

INDEPENDENT ADVISORY GROUP REPORT TO THE FSA ON THE DEVELOPMENT OF A SYSTEM FOR BSE TESTING OF OVER THIRTY MONTHS CATTLE

SUMMARY AND RECOMMENDATIONS

Introduction

1. The Government introduced the over thirty months (OTM) rule in 1996, at the height of the BSE crisis. The OTM rule helps to protect public health by banning cattle aged over thirty months from the human food supply.
2. The Food Standards Agency (FSA) in 2002 launched a review the OTM rule because BSE in the UK had declined and rapid tests for BSE had become available. In January 2001, other EU Member States had introduced testing regimens in line with a new EU requirement that OTM cattle must have tested negative for BSE before being allowed into the human food supply.
3. The FSA's review of the OTM rule was founded on a risk assessment undertaken by a FSA/Spongiform Encephalopathy Advisory Committee (SEAC) risk assessment group. The risk assessment indicated that the additional risk to public health that would result from replacement of the OTM rule by testing would be low.
4. Following the review, the FSA advised the Government in July 2004 that replacing the OTM rule by BSE testing for cattle born on or after 1 August 1996 is justified on grounds of the food borne risk to consumers and proportionality, subject to the putting in place of a robust testing system.
5. In the light of the FSA advice, the Government announced on 1 December 2004 the start of a managed transition towards lifting the OTM rule and its replacement with a robust system for BSE testing.

The task of the Independent Advisory Group

6. The Independent Advisory Group (IAG) was appointed by the FSA in November 2004 to specify the requirements for a robust BSE testing regimen, oversee trials of the proposed regimen and report on whether it met the requirements specified. The Group was asked to include within this work the controls required to ensure that vertebral column is removed as SRM from carcasses of OTM cattle that test negative for BSE.

7. The Group considers that, for the protection of public health and to maintain public confidence in the safety of beef, a robust regimen must aim to achieve 100% compliance with the requirement that only OTM cattle that have tested negative for BSE may be allowed into the food supply.
8. The scope of the Group's work did not include advising on:
 - the specific test or tests to be used to carry out BSE testing;
 - the effectiveness of BSE testing as a means of protecting public health;
 - sensitivity of the BSE test;
 - those aspects of the proposed regimen that were predetermined by requirements of EU legislation or Government policy.

The work carried out by the Group

9. The Group began its assignment in November 2004 with an examination of the regimen proposed by Defra and DARD for OTM testing. The Group established the components of the regimen, identifying the key control points, and considered the controls and monitoring proposed by Defra and DARD to ensure compliance and the penalties for non-compliance. The Group then prepared recommendations to the FSA on
 - (a) what the Group means by "robust";
 - (b) the components of a robust, reliable and effective regimen for BSE testing of OTM cattle; and
 - (c) the proposed approach to trial the testing regimen.
10. The FSA Board in December 2004 accepted the Group's recommendations on the components of a robust regimen for BSE testing and the approach to assessing its performance and agreed that the regimen should proceed to full trials.
11. The Group then oversaw two phases of trials of the testing regimen undertaken at a range of abattoirs throughout the UK. The Group considers that these trials demonstrate that all the key components of the recommended testing regimen operate effectively and that it will provide all the necessary safeguards to public health, provided it is fully implemented, monitored and enforced.

The key features of the recommended testing regimen

12. The key features of the recommended testing regimen are:
 - **abattoir pre-requisites**
specification of the minimum facilities that abattoirs approved for testing must have to operate the testing regimen successfully;
 - **a Hazard Identification and Control plan**

a sound Hazard Identification and Control Plan, based on HACCP principles, as an essential foundation for the development of an RMOP document;

- **Required Methods of Operation (RMOP)**

a plant-specific document which sets out the specific actions or procedures which will be used by an abattoir to comply with each stage of the testing regimen and the supervision required by MHS or DARD staff;

- **an approval process**

which includes the need for the abattoir to pass a two slaughter-day assessment of the practical procedures, to ensure that the RMOP is subject to thorough assessment and review before it is approved;

- **laboratory procedures**

that ensure the samples received from the abattoir are correctly analysed and the results are returned with full traceability;

- **Cutting plants**

removal of vertebral column as SRM at cutting plants specifically licensed for that purpose, together with the FSA's power to suspend or revoke the SRM licence

Monitoring and audit of the testing regimen

13. The regimen will be subject to several layers of monitoring and audit:-

- **Plant monitoring**

the plant's Hazard Identification and Control Plan will specify effective monitoring procedures including own checks at critical control points;

- **Plant based MHS/DARD Veterinary Service (VS)**

the MHS/DARD VS team at the plant will be responsible for monitoring and enforcing the testing regimen in abattoirs;

- **Area Official Veterinarian (AOV) routine visits and inspections**

The AOV (a new position in the MHS's operational reporting structure overseeing the OVSs in a number of testing plants) will pay regular visits to the plants processing OTM cattle;

- **MHS internal audit**

MHS/DARD VS would add OTM audit checks to their general programmes of internal audit;

- **FSA audit**

The FSA would take on a new role in the ongoing audit and review of the whole system for BSE testing cattle slaughtered for food Advice to FSA;

- **Independent post implementation review**

the FSA has undertaken to carry out an independent review of the BSE testing system to be commissioned from an independent contractor and to report on the first 6 months following implementation;

- **FVO**

the UK testing regimen would also be subject to periodic audit as part of on-going audit by the EU Food and Veterinary Office.

Enforcement powers

14. The regimen will be supported by additional enforcement powers to deal with and deter non-compliance and provide reassurance to consumers.

Implementation and roll out

15. The success of any regimen, however well-designed, ultimately depends on how well it is put into practice. The implementation of the testing regimen therefore needs to be properly managed. The Group recommends that the FSA should set up an Implementation Review Group, involving all the Departments and Agencies concerned, to oversee the implementation of the testing regimen.
16. The regimen could be particularly exposed to a risk of break down if insufficient plants have been approved at the time a move to testing takes place. The Group therefore recommends that the process of approval of abattoirs for OTM testing be properly managed to avoid such problems.

Challenges

17. Finally, the Group identifies a range of issues that, although not part of its remit, may have implications for the successful implementation of the testing regimen:
 - **Public concern and Market response**

the Group highlights a number of uncertainties about how the market might respond to rule change and therefore the need for clear and regular communication with stakeholders;
 - **Maintaining a robust regimen**

the Group highlights the need for sustained vigilance and continual improvement of the regimen in the light of experience in order to continue to achieve 100% compliance with the regimen on an ongoing basis;
 - **animal identification**

the ability to identify on receipt at the abattoir OTM cattle that require testing, as well as any cattle born before August 1996 that will remain ineligible for the food supply;
 - **Response to the Inquiry into the failure to test all casualty animals**

the Group welcomes the progress being made to address the findings of the Inquiry and recommends that these should be addressed;

- **Maintenance of other abattoir controls**

the Group underlines a robust testing system must be introduced in way that is not detrimental to other work carried out by MHS and DARD in abattoirs for the protection of public health and animal welfare. In particular, routine hygiene practices in plants must not be compromised and full compliance with SRM rules must be maintained;

the Group also recommends that training should be made available to MHS/DARD staff on the identification of the signs of disease that are more likely to be seen in OTM cattle and may present a risk to human health;

- **Casualties**

the Group notes that the results of BSE tests indicate that OTM casualty cattle represent a higher BSE risk than healthy OTM cattle, but that new food hygiene legislation will, from 1 January 2006, limit the categories of livestock that may be slaughtered on farm as emergency cases for human consumption. The Group therefore recommends that guidance being prepared on the new rules be in place before a move to BSE testing of OTM cattle is made;

- **Potential for cattle identity fraud**

The Group is concerned that the number of cattle on farms that have been refused passports might provide a reservoir for potential fraud (illegal re-identification and entry into the food supply). The Group therefore recommends that the Implementation Review Group should keep the risk that the effectiveness of the testing system might be undermined by fraudulent switching of cattle identification under review. The Group also considers it essential that, following any move to testing, a purchase for destruction scheme for cattle born before August 1996 be established to provide a legitimate outlet for these cattle.

Advice to the FSA Board:

18. The Group advises that the BSE testing regimen is robust if effectively implemented, complied with and enforced.

Recommendations

19. The Group's recommendations are:

R1.	Only abattoirs that meet the pre-requisites should be considered for approval for OTM testing.
R2.	The operation of the testing regimen in individual abattoirs should be based on a Hazard Identification and Control plan, which is integrated with the plant's HACCP systems.

R3.	The staff responsible for the development of the Hazard Identification and Control plan should have attended an accredited meat plant HACCP training course delivered by an approved trainer.
R4.	Plants undertaking slaughter of OTM cattle for human consumption should be legally required to have a detailed RMOP based on the guidance document
R5.	A rigorous process for assessing the adequacy of the RMOP, including a pre-approval assessment of the controls in the plant, should take place before an abattoir is approved to carry out the slaughter and processing of OTM animals. The approval process should include the abattoir passing a two slaughter-day assessment of the practical procedures.
R6.	The abattoir RMOP should be agreed, signed off and approved by the MHS/DARD.
R7.	Plants should be able to process OTM cattle for human consumption only if approved by the MHS or DARD.
R8.	The abattoir operator should specify the detailed chain of custody of the test samples.
R9.	Test results should be communicated from the laboratory to the abattoir by a rapid, safe and secure method with full traceability.
R10.	The testing laboratory should provide feedback to abattoirs on the quality of samples received at the laboratory on a continuing basis to help maintain sample quality.
R11.	The cutting plant RMOP should be agreed and signed off by the OVS.
R12.	The current provisions for specific SRM licensing of cutting plants, and for suspension and revocation of licences in the event of breaches of licence conditions, should be maintained in relation to removal of vertebral column as SRM from OTM cattle following any change in the OTM rule.
R13.	OTM carcasses should be despatched in a sealed vehicle to the specifically-licensed cutting plant where the vertebral column is to be removed. The MHS (DARD in NI) should be present during unsealing and unloading of the OTM carcasses at the receiving cutting plant and the carcasses should be either batched or placed on a separate boning line for vertebral column removal. In co-located premises, carcasses must not be removed from sealed abattoir chillers or rails and moved to the cutting premises, except under the supervision of the MHS (DARD in NI).
R14.	The EU legislative requirement that a blue stripe label should be attached to carcasses from which removal of vertebral column is not required should be implemented.
R15.	The planned independent post-implementation review should examine a reasonable sample of the RMOP documents agreed in NI and by AOV in GB to ensure consistency and that the requirements are being met.
R16.	A comprehensive programme of monitoring and audit of the testing regimen should be introduced in order to demonstrate its ongoing effectiveness in controlling the public health risk. Corrective action should be taken where necessary commensurate with the level of non-compliance.

R17.	The independent audit of the first 6 months post implementation should be extended if necessary.
R18.	Enforcement powers should be in place before slaughter of OTM cattle for human consumption is allowed to commence.
R19.	<p>Given the level of public concern about BSE, as the independent body set up to the protect public health in relation to food, the FSA should</p> <ul style="list-style-type: none"> (a) set up and lead an Implementation Review Group involving all the Government departments and Agencies concerned, to oversee the implementation of the testing regimen and to ensure that it is rolled out successfully across the UK; (b) ensure public health and consumer interests take precedence overall others; (c) establish a clear communication strategy for consumers and other relevant stakeholders before, during and after implementation; and (d) develop performance criteria for the testing regimen.
R20.	The process of approval of abattoirs for OTM testing should be properly managed to avoid any significant operational problems for plant and enforcement staff.
R21 to 30	Issues highlighted in the challenges section of this Report should be addressed

INTRODUCTION

1. The Government introduced the over thirty months (OTM) rule in 1996, at the height of the BSE crisis. Currently only cattle aged under 30 months are allowed into the food supply¹. If infected by BSE, older cattle are more likely to have developed a significant amount of the BSE agent in any tissue. The OTM rule helps to protect public health by banning cattle aged over thirty months from the human food supply.
2. The rule is one of the three main BSE control measures. The principle control measure is the removal of specified risk material (SRM), which removes over 99% of the infectivity in cattle. The third measure is the ban on feeding mammalian meat and bone meal, which was extended to all farmed animals in 1996.
3. Several developments led the Food Standards Agency (FSA) in 2002 to review the OTM rule². First, due principally to the feed ban, BSE in the UK had continued to decline steeply from its peak in the winter of 1992/93 (see graph at Annex 1)³. Secondly, rapid tests for BSE had become available. Thirdly, in January 2001, other EU Member States introduced testing regimens, in line with a new EU requirement⁴ that OTM cattle must have tested negative for BSE before being allowed into the human food supply. This means that the OTM rule in the UK is out of step with EU legal requirements and the practices that apply in other EU Member States.
4. In the UK, OTM cattle that are ineligible for the food supply may qualify for the Over Thirty Months Scheme (OTMS). Cattle entering the Scheme are slaughtered in dedicated abattoirs or as on-farm casualties. The carcasses are destroyed and compensation paid to the producer. The ongoing cost of the Scheme is around £300 million per year.
5. The rapid BSE tests operate by detecting the presence of the abnormal form of the prion protein (PrPres), which is regarded as a marker for the disease, in the central nervous system. A sample of brain is taken from the animal following

¹ the exception is a small number of cattle from herds registered under the Beef Assurance Scheme (BAS) which may be slaughtered for human consumption aged up to 42 months

² the OTM rule is set out in The Fresh Meat (Beef Controls) (No. 2) Regulations 1996 in respect of GB and The Fresh Meat (Beef Controls) Regulations (Northern Ireland) 1996 in respect of Northern Ireland

³ the graph shows BSE cases in GB. The epidemic in Northern Ireland was much smaller: the grand total of cases confirmed in NI up to end March 2005 is 2,140.

⁴ Regulation (EC) No 999/2001 of the European Parliament and of the Council, as amended

slaughter. This tissue is taken to the laboratory and tested for the presence of PrPres. The tests approved by the European Commission for BSE testing⁵ are accurate and consistent, and allow large numbers of samples to be processed and results to be produced in a timely fashion.

6. The FSA's review of the OTM rule was founded on a risk assessment undertaken by a FSA/Spongiform Encephalopathy Advisory Committee (SEAC) risk assessment Group, chaired by Professor Peter Smith (then SEAC Chairman)⁶. The risk assessment concluded that a change to the OTM rule would cause a very small number of future vCJD⁷ infections relative to infections attributable to past exposure. Estimates provided to the FSA Board in July 2004 give a range of between none and 2.5 additional vCJD cases, over 60 years, with the central estimate of 0.5, as a result of replacing the OTM rule with BSE testing.
7. During the review, the Government decided that cattle born before August 1996 would remain permanently excluded from the food supply.
8. Following the review, the FSA advised the Government in July 2004 that replacing the OTM rule by BSE testing for cattle born on or after 1 August 1996⁸ is justified on grounds of the food borne risk to consumers and proportionality, subject to the putting in place of a robust testing system.
9. In the light of the FSA advice, the Government announced on 1 December 2004⁹ the start of a managed transition towards lifting the OTM rule and its replacement with a robust system for BSE testing. The announcement made clear that the move from the OTM rule to testing would not take place until the FSA has advised the Government that the testing system is robust.
10. Around 2.2 million cattle per year are currently slaughtered for human consumption. If the OTM rule is replaced by testing, the testing regimen would need to handle an additional 0.55 million cattle entering the food supply each year. About 716,000 cattle born before August 1996 currently still alive on farm would remain ineligible for human consumption (see paragraph 89).

⁵ under Regulation (EC) No 999/2001

⁶ see Core Stakeholder Group report 2003 - Appendix 4: www.food.gov.uk/multimedia/pdfs/otmrulerepmarch03.pdf and SEAC advice July 2004: www.food.gov.uk/multimedia/pdfs/fsa040706a3.pdf

⁷ variant Creutzfeldt Jacob Disease, a disease in humans. Its primary cause is generally accepted to be consumption of meat from cattle infected with BSE

⁸ www.food.gov.uk/aboutus/ourboard/boardmeetings/boardmeetbranch2004/boardmeeting060704/boardminutes060704#h_8

⁹ www.publications.parliament.uk/pa/cm200405/cmhansrd/cm041201/wmstext/41201m02.htm#41201m02.html_sbhd1

11. Around 300 UK abattoirs are licensed to slaughter cattle. Throughput at these abattoirs varies from 1 to 2,500 cattle a week, with the top 10 plants slaughtering 40% of the kill of cattle aged under 30 months in 2004/05. A maximum of 100 GB abattoirs and ten in NI are believed likely to enter the trade in OTM cattle. This represents sufficient additional capacity to process around 0.8 million cattle a year.

THE TASK OF THE INDEPENDENT ADVISORY GROUP

12. The Independent Advisory Group (IAG) was appointed by the FSA in November 2004 to specify the requirements for a robust BSE testing regimen, oversee trials of the proposed regimen and report on whether it met the requirements specified. The Group was asked to include within this work the controls required to ensure that vertebral column is removed as SRM from carcasses of OTM cattle that test negative for BSE.

Meaning of “robust”

13. In the context of this testing regimen, the Group has taken “robust” to mean a regimen that includes:
 - i. simple design, which is compatible with existing industry processes and may be standardised and easily implemented and operated;
 - ii. sufficient internal controls and cross checks to ensure the correct identification of the animals to be excluded and the animals to be tested, and that only carcasses that test negative, or parts of such carcasses, can be released onto the market for human consumption or any other purpose;
 - iii. adequate supervision and enforcement, mechanisms for continuous performance monitoring of all the parties involved, with measurable criteria for demonstrating reliability and effectiveness, and periodic audit.
14. BSE remains a sensitive public issue. Following a change in the OTM rule, any failure to ensure that only OTM cattle which test negative enter the food supply would increase the BSE risk to public health. Significant damage to public confidence in the safety of all beef could also result. The Group therefore considers that a robust regimen must achieve 100% compliance with the objective of ensuring only OTM cattle that test negative may be allowed to enter the food supply.

Matters outside the scope of the Group

15. The scope of the Group's work did not include advising on:
- the specific test or tests to be used to carry out BSE testing. EU Member States are required by European legislation¹⁰ to allow any of the approved tests¹¹ specified in that legislation to be used;
 - the effectiveness of BSE testing as a means of protecting public health, as that issue has been considered by the FSA Board in its review of the OTM rule⁸;
 - sensitivity of the BSE test. For the purpose of the FSA's risk assessment, it was assumed that the test would pick up infected animals only in approximately the last 3 months prior to clinical disease (see paragraph 6);
 - those aspects of the proposed regimen that were predetermined by the EU legislation (see paragraph 16) or Government policy requirements (see paragraph 17).
16. A UK testing regimen must comply with EU rules. These rules require that:
- all OTM cattle slaughtered for human consumption must be tested using an approved rapid test (see paragraph 5);
 - only those that receive a negative result may be released into the food supply;
 - all parts of the tested animals must be either retained under official control until a negative result has been obtained or sent for destruction;
 - all parts of any animal found positive to the rapid test must be destroyed;
 - the carcass preceding and two carcasses following the positive carcass on the slaughterline must also be destroyed, unless a system is in place preventing contamination between carcasses;
 - the same "1 before, 2 after" rule must be applied where, for any reason, no test result is obtained.
17. The regimen also has to comply with Government policy¹² that the abattoir operator be responsible for taking the sample for the BSE test.
18. Membership and terms of reference of the Group are at Annex 2.

¹⁰ Regulation (EC) No 999/2001 of the European Parliament and of the Council, as amended

¹¹ tests are approved by the European Commission if they perform satisfactorily in an evaluation; 11 tests are currently approved

¹² see www.defra.gov.uk/animalh/bse/publichealth/otm/review/issues.html#head

THE WORK CARRIED OUT BY THE GROUP

19. The Group commenced its assignment in November 2004. Prior to this, UK Government had been planning, on a contingency basis, for the possible replacement of the OTM rule with BSE testing. This work was being led by Defra¹³ in respect of GB and DARD¹⁴ in respect of Northern Ireland (NI).
20. As part of BSE surveillance, Defra and DARD already test all OTM cattle that would potentially be eligible to enter the food supply if the OTM rule were replaced. The majority¹⁵ of these are slaughtered at dedicated OTM Scheme abattoirs. While this testing demonstrates laboratory capability, it is not a food safety measure. No action is taken in the abattoir in the event of a positive, as all these cattle are destined for destruction.
21. Some cattle processed at fresh meat abattoirs, mainly 24 – 30 months casualty¹⁶ animals, are also currently being tested (some 2,800 in the UK in 2004). Three¹⁷ members of the Group were familiar with the arrangements for testing casualty cattle, as they had previously carried out an Inquiry¹⁸ into failures to test all relevant casualty animals.
22. The Group began its work with an examination of the regimen proposed by Defra and DARD for OTM testing. The Group established the components of the regimen, identifying the key control points, and considered the controls and monitoring proposed by Defra and DARD to ensure compliance and the penalties for non-compliance.
23. The Group then requested additional information to gain a more detailed understanding of:
 - allocation of responsibilities for meeting the requirements of the testing regimen between plant staff and the enforcement authorities;
 - the rôles and responsibilities of, and the relationships between, the different enforcement agencies, e.g. FSA, Meat Hygiene Service (MHS), Defra and DARD;
 - competencies of plant staff and levels of monitoring needed;

¹³ Department for Environment, Food and Rural Affairs

¹⁴ Department of Agriculture and Rural Development

¹⁵ except for OTMS cattle slaughtered as on-farm casualties (see paragraph 4) or BAS cattle slaughtered for human consumption aged between 30 and 42 months (see footnote 1)

¹⁶ an animal that has been subject to special emergency slaughter or found to have an abnormality at *ante mortem* inspection

¹⁷ Patrick Wall, Barbara Saunders and Peter Jinman

¹⁸ see report on investigation into testing failures published 11 October 2004 at www.food.gov.uk/news/newsarchive/2004/oct/wallreport

- how the regimen would fit into abattoir and cutting plant processes;
- the facilities required before an abattoir could be approved to operate the system;
- implications for MHS and DARD resourcing and organisation;
- cattle identification in GB and NI, with particular reference to identification of cattle born before August 1996, which would remain excluded from the food supply, and of OTM cattle that would require testing;
- brain sampling and procedures and controls in the testing laboratory;
- BSE testing practices in other EU Member States.

24. In the light of an assessment of this information against the Group's initial view of the requirements for robustness, the Group prepared recommendations to the FSA (as set out in an FSA Board paper¹⁹) on
- (a) what the Group means by "robust";
 - (b) the components of a robust, reliable and effective regimen for BSE testing of OTM cattle; and
 - (c) the proposed approach to trial the testing regimen.

The FSA Board meeting on 9 December 2004 accepted these recommendations and agreed that the regimen should proceed to full trials²⁰.

25. To prepare for the trials, the Group considered the outcome of trials of some components of the regimen that had already taken place, including a full week's trial of the entire regimen at one abattoir in NI. Group members visited abattoirs in the Republic of Ireland to observe abattoir procedures for testing and the controls in operation there. The Group also oversaw the development of a generic "Hazard Identification and Control Plan" for the testing regimen, to provide guidance to abattoirs to assist in the development of their individual Hazard Identification and Control Plans.

26. The Group then agreed the testing regimen to form the basis for the trials, the arrangements, the information needed, the conduct and monitoring arrangements, and how success or failure would be assessed.

The trials

27. The trials commenced in March 2005. Initially, a total of 9 abattoirs of varying size (5 in England, 2 in Scotland, 1 in Wales and 1 in NI) took part. The trials used cattle aged under 30 months, with animals born before a certain date

¹⁹ www.food.gov.uk/multimedia/pdfs/fsa041203.pdf

²⁰ www.food.gov.uk/aboutus/ourboard/boardmeetings/boardmeetbranch2004/boardmeeting120904/meet9dec04mins

classed as “pre-August 1996 animals” (identified and separated in the lairage as ineligible for slaughter) and animals over a certain age designated as “over 30 months” and requiring testing. In NI the use of the Date Based Export Scheme indicator on the Department’s Animal and Public Health Information System (APHIS), an EU-approved database, meant the allocation of status was random. Trials of removal of vertebral column as SRM at 5 cutting plants ran in conjunction with the abattoir trials.

28. The trials in abattoirs and cutting plants in GB were monitored and reported on by MHS internal auditors²¹. A post-trial audit of each trial was carried out by a third party auditor (CMi Consulting). In NI, parallel arrangements applied with a post-trial audit undertaken by the same third party auditor.
29. Brain samples were taken and assessed for quality by the GB and NI approved testing laboratories. Dummy results were returned to the abattoirs, including a small number of “positive” and “no test”²² results, to check their capability to deal with these appropriately. All three GB testing laboratory (LGC) sites were included in the trial, along with the NI testing laboratory at DARD Veterinary Science Division (VSD).
30. The trials demonstrated that most of the components of the testing system work well. Sample quality, correlation of the sample to the carcass and other parts of the animal from which it had been taken, transport of the sample to the laboratory and reporting back of test results were all shown to be good. The abattoirs had taken appropriate action when “positive” or “no test” results were returned.
31. The trials in GB also highlighted certain areas for further attention. The Group decided a second phase of trials in GB would help to advance the most important of these: the need for improvements in the contents and process for agreeing the RMOP (Required Methods of Operation – see paragraphs 41 to 43) which contain all the required procedures and processes customised for each particular abattoir. No further trials were required in NI as the Group agreed that the NI testing regimen is robust.

²¹ except that one cutting plant trial was reported on by a Veterinary Meat Hygiene Adviser and another by a FSA Veterinary Adviser

²² to mimic the situation in which an acceptable sample is not provided – see paragraph 53

32. The Group agreed that the further trials should involve three slaughterhouses: one small, one medium and one large; two drawn from the previous participants and one not previously involved. The trials would run consecutively, so that any lessons learnt in one trial could be applied to the next to enable continuous improvement, ending with the abattoir that had not held a trial previously.
33. The Group asked Defra to host a workshop with all involved, including managers in the abattoirs taking part, in advance of the trials. The main purpose of the workshop was to learn and share the lessons from the first round of trials (including the NI trial) and to develop a comprehensive generic Hazard Identification and Control Plan for the testing regimen (Annex 3). Two Group members attended the workshop. Each of the trial abattoirs then used the generic control plan to draw up an effective control system for their specific premises to be assessed in the trials.
34. The second phase of trials took place in June 2005. The involvement of EFSIS – an independent quality management systems auditing company with specialist experience in the meat industry – in the workshop and as auditors of the trials²³ in plants added considerable value to the process. One of the trials was observed on one day by auditors from the EU Food and Veterinary Office as part of a mission to audit the BSE controls in GB. The FVO subsequently indicated they were satisfied with the approach taken by the Group.
35. The Group considers that in these trials all the key components of the testing system were shown to have operated effectively and, overall, the control of the abattoir testing process provided by the system was fully satisfactory. The trials identified some minor points, mainly in relation to refining the guidance for abattoirs.
36. The Group's recommendations and the lessons learnt from each individual trial were incorporated into the system as the process moved forward. By the end of these trials the Group was able to test a system that it considers would provide all the necessary safeguards to public health, provided it is fully and appropriately implemented, monitored and enforced.

THE KEY FEATURES OF THE RECOMMENDED TESTING REGIMEN

Introduction

37. The key features of the recommended testing regimen are:

²³ EFIS reports on these second phase trials available at: www.defra.gov.uk/animalh/bse/index.html

- abattoir pre-requisites
- a Hazard Identification and Control Plan
- Required Methods of Operation (RMOP)
- an approval process
- laboratory procedures
- cutting plants
- monitoring and audit

as detailed below.

Abattoir pre-requisites

38. A pre-condition for any abattoir wishing to slaughter and process OTM cattle is that it must have certain minimum facilities to enable it to operate the testing regimen successfully. The key requirements identified include:

- sufficient lairage capacity and facilities to allow animals to be identified and physically segregated into batches of OTM cattle requiring testing, non-OTM cattle and others as necessary;
- sufficient slaughter capacity and facilities to handle any additional volume predicted;
- sufficient staff trained and competent to take the correct samples;
- suitable facilities for taking samples;
- sufficient and suitable chiller space for holding securely the carcasses and any other parts of tested animals intended for human consumption until the results of tests are received; and
- a means of receiving test results either by fax or electronically.

Recommendation

R1 Only abattoirs that meet the pre-requisites should be considered for approval for OTM testing.

Hazard Identification and Control Plan

39. The Group considers that the cornerstone of a robust regimen will be the development of a sound Hazard Identification and Control Plan, properly based on HACCP²⁴ principles, for the parts of the testing process that take place in the abattoir. The Group sees such a plan as an essential foundation for the development of an RMOP document (see paragraphs 41 to 43) that contains appropriate measures to deal with the hazards that could potentially affect the

²⁴ Hazard Analysis and Critical Control Point

²⁵ Hazard Analysis and Critical Control Point

reliability and effectiveness of the system. Operators should integrate the hazards and controls identified in the plan with current HACCP systems in the plant. In order to ensure that the plan is drawn up competently, plants must either have demonstrable in-house expertise in HACCP to a recognisable level or acquire outside expertise. The Group notes that an accredited training course in meat plant HACCP practice, linked to the FSA Meat Plant HACCP Manual, is available.

40. The Group emphasises that the responsibility for developing the control plan and for understanding what measures are needed in what circumstances rests entirely with the operator. However, the Group notes that part of the MHS/DARD role is to provide help and advice to the operator to help ensure that the plan would provide an appropriate level of control.

Recommendations

- | | |
|----|---|
| R2 | The operation of the testing regimen in individual abattoirs should be based on a Hazard Identification and Control plan, which is integrated with the plant's HACCP systems. |
| R3 | The staff responsible for the development of the Hazard Identification and Control plan should have attended an accredited meat plant HACCP training course delivered by an approved trainer. |

The Required Methods of Operation (RMOP)

41. The RMOP is a plant-specific document which sets out the specific actions or procedures which will be used by an abattoir to comply with each stage of the testing regimen and the supervision required by MHS or DARD staff. The RMOP must contain sufficient detail to enable abattoir staff to understand the actions they are required to take and what will be expected of them by MHS/DARD.
42. The Group has produced guidance to abattoirs on the establishment of control procedures and the drawing up of a plant-specific RMOP document. This guidance consists of a protocol (Annex 4) which sets out the procedures an abattoir needs to have in place before processing of OTM cattle for human consumption can start and guidance instructions for drafting the RMOP (Annex 5)²⁶.

²⁶ these are the Defra/MHS versions. Corresponding documents would be used by DARD in NI.

43. The guidance document includes the following processes which the Group considers must, in the interests of effective control, be specified in the RMOP:-

- **Cattle identification and segregation**

The identification and age of cattle presented for slaughter, and hence their eligibility for human consumption and testing, must be established while the animals are in the lairage. There must be appropriate procedures for handling casualty or emergency slaughter cattle if these are to be processed.

- **Correlation of sample to carcass and all other body parts.**

Traceability must be maintained between the identification of the animal, the brain stem sample taken from that animal and the carcass and all other body parts, including the hide, that have been kept under official control until a test result is received. This may be achieved by a paper-based system, although, especially in high-throughput premises, the Group sees advantages in IT systems that operate throughout the plant.

- **Chain of custody of samples and receipt of results**

Storage of samples until they are despatched to the laboratory and the means of receiving test results from the laboratory must be secure from any interference.

- **Identification and retention of carcasses and all other body parts**

Both sides of the carcasses of all tested animals must be clearly identified and securely retained pending results before being health marked. Similarly the corresponding body parts and offal must be retained²⁷ and clearly identified, individually or in batches, pending the results or sent directly for incineration or rendering and subsequent incineration.

- **Sequence of carcasses in the chiller**

Carcasses must be maintained in slaughter sequence while retained in the chiller, to facilitate the identification of the carcasses of any animals which test positive or for which there is no test result, plus the carcass before and two after on the slaughter line, in accordance with EU requirements. The RMOP must also contain detailed procedures for handling carcasses detained by MHS or DARD and taken out of slaughter sequence.

²⁷ except for the hides which may be moved to a hide premises where they are retained under official control by the MLC

- **Health marking**

The application of the health mark is under the control of the MHS/DARD. It must **not** be applied to any carcass or other parts of tested animals intended for human consumption until a negative test result has been received.

Recommendation

R4 Plants undertaking slaughter of OTM cattle for human consumption should be legally required to have a detailed RMOP based on the guidance document (Annex 5)

Approval process

44. The RMOP is a key component of the regimen and, through its agreement and approval, the MHS or DARD can ensure that reliable and effective controls are in place before an abattoir is permitted to begin slaughter of OTM cattle for human consumption.
45. The key stages of the approval process are application; assessment; and approval (see process map drawn up by the MHS for GB at Annex 6). This process is intended to ensure that the RMOP is subject to thorough assessment and review, in discussion with the operator, before it is approved by the OVS. The process should include the need for the abattoir to pass a two slaughter-day assessment of the practical procedures.
46. In GB the OVS would be supported in the process of checking and approving the RMOP by an Area Official Veterinarian (AOV), a new position in the MHS's operational reporting structure.
47. The AOV should assume responsibility for specific OTM testing plants, with each in-plant OVS reporting directly to the AOV on veterinary and technical matters. The AOV should have a rôle in training plant teams and reviewing and auditing the draft RMOP. In addition all RMOPs should be checked and approved by a specialist Veterinary Adviser (VA) in MHS HQ, whose rôle will be to ensure the consistency of RMOPs and that any lessons learned in one part of the country are captured and disseminated throughout the organisation.

48. A similar system would be operated by DARD in NI, except that the rôle of the GB AOV and MHS HQ VA will be amalgamated and carried out by DARD's VPHU DVO. The plant OVSs would be given technical support in relation to BSE testing directly by the HQ VS.
49. The Group considers that independent assessment of the approval process is essential to check that the documents being approved are of a sufficient standard to deliver effective controls in abattoirs. Such an assessment should be included in third-party audit and review of the roll out and first 6 months of operation of the OTM testing regimen (see paragraph 75).

Recommendations

- R5 A rigorous process for assessing the adequacy of the RMOP, including a pre-approval assessment of the controls in the plant, should take place before an abattoir is approved to carry out the slaughter and processing of OTM animals. The approval process should include the abattoir passing a two slaughter-day assessment of the practical procedures.
- R6 The abattoir RMOP should be agreed, signed off and approved by the MHS/DARD.
- R7 Plants should be able to process OTM cattle for human consumption only if approved by the MHS or DARD.

Laboratory procedures and arrangements for sampling

50. The abattoir is responsible for taking samples of the correct quality and for arranging the transport of samples to the laboratory (and for any liability that flows from failure to do so). The testing laboratory is responsible for ensuring that the samples received from the abattoir are correctly analysed and the results are returned with full traceability.

Recommendation

- R8 The abattoir operator should specify the detailed chain of custody of the test samples.
- R9 Test results should be communicated from the laboratory to the abattoir by a rapid, safe and secure method with full traceability.

51. All UK testing laboratories are approved by the UK National Reference Laboratory (NRL), which is the Veterinary Laboratories Agency²⁸, before being allowed to participate in BSE testing. Approved laboratories are subject by the NRL to a schedule of quality assurance exercises over the year, including periodic (quarterly) tests of blind-coded positive and negative samples and an annual inspection. From January 2006, under EU law²⁹, only accredited laboratories will be able to obtain approval to perform legally-required BSE tests.
52. The Group is satisfied that the system for approval and monitoring by the NRL, and the EU legal requirements, provide a sufficient assurance of the quality and reliability of the testing and traceability systems within the laboratory.
53. The Group was concerned that measures should be in place to ensure that satisfactory samples are supplied by the abattoir to the laboratory for testing. In particular the Group recommends that the sample must include the part of the brain stem (the obex) most likely to produce a positive result if abnormal prion protein was present. The Group therefore agreed that any samples where the obex was not identifiable should be issued with a “no test” result³⁰. The Group noted that this recommendation has been incorporated into the laboratory procedures and that detailed guidance with colour pictures of the correct sample have been produced for training abattoir staff.
54. The Group was also reassured that the trials demonstrated that abattoirs are capable of taking good quality samples and that the laboratory is able to provide feedback to abattoirs on the quality of the samples they were receiving from them.

²⁸ the laboratory designated in EU legislation as responsible among other things for verifying diagnostic methods and co-ordination of diagnostic standards within the EU Member State

²⁹ Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls

³⁰ such samples would still be tested and appropriate action taken if found positive, but negative results would be considered unreliable. All parts of the “no-test” animal, along with those of the one before and two after on the slaughter line (with the exception of their hides), would then be required to be destroyed.

Recommendation

R10 The testing laboratory should provide feedback to abattoirs on the quality of samples received at the laboratory on a continuing basis to help maintain sample quality.

Cutting plants

55. Currently there is no requirement to remove vertebral column from UK cattle aged under 30 months. In most of Europe, vertebral column has to be removed as SRM from cattle over 12 months³¹.
56. Vertebral column therefore does not generally have to be removed from UK cattle entering the food supply, because the OTM rule is in place. However, vertebral column does have to be removed in the UK from cattle aged over 12 months at slaughter imported into this country either live or as carcase meat. Following any change in the OTM rule, the vertebral column would be required to be removed as SRM from the carcasses of UK OTM cattle that test negative for BSE before they could enter the food supply.
57. The current rule in the UK is that removal of vertebral column as SRM may take place only in cutting plants specifically licensed for that purpose by the FSA. At present around 60 cutting plants hold such a licence (handling mainly imported meat). Before the specific SRM licence is issued, the plant will go through an application, assessment and approval process as set out in the protocol at Annex 7. As part of that process cutting plant operators must agree an RMOP with the OVS, who must be satisfied that the plant has the appropriate facilities, equipment and suitably trained staff to enable it to remove SRM vertebral column correctly. The OVS will be supported in this rôle by the MHS AOV, in turn supported by the MHS HQ VA, whose rôle will be to ensure consistency. A similar system would be operated by DARD in NI.

Recommendation

R11 The cutting plant RMOP should be agreed and signed off by the OVS.

58. The licence requires that SRM vertebral column must be removed, stained, stored and disposed of in full compliance with the SRM controls. The FSA has the power to suspend or revoke a specific SRM licence where any of its conditions has not been complied with, thus preventing the cutting plant from

³¹ the EU SRM rules (Regulation (EC) 999/2001) specify that vertebral column is SRM at 12 months but provide a derogation from that rule which requires vertebral column to be removed from UK cattle at 30 months

continuing this activity. The Group considers such licence revocation a powerful sanction that should help provide reassurance to the public.

Recommendation

R12 The current provisions for specific SRM licensing of cutting plants, and for suspension and revocation of licences in the event of breaches of licence conditions, should be maintained in relation to removal of vertebral column as SRM from OTM cattle following any change in the OTM rule.

59. The main hazard in the control of removal of vertebral column is that the carcasses of OTM cattle may, without adequate controls, lose traceability between the abattoir and the cutting plant where the vertebral column is to be removed. Therefore the Group recommends that, following any change in the OTM rule, the FSA should extend the current controls on removal of SRM vertebral column to the carcasses of OTM cattle. Those controls require carcasses containing SRM vertebral column to be despatched from the abattoir in a sealed vehicle to a specifically-licensed cutting plant where the vertebral column is removed. In co-located cutting premises, carcasses must not be removed from sealed abattoir chillers or rails and moved to the cutting premises, except under the supervision of the MHS (DARD in NI).

Recommendation

R13 OTM carcasses should be despatched in a sealed vehicle to the specifically-licensed cutting plant where the vertebral column is to be removed. The MHS (DARD in NI) should be present during unsealing and unloading of the OTM carcasses at the receiving cutting plant and the carcasses should be either batched or placed on a separate boning line for vertebral column removal. In co-located premises, carcasses must not be removed from sealed abattoir chillers or rails and moved to the cutting premises, except under the supervision of the MHS (DARD in NI).

60. It is a requirement in EU legislation for a blue stripe label to be attached to carcasses from which removal of vertebral column as SRM is not required. Any carcass to which a blue stripe label is not attached would be deemed to be OTM and vertebral column removed.

Recommendation

R14 The EU legislative requirement that a blue stripe label should be attached to carcasses from which removal of vertebral column is not required should be implemented.

Monitoring and audit of the testing regimen

61. Regular monitoring and audit of the testing regimen is essential to provide assurance that compliance with the system is being maintained and that it continues to operate effectively. The regimen will be subject to several layers of monitoring and audit:-

- **Plant monitoring**

62. It is the plant's responsibility to demonstrate full compliance with the requirements of the Hazard Identification and Control Plan. This should specify effective monitoring procedures including own checks at critical control points during the processing day and detailed record keeping.

- **Plant based MHS/DARD Veterinary Service (VS)**

63. As proposed, the MHS (DARD VS in NI) should be responsible for monitoring and enforcing the testing regimen in abattoirs. The MHS/DARD VS team at the plant should be required to carry out a range of controls, including checks on animal identification, chiller security, test results and a percentage of random checks on the operator's procedures throughout the processing day. MHS/DARD staff should be required to record the checks carried out on each day the plant slaughters OTM cattle. All MHS/DARD VS records should be retained and made available for inspection. Information should be provided to the Implementation Review Group (see paragraph 74) on a monthly basis on the number of OTM cattle slaughtered, the number of samples received at the approved testing laboratories and BSE test results; any discrepancies between the figures, and names of any plants that have recorded more than one "no test" result.

- **AOV³² routine visits and inspections**

64. The AOV should pay regular visits to the plants processing OTM cattle in the first few weeks and months following approval, thereafter the level of visits should be commensurate with the performance. Any findings should be reported to MHS/DARD VS HQ and the Implementation Review Group.

65. Following approval, plants should be subject to routine visits and inspections by the AOV. The AOV would check to ensure that the testing system is running as set out in the approved RMOP. The AOV should also review the paperwork generated at the plant. The AOV should compile a report for each visit to be submitted to the MHS HQ Veterinary Adviser/DARD's VPHU DVO and the MHS

³² In Northern Ireland the AOV will be assisted in all monitoring tasks by the VPHU internal auditor.

Operations Support Unit. These reports should be made available to the Implementation Review Group.

- **MHS internal audit**

66. MHS/DARD VS would add OTM audit checks to their general programmes of auditing for their internal controls and assurances.

- **FSA audit**

67. The Government has asked the FSA, in the event of a move to BSE testing, to take on a new role in the ongoing audit and review of the entire system for BSE testing cattle slaughtered for food. The audit would aim to provide assurance that measures were in place to ensure that the entire BSE testing system was working effectively. The audit would need to demonstrate that the MHS and DARD internal audit systems were effective and ensure that satisfactory arrangements were in place in the MHS and DARD for implementing the requirements of the BSE testing system. The audit would also aim to ensure that effective systems were in place in other relevant organisations. This would include the laboratory services carrying out analysis of brain samples and the Meat and Livestock Commission (MLC) in relation to hides²⁶. The audit would also cover DNA testing of a sample of carcasses retained pending test results at the abattoir and brain samples sent to the testing laboratory as a cross-check on traceability.

- **Independent post implementation review**

68. The FSA has undertaken to carry out an independent review of the BSE testing system, following any change in the OTM rule. The review would report on the first 6 months following implementation and be commissioned from an independent contractor. Its purpose would be to assess whether the Group's recommendations on a reliable and effective testing system had been rolled out correctly. The Group strongly supports this approach.

69. The Group considers that independent assessment of the abattoir approval process is essential to check that the documents being approved are of a sufficient standard to deliver effective controls in abattoirs.

Recommendation

R15 The planned independent post-implementation review should examine a reasonable sample of the RMOP documents agreed in NI and by AOV in GB to ensure consistency and that the requirements are being met.

• FVO

70. The UK testing regimen would also be subject to periodic audit as part of ongoing audit missions by EU Food and Veterinary Office teams.

Recommendation

R16 A comprehensive programme of monitoring and audit of the testing regimen should be introduced in order to demonstrate its ongoing effectiveness in controlling the public health risk. Corrective action should be taken where necessary commensurate with the level of non-compliance.

R17 The independent audit of the first 6 months post implementation should be extended if necessary.

POWERS OF ENFORCEMENT

71. A robust regimen must include effective powers to enforce the rules in the event of non-compliance. EU legislation already requires that only test-negative OTM cattle may be health marked. The Group notes that the ability to withhold the health mark therefore provides the MHS and DARD with an effective sanction to ensure that only the carcasses or other parts of animals definitely identified as negative may be allowed into the food supply and that the carcasses or other parts of positive or “no test” animals are excluded.
72. In addition, Defra and DARD should put in place legal requirements to extend and strengthen the enforcement powers before any change in the OTM rule. These requirements should specify the provisions that must be included in the agreed RMOP and make the abattoir operator legally responsible for compliance with these provisions. In the event of non-compliance with the RMOP in relation to an OTM animal, the OVS should be empowered to direct the operator to dispose of the carcass and all other body parts of the animal concerned without compensation. There should also be scope to revoke the abattoir operator’s approval to process OTM cattle.

73. Defra and DARD should also make it an offence to consign an animal born before August 1996 to an abattoir for slaughter for human consumption.

Recommendation

R18 Enforcement powers should be in place before slaughter of OTM cattle for human consumption is allowed to commence.

ADVICE TO THE FSA BOARD:

THE GROUP ADVISES THAT THE BSE TESTING REGIMEN IS ROBUST IF EFFECTIVELY IMPLEMENTED, COMPLIED WITH AND ENFORCED.

IMPLEMENTATION AND ROLL OUT

74. The success of any regimen, however well-designed, ultimately depends on how well it is put into practice. The implementation of the testing regimen therefore needs to be properly managed and communicated. With the number of different agencies involved (see Annex 8) it is important that there is a coordinated approach with clear responsibilities, accountabilities and leadership. A structure should be developed to oversee the implementation of the testing regimen through management information and audit reports. Any enhancements that are identified should be incorporated as practicable.

Recommendation

- R19 Given the level of public concern about BSE, as the independent body set up to protect public health in relation to food, the FSA should
- (a) set up and lead an Implementation Review Group involving all the Government departments and Agencies concerned, to oversee the implementation of the testing regimen and to ensure that it is rolled out successfully across the UK;
 - (b) ensure public health and consumer interests take precedence over all others;
 - (c) establish a clear communication strategy for consumers and other relevant stakeholders before, during and after implementation; and
 - (d) develop performance criteria for the testing regimen.

75. The regimen could be particularly exposed to a risk of break down if insufficient plants have been approved at the time a move to testing takes place, with the result that the capacity of those that are undertaking OTM slaughter to deal with the supply of animals on the market is over-stretched.

Recommendation

- R20 The process of approval of abattoirs for OTM testing should be properly managed to avoid any significant operational problems for plant and enforcement staff.

CHALLENGES

76. During the course of its work, the Group has identified a range of issues that, although not entirely within its remit, may have implications for the successful implementation of the testing regimen. The Group wishes to draw these to the attention of the FSA Board.

Public concern and market response

77. The Group is aware that there are a number of uncertainties as to how the market would respond to OTM beef that could affect perceptions of the acceptability of the OTM rule replacement. These uncertainties include consumer acceptance; the policies of retailers, manufacturers and caterers; the impact these could have on price, supply and demand, and imports; and media response. Any change to the current arrangements could lead to increased public concern if not adequately communicated. Therefore, clear and regular communications with all stakeholders will be important.

Maintaining a robust regimen

78. The Group has already stated that a robust regimen must aim to achieve 100% compliance with the requirement that only test negative OTM cattle may enter the food supply. This will be an ongoing requirement. There will therefore need to be sustained vigilance and continual improvement of the regimen in the light of any lessons learnt from experience. Avoiding complacency may pose a challenge, as the likelihood of positives necessitating action in the plant will be low with the declining incidence of BSE.

Recommendation

R21 Ongoing audit and review of the testing regimen should continue under the direction of the Implementation Review Group, to ensure that consumer protection remains paramount and that the performance of the testing regimen is maintained.

Animal identification

79. The ability to identify on receipt at the abattoir OTM cattle that require testing, as well as any cattle born before August 1996 that will remain ineligible for the food supply, would be critical to the effective operation of the testing system. Under the plans to make the system legally enforceable (see paragraphs 71 to 73), the RMOP would be required to include reliable systems for identifying such cattle

on arrival at the abattoir and for ensuring that no animal born before August 1996 is slaughtered for human consumption.

80. The cattle identification rules prohibit the slaughter for human consumption of cattle whose identity cannot be properly established. These rules therefore already require abattoir operators to carry out a 100% check that cattle are correctly identified before they are slaughtered. The Group stresses the importance of rigorous enforcement of these rules by MHS/DARD following any move to replace the OTM rule by testing.

Recommendation

R22 MHS and DARD should continue rigorously to enforce the rule that only cattle whose identity can be properly established may be slaughtered for human consumption.

Response to the Inquiry into the failure to test all casualty animals

81. The Inquiry¹⁸ identified a number of deficiencies that had contributed to a systems failure to deliver the testing requirement in relation to 24-30 months 'casualty' animals. Some of the deficiencies found relate to inadequacies in the support and management of MHS OVSs (in NI OVSs were found to be adequately supported).
82. The Group has been kept informed of progress on the comprehensive action plan being taken forward under the supervision of the MHS Board to implement the recommendations of the Inquiry and welcomes the progress being made. The Group has also been advised that future arrangements for improving support for OVSs will include the addition of new AOV posts, which would initially provide additional management and support to OVSs in plants which are approved to undertake the slaughter of OTM cattle for human consumption but would eventually cover the full range of MHS enforcement activity. The Group encourages the FSA to monitor the improvements in the MHS to address the recommendations in the Inquiry to ensure the service is functioning effectively and efficiently.

Recommendation

R23 The findings of the Inquiry into the failure to test all casualty animals should continue to be addressed.

Maintenance of other abattoir controls

83. OTM testing would be a major new area of high priority work for MHS and DARD, which would place additional demands on these organisations and on the staff in plants. A robust testing system must however be introduced in a way that is not detrimental to other work carried out by MHS and DARD in abattoirs for the protection of public health and the attention of plant staff to all matters related to food safety. In particular, routine hygiene in plants must not be compromised and full compliance with SRM rules must be maintained.
84. In addition, lairage facilities should be sufficient to ensure that any additional work load, or change of practices, do not compromise animal welfare.

Recommendation

- R24 With the focus on BSE testing, it is important that all other food safety procedures are complied with.
- R25 Lairage facilities should be sufficient to ensure that any additional work load, or change of practices, do not compromise animal welfare.

85. For the past ten years only UTM animals have been processed and these are much less likely to have signs of illness or disease. The majority of OVSs and meat inspectors therefore have limited recent experience of identifying signs of disease, unrelated to BSE, that are more likely to be seen in OTM cattle, both ante and post mortem, and may present a risk to human health.

Recommendation

- R26 Training should be made available to MHS/DARD staff to improve competencies in the identification of the signs and symptoms of disease in OTM cattle or meat, unrelated to BSE, that could pose a risk to public health.

Casualties

86. The results of BSE tests of casualty cattle¹⁶ accepted into the OTM Scheme indicate that these cattle represent a higher BSE risk than healthy OTM cattle. If the OTM rule is replaced, the FSA has advised that it would be acceptable on grounds of risk to allow OTM casualty cattle that had tested negative for BSE, and had cleared other public health controls, into the food supply.

87. Following any change in the OTM rule, the number of OTM casualty cattle accepted into the food supply would be likely to be less than the number currently entering the OTMS, because the rules for entry into the food supply will be stricter than those for acceptance into the OTMS. In addition, as part of the new food hygiene legislation, from 1 January 2006 stricter rules will limit the categories of cattle, that may be slaughtered on farm as emergency cases for human consumption³³. Guidance is being produced for farmers and veterinary practitioners on the new rules, to publicise the change to those who will be involved in deciding whether an ill or injured animal is eligible for slaughter for human consumption.

Recommendation

R27 The guidance being prepared on the new rules for emergency slaughter, linked to the implementation of new food hygiene legislation January 2006, should be in place before a move to BSE testing of OTM cattle is made.

R28 The numbers of OTM casualty cattle slaughtered for human consumption should be monitored by the Implementation Review Group.

Potential for cattle identity fraud

88. A number of cattle³⁴ that remain on farms have been refused passports, for example where the application for a passport was late. Such cattle are registered on the cattle tracing system and issued with a notification of registration. This enables them to be monitored, but as they have no passport they are ineligible for the food supply. The Group is concerned that these cattle might provide a reservoir for potential fraud (illegal re-identification and entry into the food supply). The Group has been informed however that the large number of checks carried out³⁵ have not revealed evidence of any particular problem of fraud associated with cattle denied passports.

³³ Under Regulation (EC) No. 853/2004 (Annex 1), where an animal is slaughtered outside a licensed slaughterhouse, only carcasses from 'an otherwise healthy animal [that] suffered an accident that prevented its transport to the slaughterhouse for welfare reasons' may be considered fit for human consumption

³⁴ around 38,000 cattle (0.4% of the total GB herd) were registered between November 2003 and April 2005 but do not have passports

³⁵ Defra advise that 12,000 cattle identification inspections of holdings are undertaken each year, covering 20% of the national herd, as well as local authority inspections (on-farm, at roadside checks and markets) covering 70,000 cattle per annum

Recommendation

R29 The Implementation Review Group should monitor the effectiveness of the cattle identification system and keep the risk that the effectiveness of the testing system might be undermined by fraudulent switching of cattle identification under review.

89. The Group considers it essential that, following any move to testing, a purchase for destruction scheme for cattle born before August 1996 is established. If producers have no legitimate outlet with reasonable compensation for those cattle that will continue to be banned, the testing system could be vulnerable to attempts fraudulently to circumvent the age controls to enable them to be sold into the food supply.

Recommendation

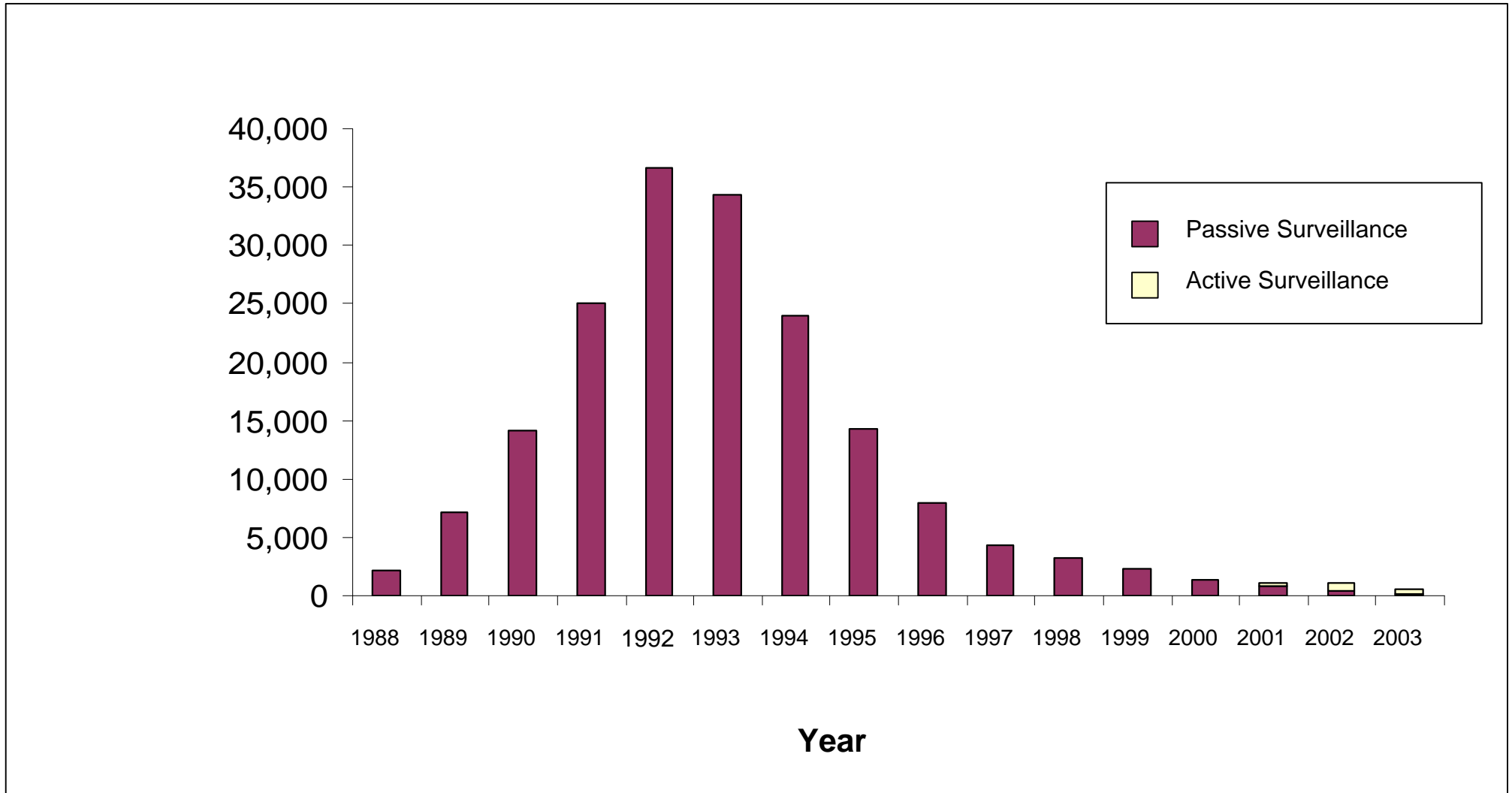
R30 A purchase for destruction scheme for cattle born before 1 August 1996 that will remain excluded from the food supply should be established for a fixed period.

ANNEXES

1. Graph showing the BSE epidemic in GB
2. IAG membership and terms of reference
3. Generic Hazard Identification and Control Plan for the testing system
4. BSE testing protocol
5. Guidance for drafting the abattoir RMOP
6. Abattoir approval process map
7. Protocol for controls on removal of vertebral column as SRM
8. Current Testing Responsibilities

Number of BSE cases in GB

ANNEX 1



INDEPENDENT ADVISORY GROUP

TERMS OF REFERENCE

- (i) To make recommendations to the Food Standards Agency on a robust regimen. In so doing to agree:
 - (a) the components of a robust, reliable and effective regimen for BSE testing of OTM cattle slaughtered for human consumption; and
 - (b) the approach to assessing the performance of the testing regimen.
- (ii) To then review those recommendations in light of a trial of the testing system, and to report to the Food Standards Agency.

AIMS

- To provide advice to the December FSA Board on the components of a robust BSE testing regimen and on the regimen to monitor performance and to ensure compliance
- Ultimately, to deliver a regimen equivalent to “best in class”.

MEMBERS

Professor Patrick Wall (Chairman)

Both a medical doctor and a veterinarian. Professor of Food Safety in the Centre for Food Safety at University College, Dublin. Former Chief Executive of the Food Safety Authority of Ireland. Also a member of the management board of the European Food Safety Authority.

Barbara Saunders OBE BA

Works as a consultant in consumer affairs. Has also served on FSA’s Food Advisory Committee and UK Advisory Committee on the Microbiological Safety of Food. Currently a lay member of the Council of the Royal College of Veterinary Surgeons.

Peter Jinman OBE BvetMed DIPArb MRCVS FCIArb

Senior partner of a veterinary practice in Herefordshire with 25 years of experience of handling agricultural veterinary issues. A member of SEAC and RCVS. Past President of the British Veterinary Association.

Professor Peter Lind D.Sc.

A senior scientist at the Danish Institute for Food and Veterinary Research with considerable expertise in laboratory issues at an EU level. Member of the European Food Safety Authority Scientific Expert Working Group on TSE Testing.

Dr Geoff Spriegel

Works as a consultant for the food industry. Gained extensive knowledge of quality assurance systems through working at senior technical level in food manufacturing and food retailing companies. Formerly Technical Director of Sainsbury’s Supermarkets Ltd. Also served on the UK Advisory Committee on Microbiological Safety of Food.

Sue Dibb BSc (As from 21.12.04)

Senior Policy Officer at the National Consumer Council. Member of the FSA’s Consumer Committee. Independent Board member of Assured Food Standards.

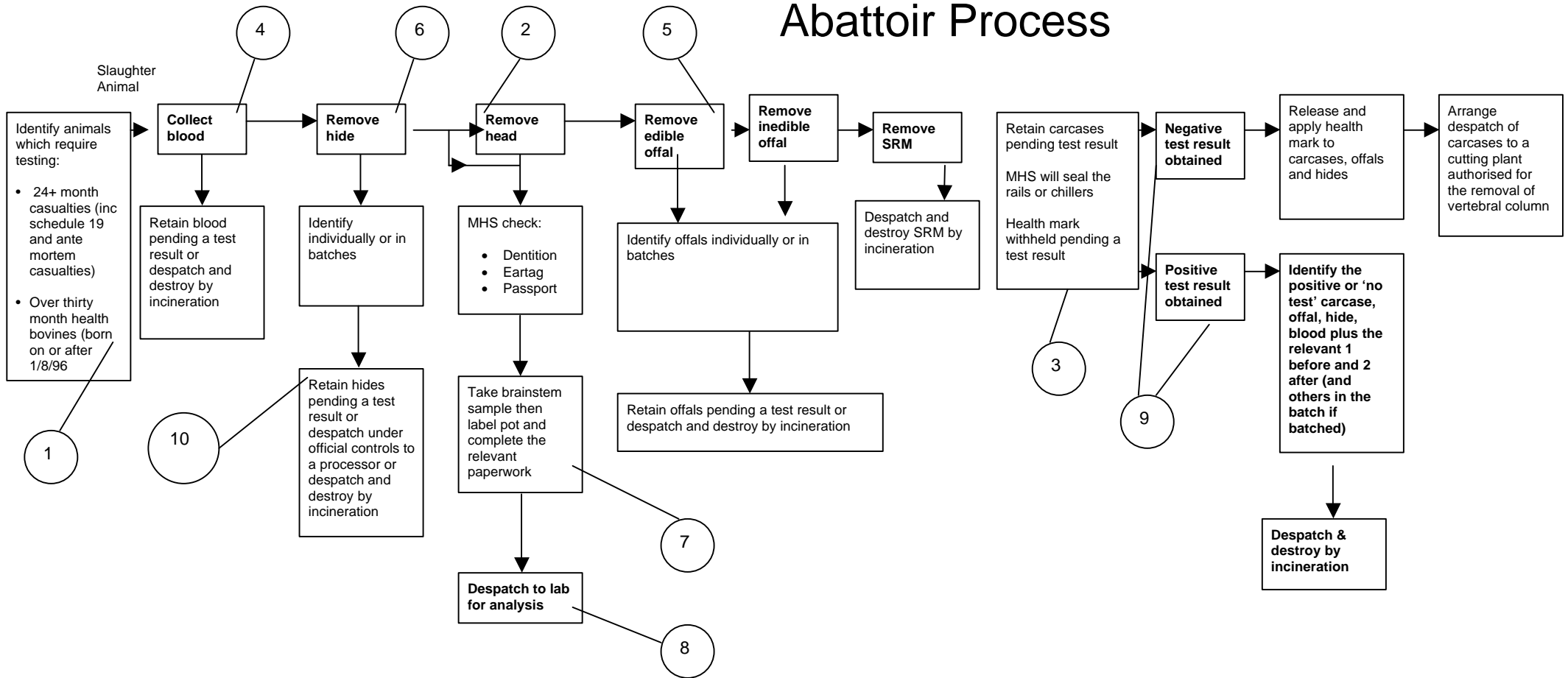
Generic Hazard Identification and Control Plan for the testing system

Before having an RMOP approved for the slaughter of OTM animals a plant will need to produce a hazard identification and control plan. This plan must set out the major hazards involved in the processing of OTM cattle and the controls identified to minimise them.

A number of points should be noted prior to starting to draft your plan:

- As a food producer you must have demonstrable competence in HACCP as set out in Regulation 20 of the Fresh Meat (Hygiene & Inspection) Regulations 1995 (as amended).
 - A fundamental requirement in the drafting of your plan is the involvement of all the relevant personnel from your plant where applicable including both technical and production teams, and MHS staff.
 - Ownership of the plan will always remain with the plant operator although if required you may choose to use external bodies to assist in the development of the plan.
 - Where individuals or staff positions are responsible for controls or monitoring of controls the relevant individual/s must be clearly identified and trained to carry out the task competently.
 - The RMOP must take account of the hazards and controls identified in the plan.
 - The plan must be regularly reviewed with those people mentioned above and amended as required.
 - As a general rule if corrective action is required it should be brought to the attention of the MHS who will verify that the corrective action will be in compliance with the legislation.
- (i) The flow chart and table below sets out the process steps that should be considered when drafting your plan. An outline of a process step identification and control plan can be found at Annex A. It should be noted that this plan is a guidance template only and individual plants will need to modify the control and monitoring procedures to suit their own local circumstances.

Abattoir Process



8 Process step

No.	Process Step	Hazards and Possible Causes	Control Measures (typical examples)
1	Receipt, identification and segregation of animals	<ul style="list-style-type: none"> • Animal requiring testing not tested • Pre August 1996 bovine enters the abattoir 	<ul style="list-style-type: none"> • Robust passport and age identification checks in the lairage • Animals requiring testing marked • Segregation of UTM, OTM, casualties and pre August 1996 • Physical application of kill number
2	Head traceability	<ul style="list-style-type: none"> • Potentially positive material enters the food chain due to a loss of correlation 	<ul style="list-style-type: none"> • Individual identification of the head • Correlation of kill number with passport and eartag
3	Carcase traceability and retention	<ul style="list-style-type: none"> • Potentially positive material enters the food chain due to a loss of correlation 	<ul style="list-style-type: none"> • Application of sequential visible kill number to both sides of the carcass • Correlation of kill number with passport and eartag • Withhold health mark • Detain carcass awaiting results (sealed chillers)
4	Blood traceability and retention	<ul style="list-style-type: none"> • Release of potentially infected blood for human consumption due to inadequate collection and disposal procedures 	<ul style="list-style-type: none"> • Collect and quarantine blood separately or in batches • Identification of batch or individual blood • Sealing of blood tanks under official control • Retain blood until a test result is received or dispose of by incineration.
5	Offal traceability and retention	<ul style="list-style-type: none"> • Release of potentially infected offal for human consumption due to inadequate collection and disposal procedures 	<ul style="list-style-type: none"> • Identification and segregation of individual offal • Batching of offal by day or selected kill number • Storage in secure chillers (sealed) • Retain offal until negative results received or dispose of by incineration.

6	Hide traceability and retention	<ul style="list-style-type: none"> • Release of hide derived from a positive or no test bovine 	<ul style="list-style-type: none"> • Individual or batch identification • Secure storage of hides • Dispose of by incineration if prior to a test result
7	Sampling	<ul style="list-style-type: none"> • Possible release of infective material into the human food chain 	<ul style="list-style-type: none"> • Sampling by trained staff • Sample labelling carried out in accordance with instructions • One head, one sample, one pot, one label at any one time (no pre-labelling) • Cross check preceding and subsequent kill numbers.
8	Sample submission to laboratory	<ul style="list-style-type: none"> • Potentially positive material enters the food chain due to a loss of correlation 	<ul style="list-style-type: none"> • Safe and secure handling of sample and sample information • Defined chain of custody in RMOP
9	Action on receipt of results	<ul style="list-style-type: none"> • Potentially positive material enters the food chain 	<ul style="list-style-type: none"> • Results interpreted by only an authorised person • MHS and agree results • Seals only broken on receipt of results • Positive, no test and 1b2a material identified and consigned for incineration • Negative material health marked
10	Communication with hide markets and tanneries	<ul style="list-style-type: none"> • Release of hide derived from a positive or no test bovine 	<ul style="list-style-type: none"> • Communication protocol in place between the abattoir and hide market or tannery. • Hides individually identified

EXAMPLE ONLY

HAZARD IDENTIFICATION AND CONTROL PLAN

In addition to the control measures set out in this plan it should be noted that the Meat Hygiene Service has it's own responsibilities with regard to identification checks and process verification. These include:

- Identification (passport ear tag checks)
- 10% random check on correlation at all stages
- 10% random check at sampling point

1. Receipt, Identification and Segregation of animals

Hazard and Cause	<ul style="list-style-type: none"> • Pre-August 96 animal entering food chain • Bovines requiring testing not identified
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> • Robust passport and age identification by Plant Operator at lairage • Animals requiring testing marked – typically with dye • Physical segregation of UTM, OTM, Casualties and pre-Aug 96 in lairage before entering kill line • Physical application of kill number whilst ear tag is still present
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<ul style="list-style-type: none"> • Ear tag and passport check
Monitoring Frequency	<ul style="list-style-type: none"> • 100%
Monitoring Responsibility	<ul style="list-style-type: none"> • Plant operator
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> • Pre-Aug 96 animals disposed of • Unidentifiable – withhold from slaughter and inform MHS/farmer. If correct passport details submitted within 48 hours animal can progress; if not, animal disposed as SRM.
Corrective Action Responsibility	<ul style="list-style-type: none"> • Plant operator
Records	<ul style="list-style-type: none"> • Printout or written list signed by Plant Operator and kept for auditing. • Exception report for those withheld (e.g. dead on arrival, pre-Aug 96, unidentifiable)
Verification Procedure	<ul style="list-style-type: none"> • Recheck identification – ear tag against passport list – for 100% of throughput. At head inspection. • End of day reconciliation – those requiring testing and those sampled
Verification Frequency	<ul style="list-style-type: none"> • Daily
Verification Responsibility	<ul style="list-style-type: none"> • MHS

2. Head traceability

Hazard and Cause	<ul style="list-style-type: none"> • Potentially positive material enters the food chain due to a loss of correlation
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> • Individual identification of head including the physical application of kill number to head • Correlation of kill number with ear tag and passport
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<ul style="list-style-type: none"> • Visual monitoring in process including a cross check with kill numbers on preceding and subsequent heads
Monitoring Frequency	<ul style="list-style-type: none"> • 100%
Monitoring Responsibility	<ul style="list-style-type: none"> • Plant operator
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> • Line stopped immediately and traceability verified by sequence of line. • If correlation cannot be rectified then carcass and all parts disposed. • If heads have been batched and correlation is lost for heads within a batch, then all carcasses and parts disposed or DNA testing of that batch to identify animal in the event of a positive.
Corrective Action Responsibility	<ul style="list-style-type: none"> • Plant operator
Records	<ul style="list-style-type: none"> • List of kill no., kill date, tag no and sample no. • Exception report

3. Carcass traceability and retention

Hazard and Cause	<ul style="list-style-type: none"> • Potentially positive material enters the food chain due to a loss of correlation or retention
Control Measure	<p>For example</p> <ul style="list-style-type: none"> • Application of sequential visible kill number to both sides of the carcass • Withhold health mark (apply interim stamp – MHS identifier stamp) • Detain carcass awaiting results (sealed chillers).
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<ul style="list-style-type: none"> • Cross check with kill numbers on preceding and subsequent carcasses • Physical check of kill number at grading point • Correlation of kill number with ear tag and passport
Monitoring Frequency	<ul style="list-style-type: none"> • 100%
Monitoring Responsibility	<ul style="list-style-type: none"> • Operator
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> • Stop line and trace back. • If correlation cannot be rectified then carcass and all parts disposed.
Corrective Action Responsibility	<ul style="list-style-type: none"> • Plant operator
Records	<ul style="list-style-type: none"> • Exception records of failure and corrective action
Verification Procedure	<ul style="list-style-type: none"> • Reconciliation of exceptions
Verification Frequency	<ul style="list-style-type: none"> • Daily
Verification Responsibility	<ul style="list-style-type: none"> • Plant operator

4. Blood traceability and retention

Hazard and Cause	Release of potentially infected blood for human consumption due to inadequate collection and disposal procedures
Control Measure	<ul style="list-style-type: none"> • Collect and quarantine blood separately or in batches. • Identification of batch or individual blood. • [MHS to seal blood tank/container. Plant operator may add lock if deemed necessary.] • Retain blood until test result received or dispose immediately by incineration
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<p>For example</p> <ul style="list-style-type: none"> • Check identity of blood against blood tank/container. If multiple tanks are in use, check what blood has gone into each tank. • Check seal on blood tank. • Check animal by-products disposal document for any blood sent directly for incineration. • Monitor quantities of blood despatched and match figures returned by processing premises
Monitoring Frequency	<ul style="list-style-type: none"> • Twice daily • Weekly check of by-products disposal documents and transport company quantity receipts.
Monitoring Responsibility	<ul style="list-style-type: none"> • [MHS for blood tank sealing] • Plant operator for all other procedures
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> • If identity lost, all blood on site disposed of by incineration • If seal broken, all blood disposed of by incineration, plus investigation, location and destruction of any blood removed. • Any deviations in quantity/transport records – investigation and action as necessary
Corrective Action Responsibility	<ul style="list-style-type: none"> • [MHS for blood tank sealing] • Plant operator for all other procedures
Records	<ul style="list-style-type: none"> • [MHS for blood tank sealing] • Plant operator for all other procedures

5. Offal traceability and retention

Hazard and Cause	<ul style="list-style-type: none"> • Release of potentially infected offal for human consumption due to inadequate collection and disposal procedures
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> • Identification and segregation of individual offal by kill number. • Correlation of kill number with ear tag and passport • Batching of offal by day or selected kill numbers. • Storage in secure chillers which are sealed under official control • Retain offals until negative result received or offal disposed before a test result by incineration.
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<ul style="list-style-type: none"> • Batches – check record of kill numbers against batches of offal • Individual – cross check number with preceding/subsequent offal
Monitoring Frequency	<ul style="list-style-type: none"> • 100%
Monitoring Responsibility	<ul style="list-style-type: none"> • Plant operator
Corrective Action Activity	<p>For example</p> <ul style="list-style-type: none"> • Stop line and trace back. • If correlation cannot be rectified then all offal disposed by incineration.
Corrective Action Responsibility	<ul style="list-style-type: none"> • Plant operator
Records	<ul style="list-style-type: none"> • Batching records • Animal by-product movement document

6. Hide traceability and retention

Hazard and Cause	<ul style="list-style-type: none"> • Release of hide derived from a positive or no test bovine
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> • Individual or batch identification (if batch, must know which hides are in which batch). • Correlation of kill number with ear tag and passport • Secure storage of hide – sealed under official control. • Disposal before test result by incineration. • Release only when negative results received. • If released before negative results available then agree protocol with operator and MLC.
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<ul style="list-style-type: none"> • For individual hides, cross check with kill numbers on preceding and subsequent hides, for batches, check of hide numbers against batch list. • Check security of storage.
Monitoring Frequency	<ul style="list-style-type: none"> • Check identification for all hides. • Daily check on storage security.
Monitoring Responsibility	<ul style="list-style-type: none"> • [MHS for hide room sealing] • Plant operator for all other procedures
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> • Stop line and trace back. • If correlation cannot be rectified then hide disposed.
Corrective Action Responsibility	<ul style="list-style-type: none"> • [MHS for hide room sealing] • Plant operator for all other procedures
Records	<ul style="list-style-type: none"> • Individual kill numbers • Kill numbers in specific batches

7. Sampling

Process Step	<ul style="list-style-type: none"> • Sampling of brain
Hazard and Cause	<ul style="list-style-type: none"> • Possible release of infective material into the human food chain
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> • Sampling by trained staff. • Adequate sample labelling as per guidelines. • One head, one sample, one pot, one label at any one time – no pre-labelling. • Cross-check preceding and subsequent kill numbers • Correlation of kill number with ear tag and passport
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<ul style="list-style-type: none"> • Samples taken individually and in sequence • Reconcile the number of samples against eligible animals at end of day. • Supervisory check of staff carrying out sampling.
Monitoring Frequency	<ul style="list-style-type: none"> • 100% • Supervisory check of staff practices – 2/daily
Monitoring Responsibility	<ul style="list-style-type: none"> • Plant operator
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> • Stop process and verify identification sequence of line. If correlation cannot be rectified then carcass and all parts disposed.
Corrective Action Responsibility	<ul style="list-style-type: none"> • Plant operator
Records	<ul style="list-style-type: none"> • Record of all samples, kill numbers, passport numbers and kill dates • Record of start and finish numbers for sequentially numbered labels each day, including any spoilt labels.
Verification Procedure	<ul style="list-style-type: none"> • End of day reconciliation check of the number of sample ready to transport to the laboratory and the number of OTMs slaughtered
Verification frequency	<ul style="list-style-type: none"> • Each day
Verification responsibility	<ul style="list-style-type: none"> • Plant operator

8. Sample submission to laboratory

Hazard and Cause	<ul style="list-style-type: none"> • Potentially positive material enters the food chain due to a loss of correlation
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> • Safe and secure handling of sample and sample information • Defined chain of custody in RMOP
Critical Limit	<ul style="list-style-type: none"> • 100%
Monitoring Procedure	<ul style="list-style-type: none"> • Movement cards – barcodes checked and sample number added or email checked and sent
Monitoring Frequency	<ul style="list-style-type: none"> • 100%
Monitoring Responsibility	<ul style="list-style-type: none"> • Plant operator
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> • If cards not sent with sample, can be sent separately • Resend email submission
Corrective Action Responsibility	<ul style="list-style-type: none"> • Plant operator
Records	<ul style="list-style-type: none"> • List of samples or Email copy • Transport paperwork – collection receipts from courier.

9. Action on receipt of results

Hazard and Cause	<ul style="list-style-type: none"> Potentially positive material enters the food chain
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> Results interpreted by only an authorised person MHS and agree results Seals only broken under MHS official control on receipt of results Positive, no test and 1b2a material identified and consigned for incineration Negative material health marked
Critical Limit	<ul style="list-style-type: none"> 100%
Monitoring Procedure	<ul style="list-style-type: none"> Identification by plant staff and checking by MHS
Monitoring Frequency	<ul style="list-style-type: none"> 100%
Monitoring Responsibility	<ul style="list-style-type: none"> Plant and MHS
Corrective Action Activity	<p>For example:</p> <ul style="list-style-type: none"> Retrieve/ recall +ve, no test plus 1 before 2 after. Any carcasses which cannot be identified and associated body parts sent for disposal
Corrective Action Responsibility	<ul style="list-style-type: none"> Plant staff under MHS supervision
Records	<ul style="list-style-type: none"> Laboratory results and disposal records
Verification Procedure	<ul style="list-style-type: none"> Daily cross check of MHS/lab record
Verification Frequency	<ul style="list-style-type: none"> Daily
Verification Responsibility	<ul style="list-style-type: none"> MHS

10. COMMUNICATION WITH HIDE MARKETS AND TANNERIES

Hazard and Cause	<ul style="list-style-type: none"> Release of hide derived from a positive or no test bovine
Control Measure	<p>For example:</p> <ul style="list-style-type: none"> Communication protocol in place between the abattoir and hide market or tannery. Hides individually identified
Critical Limit	<ul style="list-style-type: none"> 100%
Monitoring Procedure	<ul style="list-style-type: none"> MLC download results and check
Monitoring Frequency	<ul style="list-style-type: none"> Daily
Monitoring Responsibility	<ul style="list-style-type: none"> MLC
Corrective Action Activity	<p>For example</p> <ul style="list-style-type: none"> Hides retrieved and destroyed by incineration
Corrective Action Responsibility	<ul style="list-style-type: none"> MLC
Records	<ul style="list-style-type: none"> Animal by products disposal note

Glossary

1B2A	The one before and the two after.
Eartag	Cattle must have a DEFRA approved ear tag which contains a unique number which is also stated on the animals passport and will stay with it throughout it's life.
Healthmark	A mark applied to the carcass after it has passed post mortem inspection and is fit for human consumption.
Kill number	A number given to an animal at or before the point of slaughter which will be unique to that animal on the specific day, week, month or year.
MHS	Meat Hygiene Service
MLC	Meat and Livestock Commission
OTM	Over Thirty Months
Passport	A document, which contains information about the identity of an animal. Cattle passports contain information specified by EU law, and are used to record cattle movements and notify them to the Cattle Tracing System
Pre August 96 animals	Bovine animals born before 1 August 1996
RMOP	Required Methods of Operation
Schedule 19	A bovine animal which has been emergency slaughtered on farm and is accompanied to an abattoir with a veterinary declaration that it has passed ante mortem inspection and is fit for human consumption
SRM	Specified Risk Material which includes those tissues of cattle which are known to, or might potentially, harbour detectable BSE infectivity in infected animals, such as the brain and spinal cord.
Tannery	Place where hides are tanned
UTM	Under thirty months

BSE testing protocol

This document sets out the procedures an abattoir needs to have in place before they can start processing OTM cattle for human consumption. This guidance should be used when preparing a plant specific RMOP document.

Requirement	Occupier Responsibility	MHS Responsibility
<p>1. Required Methods of Operation (RMOP)</p>	<p>The plant occupier must agree and produce a detailed RMOP describing how the plant will process eligible cattle for human consumption according to the instructions given below.</p> <p><u>If a sole trader</u>, the RMOP must contain the plant licence number, name of the plant occupier and the address of the premises.</p> <p><u>If it is a limited company (PLC)</u>, the RMOP must contain the plant licence number, registered address of the limited company, the company secretary and the premises address.</p> <p>The RMOP must be signed by the plant occupier or limited company representative.</p> <p>Appeal Procedure: When agreement cannot be reached on a RMOP, there are certain appeal procedures which will apply (see separate note on the approval process in the application pack).</p>	<p>OVSs must ensure that the RMOP contains all the steps of production with detailed procedures for each step.</p> <p>OVS must sign the RMOP</p> <p>The RMOP will be subject to audit by the Audit and Verification Unit. It is a legal instrument required by law, and may be used in evidence.</p>
<p>2. Identification of eligible cattle to be tested</p>	<p>Identification of animals to be tested, 30 months and one day, from the passport/ID and rejection of ineligible animals.</p> <p>From [Date to be confirmed], eligible animals to enter the food chain are animals born on or after 1st August 1996.</p> <p>Cattle requiring testing must be identified by a suitable robust and reliable method prior to slaughter. This must be detailed in the RMOP</p> <p>Where necessary, cattle identified for testing must be separated from those that are ineligible. The method of separation must be detailed in the RMOP.</p>	<p>Passport/ID checks should ensure that cattle identified for testing are eligible for slaughter for human consumption.</p> <p>It is the responsibility of the abattoir occupier to identify and separate eligible and non-eligible animals for testing and to demonstrate that the identification and separation methods prior to slaughter are robust.</p> <p>MHS to ensure that such methods are robust and described in sufficient detail in the RMOP</p> <p>1. All OTM & UTM cattle</p> <p>(i) Checks in the Lairage</p> <p>There must be a 10% visual check of the Passport/ID against the eartag number of OTM and any UTM cattle held in the lairage. (% check subject to further review).</p>

	<p>Schedule 18, 19 or animals exhibiting abnormalities at ante mortem</p> <p>The RMOP must contain details of how these are to be managed.</p>	<p>For the different types of documents that accompany the cattle and the different tagging systems, depending on the age, please refer to CN 9, Chapter 18 of the current Operations Manual or chapter 20 of the new Operations Manual when released.</p> <p>Please refer to the Cattle ID Regulations for differences between Scotland, England and Wales with regard to animals being returned to farms.</p> <p>(ii) Checks in the slaughterhall</p> <p>A cross-check of passport/ID, eartag and dentition for all OTM and UTM animals must be undertaken in the slaughterhall and the appropriate MHS form completed immediately after each check.</p> <p>2. Schedule 18, 19 or animals exhibiting abnormalities at ante-mortem</p> <p>For a definition of animals requiring testing refer to Chapter 10 of the MHS Operations Manual.</p> <p>The following animals must be tested for BSE:</p> <ul style="list-style-type: none"> - All over 24 month aged bovines that have been slaughtered on-farm (Schedule 19 certificate animals). - All over 24 month aged bovines that during ante-mortem inspection the OVS identifies as requiring testing as defined in Chapter 10 of the MHS Operations Manual - All over 24 month aged bovines presented with a Schedule 18 certificate. <p>(i) Checks in the Lairage</p> <p>OVS to verify 100% effective segregation of animals to be tested</p> <p>(ii) Checks in the slaughterhall</p> <p>A 100% cross-check of passport, eartag and dentition for all animals must be undertaken in the slaughterhall and the appropriate MHS form completed immediately after each check.</p>
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<p>3. Slaughtering schedule</p>	<p>All eligible cattle must be identified.</p> <p>Eligible animals and non-eligible animals must be slaughtered in separate batches. Preferably, eligible animals should be the last batch down the line on any given slaughter day.</p> <p>The RMOP must describe the procedures the operator will take to minimise cross-contamination between batches of eligible and non-eligible carcasses particularly in relation to:</p> <ul style="list-style-type: none"> - Equipment used - Operatives who have handled eligible cattle - Splashing from eligible cattle on the line - Adequate space between carcasses 	<p>100 % supervision for all animals to ensure that all eligible cattle are identified and are tested. The method of identification to ensure this must be robust.</p> <p>(ii) Minimising cross-contamination does not mean elimination. For example, providing SRM is satisfactorily removed (with the exception of the vertebral column) there may be some contact between eligible non-eligible carcasses held in the chiller when there is movement of such carcasses in and out of the chiller.</p>
<p>4. Sampling Procedure</p>	<p>Brain stem samples must be obtained by trained plant operatives only. The plant occupier should ensure that a suitable number of trained staff are available to match line speed and to cover for sick and leave absences.</p> <p>The plant occupier should provide staff undertaking sampling with the necessary protective clothing and equipment (visor or goggles, gloves, aprons, etc.) and the necessary facilities (table, washing and cleaning facilities, etc.) in line with guidance provided by the Veterinary Laboratories Agency (VLA) and HSE (BSE Occupational guidance for abattoir workers) (see HSE's & Defra's BSE web-sites for further information)</p> <p>The plant occupier must keep a record of all trained operatives.</p> <p>Following sampling, all testing equipment (e.g. plastic spoon, plastic forceps and gloves) must be disposed of as clinical waste in accordance with legal requirements.</p> <p>The occupier is responsible for the packaging, labelling, collection and transport arrangements for samples. The packaging and labelling of samples should comply with packaging instructions P650 of the European Agreement Concerning the international Carriage of Dangerous Goods by Road (See Defra's BSE web-site for details).</p>	<p>The following instruction relates to the testing of 24-30 month casualty animals only (subject to review)</p> <p>Where an animal requiring testing (refer to requirement 2) is identified in an abattoir with no trained staff to remove the brain stem, it is the responsibility of the occupier to contact Defra (tel. 020 7904 6324) to arrange future VLA training, and to seek approval, for this one sample to be taken by the OVS, as an exceptional measure.</p> <p>If a further casualty over 24 months arrives prior to the receipt of formal training of staff by the VLA, the occupier should contact Defra (same number) for advice.</p> <p>All Brainstem sampling</p> <p>Once the plant staff have been trained, MHS staff <u>must not</u> undertake any sampling but must supervise that:</p> <p>Brain stem tissue for BSE testing must be extracted by a trained plant operative. Training must have been provided directly by the VLA, or failing this, from another operative who has received training in brain stem removal by VLA.</p> <p>If the samples are not taken on the slaughter line there needs to be adequate separation between the</p>

	<p>The full address of the despatching abattoir and the address of the receiving testing laboratory should be clearly printed on the packaging. There should be the following statement included in the address details: ' Urgent – BSE Testing'</p> <p>Brainstem samples must be delivered to the approved testing laboratory in a testable condition. As there is no entitlement to compensation in the event of loss or damage to a sample(s) resulting in a 'no test' result being issued by the laboratory, the operator may wish to consider taking out the necessary insurance cover.</p> <p>The plant occupier must fax or e-mail the appropriate form to the specified laboratory before samples are dispatched.</p> <p>If the plant occupiers fail to do this, the lab may not be able to schedule a test for the plant on the next day. The plant should consider obtaining proof of fax receipt.</p> <p>If samples cannot be dispatched for whatever reason they should be chilled in a fridge (samples can be stored for up to 4 days at 4°C).</p> <p>If used, the plant occupier will not require a dedicated freezer for the storage of the freezella packs so long as the packs are disinfected and there is no risk of cross-contamination of meat intended for human consumption.</p> <p>The plant occupier must ensure that any storage arrangements for brain stem sample pots or freezella packs do not allow cross contamination with food/meat intended for human consumption.</p> <p>The plant occupier must keep the necessary records to enable the reconciliation of the number of bovine animals tested with the number of samples despatched to the testing laboratory at the end of each slaughter day.</p>	<p>sampling area and other areas to minimise possible cross contamination from SRM (e.g. from spinal cord or head).</p> <p>If sampling is carried out on the line, the necessary measures to minimise possible cross contamination must be taken.</p> <p>Ensure the sampling procedure is carried out hygienically in accordance with hygiene legislation</p> <p>The despatch of samples should be done as soon as possible to ensure that the quality of the sample does not deteriorate.</p> <p>Ensure that the storage of samples and freezella packs by the plant occupier does not present a risk of cross contamination with any meat intended for human consumption.</p>
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<p>5. Brain Stem Sample Quality</p>	<p>Special care should be taken with the dressing techniques used, such as the removal of the hide with certain hide pullers which might cause tensions in the cattle neck area, as this could damage the brain stem making it untestable, resulting in a 'no test' and the disposal of the carcass and the application of the 'One before and two after' (1b2a) rule requiring the disposal of all carcasses and parts of the body of all affected animals by incineration.</p>	<p>If there are obvious sample quality issues the OVS should bring this to the attention of the plant occupier or plant manager but no advice must be given on the suitability of each sample for testing.</p>
<p>6. Traceability of sample to carcass.</p>	<p>The plant occupier is responsible for and must maintain traceability from the slaughtered animal to its brain stem sample and to its carcass and other parts of the body, by use of an identification number or system throughout the testing regime. Where offals are retained in batches, the traceability system must allow the identification of which tested animals these offals were derived from.</p> <p>Samples must be properly identified and correlated to the head, carcass and retained parts of the body of the animal that has been sampled.</p> <p>Sampling staff must take care to minimise splashes of blood on the outside of the sampling pots and to ensure that the sample pot lid is firmly screwed and securely tightened and checked prior to being packed. The Barcode label must be applied to the side of the pot, and it should be on the vertical (top to bottom), and not the horizontal (i.e. not wrapped around the pot).</p> <p>Contaminated/ leaky pots could delay the testing process in the lab and could result in delayed results.</p> <p>Occupiers will have two options for submitting samples to the laboratory: either using an electronic or a 'manual' system.</p> <p>If using the manual system occupiers must use sample barcode labels in identical pairs. One label will need to be attached to the sample pot and the other attached to a movement card taken from the animal's passport. This movement card will act as the sample submission form and contains the animal's ID in barcode form. The slaughter date and kill number must also be written or stamped on the movement card. If no movement card is available, a photocopy of the front cover of the passport, bearing the cattle ID (eartag) reference in barcode form, should be used with the sample barcode label attached to it.</p>	<p>MHS staff must verify that sample pots are identified and correlated to the animals to be tested, using the MHS sliding scale of supervision in relation to the number of samples taken.</p> <p>All traceability systems must be consistent with the requirements of existing meat hygiene regulations.</p>

	<p>If using the electronic system no hard copy documentation will be necessary. Occupiers must attach a barcode to the sample pot consisting of the necessary data (such as plant number, eartag details, kill number, kill date, etc.) to enable the testing laboratory to individually identify each tested animal, consistent with their own internal traceability system. These details on the sample barcode, will also need to be submitted electronically to the approved testing laboratory (LGC). The plant specific RMOP should contain an explanation of how any electronic system is designed to work. It is required that the plant occupier tests the effectiveness of their proposed system with the co-operation of the approved testing laboratory, prior to any actual testing of eligible cattle. A breakdown in traceability caused by a poorly designed or implemented electronic system, or by the non-receipt of electronic data by the testing laboratory, could result in the need for destruction of all affected carcasses and body parts, without the entitlement to compensation.</p>	
<p>7. <i>Traceability of all parts of eligible animal to the sample</i></p>	<p>The plant occupier must agree a reliable and robust traceability system with the OVS to identify the retained carcase(s), all parts of the body (including the hide) This system needs to be described in the RMOP. This system should include:</p> <ol style="list-style-type: none"> 1. Correlation of the carcase with the associated red offal. 2. Individual or batch correlation for offal, hides and blood. <p>If a batching system is adopted, then the whole batch must be disposed of by incineration¹. If a positive or “no test” result is obtained (see Requirement 10)</p> <ol style="list-style-type: none"> 3. Blood and other by-products from tested cattle must be retained unless disposed of by incineration¹ before the test results are received. 	<p>MHS staff must ensure that the traceability system in place is robust and can ensure that offal can be correlated with the carcase either individually or through a batch correlation system and that both half carcasses can be identified.</p> <p>All body parts and both half carcasses must also be linked to the brain stem sample, as well as related offal, hides and blood.</p>

<p>8. Retention Criteria</p>	<p>The plant occupier must have sufficient and suitable facilities for holding the carcase(s) and one before and two after as required by Regulation 999/2001 where applicable including all retained parts of the body (i.e. organs, tissues, blood and hide) of slaughtered and sampled eligible animals until the occupier receives the results, meeting the requirements of meat hygiene legislation.</p>	<p>MHS staff must ensure that the holding area is secure (including the sealing of any separate exit points in the chiller, prior to the storage of tested carcasses) and that all parts of tested animal(s) and one before and two after are retained under official control until the results are provided by the plant occupier to MHS staff.</p> <p>There must be adequate facilities at the plant to allow Test results to be received by both the plant occupier and the MHS.</p>
<p>Retention of carcasses</p>	<p>Each side of the carcase placed in a chiller, must have duplicate identification labels attached. This is to ensure no loss of traceability, in the event that a label falls off.</p> <p>Carcasses retained pending a test result must be held by the plant occupier in accordance with one of the following options:</p> <p>(a) <u>In a detained chiller.</u> Carcasses awaiting test results must not come into contact with detained carcasses awaiting further post mortem examination by an inspector or OVS in accordance with hygiene legislation.</p> <p><u>Animals unfit for human consumption</u> Test carcasses or parts of test carcasses (pending a test result) that have not been passed as fit for human consumption and are therefore animal by-products must not be stored with any other carcasses or part carcasses that have been passed as fit for human consumption.</p> <p>These carcasses or part carcasses may be destroyed immediately by incineration¹ or retained and destroyed as normal if a negative test result is received or by incineration¹ if a positive or “no test” result is received.</p> <p>The 1B2A carcasses must be identifiable so that they can be disposed of by incineration¹ if the test result is positive.</p> <p>(b) <u>In a chiller other than a detained chiller.</u> All tested carcasses must be stored in the chiller in the order of slaughter.</p>	<p>Chillers must be under the official control of the OVS/ MHI.</p> <p>(a) In the case of <u>detained chillers</u>, the current provision of the FM (H&I) Regulations 1995 requires that they must also be lockable.</p> <p>(b) In the case of other chillers whether or not used exclusively for eligible animals pending test results, either the rails containing the tested carcasses must be sealed, or, failing this, the chiller itself must be sealed.</p> <p>Locks may not be opened or seals may not be broken except by the OVS or MHI. All procedures relating to chiller controls must be recorded on the appropriate form by MHS staff, i.e. when the chiller/ rail was locked/ sealed, by whom, the seal number, when lock/rail was opened/ seal broken and by whom.</p> <p>The 1B2A rule, is a specific measure relating to the possibility of cross-contamination between carcasses <u>on the slaughterline</u>. Consequently, it does not need to be applied when : -</p> <ul style="list-style-type: none"> - there has been a break in production and - adequate space exists between eligible and non-eligible carcasses that prevents contamination and

		<p>- there has been a related clean down of equipment and facilities.</p> <p>(i.e. if the last OTM animal slaughtered on a particular day proves to be positive, the rule does not apply to the first two animals from the next days production) provided C&D post-production in accordance with Hygiene legislation is applied.</p>
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<p>Retention of the parts of the body (including blood and hide)</p>	<p>The plant occupier must have sufficient and suitable facilities for holding all parts of tested animals until test results are provided to the MHS. by the occupier , unless these parts are disposed of by incineration prior to the receipt of such results.</p> <p>After slaughter, material from tested animal(s) must be treated as below:</p> <p>All parts of the carcass and all other parts of the body of a tested animal, must be traceable to that animal for the period of retention (see Requirement no 7).</p> <p>Any red offal not disposed of by incineration prior to receipt of test results¹ (i.e. retained for human consumption) must be retained under official control as follows:</p> <p>a) If retained in a chiller where carcasses and offal from non-tested animals are also stored, the plant occupier must ensure a secure system for retention of offal of eligible animals (e.g. labelling/ tagging each piece of offal or batching offal so that it can be correlated with the carcass(es)).</p> <p>b) If retained in a chiller exclusively used for animals pending BSE test results (which could be a detained chiller in which case it has to be lockable according to hygiene legislation), only the chiller needs to be sealed.</p> <p>All blood must be retained pending a test result, unless immediately disposed of for incineration¹. Approved blood separation systems can be used, but solids must be retained or incinerated if sent for disposal before receipt of a negative test result(s).</p> <p>Specified risk material (SRM) removed from carcasses must be stained and disposed of for incineration if not held until a negative result is available.</p>	<p>MHS staff must ensure that the holding area is secure and that all parts of tested animals are retained under official control until the results are provided to the MHS by the plant occupier unless these parts are disposed of by incineration¹ prior to the receipt of such results</p> <p>Locks may not be opened or seals may not be broken except by the OVS or MHI. All procedures relating to chiller controls must be recorded on the appropriate MHS form i.e. when chiller/ rail was locked/ sealed and by whom, seal number, when lock/rail was opened/ seal broken and by whom.</p>
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	<p>Rumen contents and gut contents must be disposed of in accordance with existing procedures.</p> <p>The parts of green offal classified as SRM according to current legislation (e.g. intestines) must be stained and disposed of as SRM by incineration¹ if not held until a negative result is available.</p> <p>Parts of green offal not classified as SRM (e.g. stomachs) must be destroyed by incineration¹ if a negative result has not been received or securely retained until a negative result is confirmed at which point it can be disposed of as category 2 or 3 Animal by-products.</p>	
<p>Hides</p>	<p>Hides must either be batched or individually identified</p> <p>Batched hides must be clearly identified, indicating the number of hides in the batch and the date of slaughter. In the event of a positive result, the entire batch must be incinerated¹.</p> <p>If individually identified, this must be done using a tag of robust specification or by another secure method that is not reusable and will not be obliterated during processing and storage.</p> <p>The occupier can either:</p> <ol style="list-style-type: none"> 1) Hold hides in the hide room. The hides must be clearly labelled "pending test result". 2) Dispatch hides to a hide market or tannery before a test result is received. In this 1 situation, a separate hides protocol must first have been agreed and signed by the abattoir and hide premises operators (see the hides protocol guidance in your application pack). <p>If any of the carcasses subsequently test positive or there is no negative test result, the hide will be pulled back and destroyed by incineration by MLC staff at the hide market or tannery. If batched the entire batch will need to be destroyed by incineration.</p>	<p>Unless hides are delivered to a hide market the MHS must ensure that hides are detained under official control until the results are received.</p> <p>If hides are individually identified then any positives must be disposed of as SRM¹.</p> <p>If hides are transported to a hide market there must be a suitably documented hide protocol in place, to which the RMOP must refer.</p>

<p>9. Post Mortem inspection</p>		<p>The same procedure for post mortem inspection as for UTM cattle must be followed in accordance with the relevant hygiene legislation.</p> <p>MHS staff should be aware that eligible cattle are more likely to be affected by different pathologies. Ensure instructions in chapter 14 of the Ops Manual are followed if a notifiable disease is suspected.</p> <p>The “Personal Stamp” must be applied to identify carcasses that have undergone Post Mortem and SRM inspections, and are awaiting a negative test result before the application of the healthmark.</p> <p><u>Note</u> application of the personal stamp does mean a carcass is free of SRM</p>
<p>10. Test Results</p>	<p>The plant occupier must bring the test results to the attention of the MHS (OVS, MHI). The plant occupier is responsible for having facilities in place to receive tests results. If the plant occupier wishes to access the internet results service provided by the testing laboratory, they should contact LGC to receive their user id and password.</p> <p>If results are to be received by fax, the abattoir occupier must ensure that the fax facility is left switched on over night</p> <p>Copies of the test results must be kept for 12 months and made available to the OVS when requested.</p> <p>If ‘tested’ hides have been sent to a separate hide premises, any positive or ‘no test’ results will need to be notified to the hide premises operator in accordance with the terms of the hide protocol.</p>	<p>This same requirement applies to any MHS fax machines used for results.</p>

<p>Negative result</p>	<p>If access or health and safety issues arise in the ability to health mark the carcasses, it is the plant occupier's responsibility to ensure that suitable and safe access arrangements are made for the application of the health mark.</p>	<p>MHS staff must apply the health mark to comply with all the requirements of the hygiene Regulations. (See Section 11).</p> <p>Carcasses must remain under official control until vertebral column is removed at an additionally licenced cutting plant. Carcasses for VC removal may be transported under official control using the relevant MHS documentation</p>
<p>Positive result</p>	<p>All parts of the carcass and all other body parts of a positive animal, including the blood and the hide (or the whole batch of body parts, including the blood and the hide, if a batching system is in operation) together with the same material (with the exception of hides) from the one animal slaughtered before and the two animals slaughtered afterwards on the slaughter line, must be destroyed by incineration¹</p> <p>If the hides are stored in the slaughterhouse hide room until the test result is received and there is a positive, the individual hide or the entire batch (if not individually identified) must be destroyed by incineration¹</p> <p>Ensure accurate records of the weight disposed of as SRM¹ are maintained.</p>	<p>OVS to be satisfied of the identity of the positive carcass and the one before and two after during the identification process; offals (which may have been batched), hide, blood, etc. and will supervise despatch for destruction by incineration¹ (nb '1b2a' rule does not apply to hides).</p>
<p>No test result</p>	<p>If the testing laboratory issues a no test report, eg due to poor quality or lost sample, the carcass and all its body parts (including the blood) and all material which has been batched and contains any parts from the 'no test' carcass must be immediately disposed of by incineration¹</p> <p>Because the 1b2a rule applies to 'no test' animals, the same disposal action will be required for the one animal before, and the two animals after, the 'no-test' animal on the slaughterline.</p> <p>Ensure accurate records of the weight disposed of as SRM¹ are kept.</p> <p>Retain a copy of the lab test report for 12 months.</p>	<p>OVS to check records to ensure that the carcass and all its body parts, including blood, has been despatched for destruction by incineration¹</p>
<p>11. Health marking under the FM (H&I) Regs</p>	<p>Carcasses and offals awaiting the test result must not be health marked until a negative test result is received.</p>	<p>The health mark may be applied to the carcass only if the carcass complies with the requirements of hygiene legislation and a negative test</p>

	<p>After MHS staff have applied at least one health mark on each half carcase, the plant staff may apply all the other health marks under direct MHS supervision.</p> <p>The occupier must provide adequate facilities to allow the MHS to carry out their duties, eg platform to enable stamping of difficult to reach areas such as the hind leg.</p>	<p>result is received.</p> <p>When there are difficulties applying the healthmark, such as carcasses in chillers with difficult access to the upper areas of the carcase, plant staff may apply the health mark under strict and direct MHS control.</p>
12. Disposal	<p>Where the text refers to material being destroyed by incineration¹ this material must be destroyed by incineration or rendering and then incineration at a Defra approved premises.</p>	<p>The Regional Office holds a list of approved incinerators and approved renderers who subsequently incinerate all rendered material. Regular checks should be made that the operator is sending material only to approved premises.</p>
13. Removal of vertebral column in approved cutting plants	<p>Eligible OTM bovines slaughtered for human consumption will require the vertebral column to be treated as SRM and removed in an additionally licensed cutting plant for vertebral column removal.</p> <p>The plant occupier must ascertain the approval status of the recipient cutting premises well in advance of sending the first consignment and should satisfy the OVS by providing a copy of the additional licence.</p>	<p>All negatively tested carcasses for human consumption require the vertebral column to be removed at an additionally licensed cutting plant, an MHS officer must be satisfied that the destination cutting plant has been additionally licensed under the TSE Regulations prior to despatch.</p> <p>MHS staff at the despatching abattoir must:</p> <ul style="list-style-type: none"> – Supervise loading of the vehicle – Seal the vehicle, or directly supervise the sealing, and record the seal number, the vehicle registration number and the name of the inspector in the day book. – Complete section A of the transfer document – Take a copy of the appropriate form and retain a copy on site for 12 months. – Place the appropriate form in a sealed envelope and give it to the driver. – Notify the MHS staff at the receiving plant by telephone or fax that a shipment of carcasses is being despatched to them.
	<p>The cutting plant receiving the carcasses for the removal of the vertebral column must ensure segregation of the unloaded eligible carcasses in suitable facilities to facilitate official control by the MHS eg lockable and sealable.</p>	<p>MHS staff at the receiving approved cutting premises:</p> <ul style="list-style-type: none"> – Receive the appropriate MHS form – Unseal the vehicle and record the seal number, the vehicle

	<p>The cutting plant occupier must re-present carcasses which have had the vertebral column removed for inspection by the MHS.</p> <p>The vertebral column must be handled and stained as SRM and disposed of as category 1 animal by product and must not be allowed to accumulate in the cutting room</p> <p>The occupier will be required to record weights / numbers of vertebral columns to ensure this is consistent with the number of carcasses arriving at the cutting plant.</p> <p>SRM must be stored in clearly identifiable, leak-proof, lidded bins. Please refer to chapter 10 of the Operations Manual.</p>	<p>registration number and the name of the inspector on the appropriate form.</p> <ul style="list-style-type: none"> – Complete section B of the transfer permit. The completed permit must be stored on site for audit purposes for a minimum period of 12 months (or longer if there is a court case pending). – Supervise the unloading of the vehicle and check all carcasses are transferred to the chillers. <p>Carcasses must remain under official control until the vertebral column has been removed.</p> <p>MHS staff must re-inspect 15% of de-boned meat to ensure compliance with the TSE Regulations.</p> <p>MHS staff will verify that SRM does not accumulate in the cutting room, but is removed and stained regularly throughout the cutting process by plant staff.</p>
<p>14. Application of the Blue stripe label (in the abattoir)</p>	<p>Carcasses from bovines “Under Thirty Months” of age at slaughter, born, reared and slaughtered in the UK that contain vertebral column must have a blue stripe label attached to the carcasse to identify them as not requiring VC removal</p> <p>If such a label is not displayed, the carcasse must be consigned for vertebral column removal at an additionally licensed cutting plant. It is an offence to attach a blue stripe label to carcasses of cattle over 30 months of age.</p>	

- 1 All parts of all tested cattle for which results are not yet available must be retained or destroyed as Category 1 A or 1 B animal by-product, i.e. needing incineration as opposed to Category 1C, which can be rendered, and land filled. Similarly, all parts of an animal that tests positive (and 1B2A on slaughter line where necessary) or for which there is no clear negative test result must be destroyed by incineration.

GUIDANCE FOR DRAFTING THE ABATTOIR RMOP: GUIDANCE INSTRUCTIONS ONLY

Sole trader or partnership:	Limited company (including plc, ltd and limited partnership):
This section must include: Plant name Plant license number Premises address Name of the plant operator	This section must include: Plant name Plant license number Premises address Full company name The company registration number Full registered office address

This must include the details of your specific plant / company

Column 1 – This sets out the different processes involved in a BSE testing regime. This column should not be amended when drafting your own RMOP.

Column 2 – This column is used to describe the specific actions / procedures which will be used by an abattoir to comply with each stage of the testing regime. The column will be specific to your abattoir and will need to describe in enough detail the actions and procedures involved so that someone who does not know the specific abattoir can understand it.

Column 3 must be completed to identify the specific job title of abattoir staff responsible for abattoir actions and the MHS staff responsible for MHS actions and supervision.

All documents and records required to be maintained in accordance with this RMOP must be made available for a minimum of 12 months from creation.

WHEN DRAFTING THIS RMOP THE OPERATOR SHOULD USE THE PROTOCOL DOCUMENT (INCLUDED IN THE APPLICATION PACK) FOR GUIDANCE. THE OPERATOR WILL ALSO NEED TO BEAR IN MIND:

- Plant specific HACCP Plan
- HSE Guidance
- VLA guidance
- Hide protocol and cutting plant protocol (if applicable)
- Current hygiene and welfare legislation

The text in this column must not be amended

This needs to be a position i.e. slaughterhouse manager

Column 1	Column 2	Column 3
Requirement	Description of facility, system and control procedure by which the requirement will be met	Personnel Responsible
<p>1. Identification of all eligible cattle to be tested (See Section 2 of the testing protocol)</p> <p>There must be a system to ensure that all eligible cattle, which require testing, are identified prior to slaughter.</p>	<p>1. This section should include your procedures for dealing with non-eligible animals i.e. pre-August 1996 or UTM animals. This section must describe how 'over thirty month' animals will be identified. The section needs to include the system in place for checking ear tags and passports prior to slaughter. Then the section needs to describe the system that will be used to segregate eligible cattle from any non-eligible cattle prior to separate slaughter.</p> <p>2. A member of your staff must ensure that all OTM cattle to be tested are identified for example, with colour marking of the hide.</p>	<p>Lairage Manager (for example)</p> <p>MHS staff supervision required</p>
<p>2. Slaughtering Schedule (See Section 3 of the testing protocol)</p> <p>Identification and separation of eligible and non-eligible cattle.</p>	<p>1. This section must include a statement that all OTM bovines must be identified (as above).</p> <p>2. This section must also include the following:</p> <ul style="list-style-type: none"> • Details of when OTM cattle will be slaughtered e.g. after the completion of the slaughter of any under thirty month cattle. <p>3. This section must also set out how casualties will be dealt with.</p>	<p>Slaughterhouse manager for example</p> <p>MHS staff supervision required</p>

<p>3. Sampling procedure (See Section 4 of the testing Protocol)</p> <p>Follow the correct sampling procedure to ensure all samples are adequate to be tested and follow good hygienic practices to minimise the risk of cross-contamination. Full compliance with the relevant hygiene legislation is required.</p>	<ol style="list-style-type: none"> 1. Operatives doing the sampling must be trained to ensure they can take an adequate brain stem sample according to the instructions and training given by the Veterinary Laboratories Agency (VLA) or cascaded within plants . This section should include a statement on how training has been delivered. This statement should also include a cross reference to the location of your records of staff trained in brainstem sampling. 2. The section should also include a detailed description of where and how the sampling will take place remembering that: <ul style="list-style-type: none"> • Sampling should be carried out in a way to minimise the risk of cross-contamination; • When carrying out sampling, the operative must wear the appropriate protective clothing according to health and safety instructions issued by the HSE and complementary guidance provided by the VLA. • This section should also include confirmation that a risk assessment has been completed on all cleaning work and waste systems in your abattoir, as required by the HSE guidance 3. This section must also describe how samples will be packaged and how they will be dispatched to the testing laboratory. It should also state which testing laboratory the samples should be sent to. It should include a detailed description of who will be responsible for the custody of samples between sampling and arrival at the laboratory. It must include a statement about how the samples will be securely held whilst awaiting collection. 4. The section should also include a statement that the number of samples being submitted will be faxed or e-mailed to the laboratory in advance of delivery. The statement should include the relevant laboratory fax number. If results are to be downloaded from the LGC internet results service, this should be stated, and confirmation given that user ID and password have been obtained from LGC. 	<p>Slaughterhouse manager for example</p> <p>MHS staff supervision required</p>
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<p>4. Traceability of sample to carcass (Section 6 of the testing Protocol)</p> <p>The plant operator must maintain traceability from the slaughtered animal to its brainstem sample and to its carcass and all body parts by use of an identification number or system throughout the testing regime.</p>	<ol style="list-style-type: none"> 1. This section must include a description of how brainstem samples will be correlated to the slaughtered animal, and its carcass and other body parts throughout the slaughter retention and disposal process. 2. Such a system may be electronic (i.e. generation of barcode labels) and/or manual (i.e. physical marking or tagging) 3. The section below will also need to explain how any retained offal's are to be individually identified, or if retained in batches, how the traceability system will allow the identification of which tested animals these offal's were derived from. 4. Similar information will need to be provided for the traceability of blood and hides. 5. The text must describe the process of traceability from the slaughtered animal through to brain stem removal and subsequent retention of the carcass and body parts (see below) pending receipt of the test result. 6. The sample pot must be labelled with the correct label (using either the manual or electronically generated barcode label) and this will need to be applied vertically on the side of the pot (i.e. not wrapped around the pot). If using an electronically generated label, this Section should describe the information being recorded and the processes involved, and provide details of any contingency arrangements which have been put in place in case of IT failure or malfunction. 	<p>Slaughterhouse supervisor / manager for example</p> <p>MHS staff supervision required</p> <p>Whatever traceability system is used, it must be consistent with existing meat hygiene regulations</p>
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<p>5. Traceability of all parts of the tested cattle to the sample. (See Section 7 of the testing Protocol)</p> <p>The plant operator must agree with the OVS a reliable method to identify the retained carcass(es) and all body parts.</p>	<p>1. This Section complements the Section above. It needs to set out the system which will be used to correlate the slaughtered animal and its brain stem sample to all body parts involving the following as a minimum:</p> <ul style="list-style-type: none"> • Red offal • Green offal • Hides • Blood <p>2. This section must specify if these products will be correlated individually to a sample or correlated to a batch of samples which would lead to a requirement to incinerate the entire batch if there is a positive or no test result.</p>	<p>Slaughterhouse manager for example</p> <p>MHS staff supervision required</p>
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<p>6. Retention criteria (See Section 8 of the testing Protocol)</p> <p>There must be suitable and sufficient facilities for the holding of carcasses as required by the hygiene legislation and all body parts (ie organs, tissues, blood and hide) of slaughtered and sampled OTM animals until the operator receives the results or material must be destroyed by incineration.</p>	<p>1. This section must set out how carcasses and all other body parts will be secured whilst awaiting results. The testing protocol sets out the methods available for securing carcasses and all other body parts and these are:</p> <p><u>-In a detained chiller.</u></p> <p>Carcasses awaiting test results in a detained chiller must not come into contact with other detained carcasses awaiting further examination by an inspector or OVS in accordance with hygiene legislation.</p> <p><u>-In a chiller other than a detained chiller.</u></p> <p>Carcasses awaiting test result must be stored in order of kill and cross contamination minimised. Carcasses must be in a dedicated chiller or stored on sealed rails. The method of sealing any rails should be specified.</p> <p>(iii) The method of retaining offals, any other body parts and hides should also be explained here.</p> <p>The section must also contain:</p> <ul style="list-style-type: none"> • A description of how SRM removed from carcasses must be retained or disposed of by incineration if destroyed before a negative result is received. • A description of how any test carcass or part of a test carcass that is identified as unfit for human consumption at post mortem inspection, must be held as an animal by-product until the tests results are received. If this material is not retained until the tests results are received, it must be promptly disposed of as Category 1 Animal By-Product (SRM) by incineration. • A description setting out that if hides are retained in the slaughterhouse they must be retained either (a) individually identified, enabling correlation with the particular test result or (b) with a batch correlation system. The batch must be clearly labelled “pending test result”, including number of hides in the batch and the date of slaughter, until the test result is available. If ‘tested’ hides are to be moved from the abattoir to a hide premises prior to receipt of test results, a separate hides protocol must first have been agreed and signed by the abattoir operator, the hide premises operators and MLC. The hide protocol must be shown to the OVS and referred to in the RMOP in order to reflect the procedure the operator intends to follow for hides. <p>2. This section must also include an explanation that MHS staff will ensure that all holding areas are secure and that all parts of tested animals are retained under official control until the results are provided by the plant operator or disposed of by incineration.</p> <p>3. Locks may not be opened on detained chillers and seals may not be broken on other chillers, except by MHS staff.</p>	<p>Slaughterhouse manager for example</p> <p>MHS staff supervision required</p>
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<p>7. Disposal of by-products (See Section 8 of the testing Protocol)</p> <p>All slaughtering by-products not stored until the results are received for whatever reason, must be disposed of by incineration.</p>	<ol style="list-style-type: none"> 1. This section needs to set out how any material which is not stored awaiting a test result will be disposed of as Category 1 Animal By-Product (SRM) by incineration. 2. Rumen and gut contents must be disposed of in accordance with existing procedures and do not need to be retained or sent for disposal by incineration. 	<p>Slaughterhouse manager for example</p> <p>MHS staff supervision required</p>
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<p>8. Test Results (See Section 10 of the testing Protocol)</p> <p>Test results must be presented to the MHS staff.</p> <p>MHS staff must supervise the health marking or the disposal of carcasses. (See below).</p>	<p>The section should state whether the abattoir will be receiving results through the internet or by fax. If using the internet results service, this section should refer to the register of people to which you have given authorisation to access the service. If you have decided to use a fax system then the relevant fax number should be stated here.</p> <p>If results are to be faxed, the fax machine must be left on overnight (as the testing laboratory undertakes the testing throughout the night).</p> <p>Where hides are moved to other premises in accordance with an agreed hide protocol, the abattoir operator will need to send a copy of any positive or 'no test' test results to the hide premises operator</p> <p>This section also needs to set out what to do after receipt of results:</p> <p><u>Negative result</u></p> <p>Please set out what procedure would be used if there is a negative result.</p> <p><u>Positive results</u></p> <p>Please set out what procedure will be used if there is a positive result</p> <p>Note details of disposal by incineration plant and the method and timing of despatch should be recorded separately, to which the RMOP should refer.</p> <p>If hides are not kept on site, please confirm details of the hides premises where they are kept under official control, how they will be notified of a positive or 'no test' result, and indicate where your copy of the agreed hide protocol can be located.</p> <p><u>'No test'</u></p> <p>Please set out what procedure would be used if there is a no test result, including the details required for a positive result, as above. <u>It should be noted that the 1 before and 2 after rule will apply to any 'no test' results</u></p>	<p>Slaughterhouse manager for example</p> <p>MHS staff supervision required</p>
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<p>9. Health marking (See Section 11 of the testing Protocol) Carcases and offals that are awaiting the test result must not be health marked until a negative result is received.</p>	<p>This section must include an explanation of how 'cold' health marking of negative carcasses and offals after the results have been received, will be achieved.</p> <p>Depending on whether it has been agreed with the OVS this section can also set out a statement on whether the plant staff will provide assistance to the MHS when carrying health marking.</p>	<p>Chiller manager for example</p> <p>MHS staff supervision required</p>
<p>10. Dispatch of carcasses to remove vertebral column in an additionally licensed cutting plant (See Section 13 of the testing Protocol)</p> <p>OTM animals slaughtered for human consumption require the vertebral column removed in cutting premises licensed for the purpose under the TSE Regulations, and treated as SRM.</p> <p>Following health marking, carcasses have to be loaded for dispatch to the cutting plant by plant staff. The plant operator must ensure that the destination cutting premises is additionally licensed to remove vertebral column.</p>	<p>After OTM carcasses have been health marked they will need to be dispatched to an additionally licensed cutting plant to have the vertebral column removed. You should record details of the location of any cutting premises used, including confirmation that they are additionally licensed. This confirmation should be made well in advance of the first despatch of any consignment.</p> <p>Plant operator must inform MHS staff 48 hours (or shorter notice if agreed by both parties) of dispatch of OTM carcasses for VC removal.</p> <p><u>Note</u> The plant operator must supply MHS staff with the following information before despatch of every load for Vertebral Column removal:</p> <ul style="list-style-type: none"> - Name, licence number and location of cutting plant - Number of carcase - Anticipated date & time of dispatch <p>After loading, the operator must:</p> <ul style="list-style-type: none"> - Seal the vehicle under direct MHS supervision - Complete the commercial document - Ensure paperwork with the consignment details accompanies the load in transit 	<p>MHS staff-Slaughterhouse manager.</p> <p>MHS staff supervision required</p>

THE ABOVE DETAILS MUST NOT BE CHANGED WITHOUT FIRST HAVING GIVEN WRITTEN NOTICE TO YOUR OVS AND HAVING OBTAINED HIS/HER AGREEMENT TO THE INTENDED CHANGE. ALL THE PROCEDURES WITHIN THIS PROTOCOL BECOME BINDING BETWEEN THE PARTIES AS FROM THE DATE SPECIFIED BELOW AND CAN BE REVOKED / SUSPENDED BY THE COMPETENT AUTHORITY OR THEIR AGENTS.

THE SIGNATURES WITHIN THIS SECTION ARE FOR ADMINISTRATIVE PURPOSES ONLY, AND DO NOT FORM PART OF THE RMOP AGREEMENT

MHS Area Official Veterinarian	MHS Veterinary Advisor	MHS Official Veterinary Surgeon
Signature	Signature	Signature
Print Name.....	Print Name.....	Print Name.....
Position.....	Position.....	Position.....
Date.....	Date.....	Date.....

Slaughterhouse Occupier

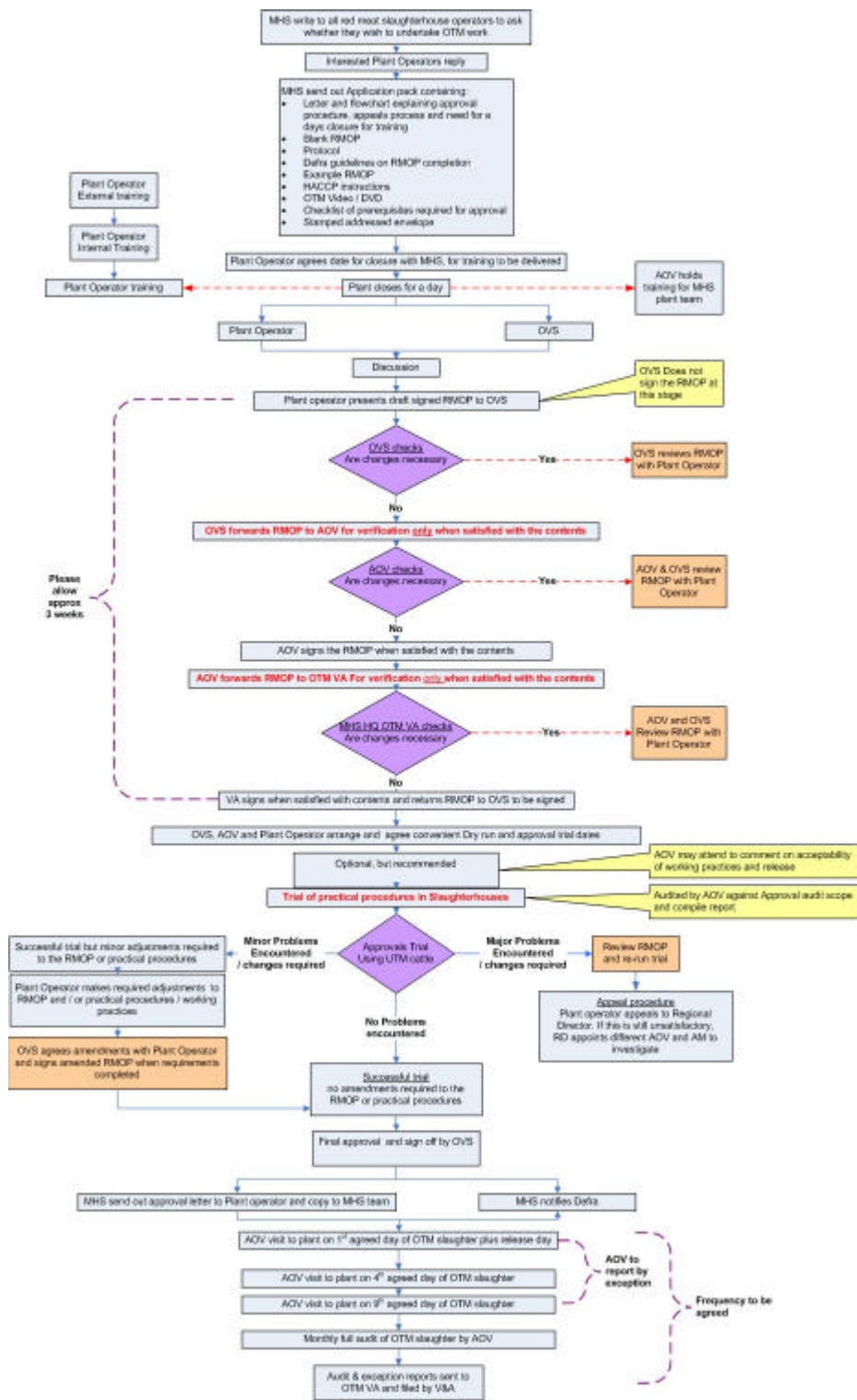
Area Official Veterinarian

(Only to be signed following a successful practical implementation trial)

Signature
 Print Name.....
 Position.....
 Date.....

Signature
 Print Name.....
 Position.....
 Date.....

ABATTOIR APPROVAL PROCESS MAP



Protocol for removal of SRM, bovine vertebral column in cutting plants

Requirement	Operator Responsibility	MHS Responsibility
Removal of vertebral column in licensed cutting plants	Bovine carcasses or part carcasses containing SRM vertebral column (VC), must be consigned to a cutting plant additionally licensed, under the TSE Regulations 2002, for the VC to be removed. (EU rules on SRM VC are attached at Appendix A)	
Applying for an additional licence	The operator should obtain an application pack from the MHS. The application form should be completed and signed and the countersignature of the OVS obtained. An RMOP should also be prepared (see below) The operator should submit the completed application form to MHS HQ only once the RMOP has also been agreed	The plant OVS should sign the completed application only once they are satisfied the plant has the facilities and expertise to remove SRM VC in compliance with the legislation. An RMOP should also have been agreed with the operator before the licence application is signed by the OVS.
Required Methods of Operation Procedures (RMOP)	Before an additional licence can be issued the cutting plant occupier must produce a detailed RMOP describing how the plant will process cattle carcasses requiring the vertebral column to be removed as SRM. (An example RMOP will be included in the application pack) The RMOP must be completed and signed by the plant occupier and agreed and signed by the plant OVS. The occupier must then submit the completed licence application and RMOP to MHS HQ.	OVSs must ensure that the RMOP contains all the steps of production with detailed procedures for each step. OVS must sign the RMOP after consulting the AOV and MHS HQ OTM VA. Once the RMOP is agreed and the OVS is satisfied the terms and conditions of the additional licence can be complied with, the licence application can be authorised. The signed licence should then be sent to MHS HQ to approve and issue the licence.
Consignment of carcasses to the cutting plant	The slaughterhouse operator must ensure that the recipient cutting premises is additionally licensed to remove SRM vertebral column well in advance of sending the first consignment. (iv) The operator must inform the plant OVS a minimum of 48 hours in advance (or a mutually agreed shorter period of notice) of despatch of OTM carcasses for boning to either on-site boning room ie combined premises, or separate* premises. Details should include - name, licence number and location	An MHS officer at the slaughterhouse must verify that the receiving cutting plant has been additionally licensed under the TSE Regulations prior to despatch. MHS staff at the despatching abattoir must: - inform MHS at the cutting plant of the intended OTM consignment, its content and anticipated date and time of despatch/arrival; - undertake random spot checks on a minimum of 15% of the carcasses

	<p>of licensed cutting premises*;</p> <ul style="list-style-type: none"> - number of carcasses or part carcasses intended for despatch which require VC SRM removal; - anticipated date and time of despatch/arrival. <p>(v) The Operator is also responsible for;</p> <ul style="list-style-type: none"> - sealing the vehicle* - completing the Commercial Document (CD)* - ensuring paperwork containing consignment details accompanies the load in transit*. 	<p>for despatch to verify that labelling and identification are in order;</p> <ul style="list-style-type: none"> - Complete section A of the transfer document - Retain a copy on site for 12 months. - Complete Day book
<p><i>Receipt of the carcasses for VC removal at the cutting plant</i></p>	<p>The receiving cutting plant operator is responsible for;</p> <ul style="list-style-type: none"> - informing the MHS that load is on site and operatives are ready for unloading - Unsealing and unloading the vehicle*. - on unloading ensuring the segregation of the carcasses or part carcasses requiring VC to be removed as SRM from those not containing SRM VC. (bovine carcasses containing VC which is not SRM should have been marked with a blue stripe label in the slaughterhouse. If such label is not displayed, the carcass must have the vertebral column removed as SRM) - agree with the MHS a time when it is anticipated that VC SRM removal will be undertaken; <p>* Applies to off-site cutting premises only. All other criteria apply to both on-site and off-site premises.</p>	<p>MHS staff at the receiving cutting premises must;</p> <p>Be aware of incoming consignments;</p> <ul style="list-style-type: none"> - schedule visits to cutting premises to cover hygiene and VC removal activities simultaneously; - remain on-site during unsealing and unloading. MHS may be on-site simultaneously undertaking hygiene checks. Any supervision of either hygiene or VC SRM removal must not adversely impact on the other; - during unloading undertake a minimum of 15% random, spot checks to verify paperwork ie MHS transfer document & CD, and that identification and labelling correlate. Note: Imported carcasses currently require 100% checks at intake. - verify segregation of carcasses containing SRM VC from non SRM VC carcasses [blue striped labelled] i.e. carcasses are stored in easily identifiable batches in the chiller. - Ensure that the operator has a satisfactory staff training programme on TSE controls, in place

<p>Removal and disposal of SRM VC</p>	<p>The occupier must;</p> <ul style="list-style-type: none"> - ensure carcasses containing SRM vertebral column are batched and processed separately - remove SRM vertebral column in accordance with the Regulations - label meat to indicate place of boning - ensure that practices limit cross contamination with SRM. - ensure SRM VC is stained and disposed of as Cat. 1 ABP. - weigh/estimate weight of SRM. - prior to disposal, store SRM in clearly identifiable, leak-proof, lidded bins. - inform MHS of destination of SRM - allow random inspection of carcasses by MHS inspectors to verify SRM removal. 	<p>MHS staff must;</p> <ul style="list-style-type: none"> - remain on-site throughout boning. MHS may be on-site simultaneously undertaking hygiene checks. Any supervision of either hygiene or VC removal must not adversely impact on the other; - verify that meat requiring VC removal as SRM is processed in one batch on one boning line; - verify VC is removed. MHS undertake at least 15% random spot checks on meat during boning. - Ensure that plant practices limit cross contamination with SRM. - check SRM collected; is weighed/weight estimated; stained and destination confirmed.
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Appendix A: Rules on bovine vertebral column

1. The Community TSE Regulation (EC 999/2001 (as amended)) specifies that the vertebral column excluding the vertebrae of the tail, the transverse processes of the lumbar and thoracic vertebrae and the wings of the sacrum, but including the dorsal root ganglia of bovine animals over 12 months is designated as specified risk material.
2. A derogation from this rule has been granted to the United Kingdom, where the rule is applied to bovines over 30 months of age at slaughter.
3. In addition, the rule does not apply to bovines which were born continuously reared and slaughtered in the following countries:

Member States:

Sweden

Third Countries

The countries listed below are exempt from the Community TSE Regulations.

Argentina, Australia, Botswana, Brazil, Chile, Costa Rica, El Salvador, Iceland, Namibia, New Zealand, Nicaragua, Panama, Paraguay, Singapore, Swaziland, Uruguay, Vanuatu

RESPONSIBILITIES FOR PROPOSED TESTING REGIMEN

Abattoir and laboratory testing instructions	Defra DARD in Northern Ireland
Approval of abattoirs and cutting plants	Meat Hygiene Service (MHS) (FSA executive agency, acting under service level agreement with Defra) for abattoirs MHS on behalf of FSA for cutting plants DARD Veterinary Service in Northern Ireland
Supervision and enforcement of abattoir procedures	MHS DARD Veterinary Service in Northern Ireland
Initial quality control of laboratory procedures	Individual laboratories (LGC in GB and DARD Veterinary Science Division in Northern Ireland)
Second layer of quality control and audit	Veterinary Laboratories Agency (VLA)
Day to day operational responsibility	Individual abattoirs and laboratories
Audit and review of the entire system	FSA

¹ All parts of all tested cattle for which results are not yet available must be retained or destroyed as Category 1 A or 1 B animal by-product, i.e. needing incineration as opposed to Category 1C, which can be rendered, and land filled. Similarly, all parts of an animal that tests positive (and 1B2A on slaughter line where necessary) or for which there is no clear negative test result must be destroyed by incineration.