

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

2011 No. 136

1. This explanatory memorandum has been prepared by the Food Standards Agency (FSA) and is laid before Parliament by Command of Her Majesty.
2. **Purpose of the instrument**
 - 2.1 This instrument amends the Official Feed and Food Controls (England) Regulations 2009 (S.I. 2009/3255), which provides for the execution and enforcement in England of Regulation (EC) 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules.
 - 2.2 This instrument will specifically remove the food business operator's right to continue to operate pending the determination of the appeal against decisions by the FSA, or local authorities where appropriate, to refuse or withdraw the approval of those establishments handling products of animal origins for which approval is required under EU legislation.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None
4. **Legislative Context**
 - 4.1 Regulation (EC) 853/2004 of the European Parliament and of the Council, laying down specific hygiene rules for food of animal origin¹, 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 FSA is the competent authority under Regulation (EC) 853/2004 for the approval of slaughterhouses, cutting plants and game handling establishments, where official controls are carried out by official veterinarians. Local authorities are the competent authorities for the approval of those establishments, such as processors of meat, fish, dairy and egg products where official controls are not the responsibility of an official veterinarian.
 - 4.2 Regulation (EC) 882/2004² of the European Parliament and of the Council, on official controls performed to ensure verification of compliance with feed and food law, requires the competent authorities (the FSA/ local authority) to visit an establishment on receipt of an application for approval. The FSA/ local authority grants full approval if the establishment infrastructure, equipment and

¹ Official Journal L 226, 25.6.2004, p.22

² Official Journal L 165 of 30.4.2004

operational requirements comply with the relevant food law. A conditional approval, up to six months, can be given if the establishment does not fully meet the requirements. After that six-month period, following a further assessment, either a full approval or a refusal must be given.

- 4.3 Regulation 12 of the Official Feed and Food Controls (England) Regulations 2009, which provides for the execution and enforcement of Regulation (EC) 882/2004 in England, allows a food business operator to appeal to a Magistrates' Court against a decision not to grant approval, and 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 was originally provided by domestic legislation and was retained when the new EU food hygiene legislation and the Food Hygiene (England) Regulations 2006 came into force on 1 January 2006.
- 4.4 This instrument removes the right of a food business operator who is not in compliance with food law to continue to operate pending the outcome of the appeal against the refusal or withdrawal of approval.

5. Territorial Extent and Application

- 5.1 This instrument applies in relation to England only. Separate but parallel legislation is being enacted for 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 FSA has come to the view that the right of the food business operator to continue with its activities, pending the outcome of the appeal, is undesirable in terms of public health protection and not consistent with EU food law.
- 7.2 The principal aim of EU food legislation is to ensure the safety of the food and to protect consumer health. In particular, the legislation makes no provision for any form of relief for food business operators, pending the determination of the appeal. Such inconsistency with EU legislation leaves the UK open to the risk of infraction proceedings by the European Commission.
- 7.3 Refusal or withdrawal of approval is a last resort enforcement action that would only be taken after all other options have been exhausted and serious deficiencies on the part of the food business operator remain. It is therefore undesirable in terms of maximising public health protection that food business operators, not in compliance with food legislation, can continue to operate until appeals are dealt with. Moreover, the appeal process can be lengthy and during this time, if the food business operator can continue to operate, continuous supervision and enforcement actions may be required to safeguard food safety.

This is not the most effective use of finite enforcement resources in the provision of public health, especially since it is the responsibility of the food business operator to ensure food safety.

- 7.4 The purpose of making this instrument is to remove the right of food business operators who are not compliant with food law to continue operating pending the resolution of an appeal against refusal or withdrawal of an establishment approval. The amendment would adequately address the associated public health risk, bring national legislation in line with EU law and remove the possibility of the Commission taking infraction proceedings against the UK.

- *Consolidation*

- 7.5 As this is the first amendment to the Official Feed and Food Controls (England) Regulations 2009 and changes are relatively minor, consolidation is not considered appropriate at this time.

8. Consultation outcome

- 8.1 The FSA held a twelve week consultation in September 2010 on the draft Regulations 2011. Approximately twelve hundred stakeholders, including food industry organisations, consumer representatives, enforcement authorities and other government departments were consulted on the draft Regulations for England and associated Impact Assessment. Separate consultations were undertaken in Scotland, Wales and Northern Ireland.
- 8.2 Fourteen responses were received in England, six in Scotland, two in Wales and one in Northern Ireland. A number of respondents supported the removal of the right to operate under appeal, although several meat industry representatives expressed concerns over the proposal, in particular with regard to possible financial losses caused by ceasing operations pending determination of the appeal.
- 8.3 A more detailed analysis of the consultation outcome is contained in the Impact Assessment.

9. Guidance

- 9.1 The Agency has developed guidance to assist UK food business operators whose premises require approval. The guidance, which can be found at <http://www.food.gov.uk/foodindustry/meat/guidehygienemeat>, will be updated to reflect the legislative changes.

10. Impact

- 10.1 Any impact on businesses from these regulatory proposals is likely to be for familiarisation costs for reading and familiarise themselves with the Regulations. The business sector that will be affected by the regulatory proposals will be food business operators, handling products of animal origin, whose establishments require approval. These proposals have no particular

impact on charities or voluntary bodies, rural areas nor on members of the ethnic communities of any particular racial group.

10.2 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The legislation applies to small businesses, but any additional burden imposed will fall only on non-compliant businesses.

12. Monitoring & review

12.1 The Agency envisages reviewing this policy as part of a proposed EU review regarding the implementation of EU law in 2013. The effectiveness of the Regulations will be also be monitored via feedback from stakeholders as part of the ongoing policy process.

13. Contact

13.1 Alan Curran at the Food Standards Agency, Tel: 020 7276 8361, Email: alan.curran@foodstandards.gsi.gov.uk can answer any queries regarding the instrument.

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: 6/01/11
	Stage: Final
	Source of intervention: EU
	Type of measure: Secondary legislation
Contact for enquiries: Donatella Howe	

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

Ministerial Sign-off For final 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 Minister: **Anne Milton** Date: **25th January 2011**

Summary: Analysis and Evidence

Policy Option 2

Description:

Price Base Year 2010	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£)		
			Low: Optional	High: Optional	Best Estimate: : -18,000

COSTS (£)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	1	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	18,000		N/A	18,000

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

One off familiarisation cost of £17,784 in England of which to £2,226 and £15,558 is attributable to enforcement authorities and businesses respectively. Over a 10 year period the total equivalent annual cost for familiarisation in England is approximately £2,138.

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 Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	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 £20,544.

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	AB savings:	Net:	Policy cost savings:	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?	England				
From what date will the policy be implemented?	01/04/2011				
Which organisation(s) will enforce the policy?	FSA/ food authorities				
What is the annual change in enforcement cost (£)?	N/A				
Does enforcement comply with Hampton principles?	Yes				
Does implementation go beyond minimum EU requirements?	No				
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)	Traded: N/A		Non-traded: N/A		
Does the proposal have an impact on competition?	No				
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?	Costs: N/A		Benefits: N/A		
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	Micro N/A	< 20 N/A	Small N/A	Medium N/A	Large N/A
Are any of these organisations exempt?	No	No	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 Statutory Equality Duties Impact Test guidance	No	16
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	16
Small firms Small Firms Impact Test guidance	No	16
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	16
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	16
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	Throughout
Human rights Human Rights Impact Test guidance	No	16
Justice system Justice Impact Test guidance	No	16
Rural proofing Rural Proofing Impact Test guidance	No	16
Sustainable development Sustainable Development Impact Test guidance	No	16

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	2,138	2,138	2,138	2,138	2,138	2,138	2,138	2,138	2,138	2,138
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	2,138	2,138	2,138	2,138	2,138	2,138	2,138	2,138	2,138	2,138
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total annual benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

* 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 £2,138

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 Statutory Instrument (SI) will bring domestic legislation into alignment with European legislation.

Background

The draft 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 of 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 will remove the food business operator's 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 Appendix 1 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. This concluded that the new arrangements would increase consumer protection by contributing to a reduction in: food-borne disease, contamination incidents and the costs associated with these. It would also lead, in turn, to increased consumer confidence in food produced within the EU and in imported food. With regard to the provisions on imports of non-Products of Animal Origin (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 a 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 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 (EC) 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 are not the responsibility of official veterinarians.

Regulation (EC) 882/2004 requires the competent authority (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 yet meet all of the relevant requirements. After that six-month period, either full approval or a refusal must be given.

The standard 6 month time limit which allows a food business operator to operate under conditional approval is set out in Article 31 of Regulation 882/2004. However the EU Food Hygiene legislation recognises the particular circumstances for certain businesses in the fishery products sector and, in the case of factory and freezer vessels, Article 3.2 of Regulation (EC) 854/2004 permits the maximum period for conditional approval to be extended, if necessary, up to a maximum of 12 months. In addition, Annex III of Regulation (EC) 854/2004 allows official controls in these establishments to be carried out by the competent authority of another Member State or permitted third country.

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, provides 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, in the Official Feed and Food (England) Regulations 2005 which came into force at the same time.

Since then, the Food Standards Agency has come to the view that 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, which makes no provision for any form of interim relief for a food business operator pending the determination of the appeal, 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 4 January 2011, the position is as follows: during 2009-2010 ten appeals were dealt with and none has been resolved quickly (Table 1a). Case 6 has been ongoing since May 2009 and remains unresolved. Case 3 has been ongoing from November 2009 to June 2010, when the appeal was withdrawn. Businesses that were eventually given approval did not have their approvals re-instated by the magistrates' court. They were granted approval (or conditional approval) subsequent to their withdrawal of the appeal and then making requisite improvements to ensure compliance with the law. Tables 1b and 1c help to put the extent of appeals into context; 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. The establishment that still had its appeal pending at the start of the consultation has had its appeal dismissed in November 2010.

Table 1a - The Appeals Duration Process 2009-2010

No. of Appellant	Dates: Refusal-Resolution	Duration	Status*
1	29.7.2009-3.2.2010	6 months	Appeal withdrawn-No New Approval given
2	25.9.2009-12.2.2010	4 months	Appeal withdrawn-New Conditional Approval given
3	3.11.2009-7.6.2010	8 months	Appeal withdrawn-Approval Revoked
4	27.5.2009-31.12.2009	7 months	Appeal withdrawn-No New Approval Given
5	25.6.2009-9.10.2009	3 ½ months	Approval reinstated
6	19.5.2009-present	11 months	Judicial review is scheduled for January 2011

7	8.2.2010-present	2 months	Lost their appeal in the Magistrates' Court at the hearing held on 22 – 23 September 2010
8	8.2.2010-6.4.2010	2 months	Appeal withdrawn-No New Approval Given
9	19.6.2009-12.2.2010	7 ½ months	Appeal withdrawn-New Conditional Approval Given
10	4.12.2009-10.2.2010	2 months	Appeal withdrawn-New Conditional Approval given

* Withdrawal of an appeal by an appellant FBO operates as an acceptance of the Agency's original refusal decision. Therefore the approval subsequently issued is a new approval.

Table 1b Extent of UK appeals against FSA's refusal of approval decision (1 January 2006 to 30 November 2010) – No. of FBOs Affected.

Appeals and Refusals Resolution	No. of FBOs affected
FBOs refused approval	67
FBOs that appealed to a court	49
FBOs that subsequently withdrew (abandoned) their appeal in order to gain new approval	38
FBOs maintaining their appeal in order to gain court decision	11
Cases determined in court in FSA's favour (i.e. the cases were dismissed)	8
Appeals upheld by courts	N/A
Appeals pending	3

Table 1c Extent of UK appeals against FSA's refusal of approval decision (1 January 2006 to 30 November 2010) – Percentage of FBOs Affected.

Appeals and Refusals Resolution	% of FBOs affected
Percentage of FBOs refused approval	5% ³
Percentage of FBOs refused approval that appealed to a court	73%
Percentage of FBOs that subsequently withdrew (abandoned) their appeal in order to gain new approval	78%
Percentage of FBOs maintaining their appeal in order to gain court decision	22%
Percentage of cases determined in court in FSA's favour (i.e. the cases were dismissed)	73% ⁴
Appeals upheld by courts	N/A
Appeals pending	27% ⁵

³ As a % of UK FSA approved establishments

⁴ As a % of FBOs maintaining appeal (8/11 = 0.727)

⁵ As a % of FBOs maintaining appeal (3/11 = 0.272)

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 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 to take day to day enforcement action to address deficiencies in compliance pending appeal. Moreover, this is questionable in terms of compatibility with EU law, since Regulation (EC) 882/2004 makes no provision for any form of interim relief for a food business operator pending the determination of the appeal.

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 for 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	226	314
Scotland	158	482	640
NI	116	172	288
UK	1,377	5,376	6,753

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 £16.94⁶ by the ten minutes taken to understand the regulation, resulting in a familiarisation cost per business of £2.82⁷. 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 in England, 5,511. This results in a one off familiarisation cost in England to businesses of £15,558. Table 3 displays the familiarisation cost to industry broken down by location.

Table 3 – Familiarisation cost to industry

Region	Familiarisation cost
England	£15,558
Wales	£886
Scotland	£1,807
NI	£813
UK	£19,065

⁶ Wage rate obtained from The Annual Survey of Household Earnings (2010) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a 'Managers In Farming, Horticulture, Forestry And Fishing' is used (£13.03 plus 30% overheads)

⁷ 10 minutes * £16.94 = £2.82

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.

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 formula. Under Standard HMT Green book guidance a discount rate of 3.5% is used.

Total one-off familiarisation costs to industry in England have been estimated to total £15,558. This yields an EAC for industry in England of approximately £1,871, over 10 years and for the UK as a whole of approximately £2,300 over 10 years.

Table 4 – EAC to industry

Region	EAC
England	£1,871
Wales	£107
Scotland	£217
NI	£98
UK	£2,292

Non-monetised Costs

Closure of food business establishments would also entail a cost relevant to the FBO. This cost is unquantifiable as it depends on the size and type of business, volume of and profit from production, and timing of appeal. However, such costs could be justified since non-compliant FBOs should not be operating.

Costs to Enforcement Authorities

Local Authorities

Familiarisation Costs

There will be a familiarisation cost for all Local Authorities (LAs) staff involved in delivering official controls in approved establishments. It is estimated that it will take an Environmental Health Officer (EHO) 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 £20.45⁸, which equates to a familiarisation cost per LA of £3.41⁹. To quantify the overall familiarisation cost to enforcement authorities we multiply the familiarisation cost per LA by the number of LAs in England. There are 354 LAs in England with responsibility for the enforcement of food hygiene legislation, who will need to familiarise themselves with this regulation. Multiplying the familiarisation cost per LA by the number of LAs in England yields a total one off familiarisation cost to LA's in England of £1,206¹⁰. Table 5 displays the familiarisation cost and the number of LAs per country.

⁸ Wage rate obtained from The Annual Survey of Household Earnings (2010) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a 'Environmental Health Officers' is used (£15.73 plus 30% overheads)

⁹ 10 minutes * £20.45 = £3.41

¹⁰ 354 * £3.41 = £1,206

Table 5 – Number of Local Authorities and familiarisation cost per country

Region	Number of LA's	Total familiarisation cost
England	354	£1,206
Wales	22	£75
Scotland	32	£109
NI	26	£89
UK	434	£1,479

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.

Equivalent Annual Costs (EAC)

As with one off costs to industry the one off cost for Local Authorities requires equivalently annualising in line with Green Book guidance. The total one-off costs to Local Authorities in England have been estimated as £1,206. This yields an EAC for industry in England of approximately £145, over 10 years and for the UK as a whole approximately £178 over 10 years.

Table 6 – EAC to Local Authorities

Region	EAC
England	£145
Wales	£9
Scotland	£13
NI	£11
UK	£178

Competent Authority (FSA)

Familiarisation Costs

We estimate that each Official Veterinarian will invest 10 minutes in reading and familiarising themselves with the Regulations and disseminating to key staff in the organisation. To quantify the familiarisation cost to the Agency we need to calculate the familiarisation cost per OV reading amendments to the Official Feed and Food Controls (England) Regulations 2011. An hourly wage rate of £22.57¹¹ has been applied to an OV, and when multiplied by the reading time equates to a familiarisation cost per OV of £3.76¹². To quantify familiarisation costs to 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 £1,019¹³. Table 7 displays familiarisation cost for the Agency broken down by region.

¹¹ Wage rate obtained from The Annual Survey of Household Earnings (2010) (<http://www.statistics.gov.uk/StatBase/Product.asp?vlnk=15313>). Median hourly wage of a 'Veterinarians' is used (£17.36 plus 30% overheads)

¹² 10 minutes * £22.57 = £3.76

¹³ 271 * £3.76 = £1,019

Table 7 – Competent Authority familiarisation cost

Region	Number of OV's	Familiarisation cost
England	271	£1,019
Wales	35	£132
Scotland	52	£196
NI	30	£113
UK	388	£1,459

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.

Equivalent Annual Costs (EAC)

One-off costs to the Agency must also be expressed as equivalent annual costs (EAC). Total one-off familiarisation costs to the Agency in England have been estimated as £1,019. This yields an EAC to the Agency in England of approximately £123 over 10 years.

Table 8 – EAC to the Agency

Region	EAC
England	£123
Wales	£16
Scotland	£24
NI	£14
UK	£175

Non-Monetised Costs

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 detailed in an Agency Board Paper. 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.

Consultation

Stakeholders were informed of the proposed change in policy at the Current and Future Meat Controls (CFMC) Working Group in June 2010. The minutes are available on the Agency's website at <http://www.food.gov.uk/multimedia/pdfs/committee/cfmcmins100625.pdf>

Stakeholders (including representatives from meat industry) were informed about the proposed change in policy at the Chief Executive's Industry Stakeholder Forum in June 2010.

The proposed change in policy was discussed at the July 2010 FSA open Board meeting. The discussion paper and the minutes are available at the links below:

<http://www.food.gov.uk/multimedia/pdfs/board/fsa100704.pdf>

<http://www.food.gov.uk/multimedia/pdfs/board/boardmins072010.pdf>

A full 12-week written public consultation on the draft SI, which is the subject of this impact assessment (IA) and a draft version of this IA was undertaken between 20 September and 10 December 2010. Respondents' views were taken into account in finalising the costs and benefits. The estimate for Official Veterinarian's salary has been revised by using median hourly wage of 'Veterinarians' (£17.36) plus 30% overheads. A few respondents commented that half of the cases that had been resolved in [Table 1](#) resulted in approval being given. This led them to the assumption that those businesses were essentially compliant and therefore the Agency should not have refused approval in the first place.

This assumption is incorrect and text has been included to provide an explanation of the outcome of appeals against FSA refusal of approval decisions. In particular, it should be noted that the withdrawal of an appeal by a food business operator confirms the correctness of the Agency's decision to refuse approval. As indicated in [Table 1](#), businesses that were subsequently given approval did not have their approval re-instated by the magistrates' court but following assessment by the Agency of a new request for approval, following completion of the necessary improvements.

The Federation of Small Businesses (FSB) believed that the draft IA did not acknowledge the potential losses to a business if it is closed whilst waiting for the outcome of an appeal and that the proposed change would affect small firms disproportionately. The overriding purpose of the aforementioned EU legislation is the protection of public health. Food business operators (whether small or large), who are not compliant with food law may pose a risk to public health. This is undesirable and not in line with EU legislation; therefore, whilst potential non-monetised costs have been noted, such costs should not undermine the primary public health aim of the legislation. If the appeal is upheld, the food business operator would have the option, through legal action, to seek redress.

A summary of the responses will be published on the Agency's website at <http://www.food.gov.uk/consultations/consulteng/2010/offcregs2011eng>

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 EU 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

Annex 2: Specific Impact Tests

STATUTORY EQUALITY DUTIES

The Agency believes that the amendment of the current regulation will have no impact on statutory equality issues.

ECONOMIC IMPACTS

The guidance of the Office of Fair Trading on competition assessments sets out four questions to establish the impact of a proposal on competition:

- **Would the proposal directly limit the number or range of suppliers?** It is envisaged that this would have minimal impact on the range and number of FBOs operating in the sector.
- **Would the proposal indirectly limit the number or range of suppliers?** This would occur primarily if the proposal raised the costs of a particular sub-group of firms in the food sector (e.g., small/large firms, new/existing firms, take-aways etc.). However, as identified in the cost-benefit analysis section, the cost imposed per business is thought to be minimal.
- **Would the proposal limit the ability of suppliers to compete?** The key consideration here is whether the proposal would impose constraints on businesses that are compliant with the Official Feed and Food Controls Regulations. This is not the case because compliant FBOs would be able to continue to operate as usual with no ongoing incremental regulatory burdens to incur.
- **Would the proposal reduce suppliers' incentive to compete vigorously?** It is thought that the proposal could add another dimension (food safety) to the competition process and reduce the costs to customers of switching between suppliers (because the risk to customers consuming products from non-compliant FBOs would be minimised).

In essence, this proposal would remove a distortion created by imperfect food safety information, thereby reinforcing the fairness and intensity of competition among food businesses.

SMALL FIRMS IMPACT TEST

The only business costs identified in the Cost Benefit Analysis would result from the need for business managers to familiarise themselves with the amended Regulations. Although this cost is a "one-off", it is too small (£2.82 per business) to have a significant effect on the performance of those businesses.

ENVIRONMENTAL IMPACTS

The FSA considers that amending current regulations will have no impact on environmental sustainability issues.

SOCIAL IMPACTS

The FSA considers that amending current regulations will have no impact on health and well being, human rights, the justice system or rural proofing issues.

SUSTAINABLE DEVELOPMENT

The FSA considers that amending current regulations will have minimal impact on sustainable development.

RACE EQUALITY ISSUES

There is no evidence to suggest at this time a differential impact of this policy on any ethnic groups.

GENDER EQUALITY ISSUES

There is no evidence at this time that indicates a significant differential impact of this policy on different genders.

DISABILITY EQUALITY ISSUES

There is no evidence to suggest any differential impacts of this policy for disabled people.