

FOOD STANDARDS AGENCY CONSULTATION

Title: The Official Feed and Food Controls (England) (Amendment) Regulations 2011

CONSULTATION SUMMARY PAGE

Date consultation launched:	Closing date for responses:						
20 September 2010	10 December 2010						
Who will this consultation be of most interest to? Feed and Food Business operators of meat establishments under veterinary control Local Authorities in England							
What is the subject of this consultation THE DRAFT OFFICIAL FEED AND FOOREGULATIONS 2011	n? DD CONTROLS (ENGLAND) (AMENDMENT)						

What is the purpose of this consultation?

To seek comments on the draft Official Feed and Food Controls (England) (Amendment) Regulations 2011. This Statutory Instrument (SI) will update the Official Feed and Food Controls (England) Regulations 2009. The proposed amendment to the Regulations would remove the right of food business operators to continue to operate, pending the outcome of an appeal against decisions by the FSA/food authority to refuse, or withdraw, the approval of those establishments handling products of animal origin, for which approval is required under EU legislation.

Responses to this consultation should be sent to:								
Name Rufina Acheampong	Postal address:							
Division/Branch Enforcement and Local Authority Delivery Division FOOD STANDARDS AGENCY Tel: 0207 276 8321 Fax: 0207 276 8447	Floor 5B Aviation House, 125 Kingsaway London WC2B 6NH Email:rufina.acheampong@foodstandards.gsi.gov.uk							
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The Official Feed and Food Controls (England) (Amendment) Regulations 2011

DETAIL OF CONSULTATION

Introduction

- 1. The Food Standards Agency is seeking your views on the draft Official Feed and Food Controls (England) Regulations 2011. This Statutory Instrument (SI), which is enclosed at Annex B, will amend the Official Feed and Food Controls (England) Regulations 2009. The reason for introducing the new SI is to remove the right of food business operators to continue to operate, when the outcome of an appeal against the refusal or withdrawal of approval is pending.
- 2. The amendment will bring the national legislation in line with EU requirements relating to official controls carried out to ensure compliance with food law, and will reinforce public health protection.
- 3. Your views are also sought on the Impact Assessment (IA) for the SI, attached at Annex C.

Background

- 4. Regulation (EC) 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (Official Journal L139, 30.4.2004, p. 55) specifies hygiene rules for businesses that produce products of animal origin which must either be registered or, where appropriate, approved by the competent authority before they can sell food. The Food Standards Agency (FSA) is the competent authority under Regulation 853/2004 for the approval of slaughterhouses, cutting plants and game handling establishments. Food authorities are the competent authority under Regulation 853/2004 for the approval of those establishments in respect of which control does not fall to an official veterinarian.
- 5. Regulation (EC) 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules (Official Journal L191, 28.5.2004, p. 1) requires the competent authority (in England the FSA or the food authority) to visit an establishment on receipt of an application for approval. The FSA/food authority grants full approval if the establishment complies with the relevant requirements of food law in relation to infrastructure, equipment and operational requirements. A conditional approval is granted if the establishment meets all the infrastructure and equipment requirements. Conditional approval can be given for a maximum period of six months where it is evident from a further visit that clear progress has been made but the establishment does not meet all of the relevant requirements. After that sixmonth period, either full approval or a refusal must be given.
- 6. Regulation 12(1) of the Official Feed and Food Controls (England) Regulations 2009, which provides for the execution and enforcement of Regulation (EC) 882/2004 in England, says that if the food business operator's approval to operate is refused or withdrawn, the food business operator can appeal against that decision to a Magistrates' Court. Regulation 12 (5) allows the food business operator to continue to operate pending the determination of the appeal. Similar legislation applies in Scotland, Wales and Northern Ireland.

- 7. The right to continue to operate pending the outcome of the appeal was previously set out in domestic legislation, which transposed the former sectoral Hygiene Directives that prescribed the structural and hygiene requirements for premises which had to be licensed to produce red, white and wild game meat. When the new EU food hygiene legislation and the Food Hygiene (England) Regulations 2006 came into force on 1 January 2006, the right to continue operating pending the hearing of an appeal against refusal or withdrawal of an approval was retained and applied to all premises requiring approval.
- 8. Since the EU regulations that deal with hygiene of food from animal origin are aimed at protecting public health, the Agency considers it inappropriate for food business operators that are non-compliant with food law, to continue to operate until appeals are dealt with. Refusal, or withdrawal of approval, is a last resort that is only applied where, despite a lengthy process of enforcement actions by the official veterinarian or the enforcement officer of the food authority working with the food business operator, serious deficiencies remain.
- 9. If the food business operator continues to operate pending the outcome of appeal, FSA Operations, or the enforcement officer of the food authority, may have to take day to day enforcement action to address deficiencies in compliance during that period. This is unsatisfactory, especially since the current appeal process in England can be lengthy. Moreover, this is inconsistent with the EU legislation which does not specifically provide such a right for food business operators. If UK rules remain as they are, they will be out of step with EU law and the UK will face the risk of infraction proceedings for breach of EU Treaty obligations.

Proposals

10. The draft Statutory Instrument (SI) proposes to remove regulation 12(5) (and regulation 12(6) and 12(7) dependent provisions) and thereby remove the food business operator's right to continue to operate pending the determination of the appeal.

Key proposal:

 Remove the right of food business operators to continue to operate, when the outcome of an appeal against the refusal or withdrawal of approval is pending.

Consultation Process

- 11. Stakeholders were informed of the proposed change in policy at the Current and Future Meat Controls (CFMC) Working Group held on 25 June 2010. The minutes will be published on the Agency's website at foodindustry/industry/committees/cfmc/
- 12. Stakeholders (including representatives from meat industry) were informed about the proposed change in policy at the Chief Executive's Industry Stakeholder Forum on 16 June 2010.
- 13. The proposed change in policy was discussed at the July 2010 FSA open Board meeting and the discussion paper is available at the link below: http://www.food.gov.uk/multimedia/pdfs/board/fsa100704.pdf. The minutes will be published on the Agency's website (food.gov.uk/aboutus/ourboard/boardmeetings/) in due course.

14. The Food Standards Agency is consulting all food business operators of meat establishments under veterinary control who may be affected by this proposal, and all local authorities (since some local authorities may be involved in refusing, or withdrawing, the approval of establishments handling products of animal origin), are being consulted. No further consultations or meetings are proposed. A summary of responses to the consultation will be published on the Agency's website. Consultations on the proposed change will be run concurrently in England, Scotland, Wales and Northern Ireland.

Questions asked in this consultation:

- Q1: Do you agree that removal of the right of food business operators to continue to operate, when the outcome of an appeal against the refusal or withdrawal of approval is pending, is appropriate?
- Q2: Do you agree with the assumptions, costs and benefits outlined in draft Impact Assessment at Annex C? If you disagree with the estimated figures, please provide evidence.
- 15. We would particularly welcome the views of food business operators of meat establishments subject to veterinary control, their representative bodies, and food authorities as they may be affected by this proposal. We would welcome answers to the questions posed above together with any evidence that can be submitted in support of comments that are made in response to this consultation. Please submit comments by email (or by post if it is more convenient) please make contact by telephone on 020 7276 8321.

Other relevant documents

16. Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules. Official Journal L191, 28.5.2004, 1-52. The text of the EU Regulation may be downloaded from the European Commission's website at: http://eur-

<u>lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0882:20081110:EN:PDF</u>

17. Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin. Official Journal 139, 30.4.2004, 55-205. The text of the EU Regulation may be downloaded from the European Commission's website at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2004R0853:20100101:EN:P

Responses

<u>DF</u>

18. **Responses are required by close** <u>10 December 2010</u>. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

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

Yours,

Rufina Acheampong

Official Controls, Enforcement Strategy Team Enforcement and Local Authority Delivery Division

Tel: 0207 276 8321

Enclosed

Annex A: Standard Consultation Information

Annex B: Draft Official Feed and Food Controls (England) (Amendment) Regulations

2011

Annex C: Impact Assessment

Annex D: List of interested parties

Queries

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

Publication of personal data and confidentiality of responses

- 2. In accordance with the FSA principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The FSA will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.
- 3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.
- 4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

- 5. A list of interested parties to whom this letter is being sent appears in Annex B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.
- 6. Please let us know if you need paper copies of the consultation documents or of anything specified under 'Other relevant documents'.
- 7. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: http://www.berr.gov.uk/files/file47158.pdf The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult

Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 — Duration of consultation exercises

Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact

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

Criterion 4 — Accessibility of consultation exercises

Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation

Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 Responsiveness of consultation exercises

Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 Capacity to consult

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

- 8. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessment at Annex C.
- For details about the consultation process (<u>not</u> about the content of this consultation) please contact: <u>Food Standards Agency Consultation Co-ordinator</u>, Room 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

- 10. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc
- 11. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc The questionnaire can also be used to update us about your existing contact details.

STATUTORY INSTRUMENTS

2011 No.

AGRICULTURE, ENGLAND

FOOD, ENGLAND

The Official Feed and Food Controls (England) (Amendment) Regulations 2011

Made - - - - 2011

Laid before Parliament 2011

Coming into force - - 1st April 2011

The Secretary of State makes the following Regulations in exercise of the powers conferred on him by section 2(2) of the European Communities Act 1972(a).

The Secretary of State has been designated for the purposes of section 2(2) of the European Communities Act 1972 in relation to measures relating to food (including drink) including the primary production of food and measures relating to feed produced for or fed to food–producing animals(\mathbf{b}), the common agricultural policy of the European Community(\mathbf{c}) and measures in the veterinary and phytosanitary fields for the protection of public health(\mathbf{d}).

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(e) there has been open and transparent public consultation during the preparation and evaluation of the following Regulations.

Title and commencement

1. These Regulations may be cited as the Official Feed and Food Controls (England) (Amendment) Regulations 2011 and come into force on 1st April 2011.

⁽a) 1972 c.68.

⁽b) S.I. 2003/2901.

⁽c) S.I. 1972/1811.

⁽d) S.I. 1999/2027.

⁽e) OJ No. L31, 1.2.2002, p.1, as last amended by Regulation (EC) No. 596/2009 of the European Parliament and of the Council adapting a number of instruments subject to the procedure referred to in Article 251 of the Treaty to Council Decision 1999/468/EC with regard to the regulatory procedure with scrutiny: Adaptation to the regulatory procedure with scrutiny – Part Four (OJ No. L188, 18.7.2009, p.14).

Amendment of the Official Feed and Food Controls (England) Regulations 2009

- **2.**—(1) The Official Feed and Food Controls (England) Regulations 2009(**a**) are amended in accordance with the following paragraph.
 - (2) In regulation 12 (right of appeal), omit paragraphs (5) and (6).

Signed by authority of the Secretary of State for Health

Parliamentary Under-Secretary of State
Date Department of Health

⁽a) S.I. 2009/3255.

EXPLANATORY NOTE

(This note is not part of the Order)

1.

Title:

THE OFFICIAL FEED AND FOOD CONTROLS (ENGLAND) (AMENDMENT) REGULATIONS 2011

Lead department or agency:

Food Standards Agency (FSA)

Other departments or agencies:

N/A

Impact Assessment (IA)

IA No: FOOD0041

Date: 16/09/10

Stage: Consultation

Source of intervention: EU

Type of measure: Secondary legislation

Contact for enquiries: Rufina Acheampong

Summary: Intervention and Options

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

Consumers are usually unable to assess the safety of products of animal origin (POAO) they purchase by their appearance and there is heavy reliance on good hygiene controls by the producer. Government intervention is needed to ensure that POAO intended for human consumption is as safe as possible. Official controls, in establishments handling POAO, require the Food Standards Agency/ food authority to grant approval if the establishment complies with the relevant requirements of food law. An amendment to the current domestic Regulations (to remove the right of food business operators to continue to operate, pending the outcome of an appeal against the refusal or withdrawal of approval) is required to enhance consumer protection by ensuring that controls are efficient and effective.

What are the policy objectives and the intended effects?

The policy objectives are to:

- Increase public health protection by removing the right of food business operators that are not compliant with food law to continue to operate until the appeal is heard.
- Ensure that appropriate legal measures, in line with EU food law, are put in place.

What policy options have been considered? Please justify preferred option (further details in Evidence Base) Option 1. Do nothing. This would retain the status quo in England in terms of allowing food business operators, not compliant with food law, to continue to operate pending determination of the appeal against the refusal or withdrawal of approval.

Option 2. Amend the Official Feed and Food Controls (England) Regulations 2009, with equivalent legislation being made elsewhere in the UK, to remove the right of food business operators to continue operating pending the outcome of an appeal; this will help enhance consumer protection, deliver assurance regarding public health and bring UK legislation into alignment with EU food law.

Option 2 is preferred. This option will align UK legislation with EU food law and will ensure a higher level of consumer protection.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 04/2014
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Chief Executive's Sign-off_For consultation stage Impact Assessments:

I have read the Impact Assessment and Lam satisfied that, given the available evidence, it represents a reasonable view of the likely costs benefits and impact of the leading options.

Signed by the Chief Executive:

Date: 17/5/19

Summary: Analysis and Evidence

Description:

Price Base	PV Base	Time Period	Net Benefit (Present Value (PV)) (£)					
Year	Year	Years	Low: Optional	High: Optional	Best Estimate: : -19,000			

COSTS (£)	Total Tra (Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		N/A	N/A
High	N/A		N/A	N/A
Best Estimate	19,000		0	19,000

Description and scale of key monetised costs by 'main affected groups'

One off familiarisation cost to enforcement authorities in England of £3,050 split £1,221 familiarisation cost for Local Authorities and £1,829 familiarisation cost to Food Standards Agency.

One off familiarisation cost in England for affected businesses of £15,893

Total one off familiarisation cost of £18,943 in England. Over a 10 year period the total equivalent annual cost is approximately £2,278

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

Legal costs incurred by Competent Authority if appeal is upheld and business seeks redress

BENEFITS (£)	Total Tra (Constant Price)	nsition Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	N/A

Description and scale of key monetised benefits by 'main affected groups'

No benefits monetised, see non-monetised benefits below.

Other key non-monetised benefits by 'main affected groups'

Potential cost savings from not having to carry out official controls to establishments that will be refused approval.

Reduced risk to consumers through enhanced consumer protection

Improved reputation in the industry from a reduction in food-borne related incidents, which may help to facilitate trade.

Key assumptions/sensitivities/risks

Discount rate (%)

3.5%

We estimate that a one-off familiarisation of 10 minutes per organisation will be required with a total cost in the UK of £23,463.

Impact on admin burden (AB) (£m):

Impact on policy cost savings (£m):

In scope

New AB: AB savings: Net: Policy cost savings: Yes/No	New AB:	3 savings:	Net:	Policy cost savings:	Yes/No
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Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?	England	England						
From what date will the policy be implemented?	01/04/20	01/04/2011						
Which organisation(s) will enforce the policy?					FSA/ food authorities			
What is the annual change in enforcement cost (£)?					2,278			
Does enforcement comply with Hampton principles?	Yes	Yes						
Does implementation go beyond minimum EU requiren	No	No						
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)					Non-t N/A	raded:		
Does the proposal have an impact on competition?			No					
What proportion (%) of Total PV costs/benefits is direct primary legislation, if applicable?	Costs: N/A			Benefits: N/A				
Annual cost (£m) per organisation (excl. Transition) (Constant Price)					dium	Large		
Are any of these organisations exempt?	No	No		No				

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on?	Impact	Page ref within IA
Statutory equality duties ¹	No	
Statutory Equality Duties Impact Test guidance		
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	
Small firms Small Firms Impact Test guidance	No	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	Yes/No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development	No	
Sustainable Development Impact Test guidance		

¹ Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	
2	
3	
4	

⁺ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£) constant prices

	Y ₀	Y ₁	Y ₂	Y ₃	Y ₄	Y ₅	Y ₆	Y ₇	Y ₈	Y ₉
Transition costs(EAC) ²	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278
Annual recurring cost	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual costs	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278	2,278
Transition benefits										
Annual recurring benefits										
Total annual benefits										

^{*} For non-monetised benefits please see summary pages and main evidence base section

² Equivalent Annual Cost – the profile shows the combined total EAC for Enforcement and Industry in England: approximately £2,280



Evidence Base (for summary sheets)

Reason for intervention

Consumers and food manufacturers need to be confident that any food product of animal origin they buy is safe, but they cannot assess this fully from its appearance when it is offered for sale. Government intervention through effective hygiene controls in the production of food is necessary to address this information asymmetry.

Government intervention is necessary to remove the right of food business operators, not compliant with food law, to continue operating pending the resolution of an appeal against refusal or withdrawal of an establishment's approval, and bring national rules in line with EU food law.

Intended effect

The principal purpose of amending the Official Feed and Food Controls (England) Regulations 2009 is to increase consumer protection against risks associated with products of animal origin. This will be achieved by removing the right of food business operators, not compliant with food law, to continue operating pending the outcome of an appeal.

In addition, since Regulation (EC) 882/2004 on official controls performed to ensure compliance with feed and food law, does not specifically provide a right for food business operators to continue operating pending the outcome of an appeal, the new SI will bring domestic legislation into alignment with European legislation.

Background

The draft Statutory Instrument (SI) which is the subject of this Impact Assessment (IA) will amend the Official Feed and Food Controls (England) Regulations 2009 (SI 2009/3255), which provides for the execution and enforcement in England to those elements Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.

The draft SI will specifically remove regulation 12(5) (and regulation 12(6) and 12(7) dependent provisions) and thereby remove the food business operator right to continue to operate pending the determination of the appeal. An explanation of the provisions of the 2011 Regulations is outlined in the consultation letter. The draft SI is at <u>Appendix 1</u> of the consultation package.

The Regulations apply to England only. Scotland, Wales and Northern Ireland are making separate but parallel legislation.

Regulation (EC) 882/2004 on official controls

Regulation (EC) 882/2004 (Official Journal L191, 28.5.2004, 1-52) sets out requirements for the authorities in EU Member States that have responsibility for monitoring and verifying compliance with, and enforcement of, feed and food law (and animal health and animal welfare rules), i.e. the 'competent authorities' responsible for organising and undertaking 'official controls'.

A risk assessment for Regulation (EC) 882/2004 as a whole was included in the associated regulatory impact assessment.³ This concluded that the new arrangements would contribute towards a reduction in food-borne disease, a reduction in contamination incidents and to increased consumer protection, and to a reduction in the costs associated with these. It would

³ The RIA developed during negotiations of the EU Regulation is available at: www.food.gov.uk/multimedia/pdfs/offcriaapr04.pdf

also lead, in turn, to increased consumer confidence in food produced within the Community and in imported food. With regard to the provisions on imports of non-POAO, by filling a gap in the current EU harmonised legislation, it was considered that these would help to improve public health protection by ensuring better targeting of controls and more effective management of risks.

Regulation (EC) 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin (Official Journal L139, 30.4.2004, 55–205) specifies hygiene rules for businesses that produce products of animal origin who must either be registered or, where appropriate, approved by the competent authority before they can sell food. The Food Standards Agency (FSA) is the competent authority under Regulation 853/2004 for the approval of slaughterhouses, cutting plants and game handling establishments where official controls are carried out by official veterinarians. Food authorities are the competent authorities for the approval of those establishments where official controls do not fall to an official veterinarian.

Regulation (EC) 882/2204 requires the competent authorities (the FSA/ food authority) to visit an establishment on receipt of an application for approval. The FSA/ food authority grants full approval if the establishment complies with the relevant requirements of food law in relation to infrastructure, equipment and operational requirements. A conditional approval is granted if the establishment meets all the infrastructure and equipment requirements. Conditional approval can be given for a maximum period of six months, where it is evident from a further visit that clear progress has been made but the establishment does not meet all of the relevant requirements. After that six-month period, either full approval or a refusal must be given.

Regulation 12(1) of the Official Feed and Food Controls (England) Regulations 2009, which provides for the execution and enforcement of Regulation (EC) 882/2004 in England, says that if the food business operator approval to operate is refused or withdrawn, the food business operator can appeal against that decision to a Magistrates' Court. Regulation 12 (5) allows the food business operator to continue to operate pending the determination of the appeal. Similar rules apply in Scotland, Wales and Northern Ireland.

The right to continue to operate pending the outcome of the appeal was previously set out in domestic legislation, which transposed the former sectoral Hygiene Directives that prescribed the structural and hygiene requirements for premises which had to be licensed to produce red, white and wild game meat.

When the new EU food hygiene legislation and the Food Hygiene (England) Regulations 2006 came into force on 1 January 2006, the right to continue operating pending the hearing of an appeal against refusal or withdrawal of an approval was retained.

The right of the food business operator, who does not comply with food law, to continue operating pending the outcome of the appeal is inconsistent with EU legislation and is undesirable in terms of maximising public health protection.

As part of an exercise to assess all establishments that were licensed to operate on 31 December 2005 for approval, a total of 61 plants in Great Britain (the majority of them located in England) have been refused approval and have exercised their right of appeal since January 2006. Not all of these cases were heard in the Magistrates' Court, as in some cases the appeal was withdrawn or the establishment ceased operating. Generally, hearings have been delayed because it took a long time for dates to be allocated in the Magistrates' Courts.

As at 14 September 2010, the position is as follows: during 2009-2010 ten appeals were dealt with and none has been resolved quickly (<u>Table 1</u>). Case F has been ongoing since May 2009 and remains unresolved. Case C has been ongoing from November to August 2009, when the appeal was withdrawn. However, now that all the plants that were operating on 31 December

2005 have been assessed for approval the number of new plants that are likely to appeal against a decision not to grant approval is likely to be much lower than the number that appealed, for example, during 2009-2010.

In Northern Ireland, three establishments have been refused approval since 2006. All three appealed, two withdrew their appeal and have since received full approval. One premise still has their appeal pending since February 2010.

Table 1 The Appeals Duration Process 2009-2010

Appellant	Dates: Refusal- Resolution	Duration	Status
A	29.7.2009-3.2.2010	6 months	Appeal withdrawn- No New Approval given
В	25.9.2009- 12.2.2010	4 months	Appeal withdrawn- New Conditional Approval given
С	3.11.2009-7.6.2010	8 months	Appeal withdrawn- Approval Revoked
D	27.5.2009- 31.12.2009	7 months	Appeal withdrawn- No New Approval Given
Е	25.6.2009- 9.10.2009	3 ½ months	Approval reinstated
F	19.5.2009-present	11 months	Trial date and judicial review outstanding
G	8.2.2010-present	2 months	Trial date outstanding
Н	8.2.2010-6.4.2010	2 months	Appeal withdrawn- No New Approval Given
I	19.6.2009- 12.2.2010	7 ½ months	Appeal withdrawn- New Conditional Approval Given
J	4.12.2009- 10.2.2010	2 months	Appeal withdrawn- New Conditional Approval given

Options

Option 1: Do nothing – maintain current 'right to operate' rules.

Option 2: Introduce the Official Feed and Food Controls (England) (Amendment) Regulations 2011 to revoke regulation 12(5) to (7) and thereby remove the food business operator's right to continue to operate pending the determination of the appeal.

Sectors and groups affected

Competent authorities

The draft Regulation is concerned with the role of the enforcement (competent) authorities responsible for organising and undertaking official feed and food controls. Refusal, or withdrawal of approval, is a last resort that is only applied where, despite a lengthy process of enforcement actions by the official veterinarian (OV) or Environmental Health Officer working with the food business operator, serious deficiencies remain.

The current appeal process is lengthy, during which time the food business operator can continue to operate. During this time FSA Operations may have take day to day enforcement action to address deficiencies in compliance pending appeal. This is unsatisfactory, in particular, if the right to carry on operating is out of step with EU law.

Food businesses

The proposed Regulations would remove the right of food business operators, not compliant with food law, to continue operating pending the resolution of an appeal against refusal or withdrawal of an establishment's approval, in order to adequately address the associated public health risk.

Consumers

The measure proposed in the draft Regulations will contribute towards the overall expected benefits of the application of Regulation (EC) 882/2004, i.e. a reduction in food-borne disease, a reduction in contamination incidents and increased consumer protection.

Costs and benefits of options

Option 1: Do nothing - no incremental costs or benefits. This is the baseline with which other options are compared against.

Option 2: Removal of the food business operator right to continue to operate pending the determination of the appeal.

Costs to industry

Familiarisation Costs

There will be a reading and familiarisation cost to food business establishments for reading the proposed draft Regulations. It is estimated that it will take 10 minutes per business to read and familiarise themselves with the Official Feed and Food Controls (England) (Amendment) Regulations 2011 and disseminate this through the business. Based on current estimation there are 5,511 food businesses operating in England that would be directly affected by the proposed Regulations. Table 2 displays the number of businesses affected in the UK broken down by location.

Table 2- Number of businesses affected

Region	FSA Approved Premises	LA Approved Premises	Total number of premises
England	1,015	4,496	5,511
Wales	88	248	336
Scotland	158	482	640
NI	55	167	222
UK	1,316	5,393	6,709

Note: the number of LA approved premises in England may include some duplication with the number of FSA approved plants. Also the number of premises under LA control tends to fluctuate (from month to month), as new businesses are established and others close. This introduces some variability in the familiarisation cost estimates for industry.

To quantify the one off familiarisation cost to industry we first calculate the familiarisation cost per business. The familiarisation cost per business is calculated by multiplying the hourly wage rate of a business manager of £17.30⁴ by the ten minutes taken to understand the regulation, resulting in a familiarisation cost per business of £2.88. To quantify the overall one off familiarisation cost to industry we multiply the familiarisation cost per firm by the number of businesses affected by the regulation. This results in a one off familiarisation cost in England to businesses of £15,893. Table 3 displays the familiarisation cost to industry broken down by location.

Table 3 – Familiarisation cost to industry

Region	Familiarisation cost	
England	£15,893	
Wales	£969	
Scotland	£1,846	
NI	£640	
UK	£19,348	

Note: Figures may not sum due to rounding

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

⁴ Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of a 'Production manager' is used (£17.30 including 30% added to cover overheads)

Do stakeholders agree with the assumptions used to calculate the familiarisation costs?

Equivalent Annual Costs (EAC)

In order for 'one-off' transition costs to be compared on an equivalent basis across policies spanning different time periods, it is necessary to 'equivalently annualise' costs using a standard formula⁵. Under Standard HMT Green book guidance⁶ a discount rate of 3.5% is used.

Total one-off costs to industry in England have been estimated as £15,893. This yields an EAC for industry in England of approximately £1,911 over 10 years and for the UK as a whole approximately £2,326 over 10 years.

Costs to Enforcement Authorities

Local Authorities

There will be a familiarisation cost to local authorities (LAs) for all staff involved in delivering official controls in approved establishments. It is estimated that it will take 10 minutes to read and familiarise themselves with the Official Feed and Food Controls (England) Regulations 2011. The familiarisation cost per LA is calculated by multiplying the reading time, 10 minutes, by the wage rate applied to an Environmental Health Officer of £20.70⁷. To quantify the overall familiarisation cost to enforcement authorities we multiply the familiarisation cost per LA by the number of LAs in the UK. There are 434 LAs in the UK with responsibility for the enforcement of food hygiene legislation, who will need to familiarise themselves with this guidance. This includes 354 in England, 32 in Scotland, 22 in Wales and 26 in Northern Ireland, which gives a one off familiarisation cost to LA's in England of £1,221⁸. Table 4 displays the familiarisation cost and the number of LAs per country.

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The equivalent annual cost formula is as follows: EAC=PVC/A, where A =[1-1/(1+r)^t]/r, where PVC is the present value of costs, r is the social discount rate and t is the time period over which the policy is being appraised.

⁶ http://www.hm-treasury.gov.uk/data_greenbook_index.htm

Wage rate obtained from The Annual Survey of Household Earnings (2009) (http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313). Median hourly wage of an Environmental health officer is used £15.92plus 30% overheads).

^{8 £20.70 * 354 = £1,221}

<u>Table 4 – Number of Local Authorities and familiarisation cost per country</u>

Region	Number of LA's	Total familiarisation cost
England	354	£1,221
Wales	22	£76
Scotland	32	£110
NI	26	£90
UK	434	£1,497

Note: Totals may not sum due to rounding

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

Competent Authority (FSA)

We estimate that each OV will invest 10 minutes reading and familiarising themselves with the Regulations and disseminating to key staff in the organisation. Hourly wage rates of £40.50 and £40.36⁹ have been applied to an OV based in Great Britain and Northern Ireland respectively, and when multiplied by the reading time equates to a familiarisation cost per OV of £6.75 in GB and £6.73 in Northern Ireland. To quantify the familiarisation cost for the Agency in England we multiply the familiarisation cost per OV by the number of OV's in England, 271, which equates to a one-off familiarisation cost of £1,829 for the Agency in England. Table 5 displays the familiarisation cost for the Agency broken down by region.

Table 5 – Competent Authority familiarisation cost

Region	Number of OV's	Familiarisation cost
England	271	£1,829
Wales	35	£236
Scotland	52	£351
NI	30	£202
UK	388	£2,618

Note: Totals may not sum due to rounding

Costs are estimated by multiplying wage rates uplifted by 30% to account for overheads. This means that the wage rates reported in the text are approximate to 2 d.p. and when grossed may result in rounding error.

⁹ 2010/11 FSA operations hourly wage rate for OV members of staff in Northern Ireland

As for industry (see above), the one-off costs to Local Authorities must also be expressed as equivalent annual costs (EAC). Total one-off costs to enforcement authorities in England have been estimated as £3,050 (includes familiarisation costs of £1,221 for Local Authorities and £1,829 for the Agency). This yields an EAC to enforcement authorities in England of approximately £367 over 10 years and for the UK as a whole approximately £495 over 10 years.

Legal Costs

Amending the Official Feed and Food Controls (England) Regulations 2009 to remove the food business operator's right to continue operating pending an appeal means that a food business operator would face a loss of income as they would be required to cease operations immediately. If the appeal is upheld, then it is possible that businesses, through legal action, may seek redress, which would be both difficult to estimate and quantify.

Benefits

Benefits to Consumers

Option 2 would deliver public health benefits as it will minimise the potential health risk to consumers posed by food business operators with poor hygiene practices. The Health Protection Agency (HPA) estimates that 894,290 indigenous cases of food poisoning occurred in 2008 in England & Wales, which caused 425 deaths. The related economic cost of £1.475 billion is derived in an Agency Board Paper¹⁰. This cost figure can be scaled up to give a UK estimate of the cost of food-borne diseases, of £1.66 billion. Although the benefits of this option are unquantifiable any option which contributes towards a reduction in the cost of foodborne disease is likely to have a significant economic benefit.

Benefits to Enforcement

Enforcement authorities will make savings derived from not having to carry out official controls in establishments, pending the determination of the appeal, as they would no longer be allowed to operate under appeal. However, uncertainty concerning the number of plants likely to be refused approval in future means we are unable to accurately estimate and quantify the potential cost savings associated with the preferred policy option.

Benefits to Industry

Industry is likely to benefit from increased consumers' confidence in food safety.

http://www.food.gov.uk/multimedia/pdfs/publication/annualscientistrep0909.pdf

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review:

The FSA envisages to review this policy as part of an EU proposed review in 2013.

Review objective:

The overall objectives of the proposed EU review are to:

- ensure the effective implementation of relevant Community law; and
- ensure that the UK enforces feed and food law and monitors and verifies that relevant requirements are met, and, that systems of official controls and other appropriate surveillance and monitoring activities, covering all stages of production, processing and distribution of feed and food, are maintained.

As part of this review the UK will examine its system of official controls for monitoring and verifying compliance with feed and food law, to ensure that in delivering these controls, account has been taken of the UK Government's regulatory reform agenda and the Better Regulation Commission Principles of Good Regulation. We will aim to continue to ensure a proportionate risk-based approach that protects public health and consumer interests, without imposing unnecessary burdens on the authorities responsible for undertaking these controls or those that are subject to them.

Review approach and rationale:

Re-evaluate the estimated costs and benefits by undertaking:

1. discussions with industry, trade organisations and enforcement bodies to establish cost/savings and increased level of consumers' protection.

Baseline:

- 1. The current baseline is given in option 1 (i.e. do nothing existing legislation remains).
- 2. The baseline for a review will be the success of the measures outlined in option 2 (i.e. remove the food business operator's right to operate)

Success criteria:

- 1. Positive feedback from consumers and consumer organisations as regards increased public health protection can be used as an indication of policy success.
- 2. Positive feedback from the relevant enforcement authorities as regards cost and time savings will also be considered in assessing the success of the policy.
- 3. Elimination of the risk of infringement proceedings taken by the Commission against Member States for failure to comply with EU Treaty obligations.

Monitoring information arrangements:

- 1. Monitoring to be carried via the requirement for competent authorities to keep approvals of all approved premises under review.
- 2. Monitoring to be carried out via discussions and other feedback from consumers, trade organisations and enforcement bodies.

Reasons for not planning a PIR:

N/A

LIST OF INTERESTED PARTIES

Heads of Service at English Local

ADAS Drayton

Agricultural Industries Confederation

Agriculture and Horticulture

Development Board

Air Conditioning and Refrigeration

Industry

Airline Operators Committee for Cargo

Allied Bakeries Ltd

American Peanut Council Anglo Beef Processors Ltd Animal Medicines Inspectorate

Artisan Biscuits Ltd

Associated British Foods plc Association of Convenience Stores Association of Frozen Food Producers

& Ice Cream Federation

Association of Independent Meat

Suppliers

Association of Meat Inspectors (UK)

l td

Association of Port Health Authorities Association of Public Analysts of

Castland

Scotland

Association of Unpasteurised Milk

Producers and Consumers Assured British Meat

Assured Food Standards Barbour Index plc Barfoots of Botley Ltd

BAYER PLC

Bartlett Media Ltd

Bee Farmers' Association of the UK

Bernard Matthews Farms Ltd

Berry Ottawayand Associates Limited

Besana Group Besana UK Ltd

Biodynamic Agricultural Association Board of Deputies of British Jews

Boots the Chemist Bourne Salads Brakes Group

British Association of Feed

Supplement & Additive Manufacturers

∟td

British Beer and Pub Association

British Cattle Veterinary Association

British Chambers of Commerce

British Coffee Association

British Deer Farmers Association

British Domesticated Ostrich

Association

British Egg Industry Council

British Egg Information Service
British Equestrian Trade Association

British Food Importers and Distributors

Association

British Frozen Food Federation

British Goat Society

British Hospitality Association

British Independent Fruit Growers'™

Association

British International Freight

Association

British Leather Confederation

British Meat Processors Association

British Medical Association British Peanut Council Ltd

British Pharmacopoeia Secretariat

British Pig Association British Ports Association British Poultry Council British Retail Consortium

British Sandwich Association British Soft Drinks Association Ltd

British Specialist Nutrition Association British Starch Industry Association

British Sugar plc

British Veterinary Association British Wild Boar Association

Britvic plc Campden BRI

CEFIC Avenue E Van Nieuwenhuyse

4, bte 2

Chamber of Shipping

Chartered Institute of Environmental

Health

Chilled Food Association Ltd Coca-Cola Great Britain & Ireland

COCERAL

Cold Storage and Distribution

Federation

Compassion in World Farming
Confederation of British Industry

Consumer Council for Northern Ireland

Consumer Focus
Co-operative Group
Corporation of London

Council of National Beekeeping

Association in the

Country Land & Business Association

Countryside Alliance

Crop Protection Association Crown Chicken Limited

Dairy Council

Dairy Crest Group plc

Dairy UK Ltd

Del Monte Foods (UK) Ltd

Department for Business, Innovation

and Skills

Department for Environment, Food

and Rural Affairs
Department of Health

European Snacks Association /

SNACMA

Exotic Farm Produce Ltd

Farm Animal Welfare Council (FAWC)

Federation of City Farms &

Community Gardens

Federation of Small Businesses Federation of Wholesale Distributors

Feed Fat Association Food and Drink Federation Food and Environment Research

Agency

FOSFA International Freedom Food Limited Fresh Produce Consortium

Frozen and Chilled Potato Processors

Association

Game & Wildlife Conservation Trust Gerald McDonald & Company Limited Grain and Feed Trade Association

Greencore Group

Haemolytic Uraemic Syndrome Help

Halal Food Authority Health Food Manufacturers'

Association

Health Nutrition and Research UK

Limited

Health Protection Agency Holland & Barrett Retail Limited

Home Office

Horticultural Development Company Horticultural Trades Association Hospital Caterers Association Humane Slaughter Association & Council of Justice to Animals

Humane Slaughter Association and

Universities Federation

Institute of Arable Crops Research Institute of Brewing and Distilling Institute of Food Science &

Technology

International Meat Traders Association

Isotron Limited J Sainsbury plc

John Lewis Partnership John West Foods Ltd

Kashrus Committee of the Union of Orthodox Hebrew Congregations

Kellogg Europe Trading Limited

Kettle Foods Lamex Food Group

LEAF - Linking Environment And

Farming

Leatherhead Food International

LGC Limited Lidl UK GmbH

Livestock Auctioneers Association Local Government Association Local Government Regulation London Chamber of Commerce and

Industry

Longbenton Foods Ltd M & W Mack Limited McCain Foods (GB) Ltd McCormick (UK) Ltd

McDonald's Restaurants Ltd

Meat Trade Journal Meat Training Council Meridian Foods Ltd

MNGP

Musgrave Retail Partners GB National Association of Agricultural

Contractors

National Association of British and

Irish Millers

National Association of Catering

Butchers

National Association of Health Stores National Association of Poultry

Suppliers

National Beef Association National Consumer Federation National Council of Women of Great

Britain

National Dried Fruit Trade Association

National Edible Oil Distributors

Association

National Farmers' Union

National Federation of Fishermen's

Organisations

National Federation of Fishmongers

Ltd

National Federation of Meat and Food

Traders

National Federation of Women's

Institutes

National Market Traders Federation National Office of Animal Health Ltd

National Pig Association National Sheep Association

National Trust Nestle UK Limited

Neville Craddock Associates

Northern Foods plc

Nutricia Ltd

Organic Farmers & Growers Ltd

Organic Food Federation Organic Trust Limited Pauls Freight Services Ltd

People 1st

PepsiCo UK & Ireland

Pet Food Manufacturers Association

Port of Dover Port of Felixstowe

Potato Prossors Council Rare Breeds Survival Trust Road Haulage Association Ltd

Rothamsted Research

Royal Pharmaceutical Society of Great

Britain

Royal Society for the Prevention of

Cruelty to Animals

Royal Society for the Prevention of

Cruelty to Animals Ryvita Co Ltd

Safefood

Seasoning and Spice Association Seed Crushers & Oil Producers

Association

Shellfish Association of Great Britain

Sidani Consultancy

SITPRO

Small & Family Farm Alliance

Small Abattoir Federation

Smithfield Market Tenants Association

Society of Food Hygiene and

Technology

Society of Independent Brewers

Soil Association

Soil Association Certification Ltd Stilton Cheese Makers Association

Sustain: the alliance for better food

and farming Tate & Lyle plc

Tennant Farmers Association

Tesco Stores plc

Tetley Group

The Food Commission

The Muslim Council of Britain

The Vegan Society

Thorntons plc

Townswomen's Guild's

Trading Standards Institute

Traditional Farmfresh Turkey

Association

UK Major Ports Group Ltd

Unilever plc

Uniq plc

Unison

Vandermoortele (UK) Ltd

Vegetarian Economy and Green

Agriculture

Veterinary Laboratories Agency

Vitrition UK Ltd

Walker & Sons (Leicester) Ltd

WCF Ltd Which?

Whitby Seafoods Ltd

Wine and Spirit Trade Association Wm Morrison Supermarkets Plc Women's Food & Farming Union