before reinforced feed ban (1 August 1996)

Estimated at 10,000 *infected* animals per million for 1993/94 birth cohort.

- Born after reinforced feed ban (1 August 1996)

Estimated at fewer than 150 *infected* animals per million for birth cohorts from 1996 onwards.

These numbers are considerably greater than the number of observed cases because of the long incubation period of the disease and the death of many infected animals before the development of detectable disease.

ii. Prevalence of BSE in Sheep in Great Britain

In December 2006, SEAC's Sheep Subgroup noted that sheep are likely to have been exposed historically to MBM in feedstuffs, although at levels far below those to which cattle were exposed, probably less than 3% of the cattle exposure. Furthermore, BSE had been shown to be transmissible to sheep, experimentally, by the oral route. Thus, it was not unlikely that, historically, sheep in the UK flock were infected with BSE. There was evidence for BSE in

a French goat (born 2000 / died 2002) which had been fed MBM, and a UK goat (born 1987 / died 1990) had been identified with probable BSE which might also have been acquired through feed. However, as described below, there was no evidence that BSE was currently present in the UK flock. Thus, if BSE ever entered the UK flock it was most likely to have been at a level that would not lead to a self-sustaining epidemic once feeding MBM to ruminants was banned in 1988. The Subgroup concluded that the most likely prevalence of BSE in the UK sheep flock was zero, and in the worst case no more than ten flocks would be infected.

In 2007, EFSA published an opinion on the residual BSE risk in sheep meat and meat products. Depending on the statistical model and the sub-set of input surveillance data, it was calculated that there was a 95% confidence that in the high risk sub-group of countries (UK, France, Ireland and Portugal) there were fewer than 0.3-0.5 cases of BSE per 10,000 healthy-slaughter animals.

iii. Prevalence of other TSEs in sheep in Great Britain

In February 2006, SEAC's Sheep Subgroup concluded that data from active surveillance show that the frequency of atypical scrapie infections in the British sheep flock is similar to that of classical scrapie, and may be slightly higher. Modelling of the abattoir survey results for the Great British sheep population over 18 months old (14 million sheep) showed that around 56,000 sheep could be infected with classical scrapie (0.4%) and around 82,000 infected with atypical scrapie (0.6%). These numbers were considerably greater than the number of known clinical cases, in part because many infected animals may be sent to the abattoir at an age before clinical signs appear, but it might also reflect a degree of under-reporting.

3. Oral Exposure Attack Rate Studies

VLA research has shown that as little as 1 milligram (the lowest dose tested) of pooled brainstem homogenate from a BSE-infected animal is sufficient to infect a calf, when administered orally at 4-5 months of age (Wells *et al.* 2007).

VLA research (Bellworthy 2007) has shown that:

- i. as little that 50 milligrams of infective bovine BSE brain given orally caused BSE in sheep.
- ii. sheep become infected when dosed orally with 1000 milligrams of a brain pool prepared from scrapie-infected sheep.

4. Age Susceptibility

Cattle are most at risk¹² of infection with BSE during the first 12 months of life (Arnold, M.E. & Wilesmith, J.W., 2004) (Supervie, V. & Costagliola, D. 2004). This may be due to the age-dependent development of lymphoid tissue in the intestine (St Rose, S.G. *et al.* 2006). Experiments also suggest a similar age-dependency to oral TSE challenge in sheep.

5. Cross-Contamination

In July 1988, Great Britain / In January 1989, Northern Ireland banned the feeding of ruminant protein to ruminants. Although this has been estimated to have reduced the risk of infection for birth cohorts born after the ban by approximately 70%, it was not fully effective. Epidemiological studies in Great Britain have demonstrated a link between the geographical area of birth of cattle born after the introduction of the ruminant to ruminant feed ban and the relative density of pigs compared to cattle. These findings support the role of low level cross-contamination of cattle feed during the manufacture and supply of pig feed as an influence on BSE incidence risk as the epidemic evolved. Studies have demonstrated a similar phenomenon in several other countries.

In 1994, the EU banned the feeding of mammalian MBM to ruminants¹³.

In April 1996, the UK banned the feeding of mammalian MBM to farmed animals, fish and equine animals. Following a voluntary feed recall scheme, the ban is considered "effective" from 1 August 1996. By 7 September 2007, BSE had been confirmed in 172 cattle born in the UK since 1 August 1996. This represents less than 0.1% of the total BSE cases in the UK to date.

In 2001, the European Union (EU) extended the ban on feeding mammalian meat and bone meal (MBM) to ruminants to a ban (with certain exceptions¹⁴) on feeding animal protein to ruminants and feeding processed animal protein (PAP) to all animals farmed for food production¹⁵.

By the end of 2006, there were 22 BSE cases born in 2001 and 5 cases born in 2002, in the EU. By 7 September 2007, BSE had been confirmed in 9 cattle born in the UK since 1 January 2001.

An independent review of BSE cases born after July 1996, published in 2005, concluded that the elimination of feed borne sources of BSE remained the key to eliminating the disease and recommended that it was essential that

¹² Arnold and Wilesmith concluded that dairy cattle were most at risk of BSE infection, a combination of susceptibility and exposure, during the first 6 months of life. Supervie and Costagliola concluded that most BSE infections occur between 6 and 12 months of age.

¹³ Commission Decision 94/381/EC

¹⁴ Further information on the current scope of the feed ban is available at

<http://www.defra.gov.uk/animalh/bse/animal-health/feedbanguide.pdf>

¹⁵ Council Decision 2000/766/EC

appropriate, risk-based feed controls and monitoring should be maintained. In its response Defra noted that BSE controls must:

- ensure that consumers and animal health are fully protected;
- be based on sound science, taking account of the latest scientific developments;
- be proportionate to the known risk; and
- be practicable and enforceable.

Defra noted that this did not rule out changes to the current control regime but the overall objective of protection of public and animal health was paramount and this was its basis for negotiations on the TSE Roadmap.

6. Robustness of Microscopic Analysis Test (MAT)

Annex IV of Regulation (EC) No.999/2001 requires Member States to carry out the MAT on feed in accordance with a standard protocol¹⁶. In 2006, the EU Community Reference Laboratory¹⁷ for animal proteins in feed (CRL-AP) carried out an interlaboratory trial of 22/27 EU National Reference Laboratories (NRLs). [*Hard copy of report has been provided – see Annex 7 References*]. The purpose of the ring trial was to:

- Assess NRL proficiency for qualitative detection of MBM and fish in feed.
- Evaluate the robustness of the quantitative method for the determination of animal constituents in feed.

using the MAT method in Commission Directive 2003/126/EC.

i. Qualitative Assessment

Each NRL received 19 blind samples that included the following: blank (no animal protein), 0.1% MBM, 0.5% fish meal (Type III), 0.25% fish meal (Type III), 1.5% fish meal (Type III), 1% fish meal (Type III), 0.1% MBM plus 5% fish meal (Type I) and 1% fish meal (Type I).

Results

- 18/22 (82%) NRLs performed satisfactorily and 4/22 (18%) NRLs underperformed for the detection of MBM (<0.95 sensitivity).
- 17/22 (77%) NRLs performed satisfactorily and 5/22 (23%) NRLs underperformed for the detection of fish meal (<0.95 sensitivity).

¹⁶ Commission Directive 2003/126/EC as referred to in Article 61 and Annex VIII of Regulation (EC)No.882/2004

¹⁷ Centre Wallon de Recherches Agronomiques (CRA-W), Belgium

- 12/22 (55%) NRLs performed satisfactorily overall.
- 17/22 (77%) NRLs performed above 95% consolidated accuracy. 4 NRLs had single false positive results. 1 NRL had a false negative result for 0.1% MBM + 5% Fish (Type I).
- Remaining 5/22 (22%) NRLs would benefit from further training.

Conclusions

The CRL-AP concluded that the qualitative method in Commission Directive 2003/126/EC was reliable. The CRL-AP also concluded that the qualitative standard was the highest achieved to date in EU interlaboratory trials using the Commission Directive 2003/126/EC method.

Further to this report, the Community Reference Laboratory's report on the 2007 inter-laboratory trial on qualitative tests for the presence of animal proteins in feed has since been provided to Member States. 25 National Reference Laboratories (NRLs) participated fully (compared to 22 in the 2006 study). Of these, 17/25 (68%) NRLs performed satisfactorily overall (compared to 12/22 (55%) NRLs in the 2006 study). *[A hard copy of the report has been provided to the Committee].*

ii. Quantitative Assessment

Each NRL received 10 blind samples that included the following: 0.5% fish meal (Type III), 0.25% fish meal (Type III), 1.5% fish meal (Type III), 1% fish meal (Type III) and 1% fish meal (Type I).

Results

- 5/22 (23%) NRLs failed to quantify. There was significant variation in the quantitative results from the remaining 17 NRLs.

Conclusions

The CRL-AP concluded that the quantitative method for the determination of animal constituents in feed in Commission Directive 2003/126/EC was not robust.

7. Markers

Regulation (EC) No.1774/2002 provides for the use of markers for "high risk" Category 1 and 2 material disposed of by processing. However currently the only markers available are visible markers such as the food dye, Patent Blue V (E131) used to stain specified risk material (Category 1). The ideal marker would be visible and detectable by its olfactory properties, non-toxic, safe for handlers, commercially available, inexpensive, stable, recoverable and easy

to analyse. It would ensure identification and traceability of products to be disposed of and eliminate risk of fraud.

The European Commission has been funding research into chemical markers such as glycerol triheptanoate (GTH). GTH is resistant to processing and detectable through gas chromatography coupled to mass spectrometry (GC-MS).

On 11 September 2007, the EU's Standing Committee on the Food Chain and Animal Health (SCoFCAH) agreed a proposal to use GTH as a marker for processed products derived from Category 1 or Category 2 material.

8. Test Development

The review paper by Gizzi et al. (2003) provides an overview of tests for animal tissues in feeds. *[Hard copy of paper has been provided – see Annex 7 References]*. Regulation (EC) No.999/2001 requires Member States to carry out the MAT on feed.

a) Current Situation

The Veterinary Laboratories Agency applies the following tests to detect animal protein and PAP in feed in the UK:

- MAT – to detect bone fragments and muscle fibres.
- Polymerase Chain Reaction (PCR) – to detect species specific animal material.
- Counter Immuno-Electrophoresis (CIE) – to detect unprocessed or partially processed protein, e.g. spray-dried blood proteins.

b) Test Development at EU Level

(i) STRATFEED

The 42 month EU-funded STRATFEED project was agreed in 2000. Its main objectives were to:

- Harmonise and improve efficiency of MAT.
- Develop and validate new testing methods based on alternative techniques that permit the rapid testing, species differentiation and the reliable quantification of the addition of MBM. For example PCR, near-infrared spectroscopy (NIRS¹⁸) and near-infrared microscopy (NIRM).

(ii) SAFEED-PAP

¹⁸ NIRS involves mathematical matching near infra red spectra from a sample against a large database of controls. In order to be successful the database has to be populated with vast data sets for each species, plant ingredient and processing condition.

The 36 month EU-funded SAFEED-PAP was agreed in 2006. The project has three main objectives:

- development of suitable validated methods for the species specific detection and quantification of animal protein in compound feed in order to allow the amendment of the extended total ban;
- development of tools and analytical kits for the correct implementation of the methods in the labs; and
- to set up the appropriate environment for the optimum application of the methods.

SAFEED-PAP is looking at immunoassay approaches (e.g. lateral flow and fluorescent antibody techniques), PCR, Mass Spectrometry / High Performance Liquid Chromatography and NIRM as well as improvements in the MAT. It is also looking at using combinations of techniques (e.g. NIRM plus PCR) to improve detection – particularly species specific detection.

Defra is contributing to the SAFEED-PAP project through the funding of the VLA and CSL collaborators.

- Defra Project, SE1797¹⁹ – Detection of presence of species specific PAPs in feed (VLA).
- Defra Project, SE1798²⁰ – Detection of presence of species specific PAPs in feed (CSL).

9. Species Barrier

In 1999, the Scientific Steering Committee (SSC) provided an opinion on the risk born by recycling animal by-products as feed with regard to propagating TSE in non-ruminant farmed animals.

The SSC concluded that recycling of animal material, in general, would increase the risk that cases of TSE occur or that undetected pools of infectivity develop and that intra-species recycling would increase that risk further, due to the lack of a species barrier.

The SSC concluded that if recycling, and in particular intra-species recycling of animal material to farmed animals could not be avoided, all measures that reduced the recycled infectivity would reduce the risk. Such measures include:

¹⁹<http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=14459&FromSearch=Y&Publisher=1&SearchText=SE1797&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description>

²⁰<http://randd.defra.gov.uk/Default.aspx?Menu=Menu&Module=More&Location=None&ProjectID=14900&FromSearch=Y&Publisher=1&SearchText=SE1798&SortString=ProjectCode&SortOrder=Asc&Paging=10#Description>

- i. method 1 rendering;
- ii. excluding SRM;
- iii. excluding fallen stock; and
- iv. stopping feeding potentially contaminated feed a sufficient time before slaughter to reduce the risk of recycling infectivity through gut content.

The SSC also concluded that the possible risk-reduction measures would not be able to reach a zero risk, should infectivity enter the recycling loop and that due to the long incubation period a significant risk would build up before the disease became apparent.

Under Regulation (EC) No.1774/2002, the feeding of a species with PAP derived from the bodies or parts of the bodies of the same species, is prohibited. Manure and digestive tract (DTC) content are Category 2 animal by-product. DTC means the content of the DTC of mammals and ratites (e.g. ostriches), whether or not it is separated from the digestive tract. This measure is intended to prevent the inadvertent intra-species recycling of PAP contained in the gut contents of mammals and ratites. However it does not apply to poultry or fish. Regulation (EC) No.811/2003 requires that farmed fish must not be fed with PAP derived from farmed fish of the same species and that fish-derived feed intended for fish must only originate from wild fish.

10. Decontamination

There is some evidence that although Method 1 pressure processing (3 bar, 133°C, 20 minutes) significantly reduces the level of TSE infectivity (up to 1000-fold), it may not be robust under worst case conditions (Taylor, D. and Woodgate, S.L. 2003). [*Hard copy of report has been provided – see Annex 7 References*].

Any increase in minimum processing standards beyond the Method 1 specifications would be likely to have a detrimental effect on the performance of the assays currently being developed such as PCR, immunoassays and possibly mass spectroscopy methods.

11. Control Issues

Animal Health monitors compliance with the feed ban in Great Britain, through the risk-based framework of the National Feed Audit (NFA). The Department for Agriculture and Rural Development operates a similar programme in Northern Ireland.

The NFA was designed on the basis of EU requirements such as Commission Recommendation 2005/925/EC which required a minimum number of

inspections and official samples collected per year²¹. Despite the number of inspections and samples far exceeding previous minimum requirements²², it was recognised that, for practical reasons, not all feed samples in Great Britain have been collected by the official method specified in European Directive 76/371/EEC²³ (as required by Commission Decision 2003/126/EC). Defra commissioned two studies from VLA. The first used 2005/06 NFA data to examine the effect of percentage reductions in the number of samples and inspections on the number of breaches detected. The second ongoing study is comparing the relative efficacies of the official and non-official sampling methods in their ability to detect prohibited proteins in feed consignments.

The NFA results²⁴, indicate widespread compliance with the feed ban in Great Britain. In 2006, 11 procedural (not sample) breaches were detected during a total of 2256 inspections and there were only 17 non-compliant feed samples out of a total of 14,439 tested. Of the 17 non-compliant samples, 10 related to the detection of PAP (5 in ruminant compound feed) and 7 related to the detection of fish meal.

Some of the future proposals for relaxing the feed ban present control issues. For example:

- a zero tolerance or maximum tolerance (e.g. <0.1%) approach is easier to implement, but may present greater risk, than a case-by-case risk-based approach;
- ensuring that feed containing fish meal is only fed to young ruminants may present practical difficulties, particularly where these are kept on the same premises as adult ruminants; and
- preventing the inadvertent intra-species recycling of feed material contained in the gut presents practical difficulties.

²¹ Annual minimum of 10 inspections and 20 official samples per 100000 tonnes of compound feed produced. UK produces approximately 10 million tonnes of compound feed per year.

²² Official feed controls are now carried out under Regulation (EC) No. 882/2004 which requires Member States to adopt a risk-based approach to their implementation.

²³ Available at

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31976L0371:EN:HTML>

²⁴ Available at <http://www.defra.gov.uk/animalh/bse/statistics/nfa.html>

ANNEX 4 - SCIENTIFIC CONSIDERATIONS RELATING TO THE FEEDING OF FISH MEAL

The feeding of fish meal to farmed animals was not prohibited in the UK until 2001, when the EU total feed ban came into force. The fish meal feed ban was introduced because of concerns that fish meal might mask the presence of ruminant MBM in ruminant feed, rather than because of a specific concern about the inherent TSE risk of fish meal. Fish meal continues to be fed to non-ruminants. Typical inclusion rates for fish meal in animal diets range from 2-10% for terrestrial animal species, but can exceed 40% in fish diets.

In 2001, the Food Standards Agency's Advisory Committee on Animal Feedingstuffs (ACAF) concluded that:

- i. there were no specific risks to animal or fish health from the inclusion of fish meal in animal or fish feed;
- ii. cross contamination or adulteration of fish meal with meat and bone meal (MBM) was unlikely when material arrived in UK direct from South America; and
- iii. the risk of cross contamination of fish meal with MBM, would not warrant a ban providing the existing rules on MBM use were fully adhered to, and the production / supply chain was assured and protected.

In 2007, EFSA published a detailed opinion on the risks of feeding fish meal to ruminants with regard to TSE. EFSA concluded that:

- i. there was no indication that natural TSEs occur in fish;
- ii. current research does not indicate that mammalian prions induce formation and replication of fish prions; and
- iii. if there is any risk of TSE in fishmeal, this could arise from MBM-contaminated feed having recently been fed to fish or through fish meal contaminated by MBM.

EFSA also made a number of conclusions regarding detection methods and provided recommendations regarding risk quantification, further research and test development.

ANNEX 5 - SCIENTIFIC CONSIDERATIONS RELATING TO THE FEEDING OF NON-RUMINANT DERIVED MBM

The feeding of poultry meal to farmed animals was not prohibited in the UK until 2001, when the EU total feed ban came into force. The poultry meal feed ban was introduced because of concerns that poultry meal might mask the presence of ruminant MBM in ruminant feed, rather than because of a specific concern about the inherent TSE risk of poultry meal.

Swill, containing catering waste (potentially of non-ruminant and ruminant origin) which had been boiled at 100°C or more for at least 1 hour²⁵, could be fed to pigs and poultry until May 2001, when it was banned²⁶ because of the exotic virus risk.

It is generally accepted that pigs and poultry in the UK were potentially exposed to the BSE agent in feed. Maximum inclusion rates for MBM in pig and poultry feed in the 1980s ranged from 2.5-8.0%.

An assessment carried out by Det Norske Veritas Ltd (DNV) in 2006 concluded that allowing non-ruminant PAP to be used as an ingredient in non-ruminant animal feed in the EU would not result in any significant level of exposure of the EU cattle population to BSE infectivity (DNV 2006).

i. Pigs

Both completed and ongoing experiments have shown that pigs are susceptible to multiple parenteral (including intracerebral) challenge with BSE-infected brain tissue, but highly resistant to oral challenge with high doses of BSE-infected brain homogenate. Experiments have also shown that pigs are resistant to oral challenge with scrapie (Matthews, D. & Cooke, B.C. 2003). *[Hard copy of report has been provided – see Annex 7 References].*

Very limited surveillance exercises in Ireland (in pigs reared before the 2001 total feed ban) and in Switzerland have failed to detect the presence of naturally occurring TSE in pigs.

In 2003, the SSC provided an opinion on the potential requirement for specified risk material controls in pigs. On the basis of available evidence, the SSC concluded that the cattle-pig species barrier reduced the effective oral exposure by as much as 100-fold or more.

The SSC noted the potential for inadvertent intra-species recycling of animal protein contained in feed in the gut lumen, but noted that this eventuality was prevented by the animal by-product controls in the EU.

²⁵ Animal By-Products Order 1999 (SI 1999 No.646)

²⁶ Animal By-Products (Amendment) Order 2001 (SI 2001 No. 1704)

The SSC concluded that evidence from the unsuccessful transmission of BSE to pigs after experimental oral exposure to a dose of BSE agent approximately 50 000 times more than calculated in the field and evidence that repeated primary exposures of commercial pigs to BSE including the considerable potential for pig-to-pig recycling in Britain, did not result in natural cases of TSE in pigs, indicated that there was no basis on which to suspect that pigs had become infected with BSE.

ii. Poultry

Experimental studies have failed to find any evidence of transmission of BSE to domestic fowl challenged intra-cerebrally and then intra-peritoneally or to domestic fowl challenged orally.

In 1991, there was a report of a possible spongiform encephalopathy-like disease in three ostriches in a German zoo. However transmissibility was not proven.

ANNEX 6 - SCIENTIFIC CONSIDERATIONS RELATING TO THE FEEDING OF RUMINANT DERIVED MBM

Early epidemiological investigations into BSE linked the emerging epidemic in the UK to the use of ruminant-derived protein in cattle feed. In 1986, a typical dairy cow compound feed would have contained 3-5% high protein supplement of MBM or fish meal (plus cereals and cereal by-products, oils and minerals). At this inclusion rate and based on a maximum inclusion rate of 40% compound feed in the total diet (dry matter intake/day²⁷), the MBM component represented a relatively small component of the daily diet – less than 500 grams per cow per day.

In 2005, the EFSA published a quantitative risk assessment of the animal BSE risk posed by MMBM. The opinion largely supported a 1998 opinion of the Scientific Steering Committee, which concluded that only a zero level of cross contamination of animal feed with mammalian MBM can exclude any risk from it. The assessment concluded that the risk is determined by various factors including feed composition (%MMBM), feeding system (intensive/extensive), GBR²⁸ status, SRM removal and reliability of BSE surveillance.

As an unrealistic worst case scenario, cattle in an intensive system consuming 8 kilograms of compound feed containing 0.1% meat and bone meal (MBM) with a 40% bovine origin from a GBR IV country with unreliable BSE surveillance and no SRM removal prior to rendering, could be exposed to a median (p50) of 5×10^{-5} CoID50 units of BSE infectivity per animal per year. Based on a UK cattle population of 10 million (assuming all equally exposed), this would result in 500 new BSE *infections* per year.

However cattle in an extensive system consuming 1.5 kilograms of compound feed containing up to 2% MBM with a 40% bovine origin produced in a GBRIII country with reliable surveillance and all SRM removed prior to rendering, could be exposed to an average of 1.2×10^{-7} CoID50 units of BSE infectivity per animal per year. Based on a UK cattle population of 10 million (assuming all equally exposed), this would result in fewer than 2 new BSE *infections* per year.

²⁷ Assumes daily dry matter intake of 20kg per cow of which 12 kg is forage and 8 kg is compound containing 5% MBM.

²⁸ GBR is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where the presence of BSE is confirmed, the GBR gives an indication of the level of infection. There are four levels: I – highly unlikely; II-unlikely but not excluded; III-likely but not confirmed, or confirmed at a lower level; IV-confirmed at a higher level.

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- To poultry MO3002 and MO3003
- To pigs MO3004, MO3005, MO3010 (ongoing)

Further information is available at :

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ANNEX 8: OVERVIEW OF THE STANDARD ANALYTICAL METHODS USED TO QUALITATIVELY AND QUANTITATIVELY ASSESS MBM AND FISHMEAL IN ANIMAL FEEDS

The Veterinary Laboratories Agency offers two primary tests for the detection of processed animal proteins in animal feedstuffs (microscopic analysis test and real-time PCR). Both of these methods aim to detect a different type of target and cover a wide range of prohibited material.

The microscopic analysis method is the only method officially approved by the European Community to test for the presence of animal protein in feed. This test relies on the visual detection of solid animal structures (i.e. bone, muscle, feather etc) against a background of vegetable/ mineral structures. A combination of direct examination of the test material and a bone sedimentation phase gives good detection capabilities. This test is, however, operator dependant and requires a good deal of operator expertise to execute the test reliably. The sensitivity of the test is dependent on the contaminant being presented under the microscope, therefore, the overall sensitivity of the test is dependant on a combination of operator competence and sample handling. CRL interlaboratory studies have demonstrated competence across Member States at detection of 0.1% MBM in a feed containing 5% fishmeal.

The primary limitation of the test is the lack of species level detection. Reliable differentiation between fish and terrestrial bone fragments can be made, but differentiation between terrestrial (including avian) bone particles cannot be made using this method. Also, this test is restricted to the detection of solid structures that can survive rendering and any soft tissues are not detectable under the microscope.

With the growing use of real-time PCR techniques in laboratories, attention has turned to using DNA as a marker for the detection of PAP. The VLA approach combines an initial large test sample (40g) with a two tier general animal and species specific real time PCR assay. This gives good reproducibility, rapid and cost effective screening. The sensitivity of this test is <0.2% (based on 133°C, 3bar pressure, 20minute processing) with species level detection (bovine, ovine, porcine and avian).

The benefit of this, and other PCR methods, is that the test will detect a wide range of prohibited material including DNA derived from soft tissues. However, these tests will also detect DNA from non-prohibited source such as milk products.

The presentation at the meeting will set out the basic test approach for these two methods outlining the pro's and con's of each in terms of detection capabilities, quantification potential, sensitivity, repeatability and method robustness. In addition, new test developments being carried out under the EU SAFEED_PAP project will be described, particularly concentrating on species level detection and likelihood of achieving quantification.

