EXPLANATORY MEMORANDUM TO

THE FOOD HYGIENE (ENGLAND) (AMENDMENT) REGULATIONS 2010

2010 No. 534

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instrument

2.1 The Food Hygiene (England) (Amendment) Regulations 2010 will provide for the execution and enforcement of a number of transitional and implementing measures in respect of the EU Food Hygiene Regulations. It will also provide for the application of two national measures that exempt (former) low throughput slaughterhouses from certain hygiene requirements.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 There are further amendments to the EU Food Hygiene Regulations which are subsequent to the amendments which are the subject matter of the Food Hygiene (England) (Amendment) Regulations 2010. The Statutory Instrument (SI) which will provide for the execution and enforcement of those further amendments is the subject of a separate consultation exercise.

4. Legislative Context

4.1 The EU Food Hygiene Regulations, which applied from 1 January 2006, had as their primary objective the optimisation of public health protection through consolidation and modernisation of the previous sector specific EU legislation. The EU Food Hygiene Regulations are directly applicable in EU Member States

4.2 The necessary powers of entry, penalties and offences required to execute and enforce the EU Regulations are provided through national legislation in the form of an SI in England.

4.3 Since 1 January 2006, the European Commission has adopted a number of implementing and transitional Regulations for which provision must also be made in national legislation.

4.4 This SI is made under the powers given by section 2 (2) of the European Communities Act (ECA) 1972.

5. Territorial Extent and Application

5.1 This instrument applies to England.

5.2 Parallel legislation is being developed in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 The EU Regulations which are the subject matter of this Instrument amend or, in some cases, apply transitional measures to the following policy areas:

- record keeping for small fishing vessels (Regulation (EC) 1243/2007);
- the production of gelatine (Regulation (EC) 1243/2007);
- the criteria for competent authorities to apply when determining Official Veterinarian attendance during post-mortem inspection (Regulation (EC) 1244/2007);
- the criteria for the 'visual only' inspection post-mortem of young animals(Regulation (EC) 1244/2007);
- the use of an alternative form of pepsin for the detection of Trichinella (Regulation (EC) 1245/2007);
- microbiological criteria (Regulation (EC) 1441/2007); and,
- the screening of live bivalve molluscs for Amnesic Shellfish Poisoning (Regulation (EC) 1244/2007).

7.2 There are a number of policy areas where the EU Regulations allow member states to adopt certain provisions in their national legislation. These are the basis for national measures that will exempt (former) low throughput slaughterhouses from the need for:

- cleansing and disinfection facilities; and,
- detention facilities for meat.

7.3 We propose to achieve this -
(a) as regards the EU transitional and implementing measures by substituting a revised Schedule 1 to the Food Hygiene (England) Regulations 2006 (SI 2006/14); and
(b) as regards the national measures by substituting a revised regulation 17 and by inserting new Schedules 3A, 3B, 3C and 3D into the Food Hygiene (England) Regulations 2006 .

8. Consultation outcome

8.1 The Food Standards Agency consulted stakeholders (for 12 weeks) on the draft Food Hygiene (England)(Amendment) Regulations 2008 (as they were then titled) and the IAs for both the Commission measures and national measures - this consultation closed on 4 January 2008.

8.2 No significant concerns arose from stakeholders' comments, a summary of which can be seen on the Agency's web site at:
http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

8.3 Following discussions with the European Commission, the national measures have now been revised from those proposed in the stakeholders' consultation. The Commission's periods of scrutiny of the draft national legislation have contributed to the gap between the original date when the EU measures were adopted and the making of this SI.

8.4 Originally another national measure was included in the consultation. This measure set out the form for a national mark applying to red meat from animals slaughtered in emergency circumstances (i.e. outside of an approved slaughterhouse). This has since been separated from these EU measures and the two national measures and will be subject to further consultation during 2010.

8.5 Consultations also took place in Scotland, Wales and Northern Ireland as separate national legislation is needed; this will be enacted in parallel in those countries.

8.6 Impact Assessments have been prepared for this instrument and is attached at Annex B of this package.

9. Guidance

9.1 The European Regulations to which this instrument applies domestic execution and enforcement legislation amended existing EU Regulations for which an extensive range of guidance already exists.

9.2 Guidance for industry on the two national measures concerning exemptions for (i) certain low throughput slaughterhouses for detained facilities for meat and (ii) for cleansing and disinfection facilities for vehicles will be included in the Agency's Meat Industry Guide. Guidance will also be made available to enforcement officials through amendment of the Manual of Official Controls.

10. Impact

10.1 Seven Impact Assessments (IAs) are attached to this memorandum. Please note that the IAs reflect costs and benefits for 2008.

11. Regulating small business

11.1 The legislation applies to small business. The consultation which took place with such businesses and the impact upon them is detailed in the attached Impact Assessments.

12. Monitoring & review

12.1 The policies contained in the EU Regulations will be reviewed 5 years after application (i.e. November 2012) and the two national measures will be reviewed 5 years after implementation (i.e. April 2015).

13. Contact

Philip Flaherty at the Food Standards Agency (Tel: 020 7276 8549 or e-mail: philip.flaherty@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of measures that amend the rules (i) for record-keeping for some fishing vessels and (ii) the manufacture of gelatine (Regulation (EC) 1243/2007)**	
Stage: Final	**Version: 1**	**Date: 19 February 2010**

Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:281:0008:0011:EN:PDF

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

Contact for enquiries: David Gray **Telephone:** 020 7276 8940

What is the problem under consideration? Why is government intervention necessary?

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry.

The legislation for record-keeping for fishing vessels and manufacture of gelatine is designed to address this information asymmetry. However, it needs to be amended because i) it creates an administrative burden beyond that necessary to safeguard public health, and ii) it needs to take account of developments in science and technology so that food businesses can make full use of such developments as long as public health protection remains safeguarded.

What are the policy objectives and the intended effects?

Regulation (EC) 1243/2007 provides:

(i) a derogation for small coastal fishing vessels from some record keeping, thus reducing administrative burdens for food business operators in that sector; and,

(ii)for the addition of two further methods of production of gelatine; changed requirements for wrapping and packaging, and other minor changes to the legislation that provide clarity of interpretation in order that gelatine manufacturers can make use of all available technologies, where it is established that there is no negative impact on public health.

What policy options have been considered? Please justify any preferred option.

1. Do nothing.
2. Support the introduction of these measures and provide for their execution and enforcement in English law.

Option 2 is the preferred option because there is a strong likelihood that the measures will (i) lower the administration burden on a small business sector and (ii) provide flexibilities in the manufacture of gelatine.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? November 2012

Ministerial/CEO Sign-off For final/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Gillian Merron.....Date: ***25th February 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: On the derogation from Annex I, Part A, III (7) of Regulation (EC) 852/2004 requiring small coastal vessels to keep certain records and allow for two further methods for the production of gelatine.

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' None identified.
One-off (Transition)	**Yrs**	
£ 0	5	
Average Annual Cost (excluding one-off)		
£ 0		**Total Cost** (PV) **£ 0**

Other **key non-monetised costs** by 'main affected groups'

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'. Reduced administrative burden.
One-off	**Yrs**	
£ 0	5	
Average Annual Benefit (excluding one-off)		
£ 26,500		**Total Benefit** (PV) **£ 123,800**

Other **key non-monetised benefits** by 'main affected groups' Decrease in enforcement costs (fewer records to check). Increase in flexibility for those considering gelatine manufacture in England (currently no such manufacturers in England.)

Key Assumptions/Sensitivities/Risks Assumed that the derogation from some record-keeping will save 55% of relevant record keeping for all salient fishing trips undertaken by small vessels. Relevant record keeping is assumed to take 5-6 minutes in total per vessel per day. Responses to consultation suggest this may overestimate the realised savings.

Price Base Year 2007	Time Period Years 5	**Net Benefit Range** (NPV) **£ 100,000-150,000**	**NET BENEFIT** (NPV Best estimate) **£ 123,800**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			November 2007	
Which organisation(s) will enforce the policy?			England LAs	
What is the total annual cost of enforcement for these organisations?			£ 98.3 million	
What is the incremental annual cost of enforcing **this proposal**?			£ 0	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			N/A	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro **0**	Small **0**	Medium **0**	Large 0
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease of £ 24,500 **Net Impact** **£** -24,500

Evidence Base (for summary sheets)

Reason for intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

2. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.

3. To be efficient these hygiene standards need to be proportionate to the risk, with the costs of compliance fully justified by the benefits. To this end, the requirement in the EU food hygiene legislation on food businesses to keep records can be applied flexibly, in proportion to the nature of the business and its food safety risks, as long as public health is safeguarded. Where the legislation creates unnecessary burdens it should be reviewed and amended, to ensure that this proportionality is available to all food business operators.

4. The EU Regulations also need to be amended to take account of developments in science and technology, to ensure food businesses can make full use of such developments as long as public health protection remains.

Intended Effect

5. The intended effects are to ensure that (i) record keeping requirements in the fishing industry are proportionate to risk and (ii) to update the legislation for gelatine manufacture in line with current evidence on the food safety impacts of available technologies.

6. The EU Regulation's measures (i) provide a derogation for small coastal fishing vessels from some record keeping, thus reducing administrative burdens for food business operators in that sector, and (ii) provide for the addition of two further methods of production of gelatine; changed requirements for wrapping and packaging; and other minor changes to the legislation that provide clarity of interpretation in order that gelatine manufacturers can make use of all available technologies where it is established that there is no negative impact on public health.

Background

7. The measures revise Regulation (EC) 853/2004 to:

i. include a derogation from record keeping requirements set out in one of the European Food Hygiene Regulations (Regulation (EC) 852/2004), currently applying to small-scale coastal fishing vessels carrying out their activities for periods under twenty-four hours; and,

ii. allow two further methods of producing gelatine for human consumption, and change the requirement for the wrapping and packaging to indicate the date of preparation of the gelatine in favour of an indication of the date of minimum durability.

Options

8. Two Options were identified in relation to this measure.

- *Option 1. Do nothing*.

- *Option 2. Support the Regulation's application and provide for its execution and enforcement in English law through amendment of the Food Hygiene (England) Regulations 2006*

Costs and Benefits of Options

Option 1. Do nothing.

9. Doing nothing maintains the current position and so has no incremental costs or benefits.

10. It would mean that certain fishing vessels might continue to have to keep records where it was not justifiable on public health grounds with possible long-term unnecessary costs.

11. It would also mean that manufacturers of gelatine could not take advantage of alternative methods of production and other flexibilities provided.

Option 2. Support the Regulation's application and provide for its enforcement in English law through amendment of the Food Hygiene (England) Regulations 2006.

12. This is the preferred option; the UK supported the introduction of the Regulation and it is necessary to give effect to the measures in English law.

Benefits

i) Fishing vessels

13. The derogation from record keeping requirements for small coastal fishing vessels, within the meaning of Article 26(1) of Regulation (EC) 1198/2006, from the requirement to 'keep and retain records relating to measures put in place to control hazards' (Regulation (EC) 852/2004, Annex I, Part A, 7), will reduce administrative burdens for the operators of these vessels and will result in some small cost savings, equivalent to the cost of recording previously required information over and above that which would have been undertaken commercially. We estimate the salient wage rate to be £8.44 per hour for time used filling these forms (which coincides with the salient rate from the Annual Survey of Hours and Earnings (ASHE) in 2007 figures). This includes a 30% uplift to cover overheads. We further estimate 5-6 minutes for daily form completion, and that 45% of the currently required record keeping per salient fishing trip will anyway continue commercially regardless of government obligations. The Marine and Fisheries Agency has informed the Agency that 61,189 day trips (less than 24 hours) occurred for vessels less than 12 metres in length, between June 2006 and May 2007. Given this information and the assumptions stated there would be an annual administrative burden reduction of approximately £26,500.

14. Comments received during public consultation suggest that the burden reduction of £26,500 may be an overestimate, because the legislation already allows vessels proportionate record-keeping and vessels supplying small quantities to local markets are anyway exempt. For example, guidance for the industry produced by SEAFISH suggests record-keeping is only required in limited circumstances such as fishroom temperature and cleaning. These comments suggest that the real impact of the derogation is unlikely to be significant.

15. There may also be some benefit to enforcement officers, who no longer have to check the appropriate records. Secondary inspections of vessels will be reduced by the amount of time required for checking records.

ii) Gelatine manufacture

16. Regarding the introduction of changes to the manufacture of gelatine, the FSA is not aware of any existing businesses in England on which this measure might have an impact. All UK industry on which the measure has an impact is based in Wales. Nonetheless, the provision may benefit (and increase the likelihood of) future gelatine manufacturing operations in England.

Costs

i) Fishing vessels

17. The derogation assumes that the absence of the record keeping activity will not affect the hygiene standards employed on these vessels. It is also assumed that because the fishing and storing of fish do not extend beyond 24 hours the risk to public health is insignificant.

18. Concern was raised prior to the consultation that there might be a cost to 'on shore' industry arising from the proposed measure. Under the previous legislation, recipients of the catches from these vessels can request records relating to the health measures put in place. In the possible absence of these records, on shore food business operators may consider carrying out more detailed checks of the fish or shellfish landed. However, comments from the consultation suggest that checks would only be taken in the case of high-risk activities anyway and since much fishing is not, impact would be negligible.

19. Secondary inspections carried out by enforcement officers will not require the checking the vessel records. As noted above, this will reduce the burden of inspection, but might remove confidence that the fishing vessel has been operating to the highest safety standards. Without this assurance, enforcement officers may feel that the inspection rating and frequency for some vessel operators should be adjusted. No comments were forthcoming on this issue from the public consultation.

ii) Gelatine manufacture

20. As noted above, the Agency is unaware of any gelatine manufacturers in England. Nonetheless, the addition of additional permitted methods for the production of gelatine would not result in any costs to industry, as any affected firms could continue with their current practices if they so choose. Firms that choose to move to a new production method would do so in pursuit of a commercial benefit. Regarding the minor change to labelling requirements, this will not impose a cost as there are no manufacturers of gelatine in England, and would nonetheless be taken care of during the normal labelling cycle. No further information about gelatine manufacture was forthcoming from the public consultation.

Public consultation

21. This IA was subject to a full three-month public consultation which was issued on 2 October 2007 and closed 4 January 2008. No further evidence was received with regard to costs or benefits resulting from the measure or the effect on sustainability or other identified areas of impact.

22. The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its web site within three months of the closure of the consultation and the summary for the Draft Food Hygiene (Amendment)(England) Regulations 2008 can be seen at:

http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

Amendment of the Food Hygiene (England) Regulations 2006 (as amended)

23. The draft Statutory Instrument issued with the public consultation on 2 October 2007. Following revision, the UK was obliged to re-notify it to the European Commission under the provisions of 98/34/EC (this was the same for the corresponding SIs for Scotland, Wales and Northern Ireland), which it did so on 30 October 2008.

24. This three month period provides the Commission and Member States with the opportunity to scrutinise national legislation to ensure that it does not provide barriers to trade. In the case of this SI, the period ended on 2 February 2009.

Cost of enforcement

25. The £98.3 million figure is the **total** annual cost of enforcement (for England Local Authorities), and is **not related** to the specific cost of enforcing this measure. This total cost of enforcement figure is used in accordance with guidance from the Cabinet Office.

26. The £98.3 million figure is taken from the Chartered Institute of Public Finance and Accounting Environmental Health Statistics 2005/06, which shows, for local authorities in England, a cost of £98,303,941 for food safety expenditure on Food Hygiene and the administration of Food Safety legislation.

27. There may be some cost to stakeholders arising from the need to understand the new measures.

Sustainability and other Specific Impacts

28. The Agency considers that Option 2 is the more sustainable as there is a reduced administrative burden for the industry, and no evidence of a negative impact on human health.

29. Otherwise there will be no significant impact on the areas listed under the Specific Impact Tests Checklist.

Date policy will be implemented

30. Commission Regulation (EC) 1243/2007 applied 20 days after being published in the EU Official Journal (i.e. 20 days after 25 October 2007).

31. The effect of the measure will be reviewed in five years' time (November 2012).

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	Yes	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

Due to the minor nature of the benefits to small fishing vessels of reduced record keeping, we do not anticipate a significant effect on competition. Comments received during the public consultation did not suggest even a negligible impact on competition

Small Firms Impact Test

The proposed derogation provides for the status quo or a positive benefit to the small fishing businesses. Theoretically, where small on-shore businesses are the recipient and further work is incurred through more detailed checks, this benefit may be cancelled out, although comments received during the public consultation suggest this will be negligible.

Sustainable development

We do not envisage that this proposal will be unsustainable, as the economic effects are unlikely to endanger the business survival, or increase the burden on fish stocks. No comments were received during the public consultation on sustainability.

Race equality issues

None.

Gender equality issues

None.

Disability equality issues

None.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of measures amending rules for official controls for red meat (Regulation (EC) 1244/2007)**	
Stage: Final	**Version:** 1	**Date:** February 2010

Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_281/l_28120071025en00120018.pdf

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

Contact for enquiries: David Gray **Telephone:** 020 7276 8940

What is the problem under consideration? Why is government intervention necessary?

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry.

The EU Food Hygiene Regulations set out the duties of competent authorities as to how they undertake official controls, such as the required presence of the official veterinarian (OV) and the OV's duties. There is a need to ensure that official controls are proportionate, reflect the risk-based nature of the requirements for food businesses and reflect up-to-date expert understanding.

What are the policy objectives and the intended effects?

It is necessary to allow competent authorities alternative ways of carrying out their duties, which may bring benefits (e.g. reduction in the risk of spreading infection) as long as public health protection is maintained or improved.
The Commission Regulation sets the criteria for (i) competent authorities to apply when determining official veterinarian (OV) attendance during post-mortem inspection, and (ii) for the 'visual only' post-mortem inspection of young animals - with the public health benefit of removing the necessity, in some cases, of cutting into the meat and possibly spreading infection. Other issues in the Regulation are not the subject of this IA.

What policy options have been considered? Please justify any preferred option.

1. Do nothing.

2. Apply the EU measures and provide for their execution and enforcement by amendment of the Food Hygiene (England) Regulations as described. During EU negotiations, the UK argued against limiting reduction in OV attendance only to those slaughterhouses that practise 'discontinuous slaughter'. However, the Commission proposal was adopted through a qualified majority of Member States. We are therefore obliged to proceed with Option 2 or the UK would be in breach of its Treaty obligations.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? November 2013

Ministerial/CEO Sign-off For final implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Gillian Merron.....Date: ***25th February 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: Commission measures amending rules on official controls for red meat

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' :
One-off (Transition)	**Yrs**	Potential foregone benefits of reduced OV input at larger slaughterhouses throughout post-mortem inspection.
£ 0	**5**	
Average Annual Cost (excluding one-off)		
£ 0.07m – 0.7m		**Total Cost** (PV) **£ 0.3m – 3.2m**

Other **key non-monetised costs** by 'main affected groups':
The costs of any sample testing changes are expected to be negligible.

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'
One-off	**Yrs**	
£ 0	**5**	
Average Annual Benefit (excluding one-off)		
£ 0		**Total Benefit** (PV) **£ 0**

Other **key non-monetised benefits** by 'main affected groups':
There are unlikely to be substantive benefits from reduced post-mortem incision inspections as the time saved is likely to be invested in increased visual inspection effort re calves, lambs, and goat kids.

Key Assumptions/Sensitivities/Risks:
5 - 15% of slaughterhouses are affected by the proposal; foregone cost savings relate to 5 - 15% of total OV hours in the affected slaughterhouses. Foregone cost savings may increase significantly once meat hygiene charges are based on inspection time rather than throughput.

Price Base Year **2007**	Time Period Years **5**	**Net Benefit Range** (NPV) **£ -0.3m to -3.2m**	**NET BENEFIT** (NPV Best estimate) **£ -1.8m**

What is the geographic coverage of the policy/option?	England
On what date will the policy be implemented?	November 07
Which organisation(s) will enforce the policy?	MHS
What is the total annual cost of enforcement for these organisations?	£ 70.54 million
What is the incremental annual cost of enforcing **this proposal**?	£ nil
Does enforcement comply with Hampton principles?	Yes
Will implementation go beyond minimum EU requirements?	No
What is the value of the proposed offsetting measure per year?	£ N/A
What is the value of changes in greenhouse gas emissions?	£ N/A
Will the proposal have a significant impact on competition?	No

Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
	0	0	0	0
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** **£** N/A

Key:	**Annual costs and benefits: Constant Prices**		**(Net) Present Value**

Evidence Base (for Summary Sheets)

Reason for intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

2. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.

3. There is a need to ensure that official controls are proportionate and reflect the risk-based nature of the requirements for food businesses. It is also necessary to allow competent authorities alternative ways of carrying out their duties as long as public health protection is maintained or improved.

4. There is also a need to ensure that the rules for official controls are changed in order to make the widest possible use of developments in science and technology where there is no negative impact on public health.

Intended effect

5. The intended effect is to amend the legislation to ensure official controls are proportionate, and allow alternative ways of carrying out controls where there are benefits without any lowering of the protection of public heath. Specifically, to:

(i) set the criteria for competent authorities to apply when determining official veterinarian (OV) attendance during post-mortem inspection in establishments carrying out 'discontinuous slaughter';

(ii) set criteria for the 'visual only' (i.e. without incisions) post-mortem inspection of young animals - with the public health benefit of removing the necessity, in some cases, of cutting into the meat, which might spread infection;

(iii) set criteria for the visual only inspection of fattening pigs. Revised inspection procedures have been trialled in England and the outcome is still under discussion. This is not, therefore, an issue for the industry in England. A decision will be taken on whether to exercise the discretion provided for in the new EU provisions when the discussions are completed; and,

(iv) place an additional requirement for the post-mortem examination of solipeds (horses and mules) from countries not free of glanders. This issue is not covered in this IA as glanders is not endemic in the UK.

Background

Relevant legislation:

6. A package of consolidated EC food hygiene regulations applied from 1 January 2006. Regulation (EC) 852/2004 lays down the general rules for all food business operators (FBOs). Specific rules for FBOs manufacturing or handling foods of animal origin are laid down in Regulation (EC) 853/2004. However, Regulation (EC) 854/2004 sets out the role /obligations of 'official controls' (i.e. the requirements on Member States' competent authorities as regards enforcement). Detailed information on the hygiene legislation can be found on the Food Standards Agency (the FSA) web site at: http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/

7. Regulation (EC) 2074/2005 provides implementing measures for certain products of animal origin under Regulation 853/2004, and for official controls under Regulations 854/2004 and 882/2004. It also makes changes to official controls by amending EC Regulation 854/2004.

8. Commission Regulation 1244/2007 amends Regulation (EC) 2074/2005. It is the amendments related to meat that are the subject of this IA.

Issues – background and detail:

9. Annex I, Section 3, Chapter II, 1(a) – 'Frequency of Controls' of 854/2004 sets out that at least one Official Veterinarian (OV) is required during post-mortem inspection in slaughterhouses.

10. However, Article 5, point 5 (b) of Regulation (EC) 854/2004 allows competent authorities (in the case of England for meat, the Meat Hygiene Service or MHS) to adapt, on a risk basis, the number of official staff on a slaughter line at any given slaughterhouse, as long as the Regulation's requirements are met.

11. Regulation 1244/2007 amends the criteria to be taken into account in the risk assessment. Drawing upon reports of EU scientific committees, the Regulation established that some integrated production systems were of such a nature that the inspection criteria could be revised without a negative impact on public health. However, the amendment allows the competent authority (i.e. the MHS) to reduce OV attendance post-mortem only to those slaughterhouses that practise 'discontinuous slaughter', effectively restricting any benefits of reduction of OV attendance solely to smaller establishments, as larger slaughterhouses will not be practising 'discontinuous slaughter'.

12. Furthermore, nearly all slaughterhouses are currently charged (for OV attendance) on the basis of their throughput (i.e. number of animals) rather than time costs (i.e. the time taken by the OV or Official Auxiliary), with the difference being subsidised by the Government. This implies that the majority of cost savings would have accrued to the Government through a reduction in the level of subsidy, although savings will also have accrued to those businesses that pay for OV attendance on a time cost basis.

13. All slaughterhouses in the UK will pay for Official Controls on a time cost basis from the 28th September 2009. A level of subsidy will remain for all slaughterhouses, and the long term goal is for support to small and geographically remote plants to have ongoing support, but once charges are conducted on a time cost basis, even with ongoing subsidy, any additional time on controls will have a cost implication for the plant as well as the taxpayer.

UK negotiating position:

14. The UK strongly supports flexible legislation that reduces the burden on small businesses as long as public health is protected. However, the UK also argued against limiting this flexibility only to food business operators practising 'discontinuous slaughter' because of concerns that it would only help small slaughterhouses, and the proposal was not risk-based. However, the UK was outvoted by other Member States on this point. Summaries of meetings where this issue was discussed can be found on the Agency's website at: http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/histeu/

15. Regulation 854/2004 did not allow for simplification of the inspection of calves, lambs and goat kids. The amendment introduced by 1244/2007 allows visual-only inspection as long as the requirements set down are met. Potential benefits should arise to public health from removing the necessity, in some cases, of cutting into certain parts of those animals.

Other issues:

16. The Commission Regulation also provides for an alternative screening method for Amnesic Shellfish Poisoning. This issue is now the subject of a separate Impact Assessment (IA) (during consultation all three measures were part of one IA).

Options

17. Two Options were identified in relation to these measures:

1. *Do nothing.*
2. *Support introduction of the measures and provide for their enforcement in English law.*

Costs & benefits of Options

Option 1. *Do nothing.*

18. There are no incremental costs and benefits from the do nothing option.

Option 2. *Following the measures' application, provide enforcement through amendment of the Food Hygiene (England) Regulations 2006.*

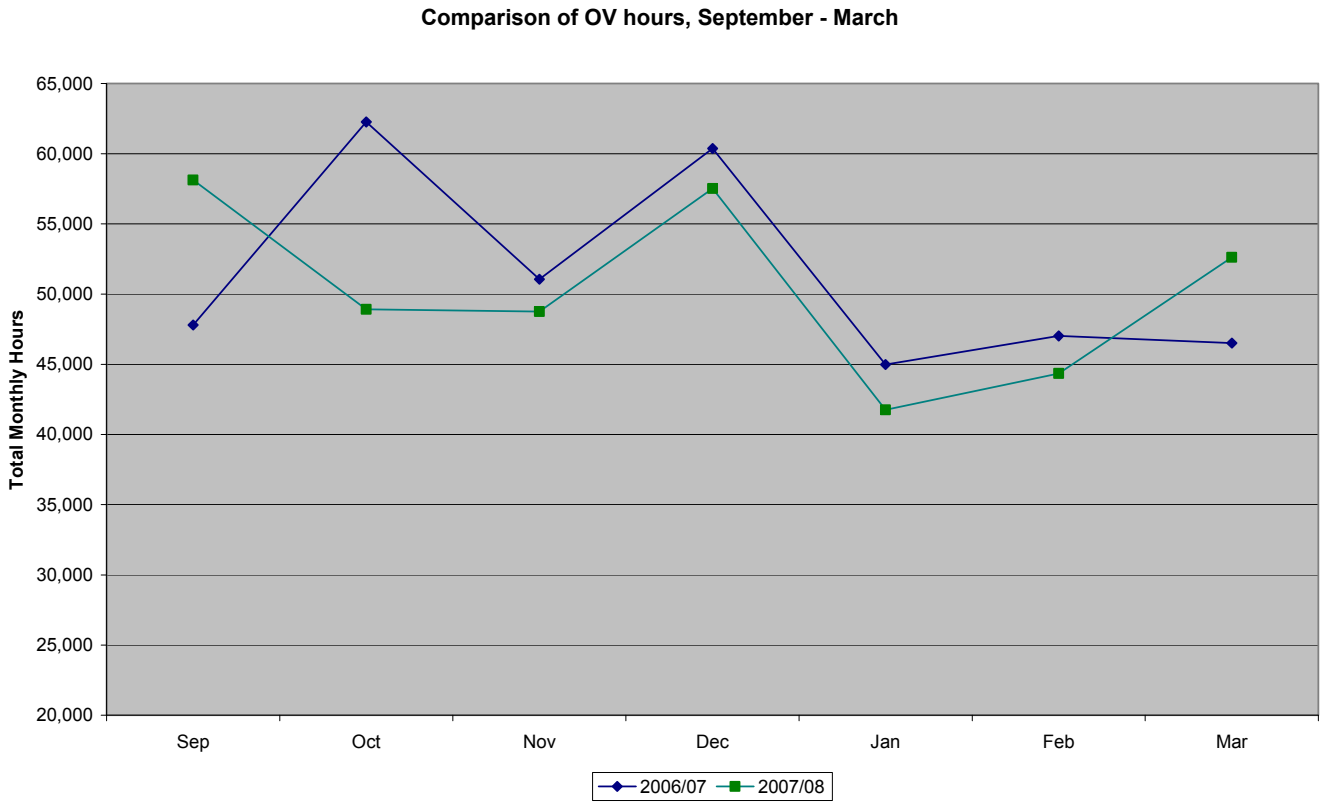
Costs

19. As far as the foregone benefits are concerned, there are potential savings which have *not* been made by the FSA/MHS owing to the 'discontinuous slaughter ' restriction.[1] That is, plants practising continuous slaughter were previously eligible to make use of flexibilities in OV time and are no longer able to do so to the same extent.

20. At the time of consultation there was limited information on both the flexibility that plants would lose and the number of plants that this would apply to. Based on the assumption that 30% of plants would be affected, and each plant would forego savings of 25% of daily OV hours (2 hours per day), 5 days per week, 50 weeks per year, total hours foregone for all plants were estimated to be 62,500. Therefore potential costs were estimated to be £2,312,500 per annum in 2007 prices. Assuming a five-year policy effect time period, after discounting, this yielded a total foregone benefit of £10,806,500. This estimate was therefore included on the original IA issued with the consultation on 2 October 2007.

21. Updated information from the MHS on the total OV hours over the relevant period indicates that potential costs detailed (in paragraph 20) above would be a significant overestimate of the real impact of the change to date. Plants previously eligible for the flexibility appear to have made relatively small reductions in OV time, and those that did appear to have been few in number.

[1] Slaughterhouses are required to have full time OV presence unless they slaughter intermittently, in which case they are classed as practising 'discontinuous slaughter'.



Source: Meat Hygiene Service

22. The above graph shows the pattern of OV hours for the period September – March in both the 2006/07 and the 2007/08 financial years. There appears to be a broadly similar pattern in the number of hours used for inspection between the two years. The requirement to have full-time OV presence in slaughterhouses was reintroduced in November 2007, and there does not appear to have been any substantial increase in OV hours after this point other than would be expected in line with seasonal variation, as indicated by the similarities between 2006/07 and 2007/08 in the above graph. This implies that the assumed 62,500 total hours per annum of time savings forgone in paragraph 20 is an overestimate, as an increase of this magnitude would be visible in some part on the graph above. Subsequently we propose to revise the assumed number of affected plants and estimated hours savings forgone downwards.

23. Uncertainty remains regarding the precise number of plants affected and the actual number of hours saved which are foregone, therefore we use a range for the key assumptions. We estimate that the actual costs relate to between 5% and 15% of the 349 slaughterhouses that were in operation in England in 2007/08 (revised down from the initial assumption of 30%), with hours savings foregone in the range of 5% to 15% (revised from 25%). Using an hourly OV full cost rate of £43.90[2], these ranges yield cost estimates of between £75,000 and £680,000 per annum (see table below). A best estimate of the annual costs is made by taking the mid-point of the range, yielding approximately £380,000 (2007 prices).

[2] Estimated 2007/08 OV full cost rates taken from MHS model using 2007/08 data.

Estimated Range of Costs			
Scenario	**5% of plants affected, 5% OV hours foregone**	**10% of plants affected, 10% OV hours foregone**	**15% of plants affected, 15% OV hours foregone**
Total number of plants affected	17	35	52
Foregone reduction in hours per plant	100	200	300
Total Cost	£74,630	£307,300	£684,840

24. Whilst it is considered that the potential costs mentioned in paragraph 20 are an overestimate of the current level of savings foregone, there is a possibility that they may be fully realised in future years, particularly in light of the move to a time cost basis for Official Control charges in slaughterhouses from 28th September 2009. Time cost charging is expected to improve the efficiency in use of Official Control time and potentially reduce OV hours. As the majority of slaughterhouses have to date had less incentive to reduce OV time when full presence was not always required, the full potential OV hour savings foregone since November 2007 have not been realised. Potential foregone savings may therefore increase under time cost charging, as a number of slaughterhouses are likely to seek ways of reducing Official Control time but may be restricted by the requirement of full time OV presence.

25. No comments on this issue were received during the public consultation.

Benefits

26. Potential savings to small slaughterhouses from the reduction in the presence of the OV when charges are based on time costs (see paragraph 12), and to Government, to the extent that OV costs are not recovered through charges.

27. Extension of the possibility for post-mortem inspection without incision ('visual-only inspection') to calves, lambs and goat kids has a potential public health benefit, although negligible financial impact. Only small numbers of calves and kids are slaughtered for human consumption in England. Visual only inspection of lambs in specified circumstances has benefits for public health protection in the potential reduction of cross-contamination and will result in a small reduction of effort by inspectors, but is unlikely to generate any operational cost savings.

28. One hundred and ninety-nine slaughterhouses were approved for slaughter of sheep in 2007/08, although all may not actually be doing so. Prior to changes in September 2009 described in paragraph 24, they were paying on throughput rather than time cost, and so any reduced MHI inspection time per lamb would not reduce their own costs, but would result in a reduction in the level of subsidy. However, there are unlikely to be benefits from reduced incisions at post-mortem inspection, as the time saved is likely to be invested in increased visual inspection.

29. On balance, Option 2 was preferred as, despite there being significant costs, it enables the benefits to improvements in the proportionality of enforcement activity in certain animal product sectors with no danger to public health – there may even be a benefit to public health in one case. Providing for Commission Regulation 1244/2007 in English law also avoids any risk of the UK failing in its Treaty obligations, with the consequence of monetary sanctions by the European Commission.

Cost of enforcement

30. For MHS: a cost of £70,540,000. This includes all enforcement action on the meat hygiene legislation including Specified Risk Material and Animal By-Products. The figures are for 2006/07.

Sustainability and other Specific Impacts

31. Impacts under all three pillars of Sustainable Development, economic, social and environmental have been considered in preparing this Impact Assessment. Option 2 is considered the relatively more sustainable as it is provides alternative forms of carrying out official controls with no negative impact on public health (a potential benefit in one case) nor on sustainability.

32. Otherwise there will be no significant impact on the areas listed under the Specific Impact Tests Checklist.

33. No comments were received during the public consultation on any of the impact areas.

Public consultation

34. This IA was subject to a 12 week public consultation which was issued on 2 October 2007 and closed 4 January 2008. No further evidence was received with regard to costs or benefits resulting from the measure, or the affect on sustainability or other identified areas of impact.

35. The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within three months of the closure of the consultation, and the summary for the Draft Food Hygiene (Amendment)(England) Regulations (2008) can be seen at: http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

The Regulation also provided for an alternative screening method for Amnesic Shellfish Poisoning which is now the subject of a separate IA (during consultation all three measures were part of one IA).

Amendment of the Food Hygiene (England) Regulations 2006 (as amended)

36. The draft Statutory Instrument issued with the public consultation on 2 October 2007. Following revision, the UK was obliged to re-notify it to the European Commission under the provisions of 98/34/EC (this was the same for the corresponding SIs for Scotland, Wales and Northern Ireland), which it did so on 30 October 2008.

37. This three month period provides the Commission and Member States with the opportunity to scrutinise national legislation to ensure that it does not provide barriers to trade. In the case of this SI, the period ended on 2 February 2009.

Date policy will be implemented

38. Commission Regulation (EC) 1244/2007 applied 20 days after being published in the EU Official Journal (i.e. 20 days after 25 October 2007).

39. The impact of measures is due to be looked at in March 2013.

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	Yes	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

The measures are not expected to have any significant effect on competition.

Small Firms Impact Test

The measures do not appear to burden small firms. The measure regarding OV attendance may have benefits for smaller firms in some circumstances.

Sustainable development

The measures do not appear to raise any issues for sustainability.

Race equality issues

None.

Gender equality issues

None.

Disability equality issues

None.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of revisions to the microbiological criteria (Regulation (EC) 1441/2007)**	
Stage: Final	**Version: 1**	**Date: 19 February 2010**

Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:322:0012:0029:EN:PDF

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

Contact for enquiries: David Gray **Telephone**: 020 7276 8940

What is the problem under consideration? Why is government intervention necessary?

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry.

Food business operators are required to ensure that the foodstuffs they handle or produce meet established microbiological criteria. There is a need to ensure these criteria are revised, or introduced where necessary, to take account of developments in scientific understanding.

What are the policy objectives and the intended effects?

Following opinions given by EU scientific bodies, the Commission Regulation (i) revises microbiological criteria for infant formula; (ii) imposes new criteria for infant and follow-on formula; (iii) harmonises testing requirements for carcases and (iv) updates the standard test method for staphylococcal enterotoxins.

Revision of the microbiological criteria to reflect updated scientific understanding will reduce the risks of illness caused by certain pathogenic micro-organisms in food and improve public health protection.

What policy options have been considered? Please justify any preferred option.

1. Do nothing.

2. Support amendment of the Microbiological Criteria for Foodstuffs Regulation. This is the preferred option; the UK supports the changes contained in Commission Regulation (EC) 1441/2007, because the amendment will allow microbiological criteria to reflect current scientific understanding and improve public health protection.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? November 2013.

Ministerial/CEO Sign-off For final/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Gillian Merron.....Date: ***25th February 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: Revisions of the microbiological criteria

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups'	
One-off (Transition)	**Yrs**		
£ N/K	5		
Average Annual Cost (excluding one-off)			
£ N/K		**Total Cost** (PV)	**£ N/K**

Other **key non-monetised costs** by 'main affected groups' Possible increases in industry testing to ensure and demonstrate compliance with the amended regulations. Potential costs of meeting more stringent Enterobacteriaceae process hygiene criterion. Possible Staphylococcal enterotoxins testing method change costs and associated training requirements.

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'	
One-off	**Yrs**		
£ N/K	5		
Average Annual Benefit (excluding one-off)			
£ N/K		**Total Benefit** (PV)	**£ N/K**

Other **key non-monetised benefits** by 'main affected groups' Possible (and some likely) public health benefits pertaining to dried infant and follow-on formulae arrangements/criteria; and Staphylococcal enterotoxins testing. Potential improvements in the clarity of the various requirements for business and enforcement officers.

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years 5	**Net Benefit Range** (NPV) **£ N/K**	**NET BENEFIT** (NPV Best estimate) **£ N/K**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			December 2007	
Which organisation(s) will enforce the policy?			English Las / MHS	
What is the total annual cost of enforcement for these organisations?			£ 140.2 mil	
What is the incremental annual cost of enforcing **this proposal**?			£ n/k	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro **N/K**	Small **N/K**	Medium **N/K**	Large **N/K**
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease of £ 0 **Net Impact** **£**0

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for Summary Sheets)

Reason for intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.

2. Food business operators are required to ensure that the foodstuffs they handle or produce meet established microbiological criteria. To be efficient, these criteria need to be revised as appropriate, or introduced where necessary, in line with current scientific understanding.

Intended effect

3. It is necessary that regulation or intervention reflects up-to-date scientific understanding to protect public health.

4. Therefore, following opinions by EU scientific bodies, Commission Regulation 1441/2007:
   - revises microbiological criteria for infant formula;
   - imposes new criteria for infant and follow-on formula;
   - harmonises testing requirements for carcases; and,
   - updates the standard test method for staphylococcal enterotoxins.

Background

<u>The Microbiological Criteria Regulation (Regulation (EC) 2073/2005)</u>

5. Food business operators (FBOs) have an obligation to withdraw unsafe food from the market. Article 4 of Regulation (EC) 852/2004 requires food business operators to comply with microbiological criteria. In order to contribute to the protection of public health and to prevent differing interpretations, Regulation (EC) 2073/2005, which applied from 1 January 2006, established, pursuant to Article 4 of Regulation (EC) 852/2004, harmonised safety criteria regarding the presence of certain pathogenic micro-organisms.

6. Microbiological criteria also give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. Where appropriate, the use of microbiological criteria should form an integral part of an FBO's implementation of HACCP-based procedures and other hygiene control measures.

Detail of Regulation (EC) 1441/2007, which amends Regulation 2073/2005

7. Commission Regulation (EC) 1441/2007 provides a replacement, in its entirety, of Annex I of Regulation (EC) 2073/2005, in which the criteria are laid down and introduces a number of revisions to Regulation (EC) 2073/2005 as follows:

   – Parallel criteria for Enterobacteriaceae (process hygiene criteria) and *Salmonella* and *E. sakazakii* (food safety criteria) in dried infant formulae unless a correlation had been

demonstrated between Enterobacteriaceae and *E. sakazakii* at individual plants. Regulation (EC) 2073/2005 provides a two-tier approach where presence of Enterobacteriaceae triggers testing for *Salmonella* and *E. sakazakii*;

- New process hygiene criteria for *Bacillus cereus* in infant formula;
- New criteria for Enterobacteriaceae (process hygiene criteria) and *Salmonella* (food safety criteria) in follow-on formulae;
- A new analytical reference method for Staphylococcal enterotoxins; and
- Harmonised carcase sampling rules.

8. The revised criteria have been introduced as the previous criteria did not reflect current scientific understanding, with the result that there were some deficiencies in the statutory controls. This could have resulted in a lack of clarity over requirements for businesses and enforcement authorities leading to a greater risk of illness occurring from certain pathogenic microorganisms in food.
9. Furthermore, where microbiological criteria do not properly reflect up-to-date science, this could weaken public health protection and lead to erosion of consumer confidence in regulators (as well as in food), and raises the possibility of legal action by consumers against food business operators.

Options and costs and benefits

10. Two Options were identified in response to the original proposals, which are set out in detail below:

Option 1. Do nothing

11. There are no incremental costs and benefits.

Option 2. Support revision of the microbiological criteria through amendment of the regulation and provide for its enforcement by amendment to the Food Hygiene (England) Regulations 2006 (as amended). This is the preferred option.

Costs

12. There will be some adjustment costs for some food businesses, but these are not expected to have introduced significant additional burdens.

Benefits

13. The revised criteria provide food business operators with tools that are based on available science to help validate and verify their food safety management systems, reducing the risk of food borne illness from certain pathogenic organisms.
14. This will improve public health protection in respect of those particular pathogenic organisms for which criteria have been revised and clarify requirements for businesses and enforcement authorities.

Public consultation

15. A twelve week public consultation took place, but no comments from industry or consumers were received regarding costs or other impacts of the Regulation.
16. Agency officials were involved in constant informal consultation with industry during negotiations on the Regulation. Consumer bodies were among those originally consulted but did not provide comments.

17. The amendments to Regulation (EC) 2073/2005 introduced by Regulation (EC) 1441/2007 reflect issues raised either by the Commission, or by other Member States (MS).

18. The UK was able to influence the outcome through active participation in the Expert Working Group on *Bacillus*, and the Working Group on Microbiological criteria. To assess the impact of the proposed changes, industry stakeholders were engaged throughout the process, including those most likely to be affected. The UK negotiating position was based on assessment of the available scientific evidence, with the aim of securing a proportionate outcome which protects public health and does not place unnecessary burdens on the industry.

19. The Agency does not expect the revisions introduced by Regulation (EC) 1441/2007 (as outlined in paragraphs 7, 8 and 9) to have a significant impact on the UK industry. These revisions mainly formalise existing procedures followed by the industry, although the new criterion for *Bacillus cereus* may result in an increase in testing by businesses to demonstrate compliance. The Agency is not aware that compliance with the revised criteria is causing industry difficulties.

20. The majority of the amendments affect the infant formula sector. This sector mainly comprises large businesses with established control plans. The Agency's understanding is that there is a small amount of infant formula production in the UK, but most of the product on the UK retail market is produced in other Member States (where, of course, the Regulation also applies). The infant and follow-on formulae sectors are currently characterised by significant concentration with three firms, Nutricia, H.J. Heinz and SMA Wyeth, accounting for 97% of sales in the UK.

21. Quantifying the benefits of the revised criteria is difficult, particularly as feedback suggests the industry is already likely to be observing the standards for infant and follow-on formulae. However, the new measures provide necessary revisions to the protection of public health as provided by Regulation (EC) 2073/2005, and the other food hygiene legislation. They should also provide greater clarity for businesses and enforcement officials on the requirements for these products.

Parallel criteria for Enterobacteriaceae, *Salmonella* and *Enterobacter sakazakii* in dried infant formulae

22. 'Parallel criteria' are criteria intended to apply independently along side or 'in parallel' with other criteria specified. Compliance is always demonstrated separately. In contrast, linked criteria are intended to apply sequentially, whereby failure to comply with one such criterion would trigger the requirement to demonstrate compliance with a further criterion. The application of linked criteria in this way is also referred to as a two-tier approach.

23. Regulation (EC) 2073/2005 provides a two-tier approach in respect of the process hygiene criterion for Enterobacteriaceae - absence in 10g of infant formula - linked to food safety criteria for *Salmonella*, and *E. sakazakii* also requiring absence. In this case, if Enterobacteriaceae are detected, this would trigger additional testing specifically for *Salmonella* and *E. sakazakii*. If either of these two organisms are detected, the product should be removed from the market. The amendment introduced by Regulation (EC) 1441/2007 changed the arrangements set out in Regulation 2073/2005 rather than introducing new criteria. The effect of this change is to remove the link between these criteria, so that the two food safety criteria generally apply independently or 'in parallel' with the process hygiene criterion. This is further explained below.

24. A similar two-tier approach was suggested during negotiations for follow-on formula where presence of Enterobacteriaceae would trigger testing for *Salmonella* (An *E. sakazakii* criterion was not considered appropriate for follow-on formula at this time). During informal consultations on the proposals, stakeholders questioned whether there was a correlation between *Salmonella* and Enterobacteriaceae detection. The potential for *Salmonella* to be present when Enterobacteriaceae are not detected by the standard method was of particular concern to the Agency, as this two-tier approach might not therefore adequately protect public health.

25. The relationship between the presence of Enterobacteriaceae and *E. sakazakii* was also being questioned by other groups, such as the Codex Working Group on infant formula. The

UK, therefore, raised this issue during negotiations on Regulation (EC) 1441/2007 and although there was some support from other Member States, the Commission were reluctant to make changes to existing criteria in the Regulation so soon after its adoption without firm evidence. The Commission, therefore, requested an EFSA opinion[3] on the relationship between Enterobacteriaceae and *Salmonella* and *E. sakazakii* in infant and follow-on formulae. The Agency also requested data from stakeholders in preparation for Working Group discussions.

26. Stakeholders were able to provide some information but, as *Salmonella* is rarely detected, it was not possible to determine whether a correlation existed. This was in line with the EFSA opinion which concluded that:

- There is a relationship between the presence of *E. sakazakii* and Enterobacteriaceae, but no universal correlation can be established. There are indications a relationship can be established at an individual plant level;
- it is not possible to establish a correlation between *Salmonella* and Enterobacteriaceae in infant or follow-on formula as *Salmonella* is so rarely present, suitable data are not available; and,
- concentrations and/or presence of Enterobacteriaceae in the production environment and in the products are useful indicators of the application of GHP/GMP.

27. The Agency considers the available evidence supports the amendment to the Regulation to provide for parallel criteria for *Salmonella*, *E. sakazakii* and Enterobacteriaceae. This includes flexibility for a two-tier approach for *E. sakazakii* and Enterobacteriaceae when food business operators can satisfy the competent authority that a correlation exists within a particular premises. We would not expect this change to have a major impact on the industry as previous feedback indicated stakeholders did not carry out two-tier testing, particularly for Enterobacteriaceae and *Salmonella*.

Process hygiene criteria for *Bacillus* cereus in infant Formula

28. Following adoption of EC Regulation 2073/2005, the Commission considered harmonisation of national criteria implemented by Member States. Several MS had national criteria for *Bacillus* spp in food and the EFSA opinion on *B. cereus* and other *Bacillus* spp in foodstuffs[4] had reviewed the available evidence on these organisms so the Commission established an Expert Working Group to consider harmonised criteria for *Bacillus* spp. The UK participated in the Expert Group.

29. The basis for the discussions was the EFSA opinion, a risk assessment by Food Standards Agency Australia/New Zealand[5], and information on infectious doses from the Netherlands. The UK assessed the evidence, seeking views from relevant stakeholders in the process. It concluded that there was very little evidence to support microbiological criteria for *Bacillus* in foods and also took into account information from the UK study on infectious intestinal disease[6] (IID). It was recognised *B. cereus* could cause food poisoning. However, food poisoning figures and the study[4] did not indicate a particular problem with this organism.

30. However, the Commission and some Member States were very keen to see microbiological criteria for *Bacillus* in food and there was strong support for a food safety criterion. If a food fails to meet food safety criteria, food businesses must remove the affected produce from the market. This could include a full scale recall with the associated costs, which in the case of *Bacillus*, the UK does not believe would be a proportionate response with little demonstrable evidence of public health protection.

[3] EFSA opinion on the relationship between Ents, Sal and Esak
[4] EFSA opinion on *Bacillus* cereus and other *Bacillus* spp in foodstuffs
[5] FSA Aus/NZ RA
[6] IID study

31. As the UK considered there was limited evidence available to support the need for a criterion for *Bacillus spp* or suggest *B. cereus* was a particular concern, it could not support a food safety criterion, and expressed that view during negotiations (a food safety criterion has not been introduced). The Expert Group concluded a Process Hygiene Criteria should be introduced for *B. cereus* in infant formula. This was supported by the EFSA opinion which recommended 10^5 spores per gram at consumption should be used as a target for food business operators to verify their HACCP system, and could be considered as microbiological criteria to test the acceptability of a process.

32. The aim of a process hygiene criterion is to help demonstrate whether a process is functioning correctly, and provide an indicative level above which corrective action is required to ensure good process hygiene. If a process hygiene criterion is not met, food businesses must review the food safety management procedures and take action to ensure the criterion is met in future. The affected product can still remain on the market. *B. cereus* is a potential hazard associated with infant formula and should already, therefore, be considered by producers as part of their food safety management procedures. While the UK had reservations (shared by stakeholders) about the public health benefit of the introduction of any criteria, it considered the impact of a process hygiene criterion to be more proportionate and supported the conclusions of the Expert Group as a compromise. Stakeholders were asked to provide information on the impact of the proposed Regulation during the negotiations, and there was no indication that the introduction of a process hygiene criterion would have a major impact on the industry.

33. The initial proposals from the Commission provided a process hygiene criterion with a limit of 100 CFU per gram. There was some support for this from some Member States. The European Trades Federation for Infant Formula (IDACE - *Association of the Food Industries for Particular Nutritional Uses of the European Union*) suggested these limits were too stringent and offered alternatives. Various suggestions were made and the Commission requested views from Member States. The UK indicated it had some sympathy with the industry's position. The Commission initiated discussions with IDACE which eventually resulted in a proposal which reflected limits suggested by the industry – a 3 class sampling plan where n=5, c=1, m=50 and M=500. The UK supported these limits as they were relevant to public health protection and would not have a disproportionate effect on the industry. The proposal was adopted with unanimous agreement in the working group and standing Committee.

34. With regard to process criteria for *Bacillus*, the Regulation (EC) 1441/2007 reflects limits considered appropriate by the industry. There may be some impact on the industry as they demonstrate compliance with the criterion. However, feedback from the industry indicates some routine testing is already carried out.

New criteria for *Enterobacteriaceae* (process hygiene criteria) and *Salmonella* (food safety criteria) in follow-on formulae

35. The EFSA opinion[7] on microbiological risks in infant and follow-on formulae recommended a performance objective for powdered follow-on formulae aiming at very low levels of *Salmonella*, e.g. absence in 1, 10 or 100kg, and verification of compliance with the performance objective is confirmed by testing for Enterobacteriaceae in the environment and in the product. As noted earlier another EFSA opinion reviewed the relationship between *Salmonella* and Enterobacteriaceae in infant and follow-on formulae, and concluded it was not possible to establish a correlation. The Commission, therefore, proposed criteria for Enterobacteriaceae (process hygiene) and *Salmonella* (food safety). As with the infant formula criteria these are parallel criteria.

36. Feedback from the UK industry has indicated the *Salmonella* criterion (absence in 30 x 25g) would have little impact as the industry have been working to the standard for a number of years; more concerns were raised about the initial proposals for Enterobacteriaceae criterion, and IDACE wrote to the Commission outlining its position. The amendment to the Regulation

[7] www.efsa.eu.int/science/biohaz/biohaz_opinions/691_en.html.

provides a more stringent criterion than that supported by IDACE. However, discussions with the UK industry indicated that the impact of this standard will not be a great concern.

A new analytical reference method for Staphylococcal enterotoxins

37. The Community Reference Laboratory for *Staphylococcus* had updated their reference method for detecting staphylococcal enterotoxins in milk and milk products referenced in Annex 1 of Regulation (EC) 2073/2005. An update, introduced by Regulation (EC) 1441/2007, of the reference method listed in Regulation (EC) 2073/2005 was agreed unanimously by MS without comment.

38. The amendment impacts mainly on the dairy sector and laboratories that carry out testing. The Agency continues to seek information on the impact of the change but no concerns have come to light. Improved testing methods are likely to offer increased protection to public health through improved detection of the staphylococcal enterotoxin. Also the method may be easier for laboratories to use.

39. Regulation (EC) 2073/2005 (Article 5.5) allows for methods other than the reference method to be used, as long as they are appropriately validated against the reference methods and, in some cases, certified by a third party. It is possible that the introduction of a new reference method may impact on the validation of these alternative methods; there may also be limited increased costs as laboratory staff are trained to use the new method. Stakeholders have been asked to provide information on the impact of the new method's introduction but none has so far been received, which indicates this impact is not significant.

Harmonised carcase sampling rules

40. Several MS supported a suggestion for further harmonisation of carcase testing, in particular the specification of the number of sites that must be sampled when testing for *Salmonella* on red meat carcases (in June 06 - MS, including the UK, argued for less prescription as this is a process hygiene criteria and the sample site should be selected taking the slaughter technology into consideration). Currently, only the minimum area per site selected is specified. The UK suggested that amending the "minimum area of 100 sq cm per site selected" to "a total minimum area of 400 sq cm" could be an acceptable proposal. This accommodated the MS wishing to use the same 4 sites as specified for APC and Enterobacteriaceae as well as those that wish to use the USDA method for export or the UK side sponge method as currently included in the Meat Industry Guide. This was accepted by the Working Group.

41. There is expected to be no impact on the UK industry as the method currently used (side sponge wipe) covers at least the minimum 400 sq cm. Industry is content with this following the explanation that in effect there is no change. The Meat Industry Guide and ukmeat.org website have been updated accordingly.

<u>Amendment of the Food Hygiene (England) Regulations 2006 (as amended)</u>

42. The draft Statutory Instrument issued with the public consultation on 2 October 2007. Following revision, the UK was obliged to re-notify it to the European Commission under the provisions of 98/34/EC (this was the same for the corresponding SIs for Scotland, Wales and Northern Ireland), which it did so on 30 October 2008.

43. This three month period provides the Commission and Member States with the opportunity to scrutinise national legislation to ensure that it does not provide barriers to trade. In the case of this SI, the period ended on 2 February 2009.

<u>Cost of enforcement</u>

44. The total cost of enforcement, £140.2 million, is the sum of the cost of enforcement for local authorities in England and of the MHS. This total cost of enforcement figure is used in accordance with guidance from the Cabinet Office.

45. A figure of £98.3 million figure is the **total** annual cost of enforcement for England Local Authorities) and is **not related** to the specific cost of enforcing these measures.

46. The £98.3 million figure is taken from the Chartered Institute of Public Finance and Accounting Environmental Health Statistics 2005/06, which shows, for local authorities in England, a cost of £98,303,941 for food safety expenditure on Food Hygiene and the administration of Food Safety legislation.

47. In the case of harmonised carcase sampling rules, the Meat Hygiene Service is the enforcement body. In 2007/08 its Net Operating Cost was £41.9 million.[8]

Date of implementation of policy

48. Commission Regulation (EC) 1441/2007 applied 20 days after being published in the EU Official Journal (i.e. 20 days after 5 December 2007).

Public consultation

49. This IA was subject to a full three-month public consultation which was issued on 2 October 2007 and closed 4 January 2008. No further evidence was received with regard to costs or benefits resulting from the measure or the affect on sustainability or other identified areas of impact.

50. The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within three months of the closure of the consultation and the summary for the Draft Food Hygiene (Amendment)(England) Regulations (2008) can be seen at:

http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

[8] http://www.food.gov.uk/news/newsarchive/2008/jul/mhsara0708

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

It is not considered that the amendments to the regulations limit the number or range of suppliers to these sectors directly or indirectly, nor will they reduce the incentives for competitive action. As such, the Agency does not consider that Regulation (EC) 1441/2007 has the scope to adversely effect competition in these sectors.

Small Firms Impact Test

The regulation is not considered to have an undue impact on small firms.

Sustainable development and carbon assessment

There are no issues for sustainability or carbon raised by the regulation.

Race equality issues

None.

Gender equality issues

None.

Disability equality issues

None.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	Impact Assessment on a measure enabling the use of liquid pepsin for the detection of Trichinella in meat (Regulation (EC) 1245/2007)	
Stage: Final	**Version:** 1	**Date:** 19 February 2010
Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:281:0019:0020:EN:PDF		

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

Contact for enquiries: David Gray **Telephone:** 020 7276 8940

What is the problem under consideration? Why is government intervention necessary?

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry.

Trichinella is a zoonotic disease, transmissible to humans through consumption of raw or uncooked meat from infected animals. Testing is undertaken to protect public health using methods set out in EU legislation. There is some evidence that pepsin powder, used in laboratory tests as a reagent for the detection of Trichinella, can cause allergic reactions in some persons and, therefore, there is a need to amend the EU legislation to provide for the use of an alternative liquid form of the reagent which does not lower public health safeguards.

What are the policy objectives and the intended effects?

This Regulation provides for the use of liquid pepsin for the detection of Trichinella in meat. This provides a choice of form of the reagent pepsin for laboratory staff undertaking official controls to use, with the potential of benefitting their health, and with no consequent lowering of the protection to public health.

What policy options have been considered? Please justify any preferred option.

1. Do nothing.

2. Support the Regulation's introduction and give effect to the Regulation's execution and enforcement in English law. This is the preferred option because it increases flexibility and is beneficial to the health of some staff, without affecting the level of public health protection.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? November 2013.

Ministerial/CEO Sign-off For final/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Gillian Merron.....Date: ***25th February 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: Amendment of the Food Hygiene (England) Regulations as described: allow use of liquid pepsin for the detection of Trichinella in meat

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups': None quantified
One-off (Transition)	**Yrs**	
£ N/A	5	
Average Annual Cost (excluding one-off)		
£ N/A		**Total Cost** (PV) **£ N/A**

Other **key non-monetised costs** by 'main affected groups': Should laboratories choose to use it, liquid pepsin may be more expensive than powdered pepsin. However, the additional cost is likely to be insignificant.

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups': None quantified
One-off	**Yrs**	
£ N/A	5	
Average Annual Benefit (excluding one-off)		
£ N/A		**Total Benefit** (PV) **£ N/A**

Other **key non-monetised benefits** by 'main affected groups': The use of liquid pepsin in testing for Trichinella will give greater choice to the Competent Authority when testing for Trichinella. It will also reduce the possibility of allergic reactions to pepsin amongst some Competent Authority staff.

Key Assumptions/Sensitivities/Risks:
N/A

Price Base Year 2007	Time Period Years 5	**Net Benefit Range** (NPV) **£ N/A**	**NET BENEFIT** (NPV Best estimate) **£ N/A**

What is the geographic coverage of the policy/option?				England
On what date will the policy be implemented?				November 2007
Which organisation(s) will enforce the policy?				N/A
What is the total annual cost of enforcement for these organisations?				£ N/A
What is the incremental annual cost of enforcing **this proposal**?				£ insignificant
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				N/A
What is the value of the proposed offsetting measure per year?				£ N/A
What is the value of changes in greenhouse gas emissions?				£ N/A
Will the proposal have a significant impact on competition?				No
Annual cost (£-£) per organisation (excluding one-off)	Micro 0	Small 0	Medium 0	Large 0
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for Summary Sheets)

Reason for Intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

2. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.

3. *Trichinella* is a zoonotic disease, transmissible to humans through consumption of raw and uncooked meat from infected animals. Testing for *Trichinella* is carried out to protect public health using methods set out in EU legislation. However, there is some evidence that the pepsin powder, previously the only form of pepsin authorised for use in these tests undertaken in laboratories, can cause allergic reactions in some persons. Therefore, there was a need to amend the EU legislation to provide for the use of an alternative form of the reagent which does not lower public health safeguards.

Intended effect

4. The intended effect is to amend the EU food hygiene legislation to ensure that alternative ways in which official controls can be undertaken are available where they will bring benefits without any consequent weakening of public health safeguards. Commission Regulation (EC) 1245/2007 provides for the use of liquid pepsin in the *Trichinella* detection method by competent authorities.

Background

5. The UK supported the introduction of this Regulation, which provides for use of liquid pepsin in the *Trichinella* detection method by laboratories undertaking duties for the purposes of official controls.

6. Methods of detection of the parasite *Trichinella* in meat destined to be human food are set out in EU legislation, and are applied consistently across Member States to protect public health. *Trichinella* as a zoonotic disease is transmissible to humans through consumption of raw or uncooked meat from animals infected with the larvae *Trichinella spiralis*, and in severe cases can cause death.

7. Normally, samples are taken by plant staff from pigs at the slaughterhouse and sent from there to approved laboratories as a public health measure.

8. Testing is also undertaken as part of a general surveillance programme – horses are also tested, as are some wild animals (carnivores and omnivores), even when they would not be expected to enter the human food chain.

9. Pepsin powder is a prescribed reagent for use in laboratories for detecting *Trichinella*. However, there is some evidence that pepsin powder can cause allergic reactions in some persons and, therefore, there is a need to amend the EU legislation to provide for the use of an alternative form of the reagent as long as safeguards for public health are maintained.

10. If used, there may be a negligible cost for competent authorities. There is no impact on business. This IA therefore contains no monetised costs or benefits.

Options

11. Two Options have been identified, the details of which are given below.

Option 1. Do nothing.

12. The 'do nothing' Option would mean that the only prescribed form of detection of *Trichinella* in meat in EU law would be the pepsin powder reagent. This might lead to allergic reactions in those handling the pepsin powder where it could have been avoided by use of the liquid form. There are no incremental costs and benefits from this option.

Option 2. Support application of the legislation and to amend the Food Hygiene (England) Regulations 2006 (as amended to provide for the Regulation's enforcement).

Non-monetised benefits: The policy has two non-monetised benefits:

- Enhanced flexibility for the Competent Authority.
- Reduced possibility of allergic reactions amongst laboratory staff who handle pepsin for the purposes of official controls.

Non-monetised costs:

- Should laboratories choose to use it, liquid pepsin may be more expensive than powdered pepsin. However, the additional cost is likely to be insignificant.

13. No stakeholder comments on this issue (from either enforcers or industry) were received during the public consultation.

Other issues

Sustainability and other Specific Impacts

14. The Agency considers that Option 2 is the more sustainable, as there is a possible benefit to the health of competent authority staff and no significant costs.
15. No environmental impact has been identified, and no significant impact on the areas listed under the Specific Impact Tests Checklist.
16. No comments on sustainability were received during the public consultation.

Public consultation

17. This IA was subject to a twelve week public consultation which was issued on 2 October 2007 and closed 4 January 2008. No further evidence was received with regard to costs or benefits resulting from the measure, or the effect on sustainability or other identified areas of impact.
18. The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within three months of the closure of the consultation and the summary for the Draft Food Hygiene (Amendment) (England) Regulations (2008) can be seen at:
http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

Date policy will be implemented

19. Commission Regulation (EC) 1245/2007 applied directly 20 days after being published in the EU Official Journal (i.e. 20 days after 25 October 2007).

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	Yes	Yes
Carbon Assessment	No	No
Other Environment	Yes	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

No firms are affected by the proposed Regulation.

Small Firms Impact Test

No firms are affected by the proposed Regulation.

Sustainable development

Nothing significant identified.

Race equality issues

No issues.

Gender equality issues

No issues.

Disability equality issues

No issues.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of an exemption for cleansing and disinfection facilities for livestock vehicles**	
Stage: Final	**Version: 1**	**Date: 19 February 2010**
Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0022:0082:EN:PDF		

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

Contact for enquiries: Simon Tudor **Telephone:** 020 7279 8339

What is the problem under consideration? Why is government intervention necessary?

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry. To be efficient the intervention needs to be proportionate to the risk.

From 1 January 2006, EU Food Hygiene Regulations required slaughterhouses to have cleansing and disinfection facilities for livestock vehicles, which is disproportionately costly for certain small slaughterhouses. The national measure is needed to allow those small slaughterhouses, not previously required to have cleaning and disinfection facilities, to be given approval to continue to operate without these facilities where there is no increased risk to public health.

What are the policy objectives and the intended effects?

The measure will ensure that certain small (and often rural) slaughterhouses without cleansing and disinfection facilities can be approved as meeting the legal requirements relating to equipment and structures, and can therefore continue to operate.

This proportionate measure will maintain jobs and the services such businesses provide to the local economy, while maintaining consumer health protection.

What policy options have been considered? Please justify any preferred option.

1. Do nothing.
2. Exempt some slaughterhouses from the need to have facilities for cleansing and disinfection of livestock vehicles so that they comply with the hygiene legislation and can be approved.

Option 2 is the preferred option because it will allow certain small slaughterhouses to continue to trade with no lowering of the protection of public health.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

April 2015.

Ministerial/CEO Sign-off For final/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Gillian Merron.....Date: ***25th February 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: **Implement the adoption of the national measure to adapt requirements of the EC Regulation**

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 0	5
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups':
None identified

Total Cost (PV)	**£ 0**

Other **key non-monetised costs** by 'main affected groups':
None identified

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ 21,600-36,000	5
Average Annual Benefit (excluding one-off)	
£ 0	

Description and scale of **key monetised benefits** by 'main affected groups':
36 Low Throughput slaughterhouses without facilities for cleansing and disinfection of livestock vehicles would be exempted from having to add them (at their own cost). Requirements of such facilities include a cold water supply, the road to be re-laid to form a trough, drainage facilities and so on.

Total Benefit (PV)	**£ 108,000-180,000**

Other **key non-monetised benefits** by 'main affected groups':
None identified

Key Assumptions/Sensitivities/Risks: The above benefits assume that affected companies already have sufficient space to accommodate the required facilities. If they do not, they may need to relocate at a considerably higher but uncertain cost. We also assume that affected slaughterhouses do not have suitable facilities located nearby.

Price Base Year 2007	Time Period Years 5	**Net Benefit Range** (NPV) **£ 108,000-180,000**	**NET BENEFIT** (NPV Best estimate) **£ 144,000**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			April 2010	
Which organisation(s) will enforce the policy?			MHS	
What is the total annual cost of enforcement for these organisations?			£ 70.54 million*	
What is the incremental annual cost of enforcing **this proposal**?			£ 0	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro 0	Small 0	Medium 0	Large 0
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** **£** N/A

K **Annual costs** **(Net)**

Evidence Base (for summary sheets)

Reason for Intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.
2. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.
3. To be efficient these hygiene standards need to be proportionate to the risk with the costs of compliance fully justified by the benefits. For certain small slaughterhouses, the requirement in the EU Food Hygiene regulations (which came into effect in January 2006) for cleansing and disinfection facilities for livestock vehicles is disproportionately costly.
4. A national measure was therefore proposed to allow such small slaughterhouses, which were not previously required to have cleaning and disinfection facilities, to be given approval to operate without these facilities where there is no increased risk to public health.

Intended effect

5. The intended effect of the exemption is to ensure that certain small and often rural slaughterhouses without cleansing and disinfection facilities can, provided they meet certain conditions, be approved as meeting the legal requirements relating to equipment and structures, and can therefore continue to operate. This will maintain jobs and the service the businesses provide to the local economy, while maintaining the necessary level of consumer health protection.

Background

6. Three EU Food Hygiene Regulations applied in all Member States on 1 January 2006, effectively replacing 17 Directives leading to the revocation of a series of domestic meat regulations including the Fresh Meat (Hygiene and Inspection) Regulations 1995.
7. The Regulations are: Regulation (EC) No. 852/2004, Regulation (EC) No. 853/2004 and Regulation (EC) No. 854/2004. These lay down, respectively, hygiene requirements for all food businesses, additional hygiene requirements for food businesses dealing in products of animal origin, and specific rules for the organisation of official controls on products of animal origin for human consumption.
8. Article 4 of Regulation (EC) No. 853/2004 requires that food business operators placing products of animal origin manufactured in the Community on the market must meet the requirements of Regulation (EC) No 852/2004, of Annexes II and III of Regulation (EC) No. 853/2004 and other relevant requirements of food law and have been approved by the competent authority as meeting the necessary requirements.
9. Point 3 of Article 10 of Regulation (EC) No. 853/2004 permits Member States to adopt national measures adapting the requirements laid down in Annex III, and point 4b states that the national measures may apply to the construction, layout and equipment of establishments.
10. Annex III (Section I, Chapter II, paragraph 6) of this Regulation requires all slaughterhouses in which domestic ungulates are slaughtered to have *"a separate place with appropriate facilities for the cleaning, washing and disinfection of means of transport for livestock. However, slaughterhouses need not have these place and facilities if the competent authority so permits and if official authorised places and facilities exist nearby."* There is a similar requirement in Section II, Chapter II, paragraph 6 (b) which requires all slaughterhouses in which poultry and

lagomorphs are slaughtered to have *"a separate place with appropriate facilities for the cleaning, washing and disinfection of… means of transport. These places and facilities are not compulsory if officially authorised places and facilities exist nearby."*

11. Some slaughterhouses that were licensed as low throughput[9] under the now revoked Fresh Meat (Hygiene and Inspection) Regulations (as amended) 1995 were exempted from having facilities for cleansing and disinfecting of livestock vehicles on site. They are now required to have those facilities on site unless these facilities exist nearby before they can be approved by the competent authority.

12. Initial discussion with the meat industry has revealed that some slaughterhouses are unable to meet the new requirement because of their location and lack of physical space. Additionally, where officially authorised facilities exist, they are not necessarily nearby or open at appropriate times.

13. This would mean that businesses without cleansing and disinfection facilities could not be approved as meeting all the relevant requirements, and this would effectively mean that they could no longer operate.

14. With the adoption of the national measure, which will be provided in domestic law, certain slaughterhouses, formerly classified as low throughput slaughterhouses, will be exempt from the new requirement that all slaughterhouses should have facilities for the cleansing and disinfection of livestock vehicles.

Options

15. The options considered in this case to implement hygiene requirements of Regulation (EC) No. 853/2004 in England were:

- Option 1 - Do nothing.
- Option 2 – Adopt a national measure to adapt requirements of the EC Regulation on facilities for cleansing and disinfection of livestock vehicles in slaughterhouses with a low throughput to exempt certain slaughterhouses from the need to have these facilities.

A third option of submitting the proposal as part of EU hygiene review was considered. This was considered and put to consultation but did not gain any stakeholder support. In view of the lengthy timescale for a wholesale review of the hygiene regulations and the possibility of infraction proceedings in the meantime, unless detention facilities were installed at a total cost of between £120,000 and £200,000, this option was discounted.

Option 2 is therefore the preferred Option.

Analysis of Options

16. Below are the analyses of the Options that were considered as part of the consultation. The preferred Option (2) is dealt with last.

17. **Option 1** is the do nothing option and provides the baseline to which all other options are compared[10].

18. **Option 2** is the preferred Option. Low throughput slaughterhouses without cleansing and disinfection facilities do not pose an increased risk to public health if certain conditions are met. A

[9] The Fresh Meat (Hygiene and Inspection) Regulations 1995 (as amended) defined a low throughput slaughterhouse as: *"a throughput of animals whose meat is intended for sale for human consumption of not more than 1,000 livestock units each year at a rate not exceeding 20 each week".*

[10] While we recognise that Option 1 will incur costs, these are considered as the benefits of Option 2 and acknowledged in the costs and benefits of Option 2.

national measure to exempt them from the requirement to have these facilities, which would be disproportionately costly, would allow them to continue to operate.

19. The adoption of a national measure to adapt the requirement for facilities for cleansing and disinfection of livestock vehicles in slaughterhouses with a low throughput would maintain the exemption that existed under the Fresh Meat (Hygiene and Inspection) Regulations 1995.

20. Certain slaughterhouses, formerly classified as low throughput slaughterhouses, would then be exempted from the requirement in Annex III of Regulation (EC) No. 853/2004 – (i.e. exempted from the requirement that slaughterhouses should have facilities for the cleansing and disinfection of livestock vehicles).

21. Conditions for approval without facilities for cleaning and disinfection of livestock vehicles would be that:

- the food business was approved as a low capacity slaughterhouse at 31 December 2005;
- the slaughterhouse otherwise meets the requirements of Regulations (EC) No. 852/2004 and 853/2004;
- vehicle drivers will need to confirm in writing with the operator that they will clean their vehicles between consignments of animals; and
- the operator accepts that they may be required, subject to the epidemiological situation and animal health legislation, to stop operating in times of an animal disease outbreak (such closures were required during the last foot and mouth disease outbreak).

Impact on Low Throughput Slaughterhouses

22. It is estimated that approximately 36 out of the 124 (29%) slaughterhouses in England do not have facilities for cleansing and disinfection of livestock vehicles.

23. If the plants were to install facilities for cleansing and disinfection of livestock vehicles, a supply of cold water with a portable pressure unit would be needed together with a supply of detergent. A suitable area for livestock vehicles would also need to be provided with the necessary drainage to remove the wash water and a screen to remove solid material. Assuming that the space is available to provide this facility, the Meat and Livestock Commission (MLC)[11] estimated that it would cost in the region of £3,000 to £5,000 to install this facility.

24. Space is one of the main obstacles for those slaughterhouses that do not have the facilities for cleansing and disinfection of livestock vehicles. The implementation of option 2 would ensure that slaughterhouses without these facilities could continue to operate and contribute to the rural economy.

25. The estimated annual turnover per abattoir is £567,000. From discussions with the industry it has been established that building a small slaughterhouse could cost between £1-2 million and renting premises approximately £12,000 a year. However, the rental only relates to the building itself and not to the initial investment the food business operator will need to make in order to convert the building into a slaughterhouse that would meet all the requirements needed to obtain approval.

26. The financial implications and other constraints such as planning permission, adequate location, and possible resistance from local residents make the option of renting or building not viable.

27. The 12 week public consultation showed broad stakeholder support for this measure with only some minor disagreement with its introduction. No further evidence was received with regard to costs or benefits resulting from the measure, or the effect on sustainability or other identified areas of impact.

28. The Agency placed a summary of stakeholder responses on its website within three months of the closure of the consultation. This can be seen at: http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

Cost of enforcement

29. The Meat Hygiene Service will remain responsible in GB for enforcement; sanctions and monitoring for meat hygiene requirements set out in the Regulations.

[11] The MLC was wound-up on 31 March 2008 as part of a reorganisation of levy boards by the Government.

Note regarding Total Annual Cost of Enforcement for MHS

30. The £70.54 million figure is the **total** annual cost of enforcement for the Meat Hygiene Service, and is **not related** to the specific cost of enforcing this measure. This total cost of enforcement figure is used in accordance with guidance from the Cabinet Office.

31. The figure of £70,540,000 includes all enforcement action on the meat hygiene legislation including Specified Risk Material and Animal By-Products. The figures are for 2006/07.

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	Yes	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	Yes	No

EU legislation is described in paragraphs 1 – 5.

Competition Assessment
The preferred option is not expected to have an impact on the way that business is conducted at these premises. It is therefore not considered likely to directly or indirectly limit the range of suppliers and neither is it considered likely that it will limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.
The exemption from the requirements to install cleansing and disinfection facilities may be perceived as unfair to new businesses wishing to enter the meat industry, which would of course have to install them as a condition of approval. However, any impact on competition is limited because the exemption is restricted only to slaughterhouses that were licensed as low throughput on 31 December 2005 under the previous legislation and for other reasons set out in this IA, would find provision of the facilities in existing premises unnecessarily burdensome or impractical. This would not be the case with brand new premises which would be built with compliance with the law being taken into account during design and construction.

Small Firm Impact Assessment
The cost for some slaughterhouses to upgrade to the standards set by the EU Regulations is significant; as a consequence small slaughterhouses that could not afford to upgrade or do not have the space needed may choose to close the business, since their profitability would be adversely affected. This will ultimately decrease the number of suppliers of meat. Option 2 will have a positive impact and ensure that small businesses can continue to operate
The Meat Hygiene Policy Forum was consulted and discussions took place with representative bodies of the meat industry, such as the Association of Independent Meat Suppliers (AIMS) and the Small Abattoir Federation (SAFE). They welcomed the proposal for a national measure, as without it the businesses could not gain approval and would be forced to close.

Sustainable Development
The impact of implementing the adoption of this national measure would not have any adverse economic consequences for local employment. It is estimated that low throughput slaughterhouses employ 348 people, of whom 29% are employed by small slaughterhouses without facilities for cleansing and disinfection of livestock vehicles. The impact of the national measure will secure the approval of those slaughterhouses and the continuation of those businesses. This will also benefit animal welfare, as animals will not have to be transported longer distances, and keep down food miles.

Race, Disability and Gender Equality
We do not believe that there are any such issues associated with this proposal.

Human Rights
We do not believe that there is any impact.

Rural Proofing
Slaughterhouses in rural areas are integral to the rural economy. Farmers with a small number of animals to slaughter want to be able to take them to a local slaughterhouse, as it may not be economical to transport the animals further to a larger slaughterhouse.
To survive some small slaughterhouses offer additional services to local farmers, for example, cutting and packaging meat for farmers to sell at farmers' markets. The closure of small slaughterhouses would impact on farmers. This proposal will enable a number of small slaughterhouses to continue to operate.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of Exempting Requirement for Detained Meat Facilities in Low Throughput Slaughterhouses**	
Stage: Final	**Version: 1**	**Date: 19 February 2010**
Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:226:0022:0082:EN:PDF		

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

Contact for enquiries: Simon Tudor **Telephone:** 0207 276 8339

What is the problem under consideration? Why is government intervention necessary?

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry. To be efficient, the intervention needs to be proportionate to the risk.

From 1 January 2006, EU Food Hygiene Regulations required slaughterhouses to have lockable facilities for detained meat, which is disproportionately costly for certain small slaughterhouses. A national measure is needed to allow those small slaughterhouses, not previously required to have detained meat facilities, to be given approval to continue to operate without these facilities where there is no increased risk to public health.

What are the policy objectives and the intended effects?

The measure will ensure that certain small (often rural) slaughterhouses without detained meat facilities can continue to operate. This will maintain jobs and a service that businesses provide to the local economy, while maintaining the level of public health protection.

What policy options have been considered? Please justify any preferred option.

Three options have been considered:

(1) Do nothing.

(2) Exempt some slaughterhouses from the EU requirement to have detained meat facilities; they will therefore comply with the legislation.

The preferred option (2) will prevent the closure of some slaughterhouses while maintaining public health protection.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? April 2015

Ministerial/CEO Sign-off For Final/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Gillian Merron.....Date: ***25th February 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: Implement the adoption of the national measure to adapt requirements of the EC Regulation

COSTS

ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups': None identified	
One-off (Transition)	Yrs		
£ 0	5		
Average Annual Cost (excluding one-off)		Total Cost (PV)	£ 0
£ 0			

Other key non-monetised costs by 'main affected groups': N/A

BENEFITS

ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups': 40 Low Throughput slaughterhouses without detained meat facilities would be exempted from having to add them (at their own cost). Such facilities require appropriate drainage, weighing facility, adequate ventilation, refrigeration, sterilisation equipment, temperature recording, lighting, easily cleaned surfaces & must be lockable.	
One-off	Yrs		
£ 24,000-40,000	5		
Average Annual Benefit (excluding one-off)		Total Benefit (PV)	£ 120,000-200,000
£ 0			

Other key non-monetised benefits by 'main affected groups': N/A

Key Assumptions/Sensitivities/Risks: The above benefits assume that affected companies already have sufficient space to accommodate detained meat facilities. It may be the case that some companies do not have such space. If this is true, they would need to relocate at a considerably higher but uncertain cost, resulting in a higher Total Benefit figure.

Price Base Year 2007	Time Period Years 5	Net Benefit Range (NPV) £120,000-200,000	NET BENEFIT (NPV Best estimate) £160,000

What is the geographic coverage of the policy/option?				England
On what date will the policy be implemented?				April 2010
Which organisation(s) will enforce the policy?				MHS
What is the total annual cost of enforcement for these organisations?				£ 70.54 million*
What is the incremental annual cost of enforcing this proposal?				£ 0
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				No
What is the value of the proposed offsetting measure per year?				£ N/A
What is the value of changes in greenhouse gas emissions?				£ N/A
Will the proposal have a significant impact on competition?				No
Annual cost (£-£) per organisation (excluding one-off)	Micro 0	Small 0	Medium 0	Large 0
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A Net Impact £ N/A

Key: Annual costs and benefits: Constant Prices | (Net) Present Value

Evidence Base (for summary sheets)

Reason for Intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.
2. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised.
3. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators. To be efficient, the intervention needs to be proportionate to the risk. For certain small slaughterhouses, the requirement in the European Food Hygiene regulations (which came into effect in January 2006) for detained meat facilities is disproportionately costly.
4. A national measure was, therefore, proposed to allow such small slaughterhouses, which were not previously required to have detained meat facilities, to be given approval to operate without these facilities where there is no increased risk to public health.

Background

EU Legislation - introduction

5. Three EU Food Hygiene Regulations came into force in all Member States on 1 January 2006, replacing and revoking the previous seventeen EU Directives, including the Fresh Meat (Hygiene and Inspection) Regulations (as amended) 1995.
6. The EU Food Hygiene Regulations are: Regulation (EC) No. 852/2004, which lays down the basic hygiene requirements for all food business operators; Regulation (EC) No. 853/2004, which lays down additional hygiene requirements for food businesses dealing in products of animal origin and Regulation (EC) No. 854/2004, which lays down rules for the organisation of official controls on products of animal origin for human consumption.

EU Legislation – relevant detail

7. Article 4 of Regulation (EC) No. 853/2004 requires that food business operators placing products of animal origin manufactured in the Community on the market must meet the requirements of Regulation (EC) No 852/2004, of Annexes II and III of Regulation (EC) No. 853/2004 and other relevant requirements of food law and have been approved by the competent authority as meeting the necessary requirements.
8. Regulation (EC) 853/2004, Article 10 point 3, permits Member States to adopt national measures adapting the requirements laid down in Annex III and point 4(b) states that the national measures shall apply to the construction, layout and equipment of establishments.
9. Regulation (EC) 853/2004, Annex III, Section I, Chapter II, point 5 requires slaughterhouses slaughtering domestic ungulates to have *"lockable facilities for the refrigerated storage of detained meat, and separate lockable facilities for the storage of meat declared unfit for human consumption."* Similarly, Annex III, Section II, Chapter II, point 5 requires slaughterhouses slaughtering poultry and lagomorphs to have *"lockable facilities for the refrigerated storage of detained meat, and separate lockable facilities for the storage of meat declared unfit for human consumption."*
10. Some slaughterhouses that were licensed as low throughput[12] under The Fresh Meat (Hygiene and Inspection) Regulations (as amended) 1995, were exempted from having refrigerated detention

[12] The Fresh Meat (hygiene and inspection) Regulations 1995 (as amended) defined a low throughput slaughterhouse as: '*a throughput of animals whose meat is intended for sale for human consumption of not more than 1,000 livestock units each year at a rate not exceeding 20 each week*'

facilities. They are now required to have those facilities before they can be approved by the competent authority.

11. Initial discussion with the meat industry has revealed that some slaughterhouses are unable to meet the new requirement because of their location, lack of physical space or because they occupy a building of historical significance.

12. The national measure is needed to allow such certain small slaughterhouses that were not previously required to have detained meat facilities, to be given approval to continue to operate without such facilities where there is no increased risk to public health.

13. The adoption of the national measure (which will be provided by English national legislation) to adapt the requirement from having refrigerated detention facilities in slaughterhouses with a low throughput will effectively maintain the exemption that was available to these businesses under the Fresh Meat (Hygiene and Inspection) Regulations 1995 (as amended).

Options

14. The options considered in this case to implement hygiene requirements of Regulation (EC) No. 853/2004 in England were
    - Option 1 - Do nothing; and
    - Option 2 - Adopt a national measure to adapt requirements of the EC Regulation on having refrigerated detention facilities in slaughterhouses with a low throughput.

15. A third option was considered which consisted of a temporary exemption for such slaughterhouses until the review of the hygiene regulations. This was considered and put to consultation, but did not gain any stakeholder support. In view of the lengthy timescale for a wholesale review of the meat hygiene regulations and the possibility of infraction proceedings in the meantime, unless detention facilities were installed at a total cost of between £120,000 and £200,000, this option was also discounted.

    Option 2 is the preferred Option.

Analysis of Options

16. Below are the analyses of the Options that were considered as part of the consultation. The preferred Option (2) is dealt with last.

17. **Option 1** is the do nothing option and provides the baseline to which all other options are compared[13].

18. **Option 2 is the preferred Option.** Low throughput slaughterhouses without detained meat facilities do not pose an increased risk to public health if certain conditions are met. A national measure to exempt them from the requirement to have detained meat facilities, which would be disproportionately costly, would allow them to continue to operate. Additionally, it will be permissible for meat to be detained if necessary at an alternative location if one exists in the locality.

19. Option 2 allows certain businesses an exemption from the requirements of Regulation (EC) 853/2004 with which they could not otherwise comply, and non-compliance would lead to the withdrawal of approval to operate. By preventing the closure of these businesses, there may be some social benefits that are not monetised. In terms of environmental costs, this option will have an additional cost if it is necessary for meat to be transported to an alternative facility in the locality for detention. However, in terms of sustainability, this exemption will mean that detained meat which is subsequently passed as fit for human consumption will not have been discarded at the outset as waste which is normal practice in these plants (see point iv below). The conditions for approval without refrigerated detention facilities would be:

[13] While we recognise that Option 1 will incur costs, these are considered as the benefits of Option 2 and acknowledged in the costs and benefits of Option 2.

i. that the food business was approved as a low capacity slaughterhouse on 31 December 2005;

ii. that the slaughterhouse otherwise meets the requirements of Regulations (EC) No. 852/2004 and 853/2004;

iii. that the operator has such control over the acceptance of animals for slaughter that the establishment rarely, if ever, produces meat that requires detention for further examination by the official veterinarian (OV);

iv. that either an alternative detention facility is available in the locality, in which case the meat must be marked as 'Detained' and then consigned there, *or* any meat deemed by the OV to require further inspection must be destroyed; and,

v. that no processing for human consumption takes place of cattle that require BSE testing or of pigs requiring Trichinella testing that would require carcases to be held while awaiting test results.

Impact on Low Throughput Slaughterhouses

20. It was estimated in 2007 that 40 of the 124 (32%) slaughterhouses formerly classified as low throughput do not have detained meat facilities[14].

21. If a plant was to install a new detained room with refrigeration, insulated walls, an overhead rail, lighting, drains and steriliser, the cost could be in the region of £3,000 to £5,000, assuming that the necessary space is available[15].

22. Lack of space is one of the main obstacles for those slaughterhouses that do not have detained meat facilities. The implementation of option 2 would mean that those slaughterhouses need not rent or build another facility.

23. From discussions with the industry it has been established that building a small slaughterhouse could cost between £1-2 million, and renting premises £12,000 a year. However, the rental only refers to the building itself, and not to the initial investment the food business operator will need to make in order to convert the building into a slaughterhouse and to obtain approval.

24. The financial implications and other constraints, such as planning permission, adequate location and possible resistance from local residents, make the option of renting or building new premises unlikely to be viable.

25. The twelve week public consultation showed most stakeholders supporting this measure with some disagreeing. No further evidence was received with regard to costs or benefits resulting from the measure, or the effect on sustainability, or other identified areas of impact. The Agency places a summary of stakeholder responses on its web site within three months of the closure of the consultation (i.e. 4 April 2008). This summary can be seen at: http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

Note regarding Total Annual Cost of Enforcement for MHS

26. The Meat Hygiene Service will remain responsible in GB for the enforcement, sanctions and monitoring for meat hygiene requirements set out in the EU Regulations. The £70.54 million figure is the **total** annual cost of enforcement for the Meat Hygiene Service, and is **not related** to the specific cost of enforcing this measure.

27. This total cost of enforcement figure is used in accordance with guidance from the Cabinet Office. The figure of £70,540,000 includes all enforcement action on the meat hygiene legislation including Specified Risk Material and Animal By-Products. The figures are for 2006/07.

[14] Figures provided by the Meat Hygiene Service.
[15] Estimated figures provided by the Meat and Livestock Commission in 2007 (*the MLC was wound–up in 2008*.).

Specific Impact Tests: Checklist

Type of testing undertaken	Results in Evidence Base?	Results annexed?
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	Yes	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	Yes	No
Disability Equality	Yes	No
Gender Equality	Yes	No
Human Rights	Yes	No
Rural Proofing	Yes	No

Competition Assessment
The preferred option is not expected to have an impact on the way that business is conducted at these premises. It is, therefore, not considered likely to directly or indirectly limit the range of suppliers, and neither is it considered likely that it will limit the ability of suppliers to compete or reduce suppliers' incentives to compete vigorously.

The exemption from the requirements to install detained meat facilities may be perceived as unfair to new businesses wishing to enter the meat industry, which would of course have to install them as a condition of approval. However, any impact on competition is limited because the exemption is restricted only to slaughterhouses that were licensed as low throughput on 31 December 2005 under the previous legislation and for other reasons set out in this IA, would find provision of the facilities in existing premises unnecessarily burdensome or impractical. This would not be the case with brand new premises which would be built with compliance with the law being taken into account during design and construction.

Small Firm Impact Assessment

The cost for some slaughterhouses to upgrade to the standards set by the EU regulations would be significant. As a consequence, small slaughterhouses that could not afford the upgrade or do not have the space may choose to exit the market, since their profitability would be adversely affected. This would ultimately decrease the number of suppliers. Option 2 would, on the contrary, have a positive impact.

The Meat Hygiene Policy Forum was consulted and discussions took place with representative bodies of the meat industry, such as the Association of Independent Meat Suppliers (AIMS) and the Small Abattoir Federation (SAFE). They welcomed the proposal for a national measure as without it the businesses could not gain approval, and would be forced to close.

Environmental Impact

No significant environmental impacts have been identified from the implementation of this national measure.

Sustainable Development

Impacts under all three pillars of Sustainable Development, economic, social and environmental, have been considered in preparing this IA. Option 2 is considered relatively more sustainable as it will mean the avoidance of costs for SMEs (sometimes) based in the countryside. Further, adoption of this national measure would not have any adverse economic consequences for local employment. The impact of the national measure would secure the approval of those slaughterhouses and the continuation of those businesses. This would also mean no increase in food miles through the transport of animals to other slaughterhouses.

However, the option to allow detained meat to be moved to an alternative facility in the locality would have an additional cost but could provide sustainability benefits if meat that would ordinarily be discarded as waste rather than being detained for later inspection were to be passed fit for human consumption following detention. On balance however, it is considered that Option 2 the preferred option is the most sustainable as it provides the exemption which could have otherwise meant closure for these affected firms.

Race Disability and Gender Equality

We do not believe that there are any such issues associated with this proposal.

Human rights

No impact.

Rural proofing

Slaughterhouses in rural areas are integral to the rural economy. Farmers with a small number of animals to slaughter want to be able to take them to a local slaughterhouse, as it may not be economical to transport the animals further to a larger slaughterhouse. This would also help to reduce food miles and enhance animal welfare.

To survive, some small slaughterhouses offer additional services to local farmers, for example, cutting and packaging meat for farmers to sell at farmers' markets. The closure of small slaughterhouses would impact on farmers. This proposal would enable a number of small slaughterhouses to continue to operate.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of a Commission Regulation measure amending rules for official controls for screening biotoxins in live bivalve molluscs (Regulation (EC) 1244/2007)**	
Stage: Final	**Version:** 1	**Date:** 19 February 2010
Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08; http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_281/l_28120071025en00120018.pdf		

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

Contact for enquiries: David Gray **Telephone:** 020 7276 8940

What is the problem under consideration? Why is government intervention necessary?

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry.

The Food Standards Agency is responsible for monitoring Live Bivalve Molluscs from classified shellfish beds for the presence of biotoxins and the measure allows the Agency, as a competent authority, the use of an alternative screening method.

What are the policy objectives and the intended effects?

The measure permits Member State competent authorities the use of an alternative screening method for the detection of Amnesic Shellfish Poisoning (ASP) toxins, which may bring high capacity at low cost without lowering the standards of public health protection.

What policy options have been considered? Please justify any preferred option.

1. Do nothing

2. Support application of the EU measure and provide for their enforcement by amendment of the Food Hygiene (England) Regulations as described. Option 2 is preferred because it allows the use of an alternative screening method, providing a choice and the potential for lower cost monitoring, while maintaining public health protection.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

November 2012

Ministerial/CEO Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:

Gillian Merron.....Date: ***25th February 2010***

Summary: Analysis & Evidence

Policy Option: 2	Description: Support application of the measure allowing an alternative method of testing live bivalve molluscs for Amnesic Shellfish Poisoning

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups':
One-off (Transition)	**Yrs**	None identified.
£ 0	5	
Average Annual Cost (excluding one-off)		
£ 0		**Total Cost** (PV) **£ 0**

Other **key non-monetised costs** by 'main affected groups':
The costs of any sample testing changes are expected to be negligible.

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups':
One-off	**Yrs**	None monetised.
£	5	
Average Annual Benefit (excluding one-off)		
£		**Total Benefit** (PV) **£**

Other **key non-monetised benefits** by 'main affected groups':
Potential improvements in the efficiency and choice of methods of sampling for biotoxins.

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years	**Net Benefit Range** (NPV) **£ N/A**	**NET BENEFIT** (NPV Best estimate) **£ N/A**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			November 2007	
Which organisation(s) will enforce the policy?			N/A	
What is the total annual cost of enforcement for these organisations?			£ 109.7 million	
What is the incremental annual cost of enforcing **this proposal**?			£ negligible	
Does enforcement comply with Hampton principles?			Yes	
Will implementation go beyond minimum EU requirements?			No	
What is the value of the proposed offsetting measure per year?			£ N/A	
What is the value of changes in greenhouse gas emissions?			£ N/A	
Will the proposal have a significant impact on competition?			No	
Annual cost (£-£) per organisation (excluding one-off)	Micro 0	Small 0	Medium 0	Large 0
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** £ N/A

Key: **Annual costs and benefits: Constant** **(Net) Present**

Evidence Base (for summary sheets)

Reason for Intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

2. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.

3. In this specific situation, government intervention takes the form of monitoring Live Bivalve Molluscs from classified shellfish beds for the presence of biotoxins. The Food Standards Agency is responsible for this monitoring. To be efficient, the monitoring methods need to be cost effective and in line with the latest scientific understanding. Therefore there is a need to update the legislation in line with the latest scientific evidence on a potential alternative screening mechanism.

Intended Effect

4. The intended effect is to update the EU food hygiene legislation to allow alternative ways of carrying out controls, which make use of developments in science and technology. In this case, specifically, to permit the use of an alternative screening method for the detection of Amnesic Shellfish Poisoning (ASP) toxins, which may have the benefit of being cheaper.

Background

5. Regulation (EC) 854/2004 requires EU Member State competent authorities to fix the location and boundaries of live bivalve mollusc (LBM) production and relaying areas. It also requires the competent authority to classify authorised LBM production areas as being Class A, B or C, with A being the cleanest. The Food Standards Agency, as the UK competent authority, is directly responsible for ensuring these rules are complied with.

6. One of the requirements set down in Regulation (EC) 854/2004 is for competent authorities to monitor LBMs for the presence of biotoxins (854/2004, Annex II, B). The role of the Agency as competent authority as regards the designation and classification of shellfish harvesting areas is set out in the National Control Plan[16], which the Agency is required to produce in line with EU Regulation (EC) 882/2004[17].

7. This measure concerns the way in which competent authorities carry out official controls, and will not have any impact on industry as testing costs are borne solely by the Agency.

<u>Detecting Amnesic Shellfish Poisoning</u>

8. The method for detecting the biotoxin Amnesic Shellfish Poisoning (ASP) was laid down in Commission Regulation (EC) 2074/2005, Chapter II and was the high performance liquid chromatography (HPLC) method. However, Commission Regulation 1244/2007 permits the use, for screening purposes, of edible parts of molluscs, of the 2006.02 ASP ELISA method (as published in the AOAC Journal of June 2006). The measure proposes a possible

[16] The UK National Control Plan 2007 – 2011. Reference to shellfish harvesting can be found in Appendix C, paragraph 16 of the FSA web site at: http://www.food.gov.uk/multimedia/pdfs/uknationalcontrolplan.pdf

[17] Regulation (EC) 882/2004 sets down the principles and approach to be to be taken by competent authorities in EU Member States that have responsibility for monitoring and enforcing compliance with feed, food, animal health and animal welfare rules.

alternative that the Agency could consider for testing official control samples and which may be more cost effective. The Agency will assess this alternative test and ensure it is at least as safe as the current testing regime before it is further considered for use.

Amendment of the Food Hygiene (England) Regulations 2006 (as amended)

9. The draft Statutory Instrument (SI) was issued with the public consultation on 2 October 2007. The SI will provide for the execution and amendment of the EU
10. measure in English law.

Options

11. Two Options were identified in relation to these Regulations:

- *Do nothing.*
- *Support the regulation's application to allow the method for screening for ASP and provide enforcement through amendment of the Food Hygiene (England) Regulations*

Costs & benefits of Options

Option 1. Do nothing.

12. There are no incremental benefits or costs.

Option 2. Support the measure's application to allow the method for screening for ASP and provide enforcement through amendment of the Food Hygiene (England) Regulations 2006 (as amended).

Benefits

.

13. The availability of an approved alternative to HPLC would mean that if HPLC became unavailable for any reason, the competent authority would still be able to conduct the requirements for testing classified shellfish beds for ASP toxins. If no alternative to HPLC were available the competent authority would be unable to carry out tests, perhaps leading to sanctions by the European Commission.

14. The measure proposes a potential alternative that the Agency could consider for testing official control samples, which is potentially both cheaper and faster, and hence could lead to savings for competent authorities when screening for Amnesic Shellfish Poisoning (ASP). The Agency will assess this alternative test and ensure it is at least as safe as the current testing regime before it is further considered for use and any potential savings made

15. Option 2 was preferred as it enables the benefit of potential improvements in the efficiency and choice of methods of sampling for biotoxins in LBMs, with no lowering of public health protection. Providing for Commission Regulation 1244/2007 in English law also avoids any risk of the UK failing in its Treaty obligations with the consequence of sanctions by the European Commission (although there is no certainty that this would follow in this particular case).

Cost of enforcement, specific impacts, public consultation and date of policy implementation

Cost of enforcement for the 'competent authority'

16. The regulations with which this IA is concerned place requirements on, or give permission to, the Food Standards Agency (FSA) as the Competent Authority. The **total** cost of the

Agency in 2007 was £109,651,000[18] which represents the cost of administration, inspections, surveillance, managing research and development, education, publicity and publications.

Sustainability and other Specific Impacts

17. The Agency considers that Option 2 is the most sustainable as it provides an alternative screening method with more flexibility but with no impact on sustainability.

18. No comments were received during the public consultation on any of the impact areas.

Public consultation

19. This IA was subject to public consultation which was issued on 2 October 2007 and closed 4 January 2008. No further evidence was received with regard to costs or benefits resulting from the measure or the affect on sustainability or other identified areas of impact.

20. The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within three months of the closure of the consultation, and the summary for the Draft Food Hygiene (Amendment) v(England) Regulations (2008) can be seen at:
http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

21. Originally this issue was issued for consultation in an IA along with two measures which impacted on the official controls for red meat. The IA has been routinely updated where relevant between the end of the consultation and clearance as a final document.

Date policy will be implemented

22. Commission Regulation (EC) 1244/2007 applied 20 days after being published in the EU Official Journal (i.e. 20 days after 25 October 2007).

23. The impact of the measure is due to be looked at in November 2012. However, it is not controversial, and the decision to allow use of the screening method described is highly unlikely to be revoked.

[18] This figure is taken from the Food Standards Agency Consolidated Resource Accounts: http://www.food.gov.uk/multimedia/pdfs/publication/470465. It represents the cost of operations at the FSA Westminster office and does not include the costs of the Meat Hygiene Service or the Agency's offices in Scotland, Wales or Northern Ireland. The number can therefore be considered a reasonable approximation of the TOTAL cost of enforcement as it applies to this IA.

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	Yes	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

The measure is not considered to have any effect on competition as it impacts solely on control bodies and not upon business.

Small Firms Impact Test

The measure is not considered to be a burden on small firms as it impacts solely on control bodies.

Sustainable development

The measure is considered to be more sustainable in that it provides more flexibility and is potentially cheaper with no lowering of the protection of public health. There do not appear to be any negative impacts on sustainability.

Race equality issues

None.

Gender equality issues

None.

Disability equality issues

None.