A TSE RISK ASSESSMENT FOR USING MEAT-AND-BONE-MEAL AS FUEL FOR THE PRODUCTION OF CEMENT

Ray Bradley CBE

Private BSE Consultant

Guildford UK

E-mail: raybradley@btinternet.com
A TSE RISK ASSESSMENT FOR USING MEAT-AND-BONE-MEAL AS FUEL FOR THE PRODUCTION OF CEMENT

Ray Bradley CBE

EXECUTIVE SUMMARY

A risk assessment has been conducted to assess direct and indirect risks from transmissible spongiform encephalopathy (TSE) agents to public and animal health as a result of changes to the fuel used by Lagan Cement Ltd, Killaskillen, Co. Meath, Republic of Ireland to produce cement. The stimulus for this risk analysis is a result of Lagan Cement making an application to the Department of Agriculture, Food and Rural Development to use lawfully produced meat-and-bone-meal (MBM) derived from rendering Irish animal by-products including specified risk materials (SRM) as a fuel for the production of cement. SRM comprises the tissues from a bovine carcase that carry a BSE risk and tissues from sheep and goat carcases with the highest risk of being infected with a scrapie agent. The risks to be assessed are those to public and animal health directly or indirectly through the food or feed chains. The BSE agent from cattle is a human pathogen but scrapie agents are not.

The assessment has been conducted following a site visit, consultation of relevant legal and scientific documents and official reports of expert committees and quantitative risk assessors and using the wide experience of the author.

The assessment has been conducted by investigating the TSE risks that might derive from the animal starting material permitted into the starting material for rendering in Ireland (the SOURCE); the effectiveness of rendering as used in Ireland to inactivate any TSE infectivity they may contain and the ability of cement manufacture to combust the MBM and destruct any remaining TSE infectivity (collectively the PROCESS). A third factor (USE) is not relevant to this assessment because there is only one use option for cement (for building) that is unchanged, no matter what fuel is used. Furthermore, as the report will show, there is no risk beyond negligible from the point at which the MBM in combusted and destroyed.

In regard to SOURCE, under European law MBM in Ireland can be produced in theory from animal materials of three Categories: 1, 2 and 3. Category 2 and Category 3 material does not present a TSE risk, so the MBM produced from such material does not present a TSE risk either and is not considered further. Category 1 material does present an actual or potential TSE risk. The level of risk in the European Union (EU) is variable depending on the nature of the starting material permitted into rendering by national law. In Ireland this is very strictly controlled and eliminates the highest TSE risk material, namely the whole carcase and all tissues and organs from those animals clinically suspected and confirmed to have BSE (passive surveillance). Targeted active surveillance and 'Rapid' testing of risk animals over 24 months old and slaughter cattle over 30 months old enables unsuspected cases of BSE to be detected beyond those identified by passive surveillance alone. The BSE infectivity actually present in the SRM from this additional population is likely to be less than that present in clinically confirmed cases because they would mostly be at an earlier stage of incubation. Thus, the BSE risk in Category 1 animal by-products in Ireland is limited to infectivity in a small proportion of the total SRM that come from infected animals that are in the early or mid stages of the incubation period and have not been, or cannot be, identified...
clinically, or by 'Rapid' testing. A small but declining risk in SRM starting materials might also result from the inclusion of potentially infected tissues from slaughter cattle cross contaminated with infected tissues from an adjacent rare slaughter animal that tests positive for BSE. The level (titre) of infectivity in the SRM from infected cattle that have tested negative for BSE is not known with certainty but is expected to be at least 10 times lower than that in the brain of a positive animal. In Ireland the BSE epidemic is past its peak, the age of positive animals is increasing so the amount of infectivity in SRM is declining year on year.

SRM from goats presents a very low risk from scrapie agents as the incidence of scrapie in goats is very low in Ireland though not many have been tested. Because a recent case of BSE in a goat in France has been identified there is a much increased active surveillance for TSE in goats throughout the EU. Even in sheep, though the incidence of scrapie is higher than in goats it is still relatively low. BSE has not been detected in sheep in any country of the world to date (March 2005). Scrapie may also be declining because of selection of resistance alleles in breeding rams and because flocks in which scrapie is diagnosed must now under EC law either be culled or genotyped with susceptible sheep eliminated. It is too early to determine the extent of scrapie in sheep in any country because active surveillance has not been in existence for long enough and is as yet incomplete. Transmissible mink encephalopathy, chronic wasting disease, TSE of captive wild ruminants and domestic cats and TSE in native-born captive wild FELIDAE do not exist in Ireland and present no TSE risk in starting materials for rendering.

Thus it is concluded that some Category 1 material in Ireland will contain TSE infectivity but the amount is small and declining and the titre of infectivity within it is relatively low.

In regard to PROCESS and rendering in Ireland all rendering plants operate to the same standard and use pressure cooking (particle size \( \leq 50 \) mm, 133° C, 3 bar, 20 min) that reduces BSE infectivity by \( \geq 3 \) logs. Furthermore, the rendering parameters adopted by law are enforced by the Department of Agriculture and are sufficiently robust to inactivate the vast majority, if not all the input infectivity in the resulting MBM. There is thus a low (and decreasing) likelihood that SRM MBM in Ireland could contain significant levels of infectivity in more than a small proportion of the total amount of MBM produced per annum (150,000 tons).

In regard to PROCESS and cement manufacture the EC has declared that Category 1 MBM must be incinerated (and the ashes buried in a licensed landfill facility) or be co-incinerated. Cement manufacture is one authorised means for disposal by co-incineration though plants that employ MBM as a fuel must be licensed to do so by the appropriate authorities. Collectively all scientific studies relating to TSE agent inactivation by dry heat indicate complete destruction at temperatures over 600° C and especially in the vicinity of 1000° C and higher. All end products have been shown to be biologically inert over 1000° C.

The MBM used as a fuel for cement manufacture will be completely combusted either directly in the flame at a temperature in excess of 2000° C or at 1400° C in the kiln. Exposure to these destructive temperatures follows pre-heating in cyclones at about 850° C and during a total transit time of c. 20 seconds for the raw (mineral) meal and c. 8 seconds for gases. The particle size of the MBM (measured in \( \mu \)m) will be the same as that for coal, and the raw (mineral) meal and will have a consistency of a fine powder. Such a small size will enable rapid heat penetration and immediate combustion in the flame or in the kiln itself thereby securing complete destruction. After combustion the newly formed clinker is pulverized into a
powder and this process is likely to destruct any inorganic replicas of $\beta$ sheeted $\PrP$ (fossil templates) that some have suggested might enable replication of $\PrP$ if introduced into animals or man. With current knowledge it is inconceivable that combusting Irish Category 1 MBM or any other category of MBM could contain any level of infectivity above negligible. Therefore the TSE risks to humans, animals and the environment are regarded as negligible if the methodology outlined in this report is followed.

CONCLUSION

The burning of Irish MBM, including SRM MBM as a fuel for the manufacture of cement under the general conditions described in this report present a negligible TSE risk for humans, animals or the environment.
INTRODUCTION

This risk analysis has been generated following a request from Dr Imelda Shanahan C Chem, MRSC, FICI, Managing Director of tms environment Ltd, Dublin, on 3 September 2004 on behalf of Lagan Cement Ltd, Killaskillen, Co. Meath, Republic of Ireland. The purpose is to assess direct and indirect risks from transmissible spongiform encephalopathy (TSE) agents to public and animal health, especially to food and feed chains, as a result of changes to the fuel used by Lagan Cement Ltd to produce cement. The stimulus for this risk analysis is a result of Lagan Cement making an application to the Department of Agriculture, Food and Rural Development (DAFRD) (hereafter referred to as the Department of Agriculture) to use lawfully produced meat-and-bone-meal (MBM) derived from rendering Irish animal by-products including specified risk materials (SRM) as a fuel for the production of cement. The risks to be assessed are those to public and animal health directly or indirectly through the food or feed chains.

The public health risk analysis addresses the direct TSE risks to bona fide Lagan Cement staff working in the cement works and in close proximity to unburned MBM fuel and indirect risks to others either on site or close to its boundaries. Indirect risks to humans and farmed food animals from consumption of food or feed crops and growing or harvested from the immediate vicinity of the works are also addressed. The animal health risk analysis specifically addresses the TSE risks to any species of farmed mammal or bird from the MBM fuel before and after combustion. Risks from direct transmission and indirect transmission via personnel, vehicles, vermin, other species of animal or bird, water, other fluids or airborne spread are considered.
CREDSNTIALS OF THE RISK ASSESSOR

Mr Raymond Bradley is a qualified veterinary surgeon (Fellow of the Royal College of Veterinary Surgeons), a trained veterinary pathologist (Fellow of the Royal College of Pathologists) and an internationally recognised expert in TSE and BSE in particular. In 1993 he received a CBE (Commander of the British Empire) award for his services to the Ministry of Agriculture, Fisheries and Food (MAFF, now Department of Environment, Food and Rural Affairs). In 1993 he also received the Silver Medaille du Mérite from the Office International des Epizooties (OIE) for international service in connection with disseminating knowledge on bovine spongiform encephalopathy. He was the Head of Pathology Department at the Central Veterinary Laboratory, Weybridge, UK (now Veterinary Laboratories Agency) of the MAFF, at the time when colleagues in his Department, in November 1986, discovered BSE. He was co-author of the first publication on BSE (Wells et al, 1987) and has since published widely on the subject (for example see Bradley, 2001). He was responsible with colleagues for setting up the initial Ministry research programme on BSE and in 1991 became BSE Co-ordinator for MAFF. He retired in 1995 to become a Private BSE Consultant. He has been an Observer and then Member of the UK Spongiform Encephalopathy Advisory Committee (SEAC) from 1990 until 2002 having completed the maximum term permitted. He is a Member of several other important committees or expert groups including the Argentine Scientific Advisory Committee on BSE and the UK TSE Working Group of the Advisory Committee on Dangerous Pathogens. He advises the European Commission (EC), World Health Organisation (WHO), OIE, governments and a range of national and international organisations, industries and private companies on the subject of BSE and related subjects. He has a wide experience of many animal by-product processes and animal and public health and safety issues connected with the livestock industry in general, and the by-products sector in particular.

METHODS

Cement

Various websites were consulted to inform on the general process of cement manufacture including as follows:

- Lafarge Cement - various documents
- Cembureau - Environmental Benefits of using alternative fuels for cement production.
- Cement Manufacturing using alternative fuels and the advantages of process modelling (Finland).

Background information on the cement project and some other relevant information had been provided progressively since 3 September 2004 by Dr Shanahan and others. This included the following documents:


Description of the Activity – Lagan Cement Ltd IPC Licence Application.

Integrated Pollution Control Revised Licence, EPA Ireland.

Meat-and Bone-Meal Risk Assessment from Edenderry Power Ltd EIS

Supplementary information was obtained from Dr Shanahan with referral back to the Company as necessary.

A site visit was undertaken on 26 November 2004 with Dr Imelda Shanahan to see the current cement production facility at Lagan Cement, Lansdown Cement Works, Killaskillen in the company of Mr Jude Lagan the Managing Director. At this visit plans for the proposed receipt, storage and use of MBM as a fuel for cement production were discussed and relevant questions answered.

Legislation

The following documents have been consulted and are relevant to the issues:

Transmissible spongiform encephalopathies (TSE)

The author’s wide experience, knowledge and publications have been used to record the principle features of these diseases, the agents that cause them, their properties and particularly their unconventional resistance to physical and chemical processes that are fatal to conventional bacteria, viruses and fungi responsible for various human and animal diseases.

THE MANUFACTURE OF CEMENT — the basic principles (See Figure 1)

Limestone and other minerals containing salts or oxides of aluminium, calcium, iron and silicon are crushed and ground to form the raw material. These sources are blended, dried and ground to a fine dust to form the ‘raw meal’. It is required that c. 15% of the milled material remains on an 88 μm screen and c. 1.5% on a 200 μm screen. There is a two stage continuous heating process — preheating followed by kiln heating. The finely divided raw meal is pre-heated in cyclones to initiate the dissociation of calcium carbonate into calcium oxide and carbon dioxide, a process called calcination. This pre-heating process is achieved by using exhaust gases from the kiln (see below and Figure 1). There is a contra-flow of gases upwards and the raw meal downwards. The temperature is maintained by burning fuel in calciner burners with a flame temperature exceeding 2000° C. During passage downwards through the five cyclones the raw meal progressively heats up from < 500° C to about 850° C. Calcination commences when the temperature reaches 820° C. The now calcined raw meal next enters the kiln where calcium oxide reacts with other elements to produce calcium aluminates and silicates at a temperature in excess of 1400° C producing cement. The reaction products leave the kiln as ‘clinker’. Clinker (granule size 3-25 mm diameter) is continuously...
analysed and any that does not come up to specification is returned to the input and appropriate adjustments are made to the constituent profile. The clinker is ground (particle size c. 10 μm) and mixed with gypsum, limestone and/or ashes to produce finely powdered cement which is dispatched either in bulk, or in bags.

Cement is a building material of major importance for the construction of buildings, roads, runways, quays, sea defences and similar large objects. When required for use it is mixed with water and sand or ballast to produce concrete. Reinforced concrete is concrete into which iron or metal rods are buried to give added strength.

The high temperatures necessary to make cement demand the use of fuels with a high caloritic value, either alone or mixed with other fuels. Air is an important component of the chemical reaction. Historically petroleum coke (pet coke) or coal/pet coke mixtures were used as fuel. In more recent times a range of solid, liquid or gaseous fuels have been used including rice chaff, nut shells, tallow, various wastes and last but not least, meat-and-bone meal (MBM).

Some of these fuels may be used alone or in combination with other fuels. For some fuels the plant may require to have a special design. At start-up some fuels (including MBM and coal) are not used but are rather introduced once the operating temperature is reached and level. Start-up fuel is usually fuel oil or gas. There are fails-safe mechanisms to prevent MBM being combusted if the temperature profiles are incorrect and during shut-down and start-up. Bag filters are used at strategic points in the processing chain to collect dust and the contents are periodically emptied into the input material for combustion.

The combustion process takes place at atmospheric pressure. The flame temperature (and point at which the MBM is combusted reaches more than 2000°C. The temperature in the pre-heater reaches levels in the range 500°C to 900°C and in the kiln will reach in excess of 1400°C.

The particle size of coal must be very small to facilitate combustion and equivalent to that for the raw meal (see above). To achieve this particle size coal is ground before use. Ground coal has the appearance of a fine powder. The same will apply to the MBM. MBM will be delivered at the particle size determined to be necessary for achieving effective combustion. The transit time of raw meal through the complete heating process is c. 20 seconds and > 8 seconds for gases). The temperatures and times exceed the minimum requirements specified in European Regulations for incineration or co-incineration of waste (EC, 2000). There are no solid or liquid waste products since all materials are incorporated into the final product. Steam and gases including oxides of carbon, nitrogen and sulphur are produced but are treated to remove particulate matter before dispersal through a 125 metre chimney to the atmosphere.

TRANSMISSIBLE-SPONGIFORM ENCEPHALOPATHIES (TSE)

Species affected and geographic distribution

TSE are progressive, fatal, neurological disorders naturally affecting mammals including man but only a few restricted members of the Orders Artiodactyla (cattle, sheep, goats, deer and various captive wild antelope), Carnivora (mink, domestic cats and captive wild cats) and Anthropoidea (lemurs and monkeys). Experimentally various TSE have been transmitted to some of these species and to Rodentia including to rats, mice, hamsters and Guinea pigs. Mice and hamsters are commonly used animals for the study of experimental TSE.
The species most commonly affected naturally are sheep and goats (scrapie), cattle (bovine spongiform encephalopathy (BSE)), domestic cats (feline spongiform encephalopathy), various captive wild cats, captive wild ruminant species, captive wild primates including lemurs, farmed mink (transmissible mink encephalopathy (TME)), deer and elk (chronic wasting disease) and man (kuru and Creutzfeldt-Jakob disease). Kuru has not been reported outside of the Fore-speaking people of Papua New Guinea. TME has never been reported in the British Isles and CWD has been reported only in North America and in the Republic of Korea.

A solitary case of BSE in a goat in France in 2003 has recently been confirmed and has resulted in an extended monitoring (active surveillance programme) for BSE in goats throughout the EU (EC, 2005).

Of all these diseases only BSE in cattle is a definite zoonosis (transmissible to man). Because the agent that causes BSE has occurred naturally in domestic cats, greater kudu and a nyala, captive wild cats and captive wild ruminant species and domestic cats and a solitary French goat could theoretically also pose a risk to man if infected. However, most of these 'exotic' diseases have occurred only in the United Kingdom (UK) or France and have probably become extinct because of the measures applied to protect animal feed from becoming infected. Nevertheless it is as well to note that a case of FSE in a domestic cat has occurred historically in Northern Ireland and FSE has been reported in a cheetah in a zoo in the Republic of Ireland.

Other than this single occurrence in an imported cheetah, the Republic of Ireland is devoid of animal TSE other than scrapie in sheep and goats and BSE in cattle. Various forms of CJD are reported from all countries in the world with adequate surveillance (including Ireland). Thus for the purpose of assessing the TSE risk in cement manufactured in Ireland the only significant risks could come only from scrapie and BSE.

Scrapie is mainly restricted to the northern hemisphere although its precise prevalence is not known. BSE in native born cattle has been mainly restricted to Europe though a small number of cases have occurred in native-born cattle in Japan, Israel and Canada.

Clinical signs of BSE, pathology and diagnosis

The clinical neurological signs of BSE are generally insidious in onset, are progressive and finally fatal. They include disorders of sensation (including hypersensitivity to sound and touch, kicking whilst being milked, excessive licking and head-shyness), mental status (apprehension, nervousness, abnormal behaviour and aggression and abnormal ear position), abnormal posture and movement (muscular tremors, gait ataxia (incoordination of gait), falling and low head carriage) and general signs (loss of weight and reduced milk yield). Not all the signs occur in all animals and at best there is an 85% confirmation rate in BSE suspect animals as several other diseases and metabolic states can produce some of the listed signs. All clinically suspect cases must be confirmed post mortem by examination of the brain by one of several approved methods including microscopic examination, immunohistochemistry, immuno-blotting or detection of 'scrapie-associated fibrils' by electron microscopy.

The mean incubation period of BSE is 60 months but cases have occurred as young as 20 months or as old as 22 years 7 months. As a result there is usually a long clinically silent
period averaging five years. Most cases of BSE occur in animals aged between 4 and 6 years old. Asymptomatic animals can be detected by so-called ‘Rapid’ testing of the brain post mortem and if such a test is positive it must be confirmed by one or other of the tests mentioned above. ‘Rapid’ tests are only effective for detecting cattle at a stage of incubation preceding clinical onset by between 3 and 6 months. This means that an animal acquiring infection as a calf will remain negative to such a test until, on average, the host is between 4 years 6 months and 4 years 9 months of age assuming the actual incubation period to be 5 years. Within the EU there are rules for applying ‘Rapid’ tests for active surveillance. This includes testing all fallen stock, casualty slaughter animals, ante mortem inspections failures over 24 months old, birth cohorts of confirmed cases, offspring of cases and animals in depopulated herds. Slaughter cattle over 30 months old are also tested.

The main diagnostic testing methods rely upon the detection of spongiform change in the brain (hence spongiform) and/or the detection of an abnormal host protein associated consistently with infectivity and called PrP^Sc or PrP-res. Most tests for BSE rely on the detection of this protein that is rich in β sheet using immunological methods. Infectivity can only be tested by inoculating experimental animals and is only used for research purposes. Nevertheless all TSE have the common features of degenerative spongiform changes in the brain (hence encephalopathy) and are experimentally transmissible. BSE is not contagious, but scrapie and CWD are though only to animals of their own kind.

Pathogenesis of BSE and specified risk materials (SRM)

Experimental studies in cattle have shown that following experimental oral challenge with virulent BSE agent from brain material there is a short period of a few months during which time no infectivity can be detected in any tissue, even by inoculation of susceptible experimental animals (the only effective way of determining infectivity). From around six months after dosing infectivity can be found intermittently and through the rest of the incubation period and into the clinical phase of disease in the distal ileum, the terminal short part of the small intestine. From three to six months before clinical onset and during the clinical phase of disease, infectivity is also progressively found (in addition to in the ileum) in the spinal cord and dorsal root ganglia, the brain and its associated ganglia. Other studies have revealed that the tonsil may be infected early during incubation and the third eyelid, retina and possibly the bone marrow may be infected in the clinical phase of disease. It is generally agreed that in all TSE the highest levels of infectivity are in the central nervous system and highest of all at the late stage of clinical disease. Infectivity in the distal ileum, tonsil, third eyelid (and bone marrow if it is infected) is likely to be at a significantly lower titre than that in the brain.

This knowledge of the distribution of infectivity over the time-span of disease enables certain tissues (or parts likely to be contaminated by them) that carry an actual or potential risk of harbouring the BSE agent to be identified. These tissues are called specified risk materials and include for Irish cattle: the skull, excluding the mandible and including the brain and eyes, the vertebral column excluding the vertebrae of the tail, the transverse processes of the cervical, thoracic and lumbar vertebrae and the wings of the sacrum, but including the dorsal root ganglia, and the spinal cord of bovine animals over 12 months, and the tonsils, the intestines from duodenum to rectum and the mesentery of bovine animals of all ages (EC, 2001, 2002a,b, 2003).
Because of the potential risk of BSE occurring in small ruminants, though none has been identified anywhere in the British Isles, some sheep and goat materials are also included in the definition of SRM. These are: the skull, brains and eyes, the tonsil and spinal cord of ovine and caprine animals aged over 12 months or which have a permanent incisor erupted through the gum, and the spleen and ileum of ovine and caprine animals of all ages.

SRM are removed mainly at abattoirs and cutting plants, stained and either incinerated or (as in Ireland) rendered at an approved rendering plant to produce SRM MBM and SRM tallow.

**Animal By-products**

For practical purposes animal by products in the EU not intended for human consumption are ascribed to one of three categories (EC, 2002b).

**Category 3 material** is that passed fit for human consumption but is chosen not to be eaten for commercial reasons, If rendered in a dedicated, approved, Category 3 rendering plant, the starting materials are devoid of any TSE risk so the resulting MBM is also devoid of a TSE risk. Indeed MBM derived from such material is permitted for inclusion into certain pet food in the EU including in Ireland.

**Category 1 material** comprises animal by-products that may carry a high risk of being infected with a TSE or containing residues of certain substances beyond a set limit. In the context of this report only the TSE risk is addressed. Material that can contribute to Category 1 material (from a TSE point of view) includes: animals suspected of being infected with a TSE, animals killed in the context of TSE eradication measures, pet animals, zoo animals and circus animals, experimental animals, wild animals suspected of being infected with diseases communicable to man and animals, SRM or entire bodies if the SRM have not been removed, floor sweepings and waste trapped in drainage filters and sludge from such systems. When any animal is found positive by a 'Rapid' test it must be destroyed as Category 1 material. If the positive animal was slaughtered for human consumption, in addition, at least the one animal before and two after it in the slaughter line must be destroyed as Category 1 material (EC 2002a). Category 1 material can be directly incinerated but if not, it is rendered (by pressure cooking in Ireland as follows: particle size ≤ 50 mm, 133°C, 3 bar, 20 min) and the resulting MBM and tallow must be incinerated or co-incinerated in approved plants at a temperature of at least 850°C for a minimum of 2 seconds (EC, 2000). Co-incineration includes the use of Category 1 MBM as a fuel in an approved cement works.

**Category 2 material** comprises manure and alimentary tract contents, drainage and similar materials not of Category 1 (such as from a pig abattoir), non-ruminant fallen stock and animals of non-ruminant species destroyed as part of disease eradication and condemned material. If Category 2 material is rendered the resulting MBM should not present a risk from TSE as no TSE infected material forms part of the starting material. In Ireland pigs and poultry are not fed with MBM under European and Irish law and so the alimentary tract material and manure present no TSE risk.

In conclusion only Category 1 material can contain TSE risk material in Ireland. Thus from the point of view of TSE risk there is none as a result of using Category 2, or Category 3 MBM as a fuel for cement manufacture.
In regard to TSE risks from Category 1 material, in 1999 a research group in University College Dublin carried out a major study entitled ‘Risk assessment of disposal options for MBM in Ireland.’ The group concluded that “Co-incineration of MBM offered a safe and energy efficient means of disposal” (IDAC, 2003). A quantitative risk assessment for the combustion of SRM-derived MBM was also completed by University College, Dublin (Cummins et al, 2002). The conclusions reached were that the TSE risks from combustion of SRM MBM were negligibly small.

**Surveillance for BSE**

Passive surveillance is surveillance resulting from farmers, veterinarians and others reporting suspect clinical cases of BSE to the Department of Agriculture. BSE was made a compulsorily notifiable disease in 1989. After compulsory slaughter brain material from these animals is tested for evidence of BSE. Historically, carcases of such animals were buried under supervision on farm, as were carcases of animals failing ante mortem inspection at the abattoir because of nervous signs (they were returned to their farm of origin). The policy was changed following the report of the BSE Scientific Advisory Committee in 1999 (BSESAC, 1999 and see Statement by the Minister for Agriculture on 31 October 2000 at: http://www.agriculture.gov.ie/index.jsp?file=pressrel/2000/153-2000.xml. If positive the carcase is frozen and stored by the Department. If negative the carcase is rendered as Category 1 material and from, 1 April 1997 the parameters in use in all rendering plants in Ireland are particle size 50 mm, 133°C, 3 bar 20 min hereafter known as pressure cooking. http://www.agriculture.gov.ie/index.jsp?file=areasofi/bse/BSETEST.xml

Targeted Active surveillance (EC, 2001, 2002a, 2003) is compulsory surveillance by the Department of Agriculture of certain categories of stock (see below) using ‘Rapid’ tests for BSE. If positive the carcase is frozen and stored by the Department. If negative the carcase is rendered as Category 1 material.

The categories of animals that are tested for BSE under EC legislation are shown in Table 1. In addition, in Ireland, not only are herds where a case of BSE has been found depopulated, slaughtered and tested but so also are the progeny of BSE affected animals, and birth cohorts of BSE-positive animals. There is a very low incidence of BSE-positive animals in any of these categories. The BSE epidemic curve for the republic of Ireland and years of introduction of key measures are shown in Figure 2.
TABLE 1

Categories of animals in the EU that are subject to either passive surveillance or targeted active surveillance using ‘Rapid’ tests.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bovine animals</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Special emergency slaughter</td>
<td>All &gt; 24 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clinical signs at ante mortem inspection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fallen stock</td>
<td>All &gt; 24 months</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Animals slaughtered for human consumption | All > 30 months      | Random sample comprising at least 10,000 animals > 30 months | All > 30 months
| BSE suspects                          | All                    | All                                       | Animals slaughtered under the OIE scheme: All animals > 30 months subject to “special emergency slaughter”, with clinical signs at ante mortem or born after 1/8/95 and > 42 months old. Random sample comprising at least 10,000 animals of retaining animals (born before 1/8/95).
| Other                                  |                        |                                           |                                           |
| Animals slaughtered for human consumption |                       | Minimal sample size in ovine and caprine animals > 18 months |
| Animals not slaughtered for human consumption |                       | Minimal sample size in ovine and caprine animals > 18 months |
| Animals in infected flocks (voluntary until 1 October 2003) |                       | Minimal sample size in ovine and caprine animals > 12 months or which have a permanent incisor erupted through the gum |

Other than bovine, ovine and caprine animals: voluntary

The number of tests conducted in 2003 and positive results by active and passive surveillance in years 2002 and 2003 are listed in TABLES 2 and 3. TABLE 4 indicates the evolution and decline.
TABLE 2

Number of tests performed for BSE by risk Category in the EU in 2003

<table>
<thead>
<tr>
<th>Country</th>
<th>Risk Category</th>
<th>BSE culling</th>
<th>Clinical signs a/d AM</th>
<th>Emergency Slaughter</th>
<th>Fallen Stock</th>
<th>Healthy Slaughter</th>
<th>BSE suspects</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgique/Belgium</td>
<td>Clínica</td>
<td>1.126</td>
<td>1.214</td>
<td>33.691</td>
<td>356.134</td>
<td>167</td>
<td>392.465</td>
<td></td>
</tr>
<tr>
<td>Danmark</td>
<td></td>
<td>1.774</td>
<td>1.739</td>
<td>33.376</td>
<td>250.558</td>
<td>38</td>
<td>239.702</td>
<td></td>
</tr>
<tr>
<td>Deutschland</td>
<td></td>
<td>1.725</td>
<td>3.254</td>
<td>5.879</td>
<td>240.556</td>
<td>127</td>
<td>2.533</td>
<td>16.333</td>
</tr>
<tr>
<td>España</td>
<td></td>
<td>2.386</td>
<td>1.810</td>
<td>1.457</td>
<td>90.916</td>
<td>13</td>
<td>567.864</td>
<td></td>
</tr>
<tr>
<td>Francia</td>
<td></td>
<td>1.669</td>
<td>0</td>
<td>0</td>
<td>283.695</td>
<td>2.920.157</td>
<td>442</td>
<td>3285.963</td>
</tr>
<tr>
<td>Irlanda</td>
<td></td>
<td>11.986</td>
<td>0</td>
<td>2.455</td>
<td>49.954</td>
<td>600.586</td>
<td>330</td>
<td>700.399</td>
</tr>
<tr>
<td>India</td>
<td></td>
<td>2.148</td>
<td>54.674</td>
<td>5.217</td>
<td>64.159</td>
<td>658.770</td>
<td>63</td>
<td>756.506</td>
</tr>
<tr>
<td>Luxemburg</td>
<td></td>
<td>2</td>
<td>0</td>
<td>27</td>
<td>3.083</td>
<td>14.598</td>
<td>4</td>
<td>17.714</td>
</tr>
<tr>
<td>Nederland</td>
<td></td>
<td>954</td>
<td>14.043</td>
<td>1.375</td>
<td>50.525</td>
<td>439.403</td>
<td>25</td>
<td>506.325</td>
</tr>
<tr>
<td>Österreich</td>
<td></td>
<td>0</td>
<td>0</td>
<td>3.755</td>
<td>13.235</td>
<td>205.658</td>
<td>2</td>
<td>222.650</td>
</tr>
<tr>
<td>Portugal</td>
<td></td>
<td>1.271</td>
<td>5.521</td>
<td>1.562</td>
<td>19.310</td>
<td>81.633</td>
<td>102</td>
<td>109.399</td>
</tr>
<tr>
<td>Suomi/Finland</td>
<td></td>
<td>0</td>
<td>4.216</td>
<td>8.087</td>
<td>10.890</td>
<td>108.198</td>
<td>5</td>
<td>131.430</td>
</tr>
<tr>
<td>Sverige</td>
<td></td>
<td>0</td>
<td>0</td>
<td>2.229</td>
<td>22.479</td>
<td>9.856</td>
<td>16</td>
<td>34.580</td>
</tr>
<tr>
<td>United Kingdom</td>
<td></td>
<td>555</td>
<td>1,8</td>
<td>148.651</td>
<td>76.532</td>
<td>237.490</td>
<td>456</td>
<td>490.652</td>
</tr>
<tr>
<td>Česká Republika</td>
<td></td>
<td>706</td>
<td>114</td>
<td>43.640</td>
<td>12.635</td>
<td>133.046</td>
<td>1</td>
<td>210.184</td>
</tr>
<tr>
<td>Estonia</td>
<td></td>
<td>0</td>
<td>0</td>
<td>1.549</td>
<td>2.415</td>
<td>19</td>
<td>0</td>
<td>3.993</td>
</tr>
<tr>
<td>Kypros</td>
<td></td>
<td>0</td>
<td>22</td>
<td>135</td>
<td>1.168</td>
<td>6.401</td>
<td>0</td>
<td>7.726</td>
</tr>
<tr>
<td>Latvia</td>
<td></td>
<td>0</td>
<td>0</td>
<td>3.631</td>
<td>1.014</td>
<td>4.383</td>
<td>11</td>
<td>6.126</td>
</tr>
<tr>
<td>Litovska</td>
<td></td>
<td>0</td>
<td>28</td>
<td>313</td>
<td>2.187</td>
<td>7.418</td>
<td>0</td>
<td>9.746</td>
</tr>
<tr>
<td>Magyarorszag</td>
<td></td>
<td>0</td>
<td>0</td>
<td>4.283</td>
<td>6.532</td>
<td>86.595</td>
<td>98</td>
<td>97.488</td>
</tr>
<tr>
<td>Malta*</td>
<td></td>
<td>0</td>
<td>0</td>
<td>90</td>
<td>40</td>
<td>1.089</td>
<td>0</td>
<td>1.199</td>
</tr>
<tr>
<td>Polska</td>
<td></td>
<td>37</td>
<td>59</td>
<td>9.401</td>
<td>17.413</td>
<td>428.452</td>
<td>51</td>
<td>455.413</td>
</tr>
<tr>
<td>Slovenija</td>
<td></td>
<td>27</td>
<td>2.866</td>
<td>399</td>
<td>8.092</td>
<td>74.751</td>
<td>32</td>
<td>86.167</td>
</tr>
<tr>
<td>Slovenská Republika</td>
<td></td>
<td>11</td>
<td>10</td>
<td>5.364</td>
<td>13.461</td>
<td>65.192</td>
<td>7</td>
<td>87.010</td>
</tr>
<tr>
<td>New Member States</td>
<td></td>
<td>781</td>
<td>19.106</td>
<td>68.072</td>
<td>84.987</td>
<td>787.501</td>
<td>195</td>
<td>945.642</td>
</tr>
<tr>
<td>Norway</td>
<td></td>
<td>0</td>
<td>4.102</td>
<td>7.322</td>
<td>1.872</td>
<td>10.726</td>
<td>2</td>
<td>24.924</td>
</tr>
</tbody>
</table>
FIGURE 2

BSE epidemic curve for the Republic of Ireland to 19 December 2004 (All cases) and key dates of measures

- BSE made a Notifiable Disease 1989
- Ruminant Feed ban 1990
- SRM ban 1997
- All species 'Real' feed ban 1 Jan 2001

Number of cases vs Years

Source OIE
TABLE 3

Positive tests for BSE by active and passive surveillance in years 2002 and 2003 and the ratio of positives per 10,000 animals in 2003 in the EU.

<table>
<thead>
<tr>
<th></th>
<th>Active monitoring</th>
<th>Passive surveillance</th>
<th>Percentage of cases detected by active monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tests No.</td>
<td>Positive</td>
<td>Ratio</td>
</tr>
<tr>
<td>Belgique/Belgium</td>
<td>392,298</td>
<td>15</td>
<td>0.03</td>
</tr>
<tr>
<td>Danmark</td>
<td>289,664</td>
<td>1</td>
<td>0.00</td>
</tr>
<tr>
<td>Deutschland</td>
<td>2,388,219</td>
<td>44</td>
<td>0.17</td>
</tr>
<tr>
<td>Ellas</td>
<td>26,532</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>España</td>
<td>567,781</td>
<td>148</td>
<td>2.61</td>
</tr>
<tr>
<td>France</td>
<td>3,205,521</td>
<td>126</td>
<td>0.39</td>
</tr>
<tr>
<td>Ireland</td>
<td>700,000</td>
<td>144</td>
<td>2.06</td>
</tr>
<tr>
<td>Italia</td>
<td>786,443</td>
<td>30</td>
<td>0.38</td>
</tr>
<tr>
<td>Lampedusa/Bugg</td>
<td>17,710</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Nederland</td>
<td>506,300</td>
<td>17</td>
<td>0.34</td>
</tr>
<tr>
<td>Österreich</td>
<td>222,448</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Portugal</td>
<td>109,397</td>
<td>105</td>
<td>9.61</td>
</tr>
<tr>
<td>Slovak/Tiolkad</td>
<td>113,425</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Sverige</td>
<td>34,344</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>460,296</td>
<td>428</td>
<td>9.30</td>
</tr>
<tr>
<td>Total EU15</td>
<td>10,036,777</td>
<td>3,068</td>
<td>1.04</td>
</tr>
<tr>
<td>Česka Republika</td>
<td>210,183</td>
<td>4</td>
<td>0.19</td>
</tr>
<tr>
<td>Eesti</td>
<td>3,983</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Kypros</td>
<td>7,320</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Latvia</td>
<td>6,115</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Lietuva</td>
<td>9,969</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Magyarorssag</td>
<td>93,390</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Malta**</td>
<td>1,159</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Polska</td>
<td>453,362</td>
<td>4</td>
<td>0.09</td>
</tr>
<tr>
<td>Slovenija</td>
<td>66,135</td>
<td>1</td>
<td>0.13</td>
</tr>
<tr>
<td>Slovenška Rep</td>
<td>87,008</td>
<td>2</td>
<td>0.23</td>
</tr>
<tr>
<td>nMIS</td>
<td>944,847</td>
<td>11</td>
<td>0.12</td>
</tr>
<tr>
<td>Norway</td>
<td>24,022</td>
<td>0</td>
<td>0.00</td>
</tr>
<tr>
<td>Total EU25</td>
<td>10,983,564</td>
<td>1,069</td>
<td>0.97</td>
</tr>
</tbody>
</table>

* : Positives per 10,000 bovine animals tested
**: March until September
Rendering

Rendering as applied to animal by-products is a cooking and separation process. Cooking is achieved by applying heat to the minced starting materials. As the temperature rises water is evaporated. Fat (tallow) is separated from the residue (greaves) by drawing off, centrifugation and pressing. The greaves is ground to produce MBM. It is this material that is proposed to be used as a fuel for making cement.

The specification of Irish MBM for use as fuel in the plant at Killaskillen is declared by Lagan Cement (Lagan Cement Personal Communication 2004) to be as follows:

- Maximum fat content 14%
- Maximum water content 5%
- Maximum particle size 4mm
- Minimum calorific value 4,300 kcal/kg

These values are consistent with values reported in the literature. MBM with a fat content of >17% tends to clog the conveyors and therefore is unacceptable for use. The protein content of MBM is around 50%.

Three main studies (Taylor, Woodgate and Atkinson, 1995; Taylor et al 1997, Schreuder et al, 1988) on the effectiveness of various rendering processes used in the EU during the late 1980s have been undertaken to determine the effect on starting materials spiked with TSE infectivity from natural cases of BSE or scrapie. The two studies by Taylor and colleagues showed that tallow (whether filtered or not) contained no detectable infectivity. In regard to MBM all three studies showed that infectivity was found in all processes other than after pressure cooking. Consequently throughout the EU, pressure cooking is the principle method adopted for processing mammalian by-products including Category 1 waste (EC, 2002b). In Ireland all Category 1 waste, including SRM, is rendered in this manner. All rendering plants...
are supervised by full time staff of the Department of Agriculture to ensure enforcement of the rules.

Some words of caution are necessary. The first is that in all the studies mentioned above, the input titre of infectivity was low or moderate, rather than high. Secondly, the bioassay used mice, so a species barrier was introduced that may underestimate the inactivating effect by a factor of around 500 times (Wells, 2001). Nevertheless, the Scientific Steering Committee (SSC) of the EC has indicated that after pressure cooking (particle size ≤ 50mm, 133°C, 3 bar, 20 min) the clearance factor is at least 3 logs (i.e., at least 1,000 times reduction of infectivity would be achieved). Although only brain tissue from cattle with natural BSE has been titrated (and the titre ranges from about $10^{3.3}$ to $10^{5.4}$ mouse intracerebral (i/c) ID$_{50}$) other SRM has not been titrated, though on the basis of evidence from other TSE the titre is likely to be at least ten times lower than in the brain. Thus it is unlikely that BSE infectivity above this level would be encountered especially in Ireland for the reasons given in the numbered paragraphs below. If this is the case then because rendering by pressure cooking provides for at least 3 logs reduction in infectivity, very little, if any, BSE infectivity could get into MBM including that from SRM and TSE risk animals under Irish conditions.

1. In Ireland **cattle suspected or confirmed to have BSE** do not enter any rendering facility. Instead since 1997 the **carcase** is frozen and stored pending incineration which currently is not available in Ireland. Such car-cases (if confirmed to have BSE) are likely to have the highest levels of infectivity of any cattle in Ireland but have never been processed to make MBM.

2. **BSE is not a contagious disease.** Nevertheless the Department of Agriculture has adopted a policy of **de-populating herds** when a single case of BSE is confirmed and these animals form part of Category I material, as are offspring of BSE cases and animals from the same birth cohort as the affected animal. All these animals are tested for BSE **post-mortem** and few are confirmed as positive (only one of 11,986 cattle from depopulated herds tested positive in 2003, **TABLE 5**). If positive animals are identified then the whole **carcase** is frozen and stored as in paragraph 1 above and is **not** rendered to produce MBM. **Carcases** of test negative animals are also rendered but could still be infected, though not in the CNS, but rather only in the ileum and perhaps the tonsil which are relatively small tissues and if infected are likely to have a titre substantially below that found in the brain of clinical cases and which would be expected to be substantially, if not completely inactivated by processing.

3. As part of EC policy, in Ireland all cattle for human consumption over 30 months old are tested for BSE using ‘Rapid’ tests. If a tested animal is positive the whole **carcase**, head and spinal cord are frozen and stored as in paragraph 1 above and are **not** rendered to produce MBM. In Ireland slaughter cattle are grouped into batches of ten. If a positive **carcase** is detected in a batch of ten, the spinal cord of the **carcase** immediately preceding the positive on the slaughter line and the spinal cord from all those after it in the batch of ten are cold-stored pending destruction by incineration’. The **carcases** of these cattle, other offal and the remaining SRM from them are sent for rendering as SRM. In 2004 of the 126 BSE confirmed cattle in Ireland 19 were identified by ‘Rapid’ testing at slaughter plants and in 2005 about 65 cases are predicted with about 11 being identified at slaughter plants (I Shanahan, personal

---

1 This measure (aimed at reducing the risks of cross contamination between a test positive **carcase** and an adjacent one) adopted in Ireland complies with Commission Regulation EC No 1494/2002 (EC 2002a) and in fact goes beyond it, as the Regulation requires only the **carcase** before and two after the positive to be destroyed.
communication resulting from a communication made to the Department of Agriculture on 22 March 2005). None of these positives will form part of the starting material for rendering into the MBM used for cement manufacture at Lagan. Remaining cattle could still be infected but not detectably in the CNS. Infectivity, if present, would be expected to be confined to the ileum and perhaps the tonsil as animals would be at a relatively earlier stage of incubation. These tissues are relatively small contributing little infectious material. Furthermore, if infected they are likely to have a titre substantially below that found in the brain of clinical cases.

4. As part of EC policy, in Ireland all bovine fallen stock, emergency slaughter and ante mortem inspection failures over 24 months are ‘Rapid’ tested. If positive and confirmed the whole carcase is dealt with as in 1 otherwise the material is rendered and classed as Category 1 waste. In 2003 there were no positive ante mortem inspection failures with neurological signs and of 2,483 emergency slaughter animals only 4 tested positive for BSE. Fallen stock account for most positive animals detected by active surveillance, (TABLE 6) but the incidence is falling.

5. Cattle under 30 months old are rarely positive by ‘Rapid’ testing. There is thus generally a relatively low BSE risk from any cattle material from cattle of this age and younger in the EU, particularly after 2003, (TABLE 7).

6. As a result of a reinforced feed ban adopted EU-wide from 1 January 2001 no mammalian protein can be fed legally to any species of farmed animal (FIGURE 2) thus reducing any previous risk there may have been (before this date) from cross-contamination of ruminant rations with rations for mono-gastric species. These rations might have previously, legally contained MBM. From 2002 there has been a decline in the number of BSE cases reported in Ireland (FIGURE 2).

7. In regard to the relationship between the UK, Ireland and the rest of the EU the peak age of occurrence of BSE is highest in the UK and next highest in Ireland indicating that Ireland is close behind the UK (the leader) in having eliminated new exposures to BSE infectivity via feed. (FIGURE 3).

8. BSE incidence in Ireland reached a peak in 2002 and is now declining. As a result the average age at which cattle get BSE in Ireland is increasing. Consequently the BSE risk in cattle under 30 months old is also falling and the age at which already exposed cases develop disease is rising. FIGURES 4 and 5 and TABLE 8.

9. In regard to scrapie, monitoring sheep and goats by active surveillance is less intense than for cattle and has been effective for less time so it is thus unable to convincingly demonstrate trends in disease occurrence either in Ireland or between Ireland and other Member States. In 2003, 49 cases of TSE (all scrapie) were reported in sheep and none in goats (TABLE 9). These numbers are very small and do not constitute a human health risk. The active monitoring of goats for evidence of TSE has been increased since a single case of BSE in a French goat has been identified (EC, 2005).

Evidence to support the above statements and derived from the official 2003 report of the EC Health and Consumer Protection Directorate General is presented below:
TABLE 5

Number of cattle tested and positive in depopulated herds in 2003 and ratio of positives per 10,000 animals tested for 2002 and 2003

<table>
<thead>
<tr>
<th></th>
<th>No.</th>
<th>Positives</th>
<th>2003</th>
<th>2002</th>
<th>Ratio*</th>
<th>Δ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgique/Belgie</td>
<td>1.126</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Danmark</td>
<td>1.774</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Deutschland</td>
<td>1.125</td>
<td>1</td>
<td>8.89</td>
<td>11.42</td>
<td>22%</td>
<td>-22%</td>
</tr>
<tr>
<td>Ellas</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>España</td>
<td>2.356</td>
<td>6</td>
<td>23.47</td>
<td>12.79</td>
<td>99%</td>
<td>99%</td>
</tr>
<tr>
<td>France</td>
<td>1.669</td>
<td>2</td>
<td>11.98</td>
<td>0.63</td>
<td>1803%</td>
<td>1803%</td>
</tr>
<tr>
<td>Ireland</td>
<td>11.936</td>
<td>1</td>
<td>0.83</td>
<td>2.14</td>
<td>61%</td>
<td>-61%</td>
</tr>
<tr>
<td>Italia</td>
<td>2.148</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Luxembourh</td>
<td>2</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Nederland</td>
<td>954</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Österreich</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Portugal</td>
<td>1.271</td>
<td>0</td>
<td>0.00</td>
<td>3.60</td>
<td>-100%</td>
<td>-100%</td>
</tr>
<tr>
<td>Svezia/Finländ</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Sverige</td>
<td>0</td>
<td>0</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>555</td>
<td>0</td>
<td>0.00</td>
<td>3.77</td>
<td>114%</td>
<td>114%</td>
</tr>
<tr>
<td>Total EU 15</td>
<td>24.966</td>
<td>10</td>
<td>3.00</td>
<td>2.77</td>
<td>44%</td>
<td>44%</td>
</tr>
</tbody>
</table>

*: positive cases per 10,000 bovine animals tested.

There is a very low incidence of BSE in depopulated herds.
Results of active surveillance of fallen stock over 24 months old in the EU in 2003

TABLE 7

<table>
<thead>
<tr>
<th></th>
<th>Prevalence of BSE in cattle of different ages in the EU total cattle population in 2003 (positive cases per 10,000 tests)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
</tr>
<tr>
<td>Belgium/Belgium</td>
<td>33,894</td>
</tr>
<tr>
<td>Danmark</td>
<td>35,576</td>
</tr>
<tr>
<td>Deutschland</td>
<td>240,356</td>
</tr>
<tr>
<td>Elba</td>
<td>1,798</td>
</tr>
<tr>
<td>España</td>
<td>90,916</td>
</tr>
<tr>
<td>France</td>
<td>283,695</td>
</tr>
<tr>
<td>Ireland</td>
<td>84,954</td>
</tr>
<tr>
<td>Italia</td>
<td>64,159</td>
</tr>
<tr>
<td>Luxembourgo</td>
<td>3,083</td>
</tr>
<tr>
<td>Nederland</td>
<td>30,525</td>
</tr>
<tr>
<td>Österreich</td>
<td>13,235</td>
</tr>
<tr>
<td>Portugal</td>
<td>19,310</td>
</tr>
<tr>
<td>Suomi/Fland</td>
<td>10,899</td>
</tr>
<tr>
<td>Sverige</td>
<td>22,479</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>76,582</td>
</tr>
<tr>
<td>Total EU 15</td>
<td>1,031,458</td>
</tr>
<tr>
<td>Slovenija</td>
<td>3,092</td>
</tr>
</tbody>
</table>

*: positive cases per 10,000 bovine animals tested

Fallen stock contribute the largest number of BSE cases in Ireland but the incidence is falling.

TABLE 7

Prevalence of BSE in cattle of different ages in the EU total cattle population in 2003 (positive cases per 10,000 tests)

<table>
<thead>
<tr>
<th></th>
<th>BE</th>
<th>DK</th>
<th>DE</th>
<th>ES</th>
<th>FR</th>
<th>IT</th>
<th>NL</th>
<th>PT</th>
<th>UK</th>
<th>EU 15</th>
<th>CZE</th>
<th>PL</th>
<th>SI</th>
<th>SK</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;24</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>24-35</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>36-47</td>
<td>0.00</td>
<td>0.00</td>
<td>0.06</td>
<td>0.16</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>48-59</td>
<td>0.00</td>
<td>0.00</td>
<td>0.41</td>
<td>1.45</td>
<td>0.02</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>60-71</td>
<td>0.41</td>
<td>0.21</td>
<td>0.26</td>
<td>0.48</td>
<td>0.09</td>
<td>0.26</td>
<td>0.02</td>
<td>0.21</td>
<td>1.03</td>
<td>0.30</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>72-83</td>
<td>0.00</td>
<td>0.00</td>
<td>0.41</td>
<td>0.37</td>
<td>0.32</td>
<td>1.22</td>
<td>1.38</td>
<td>2.48</td>
<td>2.42</td>
<td>1.59</td>
<td>0.45</td>
<td>0.00</td>
<td>0.00</td>
<td>1.01</td>
</tr>
<tr>
<td>94-107</td>
<td>0.00</td>
<td>0.00</td>
<td>0.01</td>
<td>1.50</td>
<td>1.75</td>
<td>1.75</td>
<td>0.67</td>
<td>17.50</td>
<td>21.51</td>
<td>3.64</td>
<td>0.00</td>
<td>0.00</td>
<td>1.26</td>
<td>0.00</td>
</tr>
<tr>
<td>108-119</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>3.85</td>
<td>0.64</td>
<td>0.00</td>
<td>15.09</td>
<td>63.32</td>
<td>0.84</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>120-131</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.93</td>
<td>0.89</td>
<td>0.00</td>
<td>32.27</td>
<td>67.19</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>132-143</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>3.48</td>
<td>56.47</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>144-155</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>156 &amp; &gt;</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

Very few cases of BSE now occur in cattle under 30 months of age.
FIGURE 3

Age distribution of positive cases in UK, Ireland the rest of the EU and new Member States in 2003.

In regard to the age of occurrence of BSE, Ireland is closely following the UK (the leader) and is ahead of the average for current and new Member States.

FIGURE 4

Age distribution of BSE cases in Ireland by year.

The Age of peak occurrence is progressively increasing year on year indicating that the epidemic is declining.
The average age of BSE occurrence in cattle with BSE in the EU from 2001 to 2003.

The average age of BSE occurrence in Ireland is rising. There are too few cases to observe this in cattle culled from depopulated herds.

**TABLE 8**

Average age in months of confirmed cases in target groups by year

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Belgium/Brussels</td>
<td>74,0</td>
<td>0,0</td>
<td>0,0</td>
<td>72,1</td>
<td>71,6</td>
<td>88,1</td>
<td>73,6</td>
<td>84,0</td>
<td>81,6</td>
<td>73,9</td>
<td>81,0</td>
<td>0,0</td>
</tr>
<tr>
<td>Denmark</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>57,5</td>
<td>78,6</td>
<td>89,0</td>
<td>78,0</td>
<td>84,0</td>
<td>80,0</td>
<td>48,0</td>
<td>8,0</td>
<td>66,0</td>
</tr>
<tr>
<td>Deutschland</td>
<td>61,5</td>
<td>56,3</td>
<td>52,0</td>
<td>68,4</td>
<td>78,3</td>
<td>72,7</td>
<td>63,8</td>
<td>78,0</td>
<td>77,0</td>
<td>64,7</td>
<td>70,5</td>
<td>71,7</td>
</tr>
<tr>
<td>Italy</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>56,6</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
<tr>
<td>France</td>
<td>86,0</td>
<td>78,9</td>
<td>75,6</td>
<td>86,6</td>
<td>99,7</td>
<td>79,3</td>
<td>75,5</td>
<td>97,8</td>
<td>98,7</td>
<td>74,6</td>
<td>83,9</td>
<td>81,7</td>
</tr>
<tr>
<td>Ireland</td>
<td>0,0</td>
<td>71,4</td>
<td>95,0</td>
<td>90,7</td>
<td>99,1</td>
<td>112,3</td>
<td>83,5</td>
<td>95,6</td>
<td>104,5</td>
<td>82,4</td>
<td>91,5</td>
<td>100,0</td>
</tr>
<tr>
<td>Italy</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>66,5</td>
<td>80,3</td>
<td>91,5</td>
<td>71,9</td>
<td>75,9</td>
<td>97,3</td>
<td>0,0</td>
<td>0,0</td>
<td>96,0</td>
</tr>
<tr>
<td>Luxemburg</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>73,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
<tr>
<td>Nederland</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>76,2</td>
<td>79,3</td>
<td>85,4</td>
<td>70,8</td>
<td>72,9</td>
<td>69,8</td>
<td>77,00</td>
<td>79,0</td>
</tr>
<tr>
<td>Österreich</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>70,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
<tr>
<td>Portugal</td>
<td>0,0</td>
<td>9,9</td>
<td>0,0</td>
<td>81,2</td>
<td>86,9</td>
<td>94,5</td>
<td>82,3</td>
<td>85,2</td>
<td>92,1</td>
<td>81,9</td>
<td>88,2</td>
<td>93,2</td>
</tr>
<tr>
<td>Slovak/Finland</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>82,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>57,0</td>
<td>102,0</td>
<td>105,4</td>
<td>101,0</td>
<td>110,9</td>
<td>119,2</td>
<td>89,4</td>
<td>101,0</td>
<td>108,4</td>
</tr>
<tr>
<td>EU15 average</td>
<td>72,3</td>
<td>70,5</td>
<td>72,0</td>
<td>76,2</td>
<td>85,9</td>
<td>93,1</td>
<td>88,7</td>
<td>100,0</td>
<td>107,6</td>
<td>86,5</td>
<td>96,9</td>
<td>100,5</td>
</tr>
<tr>
<td>Česká Republika</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>72,0</td>
<td>73,5</td>
<td>62,7</td>
<td>68,0</td>
<td>0,0</td>
<td>76,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
<tr>
<td>Polska</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>72,0</td>
<td>73,5</td>
<td>62,7</td>
<td>68,0</td>
<td>0,0</td>
<td>76,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
<tr>
<td>Slovenia</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>76,3</td>
<td>74,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
<tr>
<td>Slovenská Rep.</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
<td>72,6</td>
<td>93,3</td>
<td>93,0</td>
<td>78,0</td>
<td>71,3</td>
<td>72,0</td>
<td>0,0</td>
<td>0,0</td>
<td>0,0</td>
</tr>
</tbody>
</table>

In Ireland the mean age of BSE occurrence in all risk groups is rising.
In Ireland all rendering plants operate to the same standard and use pressure cooking. MBM derived from those plants not handling SRM (Category 2 and 3 processing plants) starting materials present no TSE risk. In fact material from Category 3 plants is approved for feed use for pet animals. MBM derived from SRM starting materials may have some TSE infectivity in those materials but the level of BSE-infected material is decreasing over time. Furthermore, the rendering parameters adopted by law are enforced by the Department of Agriculture and are sufficiently robust to inactivate the vast majority, if not all, the input infectivity in the resulting MBM. There is thus a low (and decreasing) likelihood that SRM MBM in Ireland could contain significant levels of infectivity in more than a small proportion of the total amount of MBM produced per annum (150,000 tons).

In summary and in conclusion and in regard to TSE risks in Irish MBM, it can be stated that the starting material used to produce MBM of any description prepared in Ireland by pressure cooking is unlikely to present a high risk of carrying high levels of BSE infectivity. Furthermore, whatever levels of infectivity do exist are progressively declining year on year as the BSE epidemic approaches elimination. In Ireland no clinically affected, confirmed cases of BSE determined by passive surveillance (which would contain the highest levels of infectivity) enter the rendering system so no MBM is produced from them. In regard to other cattle in risk categories there are very low levels of positive animals in the categories from depopulated herds, offspring of cases, birth...
cohorts of cases, ante-mortem inspection failures, healthy slaughter and emergency slaughter cattle. No animal testing positive for BSE from this group or from the potentially higher risk group of fallen stock over 24 months of age form the starting material used for rendering but rather are stored frozen pending incineration, facilities for which do not currently exist in Ireland. Thus in Ireland the only contributions to BSE infectivity in the starting material for rendering will be in the SRM from cattle that are infected but undetectable, either clinically or by testing and a small number of cattle (from which the spinal cord is removed) that might potentially be cross-contaminated from a rare test positive animal detected in a group of slaughter cattle. The infectivity titre in such material is likely to be substantially lower (at least ten times lower) than that in the brain of an animal with clinical signs, or testing positive with a ‘Rapid’ test, though it cannot be precisely quantified.

SRM from goats present very low risks from scrapie agents as the incidence of scrapie in goats is very low in Ireland though not many have been tested. Even in sheep, though the incidence of scrapie is higher it is still relatively low. It may also be declining because of selection of resistance alleles in breeding rams and because flocks in which scrapie is diagnosed must now under EC law either be culled or genotyped with susceptible sheep eliminated. It is too early to determine the extent of scrapie in sheep in any country because active surveillance has not been in existence for long enough and is as yet incomplete. BSE in sheep has not been reported anywhere in the world and BSE in goats has to date only been confirmed in a single incident in France.

It is clear that TSE infectivity (BSE and scrapie, but not TME, CWD or any form of CJD infectivity) could be in the starting material for rendering in Ireland but is likely to be declining year on year. As pressure cooking is adopted for all this type of risk material in Ireland at least 3 logs reduction of infectivity can be expected. As very little infectivity at this level is likely to enter the rendering system from cattle the MBM produced should be inert. However, the EC has declared that it must be incinerated (and the ashes buried in a licensed landfill facility) or be co-incinerated. Cement manufacture is one authorised means for disposal by co-incineration though plants that employ MBM as a fuel must be licensed to do so by the appropriate authorities.

The next part of this report will deal with the thermal resistance of TSE agents in general and then discuss TSE risks that might ensue if Irish-produced MBM as described, is used to manufacture cement and in particular at Lagan Cement, Lansdown Cement Works, Killaskillen.

RESISTANCE OF TSE AGENTS TO INACTIVATION

TSE agents are resistant to destruction by methods that are lethal to conventional bacteria, fungi and viruses, Strong alkalis and to a lesser extent strong acids can secure complete or partial inactivation especially if applied under pressure and with heat. Such methods are not applicable to fuels (including MBM) used for cement manufacture.

In regard to wet heat, autoclaving in a porous load autoclave at temperatures from 134°-136° C for 18 minutes (or 6 separate cycles of 3 minutes each, holding temperature and time) are commonly used for potentially contaminated surgical instruments to protect patients from exposure to CID after an appropriate cleaning regime. Again this is not
applicable to MBM and in any case is not far different from the pressure cooking rendering process.

Dry heat is less effective than wet heat for destroying infectivity. Experimental studies reported in 1990 using heat-resistant, freeze-dried, high-titred, hamster scrapie-infected, brain material (at a titre several orders of magnitude higher than would be expected in any Irish MBM produced by pressure cooking) showed that some infectivity could survive dry heat temperatures up to 360°C for an hour (Brown, Liberski and Wolff 1990). Subsequently Taylor, McConnell and Fennie, (1996) showed that macerates (notoriously resistant to inactivation as compared to homogenates or plain tissue) of the ME7 strain mouse-passaged scrapie agent was incompletely inactivated by dry heat up to 180°C for 1 hour but the titre of surviving infectivity reduced progressively as the temperature was increased and was undetectable after exposure to 200°C for one hour, though some infectivity was still present after 20 minutes (Taylor 1991). The authors concluded that scrapie-like agents are unlikely to survive incineration.

On the other hand, Dickinson and Fraser (1969) showed that heat treatment can modify the dose-response curve and Taylor et al (1998) reported that under certain autoclaving conditions thermostable subpopulations of TSE agents can arise that are more difficult to inactivate. This latter phenomenon is suggested to be due to the fixation of material as a result of smearing and drying of material (such as upon a surgical instrument) followed by fixation during the rapid rise in temperature in the ensuing heat process. Furthermore, Taylor (1991) using ME7 scrapie agent also reported that elemental carbon might protect residual scrapie infectivity during exposure to high, dry heat, temperatures. However, during the combustion process used in the manufacture of cement, smearing is unlikely and because of the high temperatures (in excess of 1400°C) all carbon is burned and no ash remains.

Two further studies on incineration have been reported. In the first (Brown et al, 2001) samples of hamster brain infected with the 263K strain of scrapie at a titre of 10⁹ hamster, i/c, ID₅₀/g were used. Specimens heated for 5 minutes at 150°C or 300°C were negligibly inactivated but after 15 minutes the log reductions were respectively 2-3 and 6 logs. At 600°C the ashed material had lost almost all the infectivity. Curiously no hamsters succumbed to material inoculated after 5 minutes of combustion but five out of 18 hamsters succumbed after the 15 minute combustion suggesting that infection in these inocula was near the point of extinction. Heating to 1000°C produced total inactivation and it was concluded that the thermal degradation and oxidation processes would have been pushed beyond the point where any survival was possible. Furthermore the clearing of black residue and smoke from the crucibles at 1000°C suggested that most of the carbon had been oxidised. One other point was made. Inorganic replicas (‘fossil templates’) of the molecular geometry of PrPSc might nucleate the conformational change of the PrP precursor protein in inoculated hamsters to produce its infectious β sheet form. However, in cement manufacture the pre-final product is clinker which is severely pulverised to produce a fine powder (particle size c. 10µm diameter) before final processing. Thus such inorganic replicas, if they did exist at all, are likely to be diminished or eliminated by this process. The effect on TSE infectivity of mixing the pulverised clinker with gypsum and other materials is not known.

In a second study Brown et al (2004) investigated the effectiveness of 15 minute exposures to 600°C and 1000°C in continuous flow normal or air starved, incineration-
like conditions to inactivate pooled lq brain macerates of 263K hamster scrapie brain material with an infectivity titre > 10^9 hamster i/c, ID\(_{50}\)/g. Following bioassay of ash, outflow tubing residues and vented emissions two transmissions occurred from 21 hamsters inoculated with ash of a single specimen burned in normal air at 600° C. No other material at either temperature of combustion realised scrapie positive animals. It was concluded that “at temperatures approaching 1000° C (and above) under the air conditions and times used in these experiments contaminated tissues can be completely inactivated with no release of infectivity into the environment from emissions”. It was also concluded that MBM used as a fuel in cement plants and operated to similar parameters as used in the experimental studies may be expected to provide a similar level of inactivation.

Brown et al (2004) also commented that in their studies at 600° C over 1 billion infectious doses were reduced to less than a single LD\(_{50}\). As this is related to an i/c dose, an oral dose could never realistically be achieved as the efficiency of the oral route compared to the i/c route is several orders of magnitude (perhaps as high as 10^5) less efficient (Taylor et al, 2001). It is vital of course as the authors state, that thermal treatment systems must be continuously and consistently operated to the correct parameters especially at start-up and shut down (the cement works will not use MBM fuel until the necessary operating temperatures are achieved and feed will be suspended as shut down is initiated).

No study to the author’s knowledge has investigated the specific TSE risks from using MBM akin to that available in Ireland in cement works. There is no escape for MBM from being totally combusted as analyses of cement clinker are performed as an on-going quality control process and shut down of MBM fuel introduction is immediate if any deficits are detected. The combustion process is aerobic and the temperatures reached exceed by far those considered in the experimental studies mentioned above. However, it is noted that the duration of exposure to the highest temperatures (more than 1400° C for the raw materials and in excess of 2000° C in the flame where the MBM will be burned) is likely to be less than 15 minutes and more likely on average for any MBM particle that is not immediately combusted in any of the flames to be a matter of seconds (c. 20 seconds) rather than minutes. Nevertheless, there is no evidence whatever that any fuel used in cement manufacture (including MBM) could remain un-combusted. It is thus concluded on scientific grounds with our currently available knowledge that there could be no TSE risk that is greater than negligible for humans, animals or the environment exposed to any end-product (including the cement or gaseous and particulate products from the chimney) following co-incineration in the Lagan Cement works or any other works using similar material and equipment.

The experimental studies reported above provide considerable reassurance about the TSE safety of using MBM as a fuel for cement manufacture. This reassurance is extended by a number of other factors including:

- elimination of material with the highest levels of infectivity from the starting material for rendering,
- the mixing (and thus dilution) of this material with non-infected material,
- an improving BSE and probably scrapie situation in Ireland,
- the dilution of MBM with other raw materials used for cement manufacture,
- the presence of a species barriers (especially to man),
- the unlikely occurrence of the respiratory route of transmission in any TSE and
the hydrophobic properties of prion protein that would restrict its mobility in water and soil.

On a more general note, incineration/cremation has been a time honoured way of disposing of animal and human organic matter in a safe manner. In the modern age with a focus upon residual risks in ash or other end-products of combustion and on the possibility of risks in gaseous emissions, strict control of the burning process is demanded and has been introduced by legislation which is strictly enforced in the EU. Most of the problems attributed to incineration that are actual or perceived, are related to the combustion of wastes other than from animal organic matter such as hazardous waste of a chemical or radioactive nature. Such risks do not apply to the use of MBM as a fuel as it is an entirely organic animal product. Other risks might derive from the generation of toxic chemicals as part of the combustion process. Any non-TSE risks from these will be covered in a separate report relating to environmental protection from the output from the cement works and will not be substantially different from those generated by combustion of other fuels.

Lagan Cement operates one of the most modern and sophisticated designs of a cement works with effective and continuous control of the operation parameters and a fail-safe system should any deficit be found in the critical control point parameters. Thus the major concern to be addressed here is to answer the question “Is there a measurable TSE risk to humans, animals or the environment as a result of exchanging current fuels for Irish MBM including SRM MBM?” On the basis of the above scientific evaluation of the effectiveness of incineration to inactivate TSE infectivity the conclusion is that although a zero risk is impossible to prove any risk there may be is negligible. This is supported by quantitative risk assessments on processes that do not approach the severity of the processes used for cement manufacture in general and intended to be used for cement manufacture at Lagan Cement in particular. These include the quantitative risk assessment for combustion of MBM (Cummins, et al, 2002) reported above and a BSE risk assessment made for the UK Environment Agency on the burning of rendered products from over thirty months old UK cattle in power stations by DNV Technica (DNV, 1997). Both these studies reported that the incineration of MBM results in a million fold reduction of TSE infectivity (IDAC, 2002). The starting materials that produced the rendered products in the DNV study had an increased risk over that in the starting materials proposed to be used at Lagan Cement. This is because some of the over 30 month old UK cattle would have been positive for BSE, if they had been ‘Rapid’ tested. As they would not enter any food or feed chain there was no compulsion to test them. In Ireland all cattle over 30 months old are compulsorily tested and positive animals are not rendered but rather frozen and stored.

In the DNV study no infectivity tests were conducted on end products, but hopper and fly ash were analysed for protein and amino acids (DNV, 1997) and found to be of the same order of magnitude as in similar ash from BFB combustors (Wykes, 2001) which are installed and in-use in the UK for the specific destruction of SRM MBM under EC rules. The UK SEAC advised that the overall reduction in infectivity could be as much as 6 logs or even greater (DNV, 1997), a reduction sufficient to inactivate infectivity in a cow brain with the highest infectivity yet detected.

The assessment concluded that using the starting material described, burning would produce negligible risks of infection of people via environmental pathways. Both individual and societal risks would be very small and would not normally be a cause for
concern. An uncertainty analysis has shown that the risks may vary by several orders of magnitude above or below those estimated but even a more pessimistic analysis would not give risks which were other than negligible compared to other risks in daily life (DNV, 1997). Because the BSE titres in starting materials proposed to be used by Lagan Cement are likely to be smaller than those examined in the study, the risks from the output from the Lagan Cement works are also negligible and probably lower.

OTHER RISKS

Until now the only risks considered have been from combusted material and its products. What remains to be considered are risks from the MBM delivered to Lagan Cement. Dedicated (use-specific) sealed trucks like cement tankers will be used to transport MBM from rendering plants to the cement works and the transport will be effected under the control of the Department of Agriculture. On arrival at Lagan Cement it will be stored in two dedicated sealed silos at Lagan Cement, one proximal to the pre-heater and the other close to the main kiln burner. Transfer of MBM from the vehicle to the silo will use a sealed hose system that eliminates any potential for escape of the product. From this point on the delivery of MBM will be via conveyors sealed to the exterior until mixing with other cement ingredients. There is no possible contact between the MBM and any other equipment, vehicle person or animal. As the silos are sealed there is no possible entry point for birds, vermin or insect pests. Remaining risks relate to any possible spillages that might unexpectedly occur despite the control procedures. This is more likely (but still improbable) at the delivery point and can be neutralized by a well rehearsed standard operating procedure (SOP) to prohibit further spillage, to contain what has been spilled and to destroy the spillage material and anything movable with which it has come in contact, together with appropriate disinfection procedures. An SOP should include the precautionary measures to be adopted and indicate the personal protective equipment to be worn by personnel responsible for clean up. In view of the fact that most MBM in Ireland will be devoid of significant infectivity, TSE risks to personnel, animals and the environment are likely to be negligible.

It is pertinent to note that no case of vCJD in humans has been specifically attributed to an occupational hazard including to workers in rendering plants, knackers, abattoirs, meat cutting plants, veterinary neuropathology laboratories, MBM storage facilities or cement works.

CONCLUSIONS

The use of Irish MBM as fuel for cement manufacture at Lagan Cement presents a negligible TSE risk to humans, animals and the environment.

This conclusion is supported by the following information and analysis:

- Starting material used to produce MBM in Ireland has a lower risk of containing BSE infectivity than comparable material in several other Member States
- All MBM produced in Ireland is produced using pressure cooking (particle size 50mm, 133°C, 3 bar, 20 min) which would reduce any TSE infectivity present by at least 3 logs which is likely to be less than is likely to be encountered in any starting material.
The incidence of BSE in Irish cattle is reducing and new exposures \textit{via} feed are judged to be reducing at a rate second only to that experienced in the UK (the European leader).

Although the prevalence of scrapie is incompletely known it is not large and is also like to reduce in the future as a result of the introduction of recent EC measures.

BSE in small ruminants in Ireland has never been reported. Monitoring of goats for TSE is being increased throughout the EU.

Most SRM MBM is diluted by the much higher proportion of uninfected starting material.

There is a potential risk of release of MBM at the point of delivery at Lagan Cement but only under special circumstances and any risk there may be is likely to be very small and easily contained by the introduction of a specific SOP for spillage such that it would not present more than a negligible risk to humans, animals or the environment.

A site visit revealed that from the point of delivery of MBM it would be contained within sealed silos and conveyors before mixing with other raw materials and being introduced into the combustion system. A failsafe system for managing the delivery of fuel (including MBM) was already in place that would shut down the MBM fuel supply at cold start-up, at initiation of close down and at any time the continuous analysis of cement quality showed a deviation from the standards set.

The MBM would be completely combusted in the flame at a temperature in excess of 2000°C or in the kiln at more than 1400°C which follows pre-heating the raw meal in cyclones at 500°C to 900°C. The particle size of the MBM is likely to be closely similar to that of the coal dust which it will replace and that of the raw mineral meal (mean diameter measured in \(\mu m\)). Such a small size would assist in achieving immediate combustion and any particles that were not immediately combusted in the flame would combust in the kiln itself. There could be no uncombusted MBM either in the cement product or in the exhaust gases.

After combustion the newly formed clinker is pulverized into a powder and this process is likely to destruct any inorganic replicas of \(\beta\) sheeted \(\alpha\)-PrP (fossil templates) that some have suggested might enable replication of \(\alpha\)-PrP\textsubscript{Sc} if introduced into animals or man.

Collectively all scientific studies relating to TSE agent inactivation by dry heat indicate complete destruction at temperatures over 600°C and especially in the vicinity of 1000°C and higher. All end products have been shown to be biologically inert over 1000°C.

Irish MBM is already being satisfactorily combusted in cement works in other EU Member States.

Other European countries including Norway and Switzerland (non-EU), Belgium, France, Germany, The Netherlands and Spain are already using this method for the destruction of MBM derived from native-born cattle and small ruminants.

The Inter Departmental/Agency Committee (IDAC, 2003) considers that co-incineration of MBM in cement production would be an acceptable means of disposal in Ireland.

The legal justification for the generic method of cement manufacture exists in European law.

A zero risk cannot be proved but any risk there may be would be highest for cattle (from BSE) and for sheep and goats (from scrapie). Scrapie agent is not a human
pathogen and although the BSE agent is, no case of human vCJD has been attributed to occupational exposure of any kind including to workers in rendering plants, knackeries, abattoirs, meat cutting plants, veterinary neuropathology laboratories, MBM storage facilities or cement plants.

FINAL STATEMENT

The burning of Irish MBM, including SRM MBM as a fuel for the manufacture of cement under the general conditions described in this report present a negligible TSE risk for humans, animals or the environment.

ACKNOWLEDGEMENTS

The author thanks Dr Imelda Shanahan of tms environment Ltd, Dublin for arranging visits to Ireland including to see the Lagan Cement Works in operation and for seeking relevant information from the DAFRD and others. He also thanks Mr Jude Lagan, Managing Director of Lagan Cement Ltd for showing him around the cement works, answering questions and verifying the accuracy of the description of cement manufacture. Dr Paul W Brown is thanked for provision of an early reprint (now published) of his joint 2004 article on incineration in relation to TSE agent destruction.

REFERENCES


R BRADLEY CBE
Private BSE Consultant
19 April 2005
ENVIRONMENTAL IMPACT STATEMENT

A CHANGE OF FUEL TYPE FOR THE EXISTING LAGAN CEMENT PLANT,
KILLASKILLEN, KINNEGAD, CO WESTMEATH

APPENDIX 5.111

The Hazards and Risks Estimation of the Proposed use of Meat and Bone Meal as part
of a Fuel Mixture at Lagan Cement Plant
THE HAZARDS AND RISK ESTIMATION OF THE PROPOSED USE OF MEAT AND BONE MEAL (MBM) AS PART OF A FUEL MIXTURE AT LAGAN CEMENT PLANT.

Kevin Dodd. MVB PhD MRCVS.

The inclusion of Meat and Bone Meal (MBM) as a component of a fuel mixture in manufacturing of cement is a novel proposal in the Irish context, but is well established in other parts of the European Union and elsewhere without any reported adverse effects on animal health in the vicinity of the plants. Indeed, as currently practised, MBM derived from Irish cattle has been used in cement manufacturing plants in Germany.

Because of the novelty of the proposal in Ireland, the following matters are of Veterinary concern;
1. The chain of control of movement of MBM from the plant of origin to the cement plant.
2. The transfer of the material from trucks into sealed silos before it is used in the fuel mix.
3. The impact of the use of MBM on the final air emission stream on the surrounding environment for animals.

THE MANUFACTURE AND MOVEMENT OF MEAT AND BONE MEAL IN IRELAND.

The manufacture of the MBM is under the supervision of the Irish Department of Agriculture and a movement permit is issued for the movement of the material from the point of production to any other destination within the Irish jurisdiction.

The official documentation, issued by the Department of Agriculture and which accompanies each consignment of MBM certifies as follows;
1. Permit number.
2. Premises of Origin within the State.
3. Approval number of premises.
4. Description of product (MBM)
5. Category of MBM. [produced from material containing specified risk material]
6. Processing method as defined in Annex 5, Ch. 3 of Reg. 1774/2002/EC [particle size 55mm, 133 degrees cel, at 3 bar. pressure for 20 minutes.]

7. Quantity of product moved.

8. Delivery point.

9. Licence number of purchaser.

10. Date of dispatch.

11. Seal number.

12. Vehicle number, Trailer number.

13. Signature and title of authorised Dept. official.


The permit then requires the authorised official receiver to sign for the material on arrival at the destination. Thus there is traceability of every consignment of MBM. Applying these criteria to the present proposal, the material will be loaded into dedicated closed and sealed trucks with no possibility of material spilling along the route from the point of origin to the cement plant.

CONCLUSION.

I would conclude from this that the manufacture of MBM is well regulated by the Department of agriculture officials in licensed premises and is in compliance with current legislation and that the chain of control of movement of the material is under licence from the Department of Agriculture. Further, because of the transport arrangements there will be no risk of spillage of any material during transport to the cement plant.

TRANSFER OF MBM FROM TRUCKS INTO SILOS AT THE CEMENT PLANT.

On arrival at the plant, the material will be pumped into two dedicated silos using a sealed pipe system to prevent spillage of material into the environment and there will be no outside air contact with the material from this point on. In any event it is proposed to introduce a spillage control system in the unlikely event of spillage of small amounts of material at the point of transfer from the trucks to the silos,
There will be negligible risk of spillage at the point of transfer.

3. IMPACT OF ALTERATION OF COMPOSITION OF THE STACK EMISSIONS.

Although MBM is sterilised during production due to the temperature and time [133 degrees cel, at 3 bar pressure for 20 minutes] the material becomes colonised by fungi, and airborne bacteria during storage. In addition, these temperatures will reduce but not eliminate the prions of BSE, if present in the start material. (The risk assessment associated with prions is fully dealt with in another part of the proposal, and concludes that the use of MBM presents a negligible risk for humans, animals and the environment.)

The baseline studies of the composition of the stack emissions contained in the main body of the statement indicate that there will be minimal change in the incidental creation of dioxins and related cyclic compounds during the combustion process where temperatures of up to 2000 degrees cel, will be attained, such that there will be no impact on the level of intake of these materials in animals grazing in the vicinity. None of the other predicted changes in the emission stream change in nitrogen dioxide, sulphur dioxide are of any significance to animals in the area.

CONCLUSION.

The use of MBM as part of the fuel mixture will not produce any increase risk of adverse effects in animals in the surrounding environment.

OVERALL CONCLUSION.

The use of MBM including MBM derived from basic material containing so called “specified risk material” as part of a fuel mixture in the manufacture of cement will not increase the risk of adverse effects in animals in the vicinity of the plant.
ENVIRONMENTAL IMPACT STATEMENT

A CHANGE OF FUEL TYPE FOR THE EXISTING LAGAN CEMENT PLANT,
KILLASKILLEN, KINNEGAD, CO WESTMEATH

APPENDIX 5.IV

Risks from BSE Via Environmental Pathways
Risks From BSE Via Environmental Pathways

A Summary of Risk Assessment Studies carried out by the Environment Agency

JUNE 1997

This summary document was produced by the Environment Agency.

The summary is published to co-incide with a press conference to publish the results the Agency's work to assess the risks from BSE via environmental pathways on Wednesday 25 June 1997 at the Institution of Civil Engineers in London.

The Environment Agency was assisted in this work by specialist risk assessment consultants DNV Technica.

The Environment Agency is grateful to the Government's independent advisory committee on BSE, the Spongiform Encephalopathy Advisory Committee (SEAC), and to its Chairman Professor John Pattison, for advice in relation to this work.

Requests for further copies of this summary, or for the risk assessment reports referred to in it, should be made by telephone to the Environment Agency on 01454 624400 and asking for public enquiries, or in writing to:

Environment Agency, Rio House, Waterside Drive, Aztec West, Almondsbury, Bristol BS12 4UD

Contents

- 1. SUMMARY AND MAIN CONCLUSIONS
- 2. BACKGROUND
- 3. QUANTIFYING THE RISK
- 4. RISK ASSESSMENT STUDIES

  - 4.1 An Overview of the Risks of BSE via Environmental Pathways
  - 4.2 Risks from Burning Rendered Products from the Over Thirty Month Scheme in Power Stations
  - 4.3 Risks from Disposing of BSE-infected Cattle in Animal Carcase Incinerators
  - 4.4 An Assessment of the Risk from BSE Carcases in Landfill sites
  - 4.5 Thruxted Mill Rendering Plant: Risk Assessment of Waste Water Disposal Options
1. SUMMARY AND MAIN CONCLUSIONS

1.1 Since March 1996, new measures introduced in the UK to eradicate Bovine Spongiform Encephalopathy (BSE) have resulted in the production of large amounts of cattle-derived waste material. The major contributor to the waste arising is the Government’s scheme for culling and disposing of all cattle over the age of 30 months, the ‘Over Thirty Month Scheme’ (OTMS).

The Environment Agency, as the body responsible for the regulation and management of waste disposal in England and Wales, has been examining potential options for the disposal of these cattle-derived wastes in a manner which is acceptable for both public health and the environment.

As part of this responsibility, the Agency has carried out several assessments to quantify the risk of BSE infection being transmitted to humans as a result of potential means of disposal and their associated practices.

The Agency’s risk assessment work incorporates the expert advice of the Government’s independent advisory committee, the Spongiform Encephalopathy Advisory Committee (SEAC), and has been carried out in conjunction with specialist risk assessment consultants DNV Technica.

1.2 The Environment Agency has been considering a number of options for disposal of OTMS cattle showing no signs of BSE infection, namely:

- incineration of carcasses of OTMS cattle
- incineration of the products of rendering OTMS cattle ie meat and bonemeal (MBM) and tallow, including the possibility of using coal-fired power stations
- land filling of OTMS carcasses
- land filling of MBM

Under regulations laid down by the Ministry of Agriculture, Fisheries and Food, the carcasses of confirmed BSE cases are destroyed by incineration in specially designated animal incinerators. This practice is covered by the Agency’s risk assessment.

1.3 The Environment Agency has carried out five separate studies which together provide a basis for assessing the risks of human infection by the BSE agent from the potential disposal options for OTMS material outlined above, and from incineration of confirmed BSE cases. The methodology and risk calculations used are set out in the following reports which are available from the Agency:

- An overview of the risks of BSE via environmental pathways
- This study provides a framework for all the risk assessment work and includes much of the detail of the assumptions and methodology used.

- Risks from burning rendered products from the Over Thirty Month Scheme in power stations
Risks from disposing of BSE infected cattle in animal carcases incinerators. This study also considers the risks of incinerating ‘clean’ OTMS carcases.

An assessment of the risk from BSE carcases already in landfill sites

Thruxted Mill rendering plant: risk assessment of waste water disposal options. This study was carried out and presented to a Public Inquiry in January 1997 to determine a planning application for a waste water disposal scheme at the plant.

All the above studies are based on the assumption that consumption of a sufficient quantity of BSE infectivity could cause infection in humans. Risk is measured in terms of how close the most exposed individual might come to receiving, in one year, the dose needed to cause infection. In reality, the risk to most individuals will be well below the level assigned to the most exposed person.

Assumptions about the dose needed to cause infection in humans are based on the advice of SEAC. In applying this advice, however, the Agency has erred strongly on the side of caution and assumed the required dose to be lower than even SEAC suggests, and that infectivity can be accumulated in the body although there is no medical evidence to suggest this is likely.

Likewise, very cautious assumptions regarding human behaviour and plant operational practices have been made.

In total, therefore, such assumptions will have produced a higher estimate of risk than will be the case in reality.

1.4 The broad conclusion which the Agency has drawn from its assessments is that, for all of the disposal options considered, the risk of human infection by the BSE agent is extremely small.

In all cases, the results show that in one year the most exposed individual would be unlikely to consume, from environmental sources, more than a minute fraction significantly less than one millionth part of the dose of BSE infectivity needed to cause infection in humans. This is equivalent to a risk of less than one in one million, the level which the Chief Medical Officer has suggested may be neglected. By comparison, the risk of dying from cancer is about one in three hundred per year; the risk of being killed in a road accident one in ten thousand per year; and of dying in a railway accident, one in five hundred thousand per year. In reality, the risk to the general public of being infected by BSE from environmental sources will be well below the level assigned to the most exposed individual, and will in all probability be zero.

1.5 In relation to waste disposal, the Environment Agency has concluded, therefore, that there is no significant risk to public health or the environment associated with any of the options considered for the disposal of cattle-derived waste products.

1.6 The results of the Environment Agency’s assessment of the risk of BSE infection being transmitted to humans via the waste disposal route are being published to ensure that the basis for any decisions by the Agency regarding waste disposal is clear and in the public
domain. The Agency believes the results of these assessments will help to inform the public and all those with an interest in the eradication of BSE and with measures associated with that aim. Interest groups include national and local Government, medical and health experts, regulatory bodies, the waste disposal industry and environmental interest groups.

1.7 The Agency’s conclusions do not constitute any form of approval for proposed operations to dispose of cattle-derived waste. Any application for authorisation under the relevant legislation to dispose of such waste will be considered strictly on its individual merits and within the terms of appropriate regulatory controls.

The Agency will also want to take account of other factors such as the potential disposal capacity offered by different disposal routes; likely operational difficulties; and the desirability of energy recovery where it is practicable. The latter view is in line with the requirements of the UK’s national waste strategy and the Government’s objective of achieving sustainable development.

The Agency will inform, and invite comment from, the public on any application received, and will take all views expressed into account before coming to a decision. The Agency will not grant approval for waste disposal unless it is fully satisfied that all the relevant statutory conditions are met. The Agency will use the results of its risk assessment to inform the decision-making process.

On existing plant, the Agency will require trials to be carried out before considering applications for longer term disposal operations in order to demonstrate that the proposed operation will properly protect the environment and public health. Equally, new plant will require comprehensive commissioning trials. Trials could only proceed after the Agency had issued an authorisation following the procedures laid down by statute,

2. BACKGROUND

2.1 Bovine Spongiform Encephalopathy (BSE) is a fatal neurological disease of cattle. The distinctive feature of the disease is the development of sponge-like holes in the brain tissue, leading to a deteriorating mental condition which has prompted the popular term ‘mad cow disease’. The incubation period for the disease is typically five years, but can range from 30 months to 10 years

2.2 BSE was first diagnosed in 1985 and the annual number of confirmed cases in the UK reached a peak of 36,700 in 1992. It was at this point that the Government introduced a ban on the inclusion of animal protein in feedstuffs for ruminants (e.g. cattle) on the basis of epidemiological evidence that BSE was a feed-borne infection, probably caused by the inclusion in cattle-feed of inadequately inactivated material derived from scrapie-infected sheep. (Prior to 1988, it had been the general practice to include meat and bone meal rendered from the remains of cattle and other mammals in ruminant feedstuffs). Since the introduction of the feed ban the number of confirmed cases of BSE has declined, to 22,000 in 1995, which
is consistent with the incubation period for the disease and the introduction of the ban, supporting the evidence that feedstuffs were the source of the infection.

2.3 In March 1996, the Government reported a possible connection between BSE and a new form of the human Spongiform condition Creutzfeldt Jakob Disease (CJD). Concerns over the possible spread of CJD led the European Commission to ban the export of beef and associated products from the UK.

Partly as a consequence of EC requirements that all relevant animal waste be ‘destroyed’ (EC Regulation 716/96), the UK Government introduced a number of controls, the most significant being the ‘Over Thirty Month Scheme’ (OTMS). Under the OTMS, all cattle over the age of 30 months from farms in the UK are presently slaughtered and sent for disposal. No material from the OTMS is allowed to enter the food chain.

2.4 The introduction of the OTMS presented a major challenge for the Environment Agency, which has wide ranging statutory responsibilities under the Environmental Protection Act 1990 (EPA 90) for regulating the disposal of waste in England and Wales in a manner which is acceptable for public health and the environment.

The Agency set up a cross-functional team comprising staff with expertise in water and waste regulation, Integrated Pollution Control (IPC) of large industrial processes (such as incinerators and power stations) and operational management. The team’s responsibility has been to evaluate both the regulatory and public issues raised by the BSE control regime.

2.5 As an immediate first step, the Environment Agency identified the relevant operations which might give rise to cattle-derived wastes reaching the environment (e.g. abattoirs, butchers, rendering plants, land-filling operations, incineration plants etc) and sought the advice of SEAC as to their acceptability. Advice published by SEAC in June 1996 (MAFF news release 198/96) to the effect that such practices could continue proved invaluable to the Agency in pursuing its duties in the immediately ensuing period.

The Agency recognised, however, the desirability of being able to present clear data about the risks to public health and the environment associated with the disposal of OTMS waste, and embarked (using advice from SEAC) on the development and application of a detailed methodology to quantify those risks.

The results of this work are helping the Agency to improve its own understanding of relevant waste disposal issues, to inform policy in this area and to enable it to target its regulatory resources to minimise the risk to public health and the environment.

It is the first time, as far as the Agency is aware, that a risk assessment study of this kind has been carried out in relation to BSE.
3. QUANTIFYING THE RISK

3.1 The mathematical assessment of any risk relies on the combination of a range of different factors, some of which might be precisely defined or quantified, whilst others must be based on assumptions about the real world, about how people behave, and about how complete or accurate certain pieces of information are.

In the case of BSE, science does not yet have all the answers, and while a possible link between BSE and new variant CJD has been suggested, the medical evidence is not conclusive. For example, the nature of the BSE agent itself is still unclear. It is unlike a conventional virus or bacteria in that it stimulates no immune response in the host, and is relatively resistant to inactivation by heat, chemical disinfection or radiation. Nor is it yet possible to diagnose the disease until the clinical signs appear, or to confirm the diagnosis expect by inspection of brain tissue under the microscope.

The dominant theory is that the BSE agent is a distorted form of ‘prion’ protein which causes other normal proteins to distort similarly. In this way the infection spreads through the animal from the point of origin, eventually reaching the brain.

3.2 It is against this background of incomplete scientific understanding of BSE that the Environment Agency has approached the task of quantifying the risks of human infection from the disposal of cattle-derived wastes.

The Agency’s approach has been an extremely cautious one. The following examples serve to illustrate the conservative nature of the exercise.

- On the advice of SEAC, it is assumed that the ‘species barrier’ between cattle and humans (the term is used to describe the relative susceptibility to infection of different species) is a factor of 10, with a range between 1 and 10,000.

- A ‘species barrier’ of 1 would assume that it takes the same amount of infectivity to infect humans as cattle, while SEAC’s advice that the barrier is 10 assumes a human infective dose 10 times larger than that which would infect cattle.

- It is assumed that there are, within the OTMS cattle, a number of undiagnosed cases equivalent to approximately 5% of those being presented for slaughter under the scheme, and that each one of these is fully infected. This is far higher incidence of undiagnosed cases than is likely to be the case in reality.

- It is assumed that rendering reduces infectivity by a factor of 50, although in reality if may be more.

- That incineration at the high temperatures achieved in incinerators and power stations reduces infectivity by a factor of 1 million, rather than destroying it completely.

- That the presence of any amino acids in the ash remaining after incineration indicates the presence of prions and hence infectivity.

- That some material accidentally escapes fall treatment.
The Environmental Agency believes that the outcome of such a cautious assessment is highly likely to have led to overstatement of the real risks involved.

4. RISK ASSESSMENT STUDIES

4.1 An Overview of the Risks of BSE via Environmental Pathways

This study presents an overview of the possible environmental pathways so far identified by which BSE infectivity might be transmitted to humans. The environmental pathways to humans which were identified within the scope of the study can be characterised as:

- direct ingestion by humans of material from the land eg where cattle waste has fallen or is spread
- direct ingestion by humans of untreated water from sources contaminated eg by run-off from land-spreading, burial, leachate from landfill sites
- inhalation of particles in the atmosphere eg resulting from burning or incineration of cattle-derived wastes.

The risk calculations show that the likelihood of the most exposed individual ingesting, in one year, sufficient material to cause infection is less than one in one million and that, in particular, the practices of incineration and land tilling offer high and consistent levels of protection. It is important to note that the real risk to the general public will be well below the level of the risk to the most exposed person.

4.2 Risks from Burning Rendered Products from the Over Thirty Month Scheme in Power Stations

4.2.1 It has been proposed that meat and bonemeal (MBM) and tallow rendered from OTMS cattle might be burned in coal fired power stations, such processes being attractive due to the potentially large incineration capacity and the potential to recover energy.

4.2.2 During the summer of 1996, the two power generators National Power and PowerGen carried out small-scale trials of burning MBM and tallow under test conditions and with strict supervisory control by the Environment Agency.

4.2.3 The normal waste streams from a combustion process such as a power station comprise emissions to the air from the stack and ash from the combustion chamber. In the power station trials, monitoring of the expected stack emissions (eg sulphur dioxide and dioxins) indicated that incineration of MBM and tallow would make no significant difference to emissions compared to normal coal-fired operation of a power station,
4.2.4 At present, no specific analytical technique exists to test for the presence of the BSE prion in any matter. There is no direct method, therefore, of detecting the prion in either emissions or ash. The prion is a type of protein. The best available technique, and the one adopted in the trials, is to analyse the particulate matter from burning and the ash from the combustion chamber for the presence of proteins by looking for certain linked sequences of amino acids.

Amino acids are the essential building blocks of all proteins. The pattern in which the acids are linked together determines the precise nature of the protein. Therefore, by careful analysis of the particulates and ash for amino acids, deductions can be made about the presence of proteins and, therefore, of prions.

4.2.5 The analyses of ash from the power generators’ trials showed that, while there were some amino acids still present, there were no complete sequences of acids. It would have been reasonable to deduce from this finding, then, that no intact proteins, and hence no intact prions, were present in the ash.

Nevertheless, on the advice of SEAC, the Agency has made the cautious assumption in its risk calculation that the presence of amino acids, albeit in incomplete sequences, might indicate the presence of some infectivity in the final ash.

4.2.6 The risk calculation shows that the likelihood of the most exposed individual ingesting sufficient infectivity as a result of the burning of rendered material from the OTMS scheme in power stations (assuming that the entire throughput of the scheme were to be disposed of by this route) is less than one in one billion years. This is equivalent to a risk more than one thousand times less likely than death by lightning. The real risk to the general public, however, will be well below the risk to the most exposed person.

The Environment Agency is formally responsible for regulation of combustion processes only in England and Wales. The Agency’s risk study did not specifically consider risks in Scotland or Northern Ireland, but they are considered to be no greater than those reported as a result of this study.

4.2.7 The Environment Agency’s study did not consider the risks to power station employees, as this is matter for which the Health and Safety Executive (HSE) has responsibility. The HSE has produced general guidance on occupational hazards associated with BSE materials and is currently preparing more specific guidance for workers handling MBM in storage or disposal situations. The Advisory Committee on Dangerous Pathogens has concluded that the risks to those working with MBM will be extremely low.

4.2.8 The results of the trials, including the Agency’s environmental monitoring data and the generators’ reports of monitoring and ash analyses, have been placed on the Environment Agency public registers.

4.3 Risks from Disposing of BSE-infected Cattle in Animal Carcase Incinerators
4.3.1 Since 1991, it has been the practice to incinerate the carcasses of cattle infected with BSE designated animal carcass incinerators. SEAC, in its advice of June 1996, expressed satisfaction with the practice.

4.3.2 This study uses essentially the same methodology as applied to power station burning rials in order to calculate the risk from burning infected carcasses, assuming all eight existing incinerators authorised for that purpose are in full use. There are a number of differences, however, to account for different material being incinerated, the much lower thoughput of carcass incinerators compared with power stations and the different dispersion characteristics of incinerator stack emissions.

4.3.3 The risk calculation shows that the likelihood of the most exposed individual ingesting, in one year, sufficient material to cause infection as a result of burning infected cattle in specially designated incinerators is less than one in one billion ie the same as the risk associated with power stations burning rendered OTMS material. As in other cases, the real risk to the general public will be well below the level assigned to the most exposed person.

4.3.4 In addition to the practice of burning infected carcasses, it has been proposed by the Intervention Board that OTMS carcasses might be burnt whole in purpose-built incinerators with a typical capacity of one tonne per hour, constructed singly or in groups. The risks associated with this proposed practice have been considered as part of this study, with the risks calculated on the basis of all OTMS cattle being disposed of by this route.

4.3.5 The risk calculation shows that the likelihood of the most exposed individual ingesting, in one year, sufficient material to cause infection as a result of burning OTMS carcasses in incinerators to be less than one in one billion ie the same as the risks associated with burning infected cattle. In reality, the risk to the general public will be well below this level because of lower exposure but also because the Agency has deliberately made extremely cautious assumptions about the number of undiagnosed infected cattle in the OTMS.

4.4 Assessment of the Risk from BSE Carcasses in landfill sites

4.4.1 According to MAFF figures, the carcasses of approximately 6000 BSE-infected cattle were disposed of in 59 landfill sites between 1988 and 1991. Since that time, the practice has been to incinerate infected carcasses as mentioned above. SEAC, in its advice of June 1996, concluded that the practice was likely to be satisfactory and that retrieval of the carcasses for disposal be alternative means would not be justified.

4.4.2 Earlier this year, the Environment Agency, in order to improve its own understanding of this situation, made a preliminary assessment of the sites involved on the basis of factors such as the degree of containment offered by each site, its proximity to water courses etc. From this initial investigation the Agency identified the six sites which it considered to be more likely to cause concern, albeit very minor, as the basis for a precautionary risk assessment.

4.4.3 The risk study of these six landfill sites differs from the Agency’s other risk studies in that site specific information is available. Given the varying nature of the sites, the report necessarily concludes a range of value The calculations show that the likelihood of the most exposed individual ingesting, in one year, sufficient material to cause infection as a result of the presence of infected carcasses in the sites assessed range from one in 10,000 million years.
to one in one \textit{million years}, depending on local circumstances. In reality, however, the risk to the general public in each case will be well below the level of risk to the most exposed person.

4.4.4 The Agency believes that the risks assessed for these six sites probably represent the full range of the risks posed by all 59 landfill sites. Consideration is being given to whether there is a need to carry out any further detailed risk assessments on the remaining sites in due course.

4.5 Thruxted Mill Rendering Plant: Risk Assessment of Waste Water Disposal Options

4.5.1 Thruxted Mill is an animal rendering plant in Kent which handles OTMS carcasses. Quite separately, the Environment Agency had for some time been seeking improved arrangements for the disposal of waste water from the site. The previous means of disposal had been by spreading on land. A new and substantially better waste treatment system was installed on the site but disposal was to be further improved by changing to a system where the now much cleaner waste to be injected underground, a change which required planning permission.

4.5.2 This study, which looked at the risks associated with four different disposal options, was carried out by the Environment Agency to support the planning application, and was presented at a Public Inquiry the decision of which is awaited.

4.5.3 The risk calculations show that, for all four options, the likelihood of the most exposed individual ingesting, in one year, sufficient material to cause infection is of the order of one in one billion. The only risk that could sensibly be taken into account in this case was the risk to water sources, the rest being far too small to be realistically considered.

The real risk to the general public, however, will be well below the level of risk to the most exposed person.

The results of the study supported the Agency's case for abandoning the previous disposal arrangements and moving to the improved injection system.

Environment Agency 25 June 1997