**FOOD STANDARDS AGENCY IN SCOTLAND CONSULTATION**

**CHANGES TO PIG MEAT INSPECTION IN JUNE 2014**

**CONSULTATION SUMMARY PAGE**

<table>
<thead>
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<th>Date consultation launched:</th>
<th>Closing date for responses:</th>
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<td>25 March 2014</td>
<td>28 April 2014</td>
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**Who will this consultation be of most interest to?**
Food Business Operators (FBOs) in FSA approved pig meat slaughterhouses, pig farmers and officials working in pig meat establishments.

**What is the subject of this consultation?**
UK implementation of directly applicable EU legislation that introduce changes to pig meat inspection that apply from 1 June 2014. The changes include the visual inspection of pig carcasses and offal by officials at post mortem; a strengthened Process Hygiene Criterion (PHC) for Salmonella and a more risk based Trichinella testing regime.

**What is the purpose of this consultation?**
Our plans for implementation at an advanced stage, building on extensive discussions we have had with stakeholders, including industry groups and enforcement colleagues. The purpose of this formal consultation is to seek stakeholder views on the practical application of the changes and also to determine whether the FSA’s assumptions are a fair reflection of costs, benefits and wider impacts for stakeholders. The overall objective is to ensure that the controls are proportionate and risk-based, taking into account the latest scientific evidence and information and views from producers and consumers, and continue to provide public health, animal health and animal welfare protection.

**Responses to this consultation should be sent to:**
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<table>
<thead>
<tr>
<th>Is a Business &amp; Regulatory Impact Assessment (BRIA) included with this consultation?</th>
<th>Yes</th>
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If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.
CHANGES TO PIG MEAT INSPECTION IN JUNE 2014

DETAIL OF CONSULTATION

Introduction

1. From 1 June 2014, directly applicable EU legislation introduce three changes of direct relevance for pig slaughterhouses. They are:
   a. The visual inspection of pig carcases and offal by government officials by default;
   b. A strengthened Salmonella testing regime; and
   c. A more risk based Trichinella testing regime.

2. The new regulations were published in the Official Journal of the European Union on 8th March 2014:


Background

3. The changes are based on scientific evidence from the European Food Safety Authority (EFSA) which identified that microbiological and parasitic contamination are the key hazards from pig meat and that traditional inspection measures are not effective at controlling these hazards. The changes aim to better protect public health in line with this evidence, and to provide a more risk based and proportionate system.

4. These changes form part of a programme of work to modernise meat inspection across the EU. A further series of European Commission proposals covering poultry, red meat and game meat inspection are expected to follow over the coming months.

Proposals

Visual inspection of pig carcases and offal by government officials by default

5. From 1 June 2014, officials working in pig slaughterhouses will no longer carry out routine incision and palpation of pig lymph nodes and organs. Palpation and incision will still be carried out where such further inspection procedures are deemed necessary. During ante mortem inspection, the Official Veterinarian (OV) will assess whether a batch of pigs or an individual animal requires further post mortem inspection procedures to judge the fitness for human consumption; and during post mortem inspection, officials may need to detain pig carcases or offal for closer inspection, for example where visible abnormalities suggest a generalised condition.
6. The criteria for visual inspection, developed in conjunction with industry and enforcers, are attached to this consultation, at Annex E, and we welcome final views on them.

**Salmonella testing**

7. Under existing requirements, UK food business operators (FBOs) processing over 37,500 pigs a year are required to sample carcases and test for Salmonella as a process hygiene criterion. From June, the level of permitted positives will be reduced from 5 (the current level) to 3, out of 50 samples over a ten week period. The requirement still only applies to FBOs processing over 37,500 pigs a year; for those FBOs processing less than 37,500 pigs a year (which is the majority) there is no change from the existing requirements.

8. The number of Salmonella samples taken in the slaughterhouse and the number of positive results found will be collected by the FSA. This data will be anonymised and submitted to the European Commission annually. The European Commission will gather similar data from all EU Member States.

9. Currently, OVIs need to monitor that corrective action is taken by the FBO when Salmonella trends start to approach non-compliance. From June, in the case of repeated unsatisfactory results the FBO will need to draw up an action plan to address the problem, which will be strictly supervised by the OV.

**Trichinella testing**

10. FBOs are currently required to test 100% of pigs sent to slaughter for Trichinella, but this requirement has not been fully implemented in the UK. From June the Trichinella testing requirement will become more risk based.

11. The new legislation will set out testing requirements for:
   - All sows and boars or 10% of pigs from controlled housing conditions to be tested for Trichinella;
   - All pigs that do not originate from “controlled housing conditions” to be tested for Trichinella.

12. The requirements for “controlled housing conditions”, which mainly concern farmers, are set out in Regulation 216/2014 (see link on page 2). FSA data suggests that there around 300,732 pigs that go for slaughter in Scotland each year, of which approximately 8% (24,058) are from what could be considered as holdings not operating controlled housing conditions (‘outdoor reared’ pigs that spend up to 12 weeks outdoors) and would have to be tested under the proposal. This is a high impact scenario that will be informed by further risk assessment.

13. The housing conditions on the farm will need to be stated on the Food Chain Information (FCI) accompanying the pigs from June.

14. The draft Scottish Statutory Instrument (SSI) attached, at Annex D, carries over the existing powers with regard to Trichinella currently set out in the Food Hygiene (Scotland) Regulations 2006. This SSI is necessary as the new EU Regulation amends both articles and annexes, which means that the ambulatory references could not carry over all existing powers.
Key proposals

Visual inspection of pig carcases and offal by government officials by default

The key proposal is that officials no longer carry out incision and palpation inspection tasks as routine on pig carcases and their offal. The criteria to assist officials in deciding at ante or post mortem inspection whether a carcase or its offal require palpation and incision (or other inspection methods) are attached at Annex E.

Salmonella testing

The key proposal is that the number of permitted positive results in any ten week period (or 50 samples) is reduced from five to three in slaughterhouses processing more than 37,500 pigs annually.

Trichinella testing

The key proposal is that all sows and boars or 10% of pigs from controlled housing conditions to be tested for Trichinella. To fulfil this, we propose that all sows and boars in the UK are tested (this is no change from the current situation). All pigs not from controlled housing conditions will require testing.

Consultation

15. There has been ongoing communication with stakeholders throughout the EU negotiations of the proposals and during the development of the national application of the changes. The FSA held a number of ad hoc meetings with key organisations to help inform its discussions, and these meetings have informed this consultation and the accompanying three Business and Regulatory Impact Assessments (BRIAs) attached at Annex B1 to B3.

16. The draft criteria for visual inspection have been drawn up with the input from industry groups and colleagues working in enforcement at pig slaughterhouses. We intend to gather further final views over the consultation period, including through trialling the criteria in a number of slaughterhouses across the UK. The overall delivery of the work is led by a programme board with representation from both enforcement and industry representatives on it. We intend to run a series of workshops for enforcement colleagues in April to gather views and will also hold further meetings with industry bodies and trades unions in this period.

17. This consultation seeks your views on the changes and a number of key questions are raised in the accompanying BRIAs and have been compiled in the box below for ease of reference. We would also be interested in your comments about any other aspect of the proposals that you would like to bring to our attention.

QUESTIONS asked in this consultation (contained with the individual BRIAs)

ANNEX B1: Visual inspection of pig carcases and offal by government officials by default

Consultation Question 1:
It is our assumption that the new requirement will reduce inspection times per carcase which may lead to efficiency benefits to slaughterhouses. We invite stakeholders to comment on whether this assumption is correct. If you agree or disagree, please provide us with as detailed
information and data as possible for us to be able to monetise this potential benefit (for example, in terms of a reduction in time and resources needed).

**Consultation Question 2:**
It is our assumption that having the inspection team carry out verification tasks on a daily basis during the first six months will not increase the burden on industry or enforcement. We invite stakeholders to comment on whether this assumption is correct. If you disagree, please provide us with as detailed information and data as possible for us to monetise this potential cost.

**Consultation Question 3:**
We invite stakeholders to comment on whether our assumption that reporting cases of endocarditis is likely to impose minimal costs on FBOs. If you disagree, please provide us with as detailed information and data as possible (e.g. expected reporting arrangements adopted, associated time and resource requirements) so that we can monetise this potential cost.

**Consultation Question 4:**
It is our assumption that the new requirements may cause a temporary increase in the number of detained carcases, and that this may slow down line speed and increase the inspection time per carcase. We invite stakeholders to comment on whether this assumption is correct. If you agree or disagree, please provide us with as detailed information and data as possible for us to be able to monetise this potential cost.

**Consultation Question 5**
Meat inspectors are required to declare if red offal is unfit for human consumption, but the legislation does not specify who should remove any abnormalities found. As meat inspectors would no longer routinely carry knives, we are proposing that removal of abnormalities should be carried out by the FBO. We invite stakeholders to comment on whether they agree with this approach. If you disagree, please provide as detailed information and data as possible so that we can monetise any potential cost.

**ANNEX B2. Salmonella testing**

**Consultation Question 1:**
We currently have limited data to monetise the impact of the lowering of the c value from five to three. We invite stakeholders to comment on the impact of this requirement:
- How would your current sampling frequency change in terms of number of per annum tests taken?
- How would your sampling costs change in terms of per annum pounds spent on sampling?

**Consultation Question 2:**
We invite stakeholders to comment on whether the lowering of the threshold from five to three may increase their costs of corrective action:
- How would the frequency of corrective action change, in terms of per annum occasions?
- How would your per annum costs change, in terms of time and resources spent on corrective action?
- How would the requirement of an action plan impact on costs – how much additional time and resources are likely to be spent on implementing an action plan per annum?

**Consultation Question 3:**
We envisage that the costs to slaughterhouses from CA collection of sampling data would be minimal. If you agree or disagree, please provide us with as detailed information and data as possible.
Consultation Question 4:
We invite stakeholders to comment on the potential costs to farmers from an increase in the number of on-farm investigations:

- How would the frequency of reviews of on-farm controls change, in terms of per annum occasions?
- How would your per annum costs change, in terms of time and resources spent on on-farm investigations?
- Would the regulation be associated with any familiarisation costs to farmers?

Consultation Question 5:
Currently OVs need to monitor that corrective action is taken. We invite stakeholders to comment on the costs to enforcement from a potential increase in the frequency of corrective action:

- How would the per annum costs change, in terms of time and resources spent on monitoring that corrective action has been taken?
- What would be the per annum costs of supervising the outcome of action plans in terms of time and resources spent?

ANNEX B3: Trichinella testing

Consultation Question 1:
We would welcome any evidence regarding the distribution of pigs from non-controlled housing: In Scotland what proportion of pigs from non-controlled housing is likely to be slaughtered in micro, small, medium, large slaughterhouses, and what proportion is already tested for Trichinella?

Consultation Question 2:
We invite stakeholders to comment on whether our estimates of familiarisation costs to slaughterhouses seem reasonable or not. Please provide us with as detailed information and data as possible (e.g. hours required, grade involved) for us to be able to monetise this cost.

Consultation Question 3:
We invite stakeholders to comment on whether our estimates of the cost of additional testing seem reasonable or not:

a. Do you agree with our high impact scenario (informed by discussions with industry) that approximately 8% of the total Scottish pig kill from late 2015 onwards could be considered as reared in non-controlled housing conditions? What proportion of these pigs are likely to already be tested for Trichinella?

b. Do you agree with our assumption that all additional tests under this proposal would be carried out using a private accredited laboratory, at least initially, at a cost of £4.09p per sample?

If you agree, or disagree, please provide us with as detailed information and data as possible for us to monetise this potential cost.

Consultation Question 4:
We invite stakeholders to comment on whether our estimates of the cost of setting up in-house labs seem reasonable or not. If you agree, or disagree, please provide us with as detailed information and data as possible for us to be able to monetise this cost, in particular:

a. What proportion of micro, small, medium and large slaughterhouses are likely to set up an in-house lab as a result of the new requirements?
b. What would be the approximate one-off cost to set up an in-house laboratory?
Would there be any costs involved for plants that make arrangements to use the in-house lab of a nearby FBO?

**Consultation Question 5**
We invite stakeholders to comment on whether our estimates of the cost to farmers in the following areas seem reasonable or not:

- a) changes to FCI
- b) familiarisation

Please provide us with as detailed information and data as possible for us to be able to monetise this cost.

**Responses**

18. We welcome comments from all stakeholders. Please send your response by email or post using the contact details given. All responses received as part of this consultation will be given careful consideration; they will be summarised and published on the FSA’s website within three months of the close of the consultation.

19. This is a shortened 5 week consultation and therefore responses are required by **Monday 28 April 2014**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation or company (including details of any stakeholders your organisation represents).

20. Thank you on behalf of the Food Standards Agency in Scotland for participating in this public consultation.

Yours sincerely,

Karen Robertson
Standards & Hygiene Associated Regulatory Policy

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**Enclosed:**

- Annex A: Standard Consultation Information
- Annex B: Partial Business and Regulatory Impact Assessments (BRIAs)
- Annex C: List of Interested Parties
- Annex D: Draft SSI The Food Hygiene (Scotland) Amendment Regulations 2014
- Annex E: Draft criteria for visual inspection
Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness, our office in St Magnus House in Aberdeen will hold a copy of the completed consultation. The FSA will also publish a summary of responses, which may include full name. Disclosure of any other personal data would be made only upon request for the full consultation response. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.

7. Please let us know if you need paper copies of the consultation documents or of anything specified under ‘Other relevant documents’.

8. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: http://www.berr.gov.uk/files/file47158.pdf The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult
Formal consultation should take place at a stage when there is scope to influence the policy outcome.
Criterion 2 — Duration of consultation exercises
Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact
Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises
Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees’ buy-in to the process is to be obtained.

Criterion 6 — Responsiveness of consultation exercises
Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 — Capacity to consult
Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

9. Criterion 2 states that Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible. However, this consultation is not being held for a full 12 weeks in order to be in alignment with the other UK administrations.

10. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the partial Business & Regulatory Impact Assessment at Annex D.

11. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

12. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

13. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc. The questionnaire can also be used to update us about your existing contact details.
PARTIAL BUSINESS AND REGULATORY IMPACT ASSESSMENT (BRIA)

POST MORTEM INSPECTION OF PIG MEAT AT SLAUGHTERHOUSES

File No: RPB/FSAS
Date: March 2014
Stage: Consultation
Source of intervention: EU
Contact for enquiries: Karen Robertson
Phone No: 01224 288362
Email: karen.robertson@foodstandards.gsi.gov.uk
1. Title of Proposal


1.2 These new EU Regulations will change how government officials working in slaughterhouses carry out post mortem inspections of pig carcases and offal from 1 June 2014.

2. Purpose and Intended Effect

Objectives

2.1 The policy objective is to ensure that post mortem inspection procedures delivered by government officials are risk-based, proportionate and effective at protecting public health, animal health and are in compliance with the requirements of the EU regulations.

Rationale for Government Intervention

2.2 Under existing EU legislation, pig carcases and offal are subject to ante mortem and post mortem inspection by government officials at approved slaughterhouses before their meat can be placed on the market for human consumption. These inspections are carried out to check for signs of abnormalities that would present a public health risk or indicate animal health or welfare concerns. Such abnormalities may ultimately lead to the meat and/or offal being declared unfit for human consumption. The current post mortem system consists of a visual check of the carcase and offal, as well as the routine palpation and incision of specific organs and associated lymph nodes to check for abnormalities.

2.3 Evidence from the European Food Safety Authority (EFSA), supported by research carried out by the Food Standards Agency (FSA), suggests that this system does not adequately identify risks for public health protection. This is because the main cause of foodborne disease is microbiological contamination, which is invisible to the naked eye. Current inspection methods cannot detect such contamination. In fact, the evidence from EFSA suggests that palpation and incision may actually increase the risk of microbiological contamination.

2.4 The new regulation therefore requires that officials no longer carry out palpation and incision of organs and lymph nodes as routine at post mortem inspection. Each carcase and its offal will continue to be inspected visually by an official for signs of visible abnormalities, but physical handling will be minimised and palpation and incision will only take place on a risk basis. For example the risk basis might include where the ante mortem inspection has identified the presence of a specific animal health condition that could be verified through palpation or incision.

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The new regulation is a low-impact simplification of current EU law, which ties in with the Government’s strategic aim of supporting growth. It will have a small benefit to business in terms of the speed of the production process, and will allow government resources to be more effectively deployed in the slaughterhouse. It represents a more risk-based approach to meat inspection in line with the scientific evidence, and may reduce the risk of microbiological cross-contamination of carcases at post mortem.

The regulation was supported by the UK throughout negotiations.

**Background**

**Official controls in slaughterhouses**

The EU Food Hygiene Regulations place responsibility on the operator of a slaughterhouse to ensure that all stages of the production, processing and distribution of food under their control comply with EU Food Hygiene Regulations. The safe production of food is therefore a fundamental legal obligation of the food business operator (FBO).

The FSA is the central competent authority in the UK responsible for carrying out official controls in slaughterhouses in Scotland, England and Wales. In Northern Ireland, the official controls are delivered by the Department for Agriculture and Rural Development (DARD) on behalf of the FSA.

The controls require inspections of all animals, carcases and offal to verify that FBOs comply with EU Food Hygiene Regulations. They include ensuring that the slaughter and dressing process conducted by the FBO is in accordance with the legislative requirements, and that sampling and enforcement are undertaken as required. The FSA in Scotland also undertake official controls on behalf of the Scottish Government Directorate for Agriculture, Food and Rural Communities to ensure compliance with legislative requirements on animal health and welfare.

The EU Hygiene Regulations require the competent authority to carry out ante-mortem and post-mortem inspection on all animals presented for slaughter for human consumption at the slaughterhouse. The purpose of these inspections is to detect abnormalities of public or animal health or welfare significance, or any other factor that might ultimately lead to the meat being declared unfit for human consumption. Table 1 provides an overview of both inspections.

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<th>Ante Mortem Inspection</th>
<th>Post Mortem Inspection</th>
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<tr>
<td>Livestock and poultry delivered to abattoirs in Scotland are inspected by the FSA before slaughter. Ante mortem inspection is performed by the Official Veterinarian (OV), who will check for any signs of disease, injury, fatigue, stress and mishandling.</td>
<td>Every carcase is inspected after slaughter to ensure fitness for human consumption. This is largely the responsibility of the teams of official Meat Hygiene Inspectors (MHIs) working under the supervision of the OV, but may be carried out by the OV in some circumstances.</td>
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<tr>
<td>Only clean, dry animals may progress to slaughter to reduce the risk of contamination</td>
<td>The EU Food Hygiene Legislation sets out specific and prescriptive tasks that need to be</td>
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of the resulting meat.

undertaken by the official delivering post mortem inspection, including a list of organs that require palpating and lymph nodes that require incising to check for abnormalities. Post mortem inspection findings will assist the OV in reaching a definitive diagnosis on the fitness of the carcase and offal for human consumption.

Once a carcase has been passed as fit for human consumption, a “health mark” is applied to it under the supervision of the OV.

FSA Future Meat Controls Programme

2.11 At its meeting in September 2009, the FSA Board established a programme of work to deliver a modernised system of fresh meat controls. The Board agreed that this work would be a strategic priority for the FSA, with the aim of ensuring that fresh meat controls are more risk-based, proportionate and effective. The Board recognised that change could only be achieved through legislative proposals brought forward by the European Commission, and therefore agreed that the Programme would include a significant research component in order to generate evidence that might support any case for change.

2.12 Since 2009, the Future Meat Controls research programme has undertaken 10³ projects over two distinct phases of work with a third phase in the process of being set up. The research projects have generated evidence for proportionate and risk-based approaches for all species, including cattle, wild game, sheep, poultry and pigs. On completion of a peer review, the research projects are published on the FSA website and forwarded to EFSA for consideration, and have been reflected in the EFSA opinions that form the evidence base for the European Commission proposals.

2.13 The full set of published Future Meat Controls research can be found here: http://food.gov.uk/science/research/choiceandstandardsresearch/meatcontrolsprojects/

The European Commission’s 2009 review of EU food hygiene legislation

2.14 Existing EU food hygiene laws (known as the “Hygiene Package”) have applied in the UK since January 2006. These are:

- Regulation (EC) 852/2004 on the hygiene of foodstuffs;
- Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin;

2.15 The regulations were implemented in Scotland by the Food Hygiene (Scotland) Regulations 2006. Similar regulations apply in England, Wales and Northern Ireland. As the regulations took an innovative approach to hygiene legislation, the Hygiene Package contained the legal requirement for the European Commission to submit a

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3 http://food.gov.uk/enforcement/monitoring/meat/reviewofmeatcontrols/
report to the European Parliament and Council reviewing the experience gained from their application.

2.16 A few years after the Hygiene Package came into effect, the Commission began gathering evidence for its review from Member States, industry and consumer representatives, and the Commission’s Food and Veterinary Office. The Commission submitted its conclusions to the European Parliament and to the European Council in July 2009 who adopted them⁴.

2.17 Overall, the review concluded that the implementation of the Hygiene Package was satisfactory and there was no need for an extensive revision. In relation to fresh meat controls, the report mentioned the increasing public health importance of hazards that cannot be easily detected by conventional meat inspection, the possible enhancement of the role of official auxiliaries, the need to clarify food business operator and competent authority responsibilities, and the possibility that some tasks could be more appropriately carried out by slaughterhouse staff.

2.18 In May 2010, the Commission requested that EFSA provide scientific opinions on the current inspection system and alternative meat inspection approaches, with the intention of using the outcome of these risk assessments as the primary evidence base for legislative proposals. EFSA were instructed to consider animal health and welfare risks in addition to public health risks from chemical and microbiological contamination.

The European Food Safety Authority opinion on pig meat inspection

2.19 EFSA approached the work by dividing the scientific opinions by species, beginning with pigs, on which it published its scientific opinion in October 2011⁵. EFSA have since also published opinions on poultry and red meat species inspection, for which European Commission proposals are expected to follow in 2014 and 2015.

2.20 In respect of pigs, the food-borne hazards *Salmonella*, *Yersinia enterocolitica*, *Toxoplasma gondii* and *Trichinella* were identified as priority targets at slaughterhouse level, due to their prevalence and impact on human health. It was concluded that current inspection methods do not enable the early detection of the first three of these hazards and, more broadly, do not differentiate food safety aspects from meat quality aspects, prevention of animal diseases or occupational hazards.

2.21 For biological hazards, EFSA recommended omitting the use of palpation and/or incision techniques at post mortem because of the risk of bacterial cross-contamination, introducing a pork carcase safety assurance framework to integrate preventive measures applied on-farm and at the abattoir, and improving Food Chain Information.

2.22 In the area of animal health and welfare, it was noted that the abolition of palpation and/or incision would lead to a reduction in detection of some diseases but that in cases where several organs are affected this effect was likely to be minimal. To mitigate the reduced detection probability of the proposed modified system, EFSA recommended that palpation and/or incision should be conducted as a follow-up to a visual inspection where abnormalities were identified.

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⁵ EFSA Journal 2011;9(10):2351[198 pp.], published 3 October 2011
2.23 In the area of contaminants, dioxins, dioxin-like polychlorinated biphenyls and the antibiotic chloramphenicol were identified as the chemical substances of high potential concern in pork. EFSA concluded that chemical substances at the concentrations found in swine meat are unlikely to pose an immediate or short-term health risk for consumers.

The European Commission’s legislative package for pig meat inspection

2.24 The European Commission developed a legislative package on modernising pig meat inspection in line with the EFSA opinion and presented it to Member States at the Standing Committee on the Food Chain and Animal Health on 21st September 2012. The package achieved a qualified majority of Member State agreement on 22nd May 2013.

2.25 The UK supported the proposals at the vote in May 2013 because they were in line with the negotiating principles endorsed by the FSA Board and subsequently agreed with UK health and agriculture ministers.

2.26 The package consists of three legislative measures:
   i. Visual inspection of pig meat and offal;
   ii. Revised testing processes for Salmonella; and
   iii. Revised testing processes for Trichinella.

2.27 The legislative measures for Salmonella and Trichinella are considered in more detail in separate Business and Regulatory Impact Assessments, attached at Annex B2 and Annex B3 respectively.

2.28 With regard to the other key hazards identified by EFSA, the stricter process hygiene control for Salmonella is also expected to help reduce Yersinia enterocolita microbiological contamination, as general good hygiene practices could improve controls of both microorganisms. The evidence also suggests that no longer routinely requiring the incision of the sub maxillary lymph nodes may contribute to a reduction in the risk of contamination on carcases from Yersinia enterocolita.

2.29 Legislative proposals for Toxoplasma were not proposed, as it was felt that further research was required to develop a better understanding of the epidemiological situation. The FSA is therefore currently collaborating on a Toxoplasma research project with the National Institute of Public Health and the Environment (Netherlands); Agency for Food, Environmental and Occupational Health and Safety (France); Friedrich-Loeffler-Institut (Germany); Stichting Dienst Landbouwkundig Onderzoek (Netherlands); University of Agricultural Science and Veterinary Medicine (Romania); Instituto Superiore di Sanita (Italy); and Royal Veterinary College (UK). The overall aim of the project is to gain information on the presence and infectivity of Toxoplasma cysts in meat and other edible tissues (in the main meat-producing animals), and its relationship with Toxoplasma seroprevalence in animals. The results from this project may provide evidence for future discussions about Toxoplasma controls.

2.30 The Commission opened discussions with Member States on possible improvements in relation to Food Chain Information and increased links between the farm and the slaughterhouse in December 2013. This builds on both the EFSA recommendations

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6 http://www.food.gov.uk/multimedia/pdfs/board/info111102.pdf
and also discussions held at the Lithuanian Presidency’s October conference on meat official controls (“Animals + Humans = One Health”). These negotiations are expected to continue during 2014.

2.31 The original proposals brought forward by the Commission also included a measure that would have permitted MHIs to undertake ante mortem inspection with the OV only required to be present during ante mortem if the MHI had identified abnormalities in the pigs. This was a risk based and proportionate proposal in line with the scientific evidence and was supported by the UK during negotiations. However, due to insufficient support from other Member States, the proposal did not progress.

3. **Consultation**

**Within Government**

3.1 The FSA set up a Cross Government Group on Meat Official Controls (CGGMOC) in 2010. This group includes officials from the FSA in Scotland and also the Scottish Government Directorate for Agriculture, Food and Rural Communities. The group was instrumental in developing the high level UK negotiating principles and played a key role during the negotiations.

3.2 FSA officials with responsibility for operational delivery in pig slaughterhouses are also represented on both the CGGMOC and the Current and Future Meat Controls Group (CFMC), and were engaged throughout negotiations on the pig proposals and the development of the Future Meat Controls research.

3.3 The Scottish Government’s Better Regulation and Industry Engagement team and the Access to Justice Team of the Scottish Government Justice Directorate have been consulted during the preparation of this BRIA.

**Public Consultation**

3.4 A series of nationwide citizen’s forums were conducted between June and July 2010 to explore consumer attitudes to meat hygiene and views on potential changes to meat official controls. One of the changes explored at the forums was the possible introduction of visual inspection at post mortem. Participants indicated that they would favour any changes to meat inspection that were based on robust science with a suitable monitoring system for animal diseases.

3.5 Consumer perspectives were also sought through the FSA Consumer Advisory Panel (CAP), whose role is to provide consumer insights into the FSA’s work by supplementing consumers’ views and opinions obtained from direct engagement. CAP’s preference was that an OV should continue to have oversight of the slaughter process, and advised on communication handling.

3.6 The CFMC was consulted throughout negotiations and included consumer representation.

**Business**

7 http://132968743853066968.weebly.com/index.html

3.7 The FSA has worked in collaboration with industry groups throughout the development of the Future Meat Controls programme, and more recently during the negotiations on the pig proposals. Individual slaughterhouses have assisted the development of the evidence base through contributing to the FSA’s research programme, for example through running pilots on visual inspection in pigs.

3.8 On a policy level, the CFMC includes organisations representing slaughterhouses, the meat processing industry, primary producers and consumers. The Group meets three times a year and contributes to discussions on strategy and planning, both in respect to research and future negotiations.

3.9 In 2011 the FSA established a specific Task Group of the CFMC in relation to pigs to provide comments and feedback on the Commission’s proposals and help inform the UK negotiating position. Input from the Task Group was sought throughout negotiations. This collaborative approach was a success, and a similar approach will be taken when the FSA begins negotiations on other species.

4. Options

4.1 The options considered are:

**Option 1:** Do nothing – do not update UK operational procedures in line with the EU regulation.

**Option 2:** Update UK operational procedures in line with the EU regulation.

4.2 Option 2 would involve updating UK operational procedures so that government officials working in slaughterhouses can routinely carry out visual post mortem inspection of carcases and offal in slaughterhouses, rather than using the traditional methods of palpation and incision. This would apply the rules at a national level, taking into account the UK’s epidemiological situation. The move to visual inspection only would provide a more risk based and proportionate inspection process, clarity for industry and enforcement officials, and potentially improve public health protection.

4.3 **Option 2 is the preferred option.** Issues related to the operational procedures for visual inspection by default are outlined below.

**Incision of Porcine Hearts**

4.4 Under the new regime, government officials will no longer incise porcine hearts as routine during post mortem inspection. As a result, there is a possibility that clotted blood may remain in the chambers of the heart and that porcine endocarditis (the inflammation of the smooth membrane that lines the inside of the heart in pigs) is not detected.

4.5 The presence of blood clots may become a quality issue when the hearts are placed on the market for human consumption. For quality assurance purposes, FBOs may choose to incise hearts to release blood clots. Such a quality control system would also be expected to identify and reject hearts with porcine endocarditis. Where FBOs discover porcine endocarditis during quality control checks they will be asked to
inform officials so that it can be recorded for animal health and welfare surveillance purposes.

4.6 The Risk and Benefit Assessment for Visual-Only Meat Inspection of UK Indoor and Outdoor Pigs\(^9\), funded by the FSA, assessed a large number of diseases/conditions that would potentially be affected by a change to visual inspection methods and also posed a human and/or animal health threat. Only two conditions, porcine tuberculosis and endocarditis, were considered to be of public or animal health and welfare risk and would be less likely to be spotted through visual inspection. The study concluded that very few cases of the pathogens causing endocarditis and associated with human infections are reported each year in Scotland and the majority, if not all, are linked to occupational exposure to pigs or raw pork. The risk of foodborne infection via consumption of pork was considered negligible. Table 2 below shows that the prevalence of endocarditis detected in pig hearts in Scotland over the past three years is extremely low.

Table 2: Level of endocarditis found in pig heart at post mortem inspection in Scotland

<table>
<thead>
<tr>
<th>Year</th>
<th>Total offal throughput</th>
<th>Endocarditis</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>626,729</td>
<td>75</td>
<td>0.012%</td>
</tr>
<tr>
<td>2012</td>
<td>578,034</td>
<td>52</td>
<td>0.009%</td>
</tr>
<tr>
<td>2013</td>
<td>299,957</td>
<td>19</td>
<td>0.006%</td>
</tr>
</tbody>
</table>

**Sectors and groups affected**

**Industry – pig slaughterhouses**

4.7 There are 17 approved pig slaughterhouses in Scotland – two of which are specialist pig slaughterhouses (i.e. pigs only) and the remaining 15 are multi species slaughterhouses. 75.13% of the annual throughput of pigs in 2013 took place in the two specialist pig slaughterhouses.

4.8 The new operational procedures will impact on approved pig slaughterhouses where a default system of visual inspection is adopted. These establishments will incur familiarisation costs. However, there will be potential benefits from a reduction in inspection time per carcase.

**Industry – primary producers**

4.9 We do not envisage any impact on primary producers sending animals to slaughter, as there are no additional requirements for the production of Food Chain Information. The new operational procedures use existing information routes for decision making purposes at ante mortem and post mortem inspection.

**Enforcement**

4.10 The immediate impact will be on those officials who work in approved pig slaughterhouses, such as Meat Hygiene Inspectors (MHIs) and Official Veterinarians (OVs). Changes will also impact on those in related operational management functions, such as Service Delivery Managers (SDMs) and Lead Veterinarians (LVs).
Table 3a below shows the average number of officials in the 17 approved pig slaughterhouses in Scotland and Table 3b shows the current hourly chargeout rates for these officials.

### Table 3a: Average number of officials in pig slaughterhouses in Scotland per week (2013)

<table>
<thead>
<tr>
<th>Role</th>
<th>Scotland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat Hygiene Inspectors</td>
<td>22.7</td>
</tr>
<tr>
<td>Official Veterinarians (FTE)</td>
<td>29.3</td>
</tr>
<tr>
<td>Service Delivery Managers</td>
<td>4</td>
</tr>
<tr>
<td>Lead Veterinarians</td>
<td>2</td>
</tr>
<tr>
<td>Supervisory Meat Hygiene Inspector</td>
<td>2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>60</strong></td>
</tr>
</tbody>
</table>

### Table 3b: Hourly Chargeout Rates of officials affected (2013)

<table>
<thead>
<tr>
<th>Role</th>
<th>Scotland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat Hygiene Inspectors</td>
<td>£28.50</td>
</tr>
<tr>
<td>Official veterinarians</td>
<td>£36.80</td>
</tr>
<tr>
<td>Service Delivery Managers</td>
<td>£31.60</td>
</tr>
<tr>
<td>Lead Veterinarians</td>
<td>£43.25</td>
</tr>
<tr>
<td>Supervisory Meat Hygiene Inspector</td>
<td>£28.50</td>
</tr>
</tbody>
</table>

**Consumers**

4.11 Evidence from EFSA suggests that the main public health risk associated with pig slaughter is microbiological contamination, and that incision and palpation could increase this risk. A move to a system of visual inspection could therefore have a public health benefit in a reduction of this risk.

**Benefits**

**Option 1:** Do nothing – do not update UK operational procedures in line with the EU regulation.

4.12 There would be no familiarisation time/costs incurred with this option, as there would be no change to the existing position. However, this would not prevent the new regulations from coming into force as they are directly applicable across the EU. The UK would therefore be in non-compliance with its legal obligations.

**Option 2:** Update UK operational procedures in line with the EU regulation.

**Benefits to Industry – pig slaughterhouses**

**Reduction in inspection time per carcase (Non-Monetised)**

4.13 The changes to operational procedures are expected to lead to a reduction in inspection time per carcase. This could reduce the total inspection cost in some pig slaughterhouses and therefore provide an efficiency gain as slaughterhouses may be able to allocate their resources more efficiently.
4.14 It is difficult to quantify this benefit as each slaughterhouse is different, and the benefits will vary depending on a number of variables such as the current line speed, the layout of the slaughterhouse and the organisation of inspection points. For these reasons we have been unable to monetise this benefit at this time.

Consultation Question 1:
It is our assumption that the new requirement will reduce inspection times per carcase which may lead to efficiency benefits to slaughterhouses. We invite stakeholders to comment on whether this assumption is correct. If you agree or disagree, please provide us with as detailed information and data as possible for us to be able to monetise this potential benefit (for example, in terms of a reduction in time and resources needed).

Benefits to Enforcement

Lower frequency of knife-related accidents (Non-Monetised)

4.15 Under the new operational procedures, the use of knives will no longer be required as routine. In GB between 1st April 2011 and 31st March 2012, 29 accidents involving a knife were recorded in red meat slaughterhouses, with an associated cost to the FSA of just over £20,000. It has not been possible to extract the relevant figures associated with pig or multi species slaughterhouses, but it is envisaged that visual inspection could generate a benefit in terms of a reduction in the number of knife-related accidents amongst FSA employees. We have, however, been unable to monetise this potential benefit.

Flexible Resource Allocation (Non-Monetised)

4.16 The new operational procedures are expected to lead to a reduction in inspection time per carcase. This would introduce flexibility in the resource allocation of inspectors and would allow a greater focus on high risk areas. We have however been unable to obtain any estimates of the potential time saving per slaughterhouse arising from the operational procedures, and we have therefore been unable to monetise this benefit.

Benefits to Consumers

Potential for a lower risk of cross-contamination in pork slaughterhouses (Non-Monetised)

4.17 Research has suggested that incising lymph nodes and palpating organs as routine may contribute to the risk of cross-contamination of carcases with foodborne hazards such as Salmonella spp. or Yersinia spp. If officials no longer undertake these tasks as routine, there could be benefits to public health protection. A study carried out at EU level on the “Estimation of the relative contribution of different food and animal sources to human Salmonella infections in the European Union”\(^\text{10}\) shows that the proportion of Salmonella reported cases attributable to pigs in the UK between 2007-2009 was 11.7% against other animal source.

4.18 The Annual Report of the FSA’s Chief Scientist (2012/2013)\(^\text{11}\) estimates that there are around a million cases of foodborne illness in the UK each year. In 2012, there were 9,184 confirmed cases of salmonella across the UK. The estimated cost of

foodborne illness for UK was around £1.8billion IN 2011. Any reduction in cases of foodborne illness would be welcome, but it would be difficult to link improvements specifically to these changes in operational procedures.

**Costs**

**Option 1:** Do nothing – do not update UK operational procedures in line with the EU regulation.

4.19 This option would involve taking no action to update UK operational procedures but this would not prevent the new regulations from coming into force as they are directly applicable across the EU. The UK would therefore be in non-compliance with its legal obligations.

4.20 This non-compliance would provide a lack of clarity about official operational procedures for UK FBOs, many of whom have been supportive of the changes being proposed. It may also place UK slaughterhouses at a competitive disadvantage to those in the rest of the EU as inspection tasks considered to be additional in other Member States, would remain as part of the routine inspection procedure in the UK. As set out in the Benefits to option 2, the new rules are expected to provide increased line speed in some slaughterhouses and additional operational flexibility for government, which may not be realised under this option.

4.21 The potential public health benefits from the visual inspection system would also not be realised, as officials would continue to routinely palpate and incise organs and lymph nodes despite the evidence that suggests that this may contribute to microbiological contamination on carcases.

4.22 For these reasons and the risk of costly infraction proceedings, the Do Nothing option was not supported.

**Option 2:** Update UK operational procedures in line with the EU regulation.

**Costs to Enforcement**

**Familiarisation cost (One-Off Cost)**

4.23 The new amendment will generate a familiarisation cost to enforcement officers who will need to familiarise themselves with the new changes. This includes MHIs and OVs, as well as those in operational functions such as SDMs, LVs, SMIs and DVOs/SVOs. As Table 2a shows, in 2013 the average number of officials working in the specialist approved pig slaughterhouses and multi species slaughterhouses in Scotland per week was 60.

4.24 Familiarisation costs can be monetised by multiplying the chargeout rate with the hours required for familiarisation. We envisage that it will take an official about one hour to read and familiarise themselves with the changes. Multiplying the average number of officials in each occupational group (see Table 2a) by their respective chargeout rates (see Table 2b), and then again by the time required by official (1hr) generates an approximate familiarisation cost of £1995 to the enforcement sector in Scotland, as shown below at Table 4.
Table 4: Approximate familiarisation cost to officials in pig slaughterhouses in Scotland

<table>
<thead>
<tr>
<th>Official Role</th>
<th>Cost (Scotland)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat Hygiene Inspectors</td>
<td>£646.95</td>
</tr>
<tr>
<td>Official Veterinarians (FTE)</td>
<td>£1078.24</td>
</tr>
<tr>
<td>Service Delivery Managers</td>
<td>£126.40</td>
</tr>
<tr>
<td>Lead Veterinarians</td>
<td>£86.50</td>
</tr>
<tr>
<td>Supervisory Meat Hygiene Inspector</td>
<td>£57.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£1995.09</strong></td>
</tr>
</tbody>
</table>

Training costs (One-Off Costs)

4.25 The FSA has carried out a skill gap analysis to identify the training required for officials to deliver the revised operational procedures. The analysis concluded that officials working in slaughterhouses already have the skills required to carry out visual inspection of pigs to identify abnormalities, as visual checks on carcases and offal form a part of their existing work. However, officials will need training on the new operational procedures, and training on how their professional judgement can be used to best advantage as part of these procedures. The proposed operational procedures would also mean that officials may be required to use hand-held hooks to assist with carcase and offal handling.

4.26 The main skill gaps relate to:

a. the circumstances under which a batch of animals or individual carcase require further inspection (i.e., the circumstances in which palpation of organs or incision of lymph nodes is required);

b. how to determine which further inspection tasks are required in each circumstances (i.e., which suspected conditions would require the incision of which lymph nodes or palpation of which organs); and

c. the safe use of hand-held hooks.

4.27 The primary target audience for training will be officials directly involved in front line delivery (MHIs and OVs). Those in the operational hierarchy with management functions for OVs and MHIs will also require training. The training delivery methods are still being finalised, but we envisage that a training session would take approximately four hours per official. Multiplying the average number of officials requiring training (see Table 2a) by their respective chargeout rate as presented in Table 2b, and then again by the time required by official (4hr) generates an approximate training cost of £7980 to the enforcement sector in Scotland, as shown below at Table 5.

Table 5: Approximate training cost to officials in pig slaughterhouses in Scotland

<table>
<thead>
<tr>
<th>Official Role</th>
<th>Cost (Scotland)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat Hygiene Inspectors</td>
<td>£2587.80</td>
</tr>
<tr>
<td>Official Veterinarians (FTE)</td>
<td>£4312.96</td>
</tr>
<tr>
<td>Service Delivery Managers</td>
<td>£505.60</td>
</tr>
<tr>
<td>Lead Veterinarians</td>
<td>£346.00</td>
</tr>
<tr>
<td>Supervisory Meat Hygiene Inspector</td>
<td>£228.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>£7980.36</strong></td>
</tr>
</tbody>
</table>
Increase in Post mortem verification (Negligible Cost)

4.28 OVs or LVs verify the post mortem inspection of a sample of carcases and offal that have been health marked by MHIs\(^{12}\). The frequency of verification is based on the number of days the slaughterhouse operates. In a pig slaughterhouse that operates on four or five days per week, the OV or LV will carry out verification tasks on three days per week. For those that operate fewer than four days a week, the OV or LV will carry out verification on a daily basis. The sample size for the verification tasks depend on the throughput of the establishment.

4.29 To provide assurance that visual inspection is effective in detecting conditions and that the procedures are correctly implemented, the FSA intends to require that the inspection team carries out verification tasks on a daily basis for a period of six months. This means that plants that operate on four or five days a week will see an increase in verification checks. The aim would be to check around 15% of throughput on a daily basis for the 6 month period, which keeps the checks achievable within the working day by the current inspection team. The increased verification could therefore be encompassed within existing daily plant activities, and would not place an increased burden on industry or enforcement.

Consultation Question 2:
It is our assumption that having the inspection team carry out verification tasks on a daily basis during the first six months will not increase the burden on industry or enforcement. We invite stakeholders to comment on whether this assumption is correct. If you disagree, please provide us with as detailed information and data as possible for us to monetise this potential cost.

Costs to Food Business Operators (Slaughterhouses)

Familiarisation Costs (One-Off Cost)

4.30 There are 17 approved pig slaughterhouses in Scotland – see paragraph 4.2 for further details. The new operational procedures place no new obligations on FBOs. However, we expect that most slaughterhouse managers will wish to familiarise themselves with the new procedures that officials are undertaking in their establishments. Familiarisation costs can be quantified by multiplying the wage rate of the official carrying out the familiarisation by the number of hours required for familiarisation. It is our assumption that it will be the slaughterhouse manager (wage rate of £25.80\(^{13}\)) that will familiarise himself/herself, and that familiarisation would take approximately 1 hour per slaughterhouse. This generates a total familiarisation cost of £438.60 - £25.80 per slaughterhouse manager.

Reporting Cases of Endocarditis (Non-Monetised Cost)

4.31 As mentioned in paragraphs 4.4-4.6 some FBOs may choose to start incising porcine hearts to remove blood clots for quality assurance purposes. If porcine endocarditis is identified, FBOs will be asked to inform officials so that the condition can be recorded for animal health surveillance purposes. As shown in Table 3 above, the prevalence of endocarditis in pig hearts over the past three years amount to an

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\(^{12}\) http://www.food.gov.uk/multimedia/pdfs/mocmanualch2part4rev57.pdf

average of 0.009% of total offal throughput of slaughterhouses in Scotland. This suggests that the cost of reporting is likely to be minimal; however, the cost will also be dependent on the reporting arrangements adopted, and whether the reporting of endocarditis can be incorporated in existing reporting arrangements. We have at this stage not been unable to monetise this potential cost, but we envisage it to be negligible.

**Consultation Question 3:**
We invite stakeholders to comment on whether our assumption that reporting cases of endocarditis is likely to impose minimal costs on FBOs. If you disagree, please provide us with as detailed information and data as possible (e.g. expected reporting arrangements adopted, associated time and resource requirements) so that we can monetise this potential cost.

**Increase in Number of Detained Carcases (Non-Monetised Cost)**

4.32 There may be a temporary increase in the number of carcases being detained for further inspection to compensate for uncertainty whilst MHIs and OVs familiarise themselves with the new system. This might have the effect of slowing down the production line and increase the inspection time per carcase. We have not been able to estimate the level of this temporary increase, so we are at this stage unable to monetise this potential cost.

**Consultation Question 4:**
It is our assumption that the new requirements may cause a temporary increase in the number of detained carcases, and that this may slow down line speed and increase the inspection time per carcase. We invite stakeholders to comment on whether this assumption is correct. If you agree or disagree, please provide us with as detailed information and data as possible for us to be able to monetise this potential cost.

**Red Offal**

4.33 Meat inspectors carry out post mortem inspection of red offal such as lungs and liver (see Table 1). The current legislation details when meat and offal ought to be declared unfit for human consumption, but it does not however detail who should remove the unfit part/organ. Currently, if any red offal is deemed unfit for human consumption by the meat inspector, then the meat inspector rejects and removes the affected organ.

4.34 With visual inspection, we are proposing that meat inspectors no longer carry knives as routine. This means that while they will declare meat unfit for human consumption where appropriate by tagging or marking the affected organ, it may no longer be appropriate for them remove the affected part or organ.

4.35 To apply the changes effectively, we are exploring two options during the series of trials we will run in pig approved slaughterhouses; 1) where plant staff remove the affected part/organ, 2) where meat inspectors continue to remove affected part/organ.

**Consultation Question 5**
Meat inspectors are required to declare if red offal is unfit for human consumption, but the legislation does not specify who should remove any abnormalities found. As meat inspectors would no longer routinely carry knives, we are proposing that removal of abnormalities should be carried out by the FBO. We invite stakeholders to comment on whether they agree with this approach. If
you disagree, please provide as detailed information and data as possible so that we can monetise any potential cost.

**Consumers**

4.36 The new operational procedures are not expected to generate additional costs to consumers. The FSA welcomes your views on this assumption.

5. **Scottish Firms Impact Test**

5.1 In 2011 the FSA established a specific Task Group of the CFMC in relation to pigs to provide comments and feedback on the Commission’s proposals and help inform the UK negotiating position. The CFMC includes organisations representing slaughterhouses, the meat processing industry, primary producers and consumers. Input from the Task Group was sought throughout negotiations. This collaborative approach was a success, and a similar approach will be taken when the FSA begins negotiations on other species.

5.2 We are sending this partial BRIA to all FBOs of pig slaughterhouses to provide information on the new EU Regulation and to seek comments on the potential impact the updated operational procedures may have. We will also be conducting face-to-face visits during the consultation period with FBOs of pig slaughterhouses in Scotland.

**Competition Assessment**

5.3 The incoming Regulations are not expected to have any impact either directly or indirectly on competition.

5.4 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 2) will neither directly or indirectly limit the number or range of suppliers, limit the ability of suppliers to compete or reduce suppliers’ incentives to compete vigorously.

**Test Run of Business Forms**

5.5 The updated national operational procedures for officials working in slaughterhouses do not introduce any new or additional forms to business.

6. **Legal Aid Impact Test**

6.1 These new EU Regulations will not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Scottish Government Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund.

7. **Enforcement, Sanctions, and Monitoring**

7.1 Enforcement will be the responsibility of the FSA, as the competent authority – this will be drawn from powers written within the Food Hygiene (Scotland) Regulations 2006.
Sanctions

7.2 No changes are being proposed to the criminal sanctions or civil penalties contained in the Food Hygiene (Scotland) Regulations 2006.

Monitoring

7.3 The effectiveness and impact of this EU Regulation will be monitored via feedback from stakeholders, including the CFMC Task Group, as part of the ongoing policy process.

Declaration and publication

I have read the partial Business and Regulatory Impact Assessment (BRIA) and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the options. I am satisfied that business impact will be assessed with the support of businesses in Scotland.

Signed:

Date: 24 March 2014
Professor Charles Milne
Director, Scotland

Food Standards Agency Contact point:
Karen Robertson, FSA in Scotland, Regulatory Policy Branch
Tel: 01224 288362
Email: karen.robertson@foodstandards.gsi.gov.uk
PARTIAL BUSINESS AND REGULATORY IMPACT ASSESSMENT (BRIA)

Amendments to the Salmonella process hygiene criterion (PHC) for carcases of pigs (as laid down in Regulation (EC) No 2073/2005) and the requirements for its verification by the competent authority (as laid down in Regulation (EC) No 854/2004)

File No: RPB/FSAS
Date: March 2014
Stage: Consultation
Source of intervention: EU
Contact for enquiries: Karen Robertson
Phone No: 01224 288362
Email: karen.robertson@foodstandards.gsi.gov.uk
1. Title of Proposal


2. Purpose and Intended Effect

Objectives

2.1 The policy objectives are to reduce the risk to consumers from Salmonella contamination in pig carcases by enhancing Salmonella controls in the slaughterhouse as a result of stricter parameters for the Salmonella PHC and ensuring that the new competent authority (CA) verification and reporting requirements are fulfilled.

Rationale for Government Intervention

2.2 The FSA is the central competent authority in the UK responsible for carrying out official controls in slaughterhouses in Scotland, England and Wales. In Northern Ireland, the official controls are delivered by the Department for Agriculture and Rural Development (DARD) on behalf of the FSA.

2.3 Intervention is needed to implement Commission Regulation (EU) 217/2014 and Regulation (EU) 218/2014 to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004 respectively to improve consumer protection by reducing the presence of Salmonella on pig carcases and improving official verification of FBO compliance. Adequate systems must be in place by 1 June 2014 for the UK to comply with the new sampling, verification and reporting requirements and to realise the benefits of a stricter Salmonella criterion and compliance verification system.

2.4 Salmonella is one of the commonest causes of food poisoning in the UK and can result in serious illness or death. Salmonella food poisoning has significant economic effects on society and industry through medical costs, loss of working time and consumer confidence in certain foods, and the costs of control.

Background

EU Hygiene Regulations

2.5 EU food hygiene rules for FBOs are set out in Regulation (EC) 852/2004 and Regulation (EC) 853/2004. Regulation (EC) 854/2004 lays down rules for CAs. These three Regulations, which came into force on 1 January 2006, govern the placing on the market of meat for human consumption and lay down, respectively, hygiene requirements for all food businesses, specific rules for foods of animal origin, and requirements for the organisation of official controls on products of animal origin.

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for human consumption. The Regulations together are known as the Hygiene Package.

2.6 Official controls on meat are prescribed by directly applicable EU legislation. Their objective is to detect and prevent public health hazards such as foodborne pathogens or chemical contaminants. Meat inspection also plays an integral role in the overall monitoring system for certain animal diseases and the verification of compliance with animal welfare standards.

Revision of the Hygiene Package

2.7 In July 2009, the European Commission undertook a review of the experience gained from the implementation of the Hygiene Package since 2006. It concluded that, overall, the experience of the Hygiene Package was positive and that there was no need for a fundamental overhaul. However, the Council of the EU invited the Commission to prepare legislative proposals for the modernisation of sanitary inspection in slaughterhouses.

2.8 In May 2010, the Commission asked EFSA to carry out risk assessments on official meat controls and to recommend alternative approaches to inspection. EFSA’s work was prioritised by species and its scientific advice (known as Scientific Opinion) on pig inspection was published in October 2011⁵.

2.9 The Opinion identified Salmonella as a priority target for the inspection of swine meat in abattoirs due to its prevalence and impact on human health. EFSA also concluded that the current meat inspection regime does not address current foodborne hazards, which are mostly microbiological in nature and cannot therefore be detected by the naked eye. Therefore, EFSA made a series of recommendations which included risk reduction measures in the abattoir, which focused on prevention of microbial contamination through robust process hygiene-based measures.

2.10 An EU-wide baseline survey on slaughtered pigs carried out in 2006-2007 informed the EFSA Opinion in relation to the estimated prevalence of Salmonella spp. on carcasses across Europe. For the 2006-2007 study, in the UK, 660 pigs were sampled in total at 18 abattoirs. Samples were taken from carcass surfaces of randomly selected pigs in the participating slaughterhouses. The survey report was published by EFSA in June 2008⁶. The UK abattoir prevalence estimate was 13.5% for all Salmonella types compared to an EU average prevalence of 8.3%. A similar study was conducted in 2013 but results were not available at the time of publication of this partial business and regulatory impact assessment (BRIA).

Salmonellosis in humans

2.11 Salmonellosis is an infection of animals and man caused by a group of bacteria called Salmonella. These can live in the digestive tract of a wide range of mammals (including people), birds and reptiles and are present worldwide. Infection in humans may follow contact with infected animals or contaminated items or environment. Symptoms of human salmonellosis can include fever, diarrhoea and abdominal cramps. This is usually fairly short-lived and often does not cause any obvious disease. However, it can be life-threatening if it infects the bloodstream.

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2.12 The epidemiology of salmonellosis in humans, which can be transmitted from pigs, is complex. There are many distinct types of Salmonella that can manifest themselves in different ways in pigs and humans, and the links between live pigs and human infection are not straightforward.

2.13 In 2012, 8,798 cases of laboratory confirmed salmonellosis in humans were reported in the UK. For every laboratory confirmed report of disease made to national surveillance schemes, there are estimated to be 4.7 unreported cases. This means the total number of cases in the UK in 2012 was approximately 50,000.

2.14 In 2010, an analysis of the costs and benefits of setting a target for the reduction of Salmonella in slaughter pigs estimated that the total annual human health losses at EU level due to Salmonella in pigs to be approximately €90 million (£75m) and a total cost of €600 million (£500m) for Salmonella as a whole. This corresponds to €600 (£500) per human case.

Microbiological criteria for foodstuffs

2.15 Microbiological criteria for foodstuffs are set out in Regulation (EC) 2073/2005. The safety of foodstuffs is mainly ensured by a preventative approach, such as implementation of good hygiene practice and application of procedures based on hazard analysis and critical control point (HACCP) principles. Microbiological criteria can be used in the validation and verification of HACCP procedures and are established at EU level, where their application provides additional public health benefits. These microbiological criteria are supported by risk assessment and scientific opinion from organisations such as EFSA and WHO/FAO (World Health Organization and the Food and Agriculture Organization of the United Nations).

2.16 The Regulation defines two types of microbiological criteria:

- process hygiene criteria (PHC): criteria to assess the hygiene of food production processes.
- food safety criteria: limits for certain microorganisms above which a foodstuff is deemed unacceptably contaminated.

2.17 Microbiological testing results support the validation and verification of HACCP procedures and other hygiene control measures which will be reviewed where results indicate contamination is occurring at unacceptable levels. Slaughter and dressing operations provide many opportunities for contamination of carcasses with bacteria that may be associated with animal infection or slaughterhouse environment. Testing against the PHC provides an indication of the operator’s capability to manage contamination during slaughter, dressing and production processes.

2.18 The Regulation describes the requirements for the PHC for Salmonella in pig carcasses. The UK, making use of the flexibility within the Regulation, has adapted the testing requirements based on the slaughterhouse throughput level and risk:

- **Slaughterhouses with a throughput level above 100,000 animals per annum:** FBOs must sample and test five pig carcasses each week for Salmonella. In any 10-week period, the number of positive samples (or c value) must not exceed five.

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8 http://ec.europa.eu/food/food/biosafety/salmonella/docs/fattening_pigs_analysis_costs.pdf
(out of the 50 samples taken or \( n \) value), otherwise corrective action is required. If results are satisfactory over a period of 30 consecutive weeks, these slaughterhouses are eligible to move to a reduced testing frequency of five carcases once every two weeks.

- **Slaughterhouses with a throughput level of 37,500 to 100,000 animals per annum:** FBOs must sample and test five pig carcases once every four weeks. The same \( c \) and \( n \) value as for a higher throughput level apply, as well as the requirement of corrective action in response to unsatisfactory results. These slaughterhouses are however not eligible to move to a reduced testing frequency.

- **Slaughterhouses on a throughput level below 37,500 per annum:** FBOs are exempt from testing for Salmonella.

**Table 1: Sampling regime in UK**

<table>
<thead>
<tr>
<th>Annual throughput</th>
<th>Sampling frequencies</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Initial frequency</td>
</tr>
<tr>
<td>Over 100,000</td>
<td>5 carcases once a week for 30 weeks (30( \times )5=150 samples)</td>
</tr>
<tr>
<td>100,000 - 37,500</td>
<td>5 carcases once every 4 weeks</td>
</tr>
<tr>
<td>Below 37,500</td>
<td>No testing required</td>
</tr>
</tbody>
</table>

2.19 FBOs must test samples using the reference method or an alternative that has been validated according to the requirements in the Regulation.

2.20 The Regulation requires the FBO to analyse the trend of testing results and if the trend is towards unsatisfactory results, take action to prevent microbiological risk. This includes: improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures in the farms of origin.

**Amendments to the Regulations**

2.21 Following publication of the EFSA Opinion on pig inspection, the Commission developed legislative proposals to tackle the risk from Salmonella contamination in slaughterhouses and increase consumer protection.

2.22 The Commission presented initial proposals (to amend Regulation (EC) 2073/2005 and Regulation (EC) 854/2004) at the Standing Committee on the Food Chain and Animal Health (SCoFCAH) meeting on 21 September 2012. The proposals were subject to lengthy negotiations and considerable revision, ultimately achieving qualified majority vote of Member States (MSs) in May 2013.

**Amendments to the Salmonella PHC**

2.23 The initial draft proposal amending criterion 2.1.4 (Salmonella in carcases of pigs), as set out in Regulation (EC) 2073/2005, prescribed a five-fold increase in the sampling regime, whereby FBOs would be expected to sample 25 carcases a week without exceeding the maximum threshold of 25 Salmonella positive samples in any 10-week period. The UK opposed the draft proposal on the basis of it being disproportionate when compared to the potential positive effect on consumer
protection. This proposal would have increased sampling and testing costs significantly but, as the ratio of acceptable number of positives to the total number of samples taken (1:10) had not changed, the UK had reservations about the positive impact on public health.

2.24 Following a number of proposals from the Commission and Member States and various suggested combinations of sample levels and acceptable limits, consensus was reached on a final proposal which maintained the current level of sampling\(^9\) (this is 50 samples over a 10-week period\(^{10}\)) but lowered the tolerance for positives (\(c\) value) from five to three. Therefore, the new threshold for the Salmonella PHC is three positive samples over any 10-week period. Other provisions in the amending Regulation, such as sampling frequency flexibility, remain unchanged.

**Amendments to official verification**

2.25 Regulation (EC) 2073/2005 contains a general requirement for the CA to verify compliance with the rules and criteria laid down in the Regulation. The current procedures for official verification of FBO compliance with the Salmonella PHC are described in detail in the Manual for Official Controls\(^{11}\). The Official Veterinarian (OV) is to monitor the sampling, transport of samples to the laboratory, laboratory methods used and provision of results at slaughterhouses. The interval between checks varies, depending on the sampling and audit frequency. The OV is also tasked with liaising with the FBO or representative at agreed intervals and reviewing the results.

2.26 The OV is responsible for verifying that where any further action by the FBO is required in regard to unsatisfactory testing results, this action is taken promptly and is documented within the HACCP based procedures. The OV is also responsible for taking appropriate enforcement action in the event of failure to take corrective action by the FBO, although anecdotal evidence indicates that enforcement action as a direct result of non-compliance with the Salmonella PHC is limited. Furthermore, failure to meet PHC does not result in withdrawal or recall of product.

2.27 Regulation (EU) 218/2014, which amends (EC) 854/2004, introduces a requirement that the CA collects testing data as part of the verification process. The approaches for a more robust official verification procedure are as follows:

- a) Official sampling; and/or
- b) Collection of FBO data on Salmonella PHC; and/or
- c) Collection of national control programme data on Salmonella.

**Action on repeated failures to comply with the PHC**

2.28 Regulation (EU) 218/2014 specifies that the CA must require FBOs to draw up an action plan if testing results against the Salmonella PHC are unsatisfactory on several occasions. While the need for corrective action by the FBO in the case of non-compliance with the PHC is not a new requirement, greater focus is now given to monitoring by the CA of the outcome of corrective actions. This is captured in the requirement that the CA must strictly supervise the outcome of the action plan.

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\(^9\) The UK uses an adapted sampling regime based on risk – please refer to Table 1. The sampling regime (frequency of sampling) has not changed as a result of the amendment to the Salmonella PHC.

\(^{10}\) or 10 sampling events if sampling is not done weekly.

\(^{11}\) http://www.food.gov.uk/enforcement/monitoring/meat/manual/
Reporting of testing results

2.29 Furthermore, the text includes a requirement that the total number and the number of Salmonella positive samples, irrespective of the approach used for verification (a, b or c in paragraph 2.27 above), be reported by MSs to the Commission as part of the yearly report of zoonoses and zoonotic monitoring.

3. Consultation

Within Government

3.1 The FSA set up a Cross Government Group on Meat Official Controls (CGGMOOC) in 2010. This group includes officials from the FSA in Scotland and also the Scottish Government Directorate for Agriculture, Food and Rural Communities. The group was instrumental in developing the high level UK negotiating principles and played a key role during the negotiations.

3.2 FSA officials with responsibility for operational delivery in pig slaughterhouses are also represented on both the CGGMOOC and the Current and Future Meat Controls Group (CFMC), and were engaged throughout negotiations on the pig proposals and the development of the Future Meat Controls research.

3.3 The Scottish Government’s Better Regulation and Industry Engagement (BRIE) team have been consulted during the preparation of this BRIA.

Public Consultation

3.4 A series of nationwide citizen’s forums were conducted between June and July 2010 to explore consumer attitudes to meat hygiene and views on potential changes to meat official controls. Participants indicated that they would favour any changes to meat inspection that were based on robust science, with proportionate managed communications to the public about the implications, and a robust monitoring system for animal diseases.

3.5 Consumer perspectives were also sought through the FSA Consumer Advisory Panel (CAP), whose role is to provide consumer insights into the FSA’s work by supplementing consumers’ views and opinions obtained from direct engagement. CAP’s preference was that an Official Veterinarian (OV) should continue to have oversight of the slaughter process, and advised on communication handling.

3.6 The CFMC was consulted throughout negotiations and included consumer representation.

Business

3.7 The FSA has worked in collaboration with industry groups throughout the development of the Future Meat Controls programme, and more recently during the negotiations on the pig proposals. Individual slaughterhouses have assisted the development of the evidence base through contributing to the FSA’s research programme.

3.8 On a policy level, the CFMC includes organisations representing slaughterhouses, the meat processing industry, primary producers and consumers. The Group meets three times a year and contributes to discussions on strategy and planning, both in respect to research and future negotiations.

3.9 In 2011 the FSA established a specific Task Group of the CFMC in relation to pigs to provide comments and feedback on the Commission’s proposals and help inform the UK negotiating position. Input from the Task Group was sought throughout negotiations. This collaborative approach was a success, and a similar approach will be taken when the FSA begins negotiations on other species.

4. Options

4.1 The options considered are:

**Option 1**: Do nothing. In practical terms this would mean:
- Not implementing a lower c value for the Salmonella PHC
- Not implementing a more robust procedure for official verification of FBO compliance with the Salmonella PHC
- Not reporting on Salmonella PHC sampling results to the Commission


**Sectors and groups affected**

Industry – pig slaughterhouses

4.2 Only approved slaughterhouses with a throughput of over 37,500 pigs per annum will be affected by the changes, since slaughterhouses with a lower throughput level are exempt from testing for Salmonella (see Table 1 and also paragraph 2.18). In 2013, there were 17 approved pig slaughterhouses in Scotland – two of which are specialist pig slaughterhouses (i.e. pigs only) and the remaining 15 are multi species slaughterhouses. Table 2 below shows these slaughterhouses by throughput level.

<table>
<thead>
<tr>
<th>Throughput Band</th>
<th>Number of slaughterhouses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Above 100,000</td>
<td>1</td>
</tr>
<tr>
<td>100,000 – 37,500</td>
<td>1</td>
</tr>
<tr>
<td>Below 37,500</td>
<td>15</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>17</strong></td>
</tr>
</tbody>
</table>

4.3 No changes have been introduced to the current sampling regime. This means that high throughput abattoirs (i.e. slaughtering over 100,000 pigs per year) will continue to have the option to move to reduced testing frequency as long as their sampling results remain satisfactory. This fortnightly testing frequency is subject to obtaining satisfactory sampling results for 30 weeks. ‘Satisfactory results’ has to date been defined as five or fewer positive results in any 10-week period.

4.4 However, as previously stated, from 1 June 2014 the threshold for the acceptable number of positive samples will be lowered from five to three. As the tolerance for the
number of positive results is redefined downwards, this means that slaughterhouses could be more likely to obtain unsatisfactory results, which may have an effect on:

- For slaughterhouses with an annual throughput of above 37,500 pigs, the frequency of corrective action may increase.
- For slaughterhouses with an annual throughput of above 100,000 pigs, their ability to move to a reduced sampling frequency may be affected.

Industry – primary producers

4.5 The amended tolerance level for the number of Salmonella positive samples may have an indirect effect on pig farmers. Following unsatisfactory results, slaughterhouses are expected to implement corrective action which may include a review of on-farm biosecurity. While it is envisaged that slaughterhouses will first review their slaughter hygiene and process controls, it is possible that a lower threshold may require more extensive corrective action, which may trigger reviews of on-farm biosecurity and implementation of additional controls for Salmonella. Anecdotal evidence is that such on-farm reviews are very rare. However, as a result of greater attention to on-farm Salmonella control plans by slaughterhouses, farmers may be under increased pressure to control Salmonella. Most farmers have Salmonella control plans in place, particularly if they belong to an assurance scheme (as it is often a requirement), but farmers may be under pressure to reduce Salmonella prevalence in their holdings if this is identified as the reason for high Salmonella contamination in the slaughterhouse. The actions that farmers take to control Salmonella will be specific to each holding and will vary depending on the source of contamination. As the impact on farmers is indirect we do not envisage any familiarisation costs to this group (there are no new requirements on farmers outlined in the amendments to the Regulations).

Enforcement

4.6 The FSA verifies compliance with the microbiological testing requirements for Salmonella testing in approved slaughterhouses in Scotland. The introduction of the requirements to carry out official sampling for verification purposes and/or to collect FBO sampling data by the CA, and to report on official verification data will have an impact on official resources. Procedures and resources will need to be in place in order to give effect to these requirements and to supervise action plans as a consequence of repeatedly failing to meet the PHC. Enforcement officers will also incur familiarisation costs as they will need to be aware of the changes.

Consumers

4.7 As indicated by EFSA in its Opinion, Salmonella is a priority target in pig inspection due to its prevalence and impact on human health. The purpose of microbiological testing (against PHC) is to ensure that process controls are reviewed where results indicate contamination is occurring. By lowering the number of Salmonella positive results deemed acceptable, tolerance for Salmonella contamination in the slaughterhouse is reduced. The objective of this measure is to increase process hygiene in abattoirs which is expected to have an effect on food safety and bring about public health benefits to consumers.

Benefits
**Option 1:** Do nothing.

4.8 Slaughterhouses are a key point in the pig meat production chain where stricter controls may have a significant effect on Salmonella contamination. Doing nothing would mean that the public health benefits from implementing more robust Salmonella control and compliance measures would not be accrued, and that measures that may reduce the cost of Salmonellosis to society are not implemented.

4.9 Doing nothing would not prevent the new regulations from coming into force as they are directly applicable across the EU. The UK would therefore be in non-compliance with its legal obligations.


4.10 Putting the mechanisms in place to apply and give effect to the amending Regulations is the preferred option.

**Requirement for corrective action and action plans**

4.11 Under Option 2, FBOs will be required to draw up an action plan if the Salmonella PHC is not complied with on several occasions. There is currently a general requirement for FBOs to implement corrective action when PHC are not met. This requires improvements in slaughter hygiene with review of process controls and animal origin. The new Regulations introduce a specific requirement for an action plan from the FBO which has the benefit of increasing attention to Salmonella control at all stages of the chain, including on farm.

**Official verification of compliance with the Salmonella PHC requirements**

4.12 Option 2 provides the added benefit of greater focus on CA monitoring of the outcome of corrective actions. Three alternatives are provided for data collection:

a) Official sampling (in addition to FBO sampling). At least 49 random samples to be taken by the CA in each slaughterhouse each year. The number of samples may be reduced in small slaughterhouses based on a risk evaluation; and/or

b) Collection of all information on the total number and the number of Salmonella positive samples taken by FBOs in accordance with the PHC requirements set out in Regulation 2073/2005; and/or

c) Collection of all information on the total number and the number of Salmonella positive samples taken within the frame of national control programmes.

4.13 It must be noted that these implementation options are not mutually exclusive. Each MS’s CA may implement one of the above or a combination of the above in their 13 Actions currently required in the abattoir may include: investigation of the hygiene of slaughter and dressing; improvement of the clarity of instructions issued to staff and increased staff training; improved cleaning of process equipment and the lairage; scheduling animals from farms with a history of Salmonella last in the day; undertaking special conditions during slaughter of animals with a history of Salmonella; and undertaking serotyping of Salmonella positive isolates to help identify the source. In addition, it may be required that suppliers of the animals carry out an investigation of the biosecurity and hygiene on the farm and transport to the abattoir.
territory as appropriate. These three approaches (a), (b), and (c) are further described below.

4.14 **Approach (a) (official sampling).** The requirement is for the CA to undertake sampling using the same method and sampling area as FBOs in order to verify compliance with the Salmonella PHC. As the purpose of this task is to verify that approved pig slaughterhouses comply with EU Food Hygiene Regulations, the cost of carrying out the sampling would be statutory work for which FBOs are charged. However, informal consultation with stakeholders during negotiations on the legislative amendments highlighted that this option was not seen as proportionate by the UK abattoir sector as it would increase the burden on FBOs, who already carry out extensive testing, and focused only on slaughterhouses. The Regulation already includes provisions for the CA to carry out additional testing, as necessary, to verify FBO testing against the PHC. Therefore, this option is not considered further.

4.15 **Approach (b) (collection of FBO sampling data).** This is the preferred approach. Since 2006, FBOs have been required to sample and test pig carcasses for Salmonella. Under this option FBOs would make their sampling result available to the CA. As with approach (a), the cost of collecting the data would be considered statutory tasks and therefore chargeable to FBOs. This is consistent with the current UK approach for risk-based CA sampling where the majority of sampling should be carried out by FBOs and further official sampling is only carried out if there are concerns with the FBO or the sampling and testing carried out. Approach (b) requires data transfer between FBOs and the CA. Some FBOs currently have mechanisms in place to allow for the exchange of data, such as inspection results. At present, this is done through an automatic download of data or via manual FBO input on an FSA electronic interface. Alternatively, officials in slaughterhouses could input the data provided by the FBO (five sampling results per week) on the FSA system.

4.16 **Approach (c) (national control plan data).** There is currently no national control plan for Salmonella in pigs in the UK, therefore this option cannot be considered in the short or medium term.

**Reporting on Salmonella PHC verification data**

4.17 The total number and the number of Salmonella positive samples must be reported to the Commission, via EFSA, in accordance with Article 9(1) of Directive 2003/99/EC. The report must differentiate between samples taken under approach (a), (b) and (c). Reports, and any summaries of them, must be made publicly available. Although it is an existing requirement that each year MS send to the Commission a report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance, the amendment effectively modifies the list of zoonoses that MSs must report on, adding Salmonella PHC results to the list.

**Benefits to Consumers**

4.18 There are multiple factors that can contribute to the presence of Salmonella contamination on pig carcasses, from carcass dressing practices and slaughterhouse process controls to Salmonella levels on the farm and transport conditions. However, a stricter Salmonella PHC may mean that action may be required more regularly to identify and address sources of contamination. As a result, levels of Salmonella in pig meat are likely to decrease. The effect of this on cases of human
Salmonellosis is difficult to assess; however, it can be expected that lower levels of Salmonella may lead to fewer cases of food poisoning due to improper cooking or cross-contamination with other foods. Based on estimates of the cost of Salmonella to society\(^{14}\), each human case prevented will mean a saving of €600.

**Costs**

**Option 1**: Do nothing.

4.19 This option would involve taking no action to update UK operational procedures but this would not prevent the new regulations from coming into force as they are directly applicable across the EU. Under this option, the public health benefits from implementing the new Salmonella control and compliance measures would not be accrued. Also, consumer confidence in food safety controls could be reduced if action is not taken to improve official controls on pig meat in response to the EFSA Opinion highlighting Salmonella as the key zoonotic risk.

4.20 This option also entails not being in compliance with EU legislation which could lead to infraction proceedings. The maximum fine that could be imposed on the UK is some €703,000 per day or £256 million per year\(^{15}\).


**Industry – pig slaughterhouses**

Familiarisation Costs (One-off Cost)

4.21 There will be a one-off cost to slaughterhouses from reading and familiarising themselves with the new requirements. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation by the wage rate of the person carrying it out. It is our assumption that it will be the slaughterhouse manager (wage rate of £25.8\(^{16}\)) that is responsible for familiarisation and that it will on average take one manager per slaughterhouse one hour to familiarise themselves and disseminate the information to other key staff. Multiplying the wage rate by the number of slaughterhouses that will be affected by the changes (with a throughput of over 37,500 pigs per annum) and hours required (1) generates a total familiarisation cost to slaughterhouses in Scotland of £52.

Inability to move to a reduced testing frequency (Ongoing Cost)

4.22 As described in paragraph 2.18, only slaughterhouses that slaughter more than 100,000 pigs per year are eligible for reduced sampling. Slaughterhouses producing 100,000 or fewer pigs per year are either ineligible for reduced frequency or not required to test. Therefore, a change in the threshold will potentially affect 1 plant in Scotland currently slaughtering more than 100,000 pigs a year. A consequence of lowering the threshold for the number of Salmonella positive samples from five to

\(^{14}\) [http://ec.europa.eu/food/food/biosafety/salmonella/docs/fattening_pigs_analysis_costs.pdf](http://ec.europa.eu/food/food/biosafety/salmonella/docs/fattening_pigs_analysis_costs.pdf)


three is that slaughterhouses may not be able to meet the eligibility criteria for reduced testing as frequently. This is dependent on achieving satisfactory results for 30 weeks; from June 2014, this will mean not having more than three positive results every 10 weeks over a period of 30 weeks (a total maximum of nine positive results).

4.23 We currently have limited data to monetise the impact of this change. We have, however, carried out some indicative analysis based on the EU baseline survey from 2006/07\textsuperscript{17}. This survey showed a UK abattoir prevalence of 13.5\% for all Salmonella types. Based on this prevalence, analysis suggests that a lowering of the $c$ value from 5 to 3 would reduce the probability of an average plant to achieve satisfactory results, after a 10 week period, from 32\% to 8\%. Due to data limitations we have, however, been unable to calculate any robust estimates of this potential cost.

Consultation Question 1:
We currently have limited data to monetise the impact of the lowering of the $c$ value from five to three. We invite stakeholders to comment on the impact of this requirement:

- How would your current sampling frequency change in terms of number of per annum tests taken?
- How would your sampling costs change in terms of per annum pounds spent on sampling?

Increased corrective action (Ongoing Cost)

4.24 Unsatisfactory results require corrective action by the slaughterhouse which includes improvements in slaughter hygiene and review of process controls, origin of animals and of the biosecurity measures\textsuperscript{18} in the farms from which pigs are sourced. This requirement is already in place, however, implementing a lower $c$ value means that corrective action may be required more often. The magnitude of this cost will depend on the prevalence of Salmonella in the animals and the slaughterhouse’s ability to control contamination. The new Regulations also specify that, if the PHC is not complied with on several occasions, the CA must require an action plan from the FBO and strictly supervise its outcome. We have at this stage been unable to monetise the implication of these requirements.

Consultation Question 2:
We invite stakeholders to comment on whether the lowering of the threshold from five to three may increase their costs of corrective action:

- How would the frequency of corrective action change, in terms of per annum occasions?
- How would your per annum costs change, in terms of time and resources spent on corrective action?
- How would the requirement of an action plan impact on costs – how much additional time and resources are likely to be spent on implementing an action plan per annum?

Official verification (Negligible Cost)

4.25 Under the preferred approach for verification (Approach (b) CA collection of FBO sampling data) the slaughterhouse will make their sampling data available to the CA. There are various possibilities for data exchange: (i) automatic electronic data transfer; (ii) electronic interface for FBO manual input of data; and (iii) the FBO makes the data available to the CA in hard form so it can enter the data on the

\textsuperscript{18} Biosecurity measures encompass good hygiene practices on farm including precautions taken when entering or leaving any premises with farm animals to prevent the spread of animal diseases.
system. Under all these approaches we envisage that the cost to the FBO would be minimal. Some FBOs already have systems in place for the automatic transfer of data, and for those FBOs, costs will be minimal. For FBOs which choose to input results manually, we also envisage costs to be minimal (inputting results into the system is estimated to take less than half a minute per week, hence in total less than 30 minutes per annum). For FBOs which choose to provide sample results in hard form for the CA to input them into the system, this work would be considered ‘statutory work’ and is therefore chargeable to the FBO. However, as noted above, the processing costs have been considered negligible and would therefore be absorbed by the FSA as part of the discharge of official duties. It is our working assumption that the third approach is the most likely approach to go ahead. We therefore envisage that the cost to slaughterhouses associated with this requirement would be minimal.

Consultation Question 3:
We envisage that the costs to slaughterhouses from CA collection of sampling data would be minimal. If you agree or disagree, please provide us with as detailed information and data as possible.

Industry – primary producers

Increased Number of On-Farm Investigations (Non-Monetised Cost)

4.26 Farmers that send animals to those slaughterhouses which process more than 37,500 pigs a year may potentially be affected by the new Regulations. In order to address unsatisfactory results, slaughterhouses are expected to take corrective action which may include a review of on-farm biosecurity and Salmonella control measures in place at farms from which animals are sourced. The revised c value may have an effect on the frequency at which corrective actions are taken in the slaughterhouse, which may result in an increased number of investigations of the biosecurity and hygiene on the farm and transport to the abattoir. Farmers may be under pressure from slaughterhouses to reduce Salmonella prevalence in their holdings if this is identified as the reason for high Salmonella contamination in the slaughterhouse. However, the actions that farmers take to control Salmonella will be specific to each holding and will vary depending on the source of contamination. We have at this stage been unable to monetise the implication of this requirement.

Consultation Question 4:
We invite stakeholders to comment on the potential costs to farmers from an increase in the number of on-farm investigations:
- How would the frequency of reviews of on-farm controls change, in terms of per annum occasions?
- How would your per annum costs change, in terms of time and resources spent on on-farm investigations?
- Would the regulation be associated with any familiarisation costs to farmers?

Enforcement

Familiarisation Costs (One-off Cost)

4.27 There will be a one-off cost to enforcement from reading and familiarising themselves with the new requirements. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation by the wage rate of the official carrying it out. It is OV...
that are responsible for the monitoring of Salmonella controls. There are currently 2 full-time employed OVs that will be affected by the Regulations and therefore will need to familiarise themselves with the Regulations. It is our assumption that it will take approximately one hour per OV to familiarise themselves and disseminate the information to other key staff. Multiplying the hourly wage rate on an OV (£36.8) by the number of affected slaughterhouses (2) and hours required (1) generates a total familiarisation cost to enforcement of £73.

**Increased corrective action (Ongoing Cost)**

4.28 The lowering of the threshold for the number of acceptable positive samples may result in FBO corrective action and action plans after repeated failure being required more frequently. This could have an effect on OV resources as OVs are required to monitor that corrective action is taken and to supervise the outcome of action plans. We have been unable to monetise the associated costs as we currently do not have sufficient information to be able to do so.

**Consultation Question 5:**
Currently OVs need to monitor that corrective action is taken. We invite stakeholders to comment on the costs to enforcement from a potential increase in the frequency of corrective action:

- How would the per annum costs change, in terms of time and resources spent on monitoring that corrective action has been taken?
- What would be the per annum costs of supervising the outcome of action plans in terms of time and resources spent?

**Official verification (Negligible Cost)**

4.29 Under the preferred approach for verification (Approach (b) CA collection of FBO sampling data) the slaughterhouse will make their sampling data available to the CA. There are various methods for data exchange: (i) automatic electronic data transfer; (ii) electronic interface for FBO manual input of data; and (iii) the FBO makes the data available to the CA in hard form so it can enter the data on the system. Under all three methods, the CA may incur a one-off cost for setting up a data capture/exchange system. Currently we are uncertain about which of the three methods above will be used for the exchange of data, but we are likely to start with (iii) which carries negligible costs to slaughterhouses. We anticipate the cost to the FSA of setting up this system will be negligible (as described above) and we have therefore not monetised this cost.

**Costs of reporting on Salmonella PHC official verification data (Negligible Cost)**

4.30 Although the requirement to report on the total number and the number of Salmonella positive samples taken as part of the official verification is new, the UK already reports yearly on information on monitoring of zoonoses in accordance with Directive 2003/99/EC. Therefore, the costs associated with adding this dataset to the report have been assessed as minimal. We envisage that it should not require more than one official spending two hours per annum interrogating the system and producing a report. This would generate a cost to the CA of approximately £2819 per annum.

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5. **Scottish Firms Impact Test**

5.1 In 2011 the FSA established a specific Task Group of the CFMC in relation to pigs to provide comments and feedback on the Commission’s proposals and help inform the UK negotiating position. The CFMC includes organisations representing slaughterhouses, the meat processing industry, primary producers and consumers. Input from the Task Group was sought throughout negotiations. This collaborative approach was a success, and a similar approach will be taken when the FSA begins negotiations on other species.

5.2 We are sending this partial BRIA to all FBOs of pig slaughterhouses to provide information on the new EU Regulations and to seek comments on the potential impact the updated operational procedures may have. We will also be conducting face-to-face visits during the consultation period with FBOs of the two slaughterhouses that currently test against Salmonella PHC.

**Competition Assessment**

5.3 The incoming Regulations are not expected to have any impact either directly or indirectly on competition. In light of responses following the consultation exercise we will revisit our position.

5.4 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 2) will neither directly or indirectly limit the number or range of suppliers, limit the ability of suppliers to compete or reduce suppliers’ incentives to compete vigorously.

**Test Run of Business Forms**

5.5 The updated national operational procedures for officials working in slaughterhouses does not introduce any new or additional forms to business.

6. **Legal Aid Impact Test**

6.1 The new EU Regulations will not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund.

7. **Enforcement, Sanctions, and Monitoring**

7.1 Enforcement will be the responsibility of the FSA, as the competent authority – this will be drawn from powers written within the Food Hygiene (Scotland) Regulations 2006.

**Sanctions**

7.2 No changes are being proposed to the criminal sanctions or civil penalties contained in the Food Hygiene (Scotland) Regulations 2006.

**Monitoring**
7.3 The effectiveness and impact of these EU Regulations will be monitored via feedback from stakeholders, including the CFMC Task Group, as part of the ongoing policy process.

Declaration and publication

I have read the partial Business and Regulatory Impact Assessment (BRIA) and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the options. I am satisfied that business impact will be assessed with the support of businesses in Scotland.

Signed:

Date: 24 March 2014
Professor Charles Milne
Director, Scotland

Food Standards Agency Contact point:
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Regulatory Policy Branch
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Email: karen.robertson@foodstandards.gsi.gov.uk
PARTIAL BUSINESS AND REGULATORY IMPACT ASSESSMENT (BRIA)

IMPLEMENTATION OF THE REVISED EU TRICHINELLA REQUIREMENTS

File No: RPB/FSAS
Date: March 2014
Stage: Consultation
Source of intervention: EU
Contact for enquiries: Steve Hardie
Phone No: 01224 285145
Email: steve.hardie@foodstandards.gsi.gov.uk
1. TITLE OF PROPOSAL


2. PURPOSE AND INTENDED EFFECT

Objectives

2.1 Commission Regulation (EU) No 216/2014, which comes into force on 1 June 2014, forms part of a package of revised pig meat inspection rules covering visual inspection of carcases, strengthened Salmonella controls, and more proportionate and risk based Trichinella controls. This is part of a wider European legislative framework which is intended to ensure that food is safe to eat.

2.2 The Regulation amends EU rules on official controls for Trichinella in meat and moves away from requiring all pigs to be tested for Trichinella to a more risk-based testing regime. This represents a significantly reduced Trichinella testing requirement for industry as a whole, compared to the previous requirements – it is far more proportionate and more accurately reflects the level of risk associated with the various pig housing systems used in Scotland and across Great Britain. This proportionate, risk-based approach is one that the UK has long advocated in discussions with the European Commission and at international fora such as Codex and World Organisation for Animal Health (OIE).

2.3 The revised Trichinella rules also provide a clear pathway for securing derogations from the testing requirements (which would formerly have been captured within ‘negligible risk recognition’). This has been a long standing aim of the UK to help support further trade in the medium and long term, and is fully in line with the Scottish Government’s trade and growth agenda.

Rationale for Government Intervention

2.4 Although evidence from UK testing indicates that the risk from Trichinella is low in all UK countries, the parasite can cause serious illness in humans. Consumers generally do not have sufficient information or knowledge to understand the risks associated with Trichinella, and government intervention is therefore necessary to ensure that there are safeguards in place to protect consumer health.

2.5 The previous EU requirements on Trichinella, requiring all pigs to be tested for this parasite, are currently under-implemented in the UK as the view was taken that these requirements were neither risk-based, nor proportionate. However, this new EU Trichinella regulation will move away from requiring all pigs to be tested for this parasite to a more risk-based regime. The Food Standards Agency (FSA) as the Competent Authority is required to ensure that these testing requirements are implemented.

2.6 Failure to implement the new EU Regulation would result in a high risk of infraction proceedings being taken against the UK, given the long-standing UK policy of under-implementation of the previous requirements which has been regularly highlighted by the Commission’s Food and Veterinary Office (FVO). This would have wider ramifications for government and industry, including the potential to jeopardise recently established UK trade with third countries, markets which Scottish pork processors are actively looking to develop.

2.7 Full implementation of these requirements is a necessary step towards building a strong evidence base for attaining the derogations available in the Regulation. It also provides a platform to support current UK trade and possible expansion, particularly if the criteria for the relevant derogation can be met, which will enhance potential trade opportunities for Scottish pork processors.

Background

2.8 Trichinella is parasitic worm which infects pigs, horses, wildlife such as foxes and rats, as well as humans. It is transmitted by eating infected muscle tissue and can be transferrable to humans through undercooked food. It can cause serious illness, from vomiting, fever and severe muscular pain up to cardiac problems, but can also be treated effectively if caught within 10 days of infection. The existing evidence we have from our testing indicates that there is a very low risk to public health in the UK from Trichinella. The last case from meat produced in GB was in 1977 and the most recent human cases were a cluster of 8 in North London in 2000, which was traced to the personal import of pork salami from Serbia. The FSA also provides extensive advice to consumers on the safe and hygienic preparation and cooking of pork.

Current regulatory regime

2.9 Under current EU law (EC Regulation 2075/2005), every pig slaughtered for human consumption should be tested for Trichinella. The UK considers that this is not proportionate or risk based, failing to take into account the different levels of risk for pigs raised indoors, in controlled housing, compared to the risk for pigs which spend varying periods of their life outdoors. As such, this requirement has been under-implemented in the UK. We have maintained a core testing programme with all sows, boars, horses and wild boar tested in approved slaughter premises and a number of slaughterhouses test in their own on-site labs, although only some of the testing data from these laboratories is available to the Central Competent Authority.

2.10 The UK applied unsuccessfully in June 2006 to the Commission for recognition as a region of negligible Trichinella risk; the response from the Commission and Member States focussed on the need for testing more outdoor pigs and presenting GB and NI data separately, as they have different epidemiological profiles. Applications for recognition were put on hold as the Commission developed the revised proposals, which include clear criteria for derogations from testing (along the lines of negligible risk recognition), but achieving derogations from testing requirements remains a long-term objective for the UK – the new Regulation has clear criteria for securing derogations from testing after three years, provided testing is carried out in accordance with the legislation and no positives are found.
New EU Regulation

**Testing requirements for pigs**

2.11 The new, directly applicable, EU Regulation comes into force in June 2014 and is significantly more risk-based and proportionate than Regulation 2075/2005. It recognises the different risks of different housing systems and this is reflected in the testing requirements. It also has clear criteria for securing negligible risk recognition by compartment, which is a key objective for the UK. The definition of a compartment is flexible, describing a group of holdings which apply controlled housing conditions. This can be on a geographic basis (such as Scotland) or, for example, an integrated production system. It is also possible for all holdings applying controlled housing conditions in a member state may be considered as one compartment. It should also be noted that this regulation dovetails with the direction of travel at Codex Alimentarius (which develops harmonised international food standards for trade and consumer protection) and the World Organisation for Animal Health (OIE), the international trade and veterinary organisations – these bodies are also reviewing the control, testing and negligible risk requirements for Trichinella, with a view to greater consistency between the various international standards. This should also have trade benefits, with clarity on standards and the status of derogations from testing requirements.

2.12 The new testing requirements are predicated on the identification of controlled housing holdings, a type of animal husbandry where swine are kept at all times under conditions controlled by the Food Business Operator (FBO) with regards to feeding and housing. It will therefore be necessary for the FSA to identify the pattern of holdings across GB and ensure that these are accurately reflected in the Food Chain Information (FCI) accompanying the animals from the farm to the slaughterhouse. We will also need to establish compartments as far as possible, as this will be a requirement for presenting the necessary data for implementing the derogations from testing.

2.13 The nature of the holding will then determine the testing requirements at the slaughterhouse. These testing requirements are that:

“a) all carcases of breeding sows and boars or at least 10% of carcases of animals sent in for slaughter each year from each holding being officially recognised as applying controlled housing conditions, shall be examined for Trichinella, and

(b) all carcases from holdings not being officially recognised as applying controlled housing conditions shall be systematically examined for Trichinella”.

2.14 With regard to requirement (a), the core testing programme in GB already sees all breeding sows and boars tested at approved slaughterhouses, with the cost of this being met by the FSA. We therefore consider that this allows Scotland to successfully meet the first requirement of the testing regime.

2.15 The second requirement is that all pigs not from controlled housing conditions must be tested for Trichinella. This reflects the greater risk of infection for pigs that spend time outdoors. However, there is a useful degree of flexibility in the definition of controlled housing. Alongside the general requirements relating to issues such as
pest control and secure storage of feed, which carry over from the previous regulation, there is scope for pigs to have some access to our door facilities provided that “the food business operator can show by a risk analysis to the satisfaction of the competent authority that the time period, facilities and circumstances of outdoor access do not pose a danger for introduction of Trichinella in the holding”. It is the intention that as part of the mapping exercise for holdings and compartments, the FSA will use existing evidence, such as wildlife testing data, to inform a preliminary risk assessment and reflect this in the mapping.

2.16 In terms of the production and housing systems used in Scotland, discussions with industry suggest the picture is nuanced. Of those pigs that are reared, finished and slaughtered in Scotland (i.e. excluding those reared in Scotland but finished and processed in England), around 80% (circa. 20,000 breeding sows producing 520 – 560k pigs per year) are reared using indoor farrowing systems before being finished in controlled indoor housing, with no outdoor access at all during the entire breeding/rearing cycle. The remaining 20% (circa. 5,000 breeding sows producing 105 – 110k pigs per year) will spend between 4 – 12 weeks outside before being finished indoors, in what is considered controlled housing. Based on discussions with industry we understand there are no commercial organic or free range pigs herds in Scotland that will spend their entire lives outdoors which would be considered as not applying controlled housing conditions.

2.17 We assume therefore that the 80% of pigs reared and slaughtered in Scotland that spend their entire lives indoors would be considered as applying controlled housing conditions and would not require Trichinella testing. Of the remaining 20% that spend time both outdoors and indoors, we would anticipate that they are also likely to be considered as being in controlled housing given the flexibility in the Regulation outlined above. However, where the line is drawn will need to be supported by appropriate epidemiological evidence and a risk assessment. For the purposes of this impact assessment we assume a high impact scenario whereby the 8% of pigs that are ‘outdoor reared’ and spend up to 12 weeks outdoors (circa. 2,000 breeding sows producing 40,000 pigs per year) which are likely to present the highest Trichinella risk could possibly fall outside the definition of controlled housing and require to be tested. (Please note industry has advised that these ‘outdoor reared’ pigs are unlikely to be part of the Scottish kill until late 2015 at the earliest, but they have been included in the high impact cost analysis for the purpose of impact assessment.)

2.18 Based on this high impact scenario a number of slaughterhouses will be subject to increased testing and this will have implications in practical and cost terms, particularly with regard to laboratory capacity and turn-around. This may encourage some larger plants to explore the prospect of setting up an in-house lab, which has costs for government in terms of ensuring that the lab meets the required standards and a capital outlay for the FBO. It is assumed that this will not be a feasible option for the majority of small to medium sized plants in Scotland.

**Testing requirements for horses and wild boar**

2.19 The new Regulation also requires that “Carcasses of horses, wild boar and other farmed and wild animal species susceptible to Trichinella infestation shall be systematically sampled in slaughterhouses or game-handling establishments as part of the post-mortem examination.” This carries over the requirements of the existing
Regulation and is already carried out in GB. As this is consistent with the general intention to test animals at greater risk of exposure to infection, such as wild boar and horses, the FSA intends to continue to test all horses and wild boar in slaughterhouses and game handling establishments (although there are currently no abattoirs approved to slaughter horses in Scotland). In addition, the UK will continue with the programme of surveillance with regard to susceptible wildlife, such as foxes.

Food Chain Information (FCI)

2.20 The FCI accompanying the animals from the farm to the slaughterhouse will need to capture whether the pigs need to be tested for Trichinella (i.e. if they come from a non-controlled housing holding or are a breeding sow/boar). We propose to capture this very simply with a single box, to tick where the pigs need to be tested. This will be integrated into the revision of the existing FCI forms and as such should not represent an additional cost to farmers.

Auditing and verification of controlled housing conditions

2.21 Whilst the FSA will conduct an exercise to map controlled housing holdings, it is a requirement that this be supported by a structured, risk-based audit and verification programme. The Competent Authority is obliged to “ensure that audits are carried out periodically of holdings officially recognised as applying controlled housing conditions” and that “the frequency of audits shall be risk-based, taking account of disease history and prevalence, previous findings, the geographical area, local susceptible wildlife, animal husbandry practices, veterinary supervision and farmers’ compliance”.

2.22 It is intended that auditing of controlled housing holdings in Scotland will be integrated as far as possible into existing farm inspections. We are also exploring what role can be played by earned recognition through third party farm assurance schemes, such as the QMS Specially Selected Pork scheme, which would help to minimise the impact on farmers.

Derogations from testing requirements

2.23 Aside from the continuing derogations from testing where the carcases have undergone suitable freezing treatment (as defined in the regulations) or are from un-weaned pigs aged less than 5 weeks, there is scope for what was previously described as negligible risk recognition. However, as the Regulation has been brought closely into line with the OIE requirements and terminology, negligible risk status for a country or region is no longer recognised and instead, such recognition is linked to compartments applying specific controlled housing conditions.

2.24 The mapping of compartments and holdings to determine the extent of controlled housing conditions has already been outlined. A compartment is essentially a common group and in the context of Trichinella could be a geographic area, such as Scotland or another region of the UK, or an integrated production system. The new regulation would allow for all of the controlled housing holdings in GB to be considered as a single compartment but this could present a risk were a positive to be found (the entire compartment would have any derogations from testing suspended subject to further investigation), so the assessment and mapping of compartments will be supported by a risk assessment.
2.25 Within those controlled housing compartments, the requirements for derogation is that there must have been “no autochthonous Trichinella infestations in domestic swine kept in holdings officially recognised as applying controlled housing conditions have been detected in the Member State in the past 3 years”. During this period, a testing regime compliant with the requirements set out earlier must have been fully implemented. We consider that this requirement for the derogation is a realistic aim for Scotland and the rest of GB.

2.26 Alternatively, the other option is for the Member State to present “historical data on continuous testing carried out on slaughtered swine population provide at least 95% confidence that the prevalence of Trichinella does not exceed 1 per million in that population”. The FSA has made previous assessments of the UK testing data with a view to this standard, but there are not the necessary volumes of testing over a suitable number of years to meet the statistical threshold. The assessment of historical data put the confidence percentage of 1 per million prevalence level at 85-90%. To attain the requisite 95% confidence threshold would have required a least 1.5 - 2 million additional Trichinella tests carried out per year, which would mean, at considerable expense, a very significant increase in testing for a period of several years. The FSA does not consider this a realistic prospect for securing derogation from the specified testing requirements.

Laboratories and permitted testing methods

2.27 The permitted testing methods for Trichinella will remain the same under the new regime and are set out in the legislation. With regard to carrying out testing, it is expected that some plants across GB may decide to set up their own in-house laboratory rather than sending samples to an external laboratory for testing, as this approach would allow carcases to be turned round more quickly. However, in Scotland we anticipate this only being a realistic possibility for the largest pig slaughterhouse (processing over 100,000 pigs per year) due to the capital costs that would be incurred (estimated to be around £5k, not including staff costs).

2.28 We anticipate that in-house laboratories will not be commercially viable for most small to medium sized pig processors in Scotland given the smaller size of the Scottish pig industry compared with rest of GB. Smaller slaughterhouses may prefer either to send samples to an external laboratory as most do at present, or, as already happens in some parts of the country, use the in-house laboratory of a larger FBO nearby – this innovative approach has proved useful, subject to proper procedures to ensure traceability and remove the possibility for cross-contamination.

Sensitivities

2.29 Trichinella testing is an important aspect of international trade in pig meat, both within the EU and with third countries. The Trichinella testing regime of a Member State is part of trade agreements and can come under close scrutiny, so ensuring compliance with EU regulations is critical both to safeguard existing UK trade agreements and facilitate future trading opportunities, particularly with third countries.

2.30 The current Trichinella requirements, set out in EU regulation 2075/2005, have been consistently under-implemented in the UK and this has been cited in numerous Food and Veterinary Office (FVO) audit reports over the last few years, with specific recommendations to address this matter. Should the new Trichinella requirements
not be fully implemented then not only would this present a risk to international trade but there would also be a significant risk of infraction proceedings against the UK.

3. CONSULTATION

Within Government

3.1 The FSA set up a Cross Government Group on Meat Official Controls (CGGMOC) in 2010. This group includes policy officials from all relevant UK departments, including the FSA in Scotland and the Scottish Government Directorate for Agriculture, Food and Rural Communities. The group was instrumental in developing the high level UK negotiating principles on the new pig meat inspection rules and played a key role during EU negotiations.

3.2 FSA officials with responsibility for operational delivery in pig slaughterhouses are also represented on the CGGMOC and were engaged throughout negotiations on the pig proposals and the development of supporting scientific research.

3.3 The Scottish Government Better Regulation and Industry Engagement (BRIE) team, Directorate for Justice, and Legal Directorate have also been consulted during the preparation of this BRIA.

Public Consultation

3.4 A series of nationwide citizen’s forums\(^2\) were conducted between June and July 2010 to explore consumer attitudes to meat hygiene and views on potential changes to meat official controls. Participants indicated that they would favour any changes to meat inspection that were based on robust science, with proportionate managed communications to the public about the implications, and a robust monitoring system for animal diseases.

3.5 Consumer perspectives were also sought through the FSA Consumer Advisory Panel (CAP), whose role is to provide consumer insights into the FSA’s work by supplementing consumers’ views and opinions obtained from direct engagement.

3.6 [DN: Please note this section will be completed after the public consultation has ended]

Business

3.7 The FSA has worked in collaboration with industry groups throughout the development of the revised pig meat inspection rules through the Current and Future Meat Controls (CFMC) Stakeholder Group. The CFMC includes organisations representing slaughterhouses, the meat processing industry, primary producers and consumers from across the UK, including key stakeholder bodies in Scotland. The Group meets three times a year and contributes to discussions on strategy and planning, both in respect of research and future negotiations.

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\(^2\) [link](http://food.gov.uk/multimedia/pdfs/publication/cfsummreportmeathygiene.pdf)
3.8 In 2011 the FSA established a specific Task Group of the CFMC in relation to pigs to provide comments and feedback on the Commission’s proposals and help inform the UK negotiating position. Input from the Task Group was sought throughout negotiations. This collaborative approach was a success, and a similar approach will be taken when the FSA begins negotiations on other species.

3.10 The FSA in Scotland has also held discussions with the largest pig producer co-operative in Scotland, representing around 75% of commercial pig producers, and Quality Meat Scotland (QMS) to assess the likely impacts of the new rules, and further face-to-face visits with operators of pig meat slaughterhouses are planned as part of the consultation process. Individual slaughterhouses have also been consulted and have assisted the development of the evidence base through contributing to the FSA’s supporting research programme.

4. OPTIONS

4.1 The options considered are:

**Option 1:** Do nothing.

4.2 This will involve maintaining the current core testing programme, without specifically targeting any pigs not in controlled housing conditions for more testing. The plants that conduct testing to meet export requirements would continue to test all pigs for the foreseeable future, until such as time as these requirements are amended; such a review could not begin to take place until the relevant Codex chapter (which frames international trade standards in this area) has been agreed.

4.3 This option would mean no additional costs and the framework for this is already in place, so the administrative burden would be minimal. However, this approach would mean that the UK would continue to be non-compliant with EU testing requirements and given that this would be perceived by the Commission as persistent refusal to comply, previous experience in other policy areas suggests that it would carry a significant risk of infraction proceedings. These proceedings would represent a large cost to government in financial and administrative terms and jeopardise EU and third country trade.

**Option 2:** Full Compliance

4.4 This will involve maintaining the current core testing programme to fulfil the first requirement. Meeting the requirement to test all pigs not from controlled housing will necessitate a significant mapping exercise by the FSA to ascertain holdings where all pigs need to be tested across GB, supported by epidemiological analysis and a suitable risk analysis, together with a programme of audit and verification to support the identification of holdings. Based on the high impact scenario outlined in paragraph 2.17 above, this will also require increased testing at slaughterhouses which process pigs that are not from controlled housing holdings and may have an effect on laboratory capacity, with the need for more in-house laboratories.

4.5 Whilst the core testing programme will continue, this option involves an increase in the testing of pigs not from controlled housing and will have costs for government and industry. However, if fully implemented, this will support current and future expansion of
trade and provide the necessary evidence for application of derogations from testing in due course.

**Sectors and groups affected**

**Slaughterhouses**

4.6 Under Option 2, breeding sows and boars will continue to be tested as they are at present within the core testing programme that has been in place for some years. This fulfils the first component of the testing requirements. To fulfil the second part of the testing requirements, slaughterhouses will need to test all pigs from non-controlled housing conditions.

4.7 There are currently a total of 17 slaughterhouses in Scotland that slaughter pigs. Of these, 2 are pigs only plants and 15 are multi-species slaughterhouses, which slaughter pigs as well as other species.

4.8 In 2013, a total of 300,732 pigs were slaughtered in these 17 plants. There is a significant amount of consolidation in the pig industry with the 2 pig-only plants accounting for 75% (225,934) of all pigs slaughtered in Scotland. A single multi-species plant accounts for a further 29,558 pigs, which means that combined together the 3 largest pig plants account for 85% (255,492) of all pigs slaughtered in Scotland. The remaining 45,240 pigs were slaughtered in 14 small and micro plants.

<table>
<thead>
<tr>
<th>Sector</th>
<th>Pig only</th>
<th>Multi-Species</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro</td>
<td>0</td>
<td>11</td>
<td>11</td>
</tr>
<tr>
<td>Small</td>
<td>0</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Medium</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Large</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>15</td>
<td>17</td>
</tr>
</tbody>
</table>

*Table 1: Number and size of affected slaughterhouses in Scotland*

*Source: FSA plant data from (2013). Micro: slaughterhouses killing less than 5,000 pigs per annum; Small: 5,000 to 37,500 pigs per annum; Medium: 37,500 to 100,000 pigs per annum; Large: over 100,000 pigs per annum.*

4.9 All 17 plants could be affected, as they could potentially slaughter pigs from non-controlled housing conditions based on the high impact scenario outlined in paragraph 2.17, and could therefore incur increased costs of additional testing. The calculations below reflect this possibility. However, given that almost 85% of pigs are processed in 3 plants, it is not unreasonable to expect that a significant proportion of pigs not in controlled housing will be processed at these 3 plants.

**Consultation Question 1**

We would welcome any evidence regarding the distribution of pigs from non-controlled housing:

- In Scotland what proportion of pigs from non-controlled housing is likely to be slaughtered in micro, small, medium, large slaughterhouses, and what proportion is already tested for Trichinella?
Farmers

4.10 It is anticipated that the effect on farmers will be low. The only impact on farmers is that they need to ensure that information about housing conditions is included in the FCI accompanying the pigs to the slaughterhouse. As mentioned above, this will be captured by one single, additional box on the FCI form, which farmers will need to tick if pigs have been reared under non-controlled housing conditions.

4.11 The following information on the number of pig holdings in Scotland comes from the Economic Report on Scottish Agriculture 2013. It should be noted that these figures relate to all farms with pigs, not just pig-only farms and most of these holdings have a small number of pigs as part of a mixed enterprise.

Table 2: Number of Affected Pig Holdings in Scotland

<table>
<thead>
<tr>
<th></th>
<th>North West</th>
<th>North East</th>
<th>South East</th>
<th>South West</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female breeding herd</td>
<td>168</td>
<td>118</td>
<td>120</td>
<td>153</td>
<td>559</td>
</tr>
<tr>
<td>All other non-breeding pigs (fattening pigs)</td>
<td>358</td>
<td>281</td>
<td>258</td>
<td>315</td>
<td>1,212</td>
</tr>
<tr>
<td>Total</td>
<td>399</td>
<td>295</td>
<td>279</td>
<td>355</td>
<td>1,328</td>
</tr>
</tbody>
</table>

Source: Economic Report on Scottish Agriculture 2013

Food Standards Agency

4.12 Under Option 2, the FSA will incur costs arising from the mapping of controlled housing and compartments. The Agency will also have the cost of providing support and advice on setting up new in-house laboratories. There will be also be a cost to the FSA with regard to training for OVs in slaughterhouses as Trichinella testing is done under their supervision and they will need to be familiar with the testing requirements to provide appropriate verification that testing is being carried out correctly.

Enforcement

4.13 There will be a cost to Official Veterinarians in terms of familiarising themselves with the new requirements regarding the definition of controlled housing and integrating such verification into existing audit processes, although we are exploring how far this can be supported by third party accredited schemes.

Consumers

4.14 The main direct impact of this proposal is increased testing for Trichinella by slaughterhouses, which could potentially generate health benefits to consumers, although, as mentioned above, the risk of Trichinella in the UK has been assessed as low. As the number of additional pigs to be tested in the high impact scenario is estimated to be around 8% of the Scottish pig kill, and they may well not require testing following risk assessment, the impact of this measure on consumers in terms of price changes is expected to be negligible.

3 [http://www.scotland.gov.uk/Publications/2013/06/5219](http://www.scotland.gov.uk/Publications/2013/06/5219)
Benefits

Option 1: Do nothing

4.15 The do nothing option would mean no additional Trichinella testing and familiarisation costs for industry and no additional costs for enforcement authorities and the FSA. As the framework for this option is already in place the administrative burden would be minimal.

Option 2: Full Compliance

Benefits to Consumers

Benefits to Consumers from more Stringent Trichinella Controls (Non-Monetised)

4.16 Although UK evidence from testing indicates that the risk from Trichinella is low in the Scotland, the parasite can cause serious illness in humans. The aim of the new EU Regulation is to minimise this risk and can therefore have public health benefits.

Benefits to Industry

Potential to Secure Derogations from Trichinella Testing (Non-Monetised)

4.17 The UK has a long-term objective to secure derogations from Trichinella testing. The new Regulation provides a clear path to securing that new recognition, which applies if no infections have been detected in pigs reared in controlled housing conditions for a period of three years. UK evidence from testing indicates that the risk from Trichinella is low and it is the FSA’s view that this is a realistic prospect for the UK. Compliance with the European requirements, which are in turn aligned with those governing trade and animal health and are in development at international level (Codex and OIE), will also help support further trade in the medium and long term.

Costs

Option 1: Do nothing

4.18 Under this option the UK would continue to be non-compliant with EU testing requirements and given that this would be perceived by the Commission as persistent refusal to comply, previous experience in other policy areas suggests that it would carry a significant risk of infraction proceedings. These proceedings would represent a large cost to government in financial and administrative terms and jeopardise EU and third country trade. The maximum fine that could be imposed on the UK is some €703,000 per day or £256 million per year.4

Option 2: Full Compliance

Costs to Slaughterhouses

Familiarisation Costs (One-Off Costs)

4 http://www.scotland.gov.uk/Topics/International/Europe/Legislation/Infractions
4.19 There will be costs to slaughterhouses from the need to familiarise themselves with the new Regulation. Familiarisation costs can be monetised as a time cost, multiplying the time required for familiarisation by the wage rate of the employee carrying out the familiarisation. We envisage that it will be business managers (wage rate of £25.80\(^5\)) who will need to familiarise themselves with the new requirements and that this will take approximately one hour per business. Multiplying the wage rate by the number of hours required and the 17 slaughterhouses potentially affected generates a maximum total familiarisation cost to Scottish slaughterhouses of £438.00.

**Consultation Question 2**

We invite stakeholders to comment on whether our estimates of familiarisation costs to slaughterhouses seem reasonable or not. Please provide us with as detailed information and data as possible (e.g. hours required, grade involved) for us to be able to monetise this cost.

**Costs from Additional Testing (Ongoing Cost)**

4.20 Under Option 2, there will be costs to slaughterhouses that slaughter pigs from non-controlled housing conditions. FSA pig plant data suggest that there are around 300,732 pigs that go for slaughter in Scotland each year. Based on the high impact scenario outlined in paragraph 2.17, approximately 8% (24,058) of the Scottish kill could be from what is considered as holdings not operating controlled housing conditions and therefore would have to be tested under the proposal. This would amount to an additional 24,058 samples per annum. As noted earlier, given the fact that almost 85% of pigs are processed in the 3 largest plants it is not unreasonable to expect that a significant proportion of these pigs will be slaughtered in those 3 plants.

4.21 Based on existing structures within the Scottish industry which sees all Trichinella testing conducted through the private accredited laboratory route we anticipate that all pigs not from controlled housing will be tested by private laboratories, at least initially, which means an estimated cost of £4.09 per pig tested. Based on these assumptions, the total cost to the slaughterhouse sector under this proposal would be £98,397 per annum. If, in the future, testing was to be carried out using in-house laboratories this would significantly reduce the testing cost as the cost of in-house testing is borne entirely by the FSA at £0.60p per test. If industry in Scotland were to go down this route this would result in additional testing costs of £14,434, which would be borne by the FSA.

4.22 However, this is a worst case scenario and likely to be an overestimate (as noted in paragraph 2.17 above, although these ‘outdoor reared’ pigs are bred and reared in Scotland they are unlikely to be part of the Scottish kill until early 2015 at the earliest). If, following appropriate epidemiological evidence and risk assessment, all pigs in Scotland are considered to be reared under controlled housing conditions there will be no additional testing costs to industry.

4.23 It should be noted that if the testing requirements are properly implemented for three years and there are no positive results for Trichinella in the pig population, then the UK will be in a position to apply for derogations from the testing requirements which may help to reduce costs.

Consultation Question 3

We invite stakeholders to comment on whether our estimates of the cost of additional testing seem reasonable or not:

a. Do you agree with our high impact scenario (informed by discussions with industry) that approximately 8% of the total Scottish pig kill from late 2015 onwards could be considered as reared in non-controlled housing conditions? What proportion of these pigs are likely to already be tested for Trichinella?

b. Do you agree with our assumption that all additional tests under this proposal would be carried out using a private accredited laboratory, at least initially, at a cost of £4.09p per sample?

If you agree, or disagree, please provide us with as detailed information and data as possible for us to monetise this potential cost.

Potential Costs from Moving to In-House Testing (One-Off Cost)

4.24 The new testing requirements will result in an increase in the number of Trichinella tests that slaughterhouses need to carry out. Testing must be carried out using the methods set out in the regulation at a designated laboratory. Based on current information about testing practices, we would expect that most plants in Scotland will seek to use a private accredited laboratory if additional testing is required, or possibly to make an arrangement to use the laboratory of a nearby FBO or send samples.

4.25 While some larger plants may wish to explore setting up their own in-house testing to facilitate faster turnaround of carcases, we anticipate this only being a realistic possibility for the largest pig slaughterhouse (processing over 100,000 pigs per year) due to the capital costs that would be incurred. We anticipate that in-house laboratories will not be commercially viable for most small to medium sized pig processors in Scotland given the smaller size of the Scottish pig industry compared with rest of GB.

4.26 However, if we assume a high-impact scenario where all small, medium and large slaughterhouses (6 in total) would need to set up an in-house laboratory, the total one-off cost to industry would be between £18,000 and £30,000 (using the cost range of £3-5k above), with a best guess estimate of £24,000 (based on the average of the range). Table 3 below shows the central (best guess) scenario, although this is likely to be an overestimate for the reasons outlined above.

Table 3: Costs to slaughterhouses from setting up an in-house lab (£)

<table>
<thead>
<tr>
<th></th>
<th>Micro</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>0</td>
<td>16,000</td>
<td>4,000</td>
<td>4,000</td>
<td>24,000</td>
</tr>
</tbody>
</table>
Consultation Question 4

We invite stakeholders to comment on whether our estimates of the cost of setting up in-house labs seem reasonable or not. If you agree, or disagree, please provide us with as detailed information and data as possible for us to be able to monetise this cost, in particular:

a. What proportion of micro, small, medium and large slaughterhouses are likely to set up an in-house lab as a result of the new requirements?
b. What would be the approximate one-off cost to set up an in-house laboratory?
c. Would there be any costs involved for plants that make arrangements to use the in-house lab of a nearby FBO?

Costs to Farmers

Familiarisation (One-Off Cost)

4.27 The main direct impact on farmers from the new Regulation is that the food chain information that need to accompany pigs from the farm to the slaughterhouse will need to include information on whether the pigs are from non-controlled housing or not (see paragraph 20 above). To farmers this essentially means ticking a box if the pigs they supply are from non-controlled housing. We envisage that this will involve some familiarisation costs to farmers. Familiarisation costs can be monetised by multiplying the wage rate of the person carrying out familiarisation by the time required. We envisage that it will be the farm manager (wage rate of £17.2\(^6\)) that will familiarise themselves with the changes, and that half an hour per farm would be sufficient; as only a proportion of the new requirements apply to farmers. Multiplying the wage rate by the time required, and again by the number of farms (see Table 2) generates a total one-off cost of familiarisation to farmers of £11,420.

Changes to Requirements on Provision of Food Chain Information (Ongoing Cost)

4.28 As outlined above, the new Regulation requires that FCI includes information on whether pigs are from non-controlled housing or not. The amendment to the FCI form will consist of one additional box, which the farmer will need to tick to indicate whether or not the farm has controlled housing conditions, and therefore whether or not the pigs need to be tested for Trichinella. We envisage that this requirement will result in a negligible cost to farmers, as they already need to fill in the rest of the form, and the additional tick will require negligible time.

Consultation Question 5

We invite stakeholders to comment on whether our estimates of the cost to farmers in the following areas seem reasonable or not:

a) changes to FCI

---

b) familiarisation

Please provide us with as detailed information and data as possible for us to be able to monetise this cost.

**Costs to Enforcement**

**Familiarisation (One-Off Cost)**

4.29 There will be costs to enforcement from the need to familiarise themselves with the new Regulation. We envisage that the main impact will be on OVs as they are responsible for monitoring Trichinella testing. We envisage that familiarisation would require one OV per slaughterhouse and that familiarisation would take approximately one hour. As mentioned above, familiarisation costs can be monetised as a time cost, multiplying the time required for familiarisation by the wage rate of the employee carrying out the familiarisation. Multiplying the wage rate of an OV (£36.8, FSA internal data) by the number of hours required and the number of slaughterhouses (see Table 1) generates a total cost to enforcement of £625.

**Training (One-Off Cost)**

4.30 We anticipate that enforcement officers will incur training costs as a result of the Regulation, as they are responsible for the supervision of Trichinella testing. These costs will be borne by the FSA and costs have therefore been presented in the section on costs to the Food Standards Agency (see paragraph 4.33).

**Audit and Verification On-Farm (Ongoing)**

4.31 With regard to the costs of auditing and verification this will be integrated as far as possible within existing on-farm inspections and visits, in line with the recommendations of the Interim Report on Doing Better Initiative to Reduce Red Tape in Agriculture. The most appropriate body to carry out audit and verification functions in Scotland has still to be agreed, although AHVLA may be best placed as a number of the criteria for determining whether a holding has controlled housing relate to core issues such as biosecurity and compliance with animal by-products regulations. These factors are also assessed in audits by accredited third party assurance schemes, such as the QMS Specially Selected Pork scheme, and we anticipate that the on-farm verification can be supported by such third party schemes. The final costs associated with this aspect of enforcement, including related issues such as communication, have still to be determined.

**Costs to Food Standards Agency**

**Cost of mapping controlled housing (One-Off Cost)**

4.32 The new Regulation requires that all pigs from non-controlled housing conditions are tested for Trichinella. The FSA is currently undertaking an exercise to map controlled housing holdings (see paragraph 4.4 above), supported by evidence from historic testing data and wildlife surveillance. The estimated cost to the FSA associated with this mapping exercise is £10k.
Cost of additional testing for Trichinella (Ongoing)

4.33 The new Regulation requires that all pigs from non-controlled housing conditions are tested for Trichinella. While the cost of in-house testing is borne entirely by the FSA at £0.60p per test, and this will continue under the new proposal, no in-house testing is currently carried out in Scotland at present. Therefore there are no additional costs to the FSA from this Regulation. As outlined in paragraph 4.21, if industry in Scotland were to go down the in-house laboratory route in the future we estimate that this would result in additional testing costs to the FSA of £14,434.

Cost of training OVs (Ongoing)

4.34 We anticipate that the Regulation will result in training costs to OVs. These costs will be borne by the FSA. We envisage that training will take one OV per slaughterhouse approximately one hour and consist of an on-line course. Just as familiarisation costs, training costs can be monetised as a time cost. Multiplying the wage rate of an OV (£36.8, FSA internal data) by the number of hours required and the number of slaughterhouses (see Table 1) generates a total cost to enforcement of £625.

5. SCOTTISH FIRMS IMPACT TEST

5.1 As part of the public consultation we are sending this partial BRIA to all FBOs of pig slaughterhouses in Scotland to seek comments on the potential impact the new Trichinella testing requirements may have. We will also be conducting face-to-face visits with FBOs of the 3 largest pig slaughterhouses that account for 85% of all pigs slaughtered in Scotland, as well as a number of FBOs from smaller plants, to discuss their views and comments in more detail.

5.2 [DN: Please note this section will be completed after the public consultation has ended]

Competition Assessment

5.3 The incoming Regulation is not expected to have any impact either directly or indirectly on competition.

5.4 Using the Office of Fair Trading (OFT) competition assessment framework, it has been established that the preferred policy option (option 2) will neither directly or indirectly limit the number or range of suppliers, limit the ability of suppliers to compete or reduce suppliers’ incentives to compete vigorously.

Test Run of Business Forms

5.5 The amendment to the FCI form will be one additional box, to indicate whether the pigs from the farm need to be tested for Trichinella (based on whether the farm has controlled housing). It is anticipated that the cost of this change will be very low. As the changes to the existing form are so minimal we do not anticipate a need to test run the form with business again.
6. **LEGAL AID IMPACT TEST**

6.1 This new EU Regulation will not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Access to Justice Team of the Justice Directorate who concur that there will be no impact on the legal aid fund.

7. **ENFORCEMENT, SANCTIONS, AND MONITORING**

7.1 Enforcement of the new Trichinella rules in approved slaughterhouses and game handling establishments will be the responsibility of the FSA. The relevant enforcement powers are provided within the Food Hygiene (Scotland) Regulations 2006.

Sanctions

7.2 No changes are being proposed to the criminal sanctions or civil penalties contained in the Food Hygiene (Scotland) Regulations 2006.

Monitoring

7.3 The effectiveness and impact of this EU Regulation will be monitored via feedback from stakeholders, including the CFMC Task Group, as part of the ongoing policy process.

8. **IMPLEMENTATION AND DELIVERY PLAN**

8.1 Implementation of the new Trichinella rules will involve identifying and mapping holdings in liaison with industry and AHVLA, using wildlife testing and other data to support the risk profile as outlined in paragraph 4.4 above. To support this mapping exercise an audit and verification programme will need to be designed within the existing audit framework, supported by third party accreditation where possible. The demand for in-house laboratories will also need to be assessed, as will the new FCI requirements to ensure it captures the necessary information on farm and that this is communicated successfully to the slaughterhouse.

Post-Implementation review

8.2 A review to establish the actual costs and benefits and the achievement of the desired effects will take place in June 2019 (i.e. 5 years from the direct application of Regulation (EU) No. 216/2014 in the UK).

8.3 A formal review will take place within 10 years of the legislation coming into force to ensure it is still fit for purpose.

9. **SUMMARY AND RECOMMENDATION**

9.1 The preferred option for implementation in Scotland is Option 2, full implementation of the requirements set out in the Regulation. This will ensure consumers are
protected through proportionate and risk-based Trichinella controls and mitigate the likelihood of action from the European Commission, while supporting the longer term trade objectives of the UK and Scottish Governments.

9.2 [DN: A summary table outlining the overall costs and benefits will be added to the final BRIA]

10. DECLARATION AND PUBLICATION

I have read the partial Business and Regulatory Impact Assessment (BRIA) and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the options. I am satisfied that business impact will be assessed with the support of businesses in Scotland.

Signed:

[Signature]

Date: 24 March 2014
Professor Charles Milne
Director, Scotland

Contact point:
Steve Hardie
Regulatory Policy Branch
Food Standards Agency
Tel: 01224 285145
Email: steve.hardie@foodstandards.gsi.gov.uk
List of Interested Parties

Aberdeen City Council
Aberdeenshire Council
Angus Council
Animal Health & Veterinary Laboratories Agency
Aberdeen Northern Marts Group Ltd
AP Jess (Brechin) Limited
Argyll & Bute Council
Avonvogie Enterprises Ltd
Biobest Laboratories Ltd
British Medical Association Scotland
British Veterinary Association
Brown Brothers Ltd.
Calder Millerfield Ltd
Castle MacLellan Foods
Charcuterie Continental
Chief Medical Officer Directorate
Chief Veterinary Officer Directorate
City of Edinburgh Council
Clackmannanshire Council
Comhairle Nan Eilean Siar
Consumer Focus Scotland
Convention of Scottish Local Authorities
D S (Slaughterhouse) Ltd
Dumfries & Galloway Council
Dunbia
Dundee City Council
East Ayrshire Council
East Dunbartonshire Council
East Lothian Council
East Renfrewshire Council
Falkirk Council
Federation of Small Businesses
Fife Council
Food Storage & Distribution Federation
Food Training & Consultants Company
Glasgow Caledonian University
Glasgow City Council
Glasgow University Veterinary School
GMB Scotland
Hallmark Meat Hygiene Ltd
Haemolytic Uraemic Syndrome Help
Ian Hain Associates
Institute of Auctioneers & Appraisers in Scotland
Inverclyde Council
John M Munro Ltd
John Robertson & Sons (Ham Curers) Ltd
Karro Food Group
Lochmaddy Slaughterhouse
Lockerbie Abattoir
Midlothian Council
Millers of Speyside
Moredun Research Institute
Mull Slaughterhouse Ltd
National Farmers Union Scotland
North Ayrshire Council
North Lanarkshire Council
Orkney Islands Council
Orkney Meat Processors Ltd
Perth & Kinross Council
Quality Meat Scotland
Renfrewshire Council
Royal Environmental Health Institute for Scotland
Royal Highland & Agricultural Society of Scotland
Schotts Abattoir
Scotbeef Ltd
Scotland Food and Drink
Scotlean Pigs Ltd
Scottish Association of Meat Wholesalers
Scottish Borders Council
Scottish Chambers of Commerce
Scottish Crofting Federation
Scottish Federation of Meat Traders Association
Scottish Food and Drink Federation
Scottish Food Enforcement Liaison Committee
Scottish Food Quality Certification Ltd
Scottish Government
Scottish Grocers Federation
Scottish Midland Co-op Society
Scottish Organic Producers Association
Scottish Pig Producers Ltd.
Scottish Salmonella Reference Laboratory
Scottish Wholesale Association
Shetland Abattoir
Shetland Islands Council
South Ayrshire Council
South Lanarkshire Council
SRUC
Stirling Council
Stornoway Abattoir
The Association of Meat Inspectors
The Highland Council
The Moray Council
Unison Scotland
Unite the Union
University of Aberdeen
University of Glasgow
University Of Paisley
Verner Wheelock Associates
West Dunbartonshire Council
West Lothian Council
Which?
Wishaw Abattoir Ltd
The Scottish Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972(a).

There has been consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(b).

Title and commencement

1. These Regulations may be cited as the Food Hygiene (Scotland) Amendment Regulations 2014 and come into force on 1 June 2014.

Amendment to the Food Hygiene (Scotland) Regulations 2006

2. In Schedule 1 (definitions of EU legislation) to the Food Hygiene (Scotland) Regulations 2006(c), for the definition of “Regulation 2075/2005” substitute—

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(a) 1972 c.68. Section 2(2) was amended by paragraph 15(3) of Schedule 8 to the Scotland Act 1998 (c.46)(“the 1998 Act”), section 27 of the Legislative and Regulatory Reform Act 2006 (c.51)(“the 2006 Act”) and Part 1 of the Schedule to the European Union (Amendment) Act 2008 (c.7)(“the 2008 Act”). The functions conferred on the Minister of the Crown under section 2(2), in so far as exercisable within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. Insofar as not transferred, and insofar as relating to food (including drink) including the primary production of food, relevant functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849). Paragraph 1A of Schedule 2 was inserted by section 28 of the 2006 Act and has been amended by section 3(3) of and the Schedule to the 2008 Act.


(c) S.S.I. 2006/3, as amended by S.S.I. 2012/75.

Authorised to sign by the Scottish Ministers

St. Andrew’s House,
Edinburgh
2014

EXPLANATORY NOTE
(This note is not part of the Regulations)


These Regulations implement the Commission Regulation by amending the Food Hygiene (Scotland) Regulations 2006 so that the definition of Regulation 2075/2005 includes the amendments made to its articles by Regulation 216/2014 (regulation 2).

2. A Business and Regulatory Impact Assessment of the effect that these Regulations will have on the costs of business, the voluntary sector and the public sector, has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency in Scotland, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ and online at www.legislation.gov.uk.
Draft Criteria for Visual Inspection Procedures in Pigs
February 2014

Issue

From 1st June 2014 the default post-mortem inspection criteria for all pigs will be Visual Inspection Procedures (VIPs), as detailed in Regulation (EC) 854/2004 as amended by Part B of Chapter IV of Section IV, POINT 2. A small percentage of pigs will be required to undergo Further Inspection Procedures (FIPs), which may include a range of inspection options such as palpation, incision, and/or sample taking as deemed appropriate by the OV. This paper sets out the criteria for deciding where FIPs may be required.

Purpose of Criteria

The overall purpose of setting up and agreeing the criteria for VIPs or FIPs is to help:

- Official Veterinarians (OVs) and Meat Hygiene Inspectors (MHIs) to make professional judgements/decisions as whether a batch of pigs/carcases or an individual animal/carcase requires FIPs; and
- Food Business Operators (FBOs) to facilitate the application of VIPs or FIPs, for example through identifying abnormal live animals when the OV is not present at the time of unloading pigs, and by setting up and agreeing the written procedures for identifying and marking animals that require FIPs.

Basic Principles

The basic principles that underpin these criteria are:

- New legislation requires that VIPs are the default post mortem procedure for all pigs (including sows and boars) and their offal from June 2014;
- Minimal carcase and offal handling at both VIPs and FIPs will minimise cross contamination in line with scientific evidence;
- Each slaughterhouse is different; the layout, equipment, ante and post mortem inspection facilities and arrangements vary;
- The guidelines/criteria intentionally leave a room for OVs to exercise their professional judgement at ante-mortem inspection, and for OVs/MHIs to exercise their judgment at post-mortem inspection. It is neither possible nor appropriate to cover/describe every condition which might require FIPs;
- However, inconsistencies will be minimised by agreeing the majority of common abnormalities/conditions which would require FIPs;
- Undertaking additional inspection tasks and associated costs for specific third country export requirements is a commercial decision for the FBO;
- Traceability of animals/carcases (batch and individual) up to post-mortem inspection should be ensured by FBOs.
• Other responsibilities, such as vigilance for notifiable diseases, remain unchanged.

**INSPECTION CRITERIA AT ANTE AND POST MORTEM INSPECTION**

Before outlining the basic inspection criteria at ante and post mortem inspection it is worth noting that:

• The responsibilities for ante mortem and post mortem inspection are not changing - for clarity these are set out in the Annex to this document.

• The current Collection and Communication of Inspection Results (CCIR) list containing the named conditions is being used as a starting position for the OV to consider FIPs. However, the OV is not limited to these conditions. For example, the OV/MHI may decide that an animal or carcase requires FIPs at post mortem inspection because of a suspected notifiable disease that is not on the current CCIR list.

**Inspection Criteria at Ante Mortem Inspection**

Ante mortem inspection is carried out by the OV and includes an assessment of Food Chain Information (FCI). It may be carried out as clinical observations (routine ante mortem inspection), clinical inspections and/or clinical examinations.

Based on FCI and the outcome of ante mortem, from June 2014 the OV will decide whether there is a need to subject an animal or batch of animals to FIPs at post mortem inspection instead of the default VIPs requirement. The OV’s judgement will take into consideration the “severity” of the abnormality and whether the abnormalities are localised, generalised, and systemic, and/or if there is any indication of possible risks to public health, animal health or welfare.

The OV has three options at ante mortem inspection:

1) To proceed with VIPs at post mortem inspection as the default position;

2) To decide that FIPs are required on the pig carcases and/or offal at post mortem inspection; or

3) To reject the pigs at ante mortem inspection.

For the majority of the conditions listed on the current ante mortem inspection sheet there would be no need for pigs to undergo FIPs.
However, it has been considered that the following conditions from the ante mortem inspection list may justify FIPs at post mortem inspection.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Post Mortem Procedure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mastitis</td>
<td>FIPs</td>
<td>Marked/Detained for FIPs only if associated with general signs.</td>
</tr>
<tr>
<td>Moribund, Recumbent</td>
<td>FIPs</td>
<td>Marked/Detained for FIPs or any other examination that OV considers it necessary.</td>
</tr>
<tr>
<td>Orchitis</td>
<td>FIPs</td>
<td>Marked to consider <em>Brucella</em> (occupational zoonoses).</td>
</tr>
<tr>
<td>Slaughtered in lairage</td>
<td>FIPs</td>
<td>Marked/detained for FIPs.</td>
</tr>
<tr>
<td>Suspect emaciation, poor condition</td>
<td>FIPs</td>
<td>Marked/detained for FIPs.</td>
</tr>
<tr>
<td>Suspect fever</td>
<td>FIPs</td>
<td>Marked/detained for FIPs.</td>
</tr>
</tbody>
</table>

**Inspection Criteria at Post Mortem Inspection**

Visual inspection is the default requirement at post mortem. VIPs would be used for some localised carcase/offal conditions and generalised carcase conditions such as contamination, machine damage and bruises. However an additional and detailed examination of the carcase and correlated offal (FIPs) may be justified, if necessary and possible, to ascertain:

1. The cause of the named condition;
2. Whether or not a condition (e.g. contamination, machine damage, as presented) has masked other pathological signs; and
3. The collection of necessary evidence for enforcement purposes (e.g. severe bruising).

The FIPs should be carried out on either a separate detained rail or on a moving line depending on the slaughterhouse layout.
Localised conditions at post mortem inspection

When the MHI/OV observes localised conditions on pig carcases that are listed on the current post mortem inspection list, FIPs normally cannot be justified unless a generalised and septic condition is also observed.

Depending on slaughterhouse layout and local arrangements, the majority of localised abnormalities will be marked and removed on line (and confirmed by verification), without the need for the carcase to be detained.

It has been considered that the following conditions from the post mortem inspection list may justify detaining the carcase or offal for FIPs at post mortem inspection.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Post Mortem Procedure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abscess</td>
<td>FIPs</td>
<td>In cases of multiple abscesses (e.g. two or more in posterior or anterior part of the carcase) the carcase may require FIPs.</td>
</tr>
<tr>
<td>TB like lesions</td>
<td>FIPs</td>
<td>In cases of enlarged lymph nodes e.g. mesenteric, submaxilary bronchial, or enlarged area around lymph nodes.</td>
</tr>
</tbody>
</table>

Generalised conditions at post mortem inspection

In some cases when the MHI/OV suspects a generalised carcase condition that is listed on the current post mortem inspection list, the appropriate decision about the fitness of the meat for human consumption cannot be made without further examinations.

It has been considered that the following conditions from the post mortem inspection list may justify detaining the carcase or offal for FIPs at post mortem inspection.
<table>
<thead>
<tr>
<th>Condition</th>
<th>Post Mortem Procedure</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaemia</td>
<td>FIPs</td>
<td>Anaemia is rare, but it may be a part of other generalised condition.</td>
</tr>
<tr>
<td>Badly bled</td>
<td>FIPs</td>
<td>A badly bled carcass may mask some other post mortem signs.</td>
</tr>
<tr>
<td>Contamination gut content</td>
<td>VIPs</td>
<td>If masking other conditions, the carcass may be detained for additional examination.</td>
</tr>
<tr>
<td>Cysticercus cellulosae</td>
<td>FIPs</td>
<td>Not present in UK, and would require careful additional examination.</td>
</tr>
<tr>
<td>Emaciation/ Generalised oedema</td>
<td>FIPs</td>
<td>May include a range of inspection options (palpation, incision, sample taking etc.) as appropriate.</td>
</tr>
<tr>
<td>Erysipelas</td>
<td>FIPs</td>
<td>Suspected generalised condition - occupational zoonosis.</td>
</tr>
<tr>
<td>Generalised tuberculosis (suspect)</td>
<td>FIPs</td>
<td>May include a range of inspection options (palpation, incision, sample taking etc.) as appropriate.</td>
</tr>
<tr>
<td>Generalised tumours/ Melanosis</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>Jaundice</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>Machine damage</td>
<td>VIPs</td>
<td>If masking other conditions the carcass may be detained for additional examination.</td>
</tr>
<tr>
<td>Poly-Arthritis</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>Septic Peritonitis</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>Septic Peritonitis &amp; Pleurisy</td>
<td>FIPs</td>
<td>May include a range of inspection options (palpation, incision, sample taking etc.) as appropriate.</td>
</tr>
<tr>
<td>Septic Pleurisy</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>Suspect Pyaemia/ Multiple abscesses</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>- Tail bite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-------</td>
<td></td>
</tr>
<tr>
<td>Suspect Pyaemia/ Multiple abscesses</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>- Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Suspect Uraemia/ Abnormal odour</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>Suspect Fever/ Septicaemia</td>
<td>FIPs</td>
<td></td>
</tr>
<tr>
<td>Suspect Residues</td>
<td>FIPs</td>
<td></td>
</tr>
</tbody>
</table>
ANNEX: Responsibilities for live and slaughtered animals

Responsibilities for live and slaughtered animals are not changing. For the purposes of clarity, the table below sets out the ante mortem and post mortem process from June 2014 with the new requirements highlighted. As is usual with any change of process, FBOs and officials will need to work together to review ante mortem and post mortem processes to ensure they remain effective.

<table>
<thead>
<tr>
<th>Stages</th>
<th>Responsible</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arrival/unloading/lairaging animals including receiving Food Chain Information (FCI).</td>
<td>FBOs</td>
<td>Depends on slaughterhouse arrangements. The OV may carry out ante-mortem inspection at the time of unloading.</td>
</tr>
<tr>
<td>Identification of abnormal animals (either from FCI or from observation at the time of unloading).</td>
<td>FBOs/OVs</td>
<td>FBOs need to check FCI and inform the OV of information that raises health concerns.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Depending on slaughterhouse arrangements (e.g. if animals are unloaded with no OV presence) then the FBOs may be responsible for identifying obviously abnormal animals.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>If an OV carries out ante-mortem at the time of unloading then the OV is responsible for identifying abnormal animals. MHIs may also assist OVs by making initial checks.</td>
</tr>
<tr>
<td>Marking and /or segregation of abnormal animals requiring additional ante mortem inspection e.g. clinical inspection or examination</td>
<td>FBOs</td>
<td>Each slaughterhouse is different. FBOs will have a written procedure which has been agreed with the OV. For example marking abnormal animals may be carried out by the FBO before ante mortem inspection is carried out.</td>
</tr>
<tr>
<td>Ante mortem inspection</td>
<td>OVs</td>
<td>Each slaughterhouse different. The OV decides on the ante mortem inspection procedure (<em>routine, clinical inspection or examination</em>), and based on his /her judgement, whether the animals require FIPs at post mortem inspection.</td>
</tr>
<tr>
<td>Maintaining the carcase identification and separation up to post mortem inspection. Slaughter of marked animals (correctly identified).</td>
<td>FBOs/OVs/MHIs</td>
<td>Each slaughterhouse is different. FBOs will have a written procedure which has been agreed with the OV. The OV establishes the way to communicate ante-mortem findings with MHIs on line.</td>
</tr>
</tbody>
</table>
## SLAUGHTERED ANIMALS - POST MORTEM INSPECTION ARRANGEMENTS FROM JUNE 2014

**NEW REQUIREMENTS ARE HIGHLIGHTED IN RED**

<table>
<thead>
<tr>
<th>Stages</th>
<th>Responsible</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dressing/Evisceration etc.</td>
<td>FBOs</td>
<td></td>
</tr>
<tr>
<td>Presentation for PMI</td>
<td>FBOs</td>
<td>FBOs to identify and deal appropriately with contamination etc.</td>
</tr>
<tr>
<td>Post mortem inspection</td>
<td>MHIs/ OVrs</td>
<td>VIPs as the default post mortem procedure.</td>
</tr>
</tbody>
</table>

### References:

- **Manual for Official Controls (MOC):**
  - [http://multimedia.food.gov.uk/multimedia/pdfs/mocmanualch2part1rev60.pdf](http://multimedia.food.gov.uk/multimedia/pdfs/mocmanualch2part1rev60.pdf)

- **European Food Safety Authority (EFSA):**

- **Animal Health and Veterinary Laboratories Agency (AHVLA):**