

**EXPLANATORY MEMORANDUM TO
THE OFFICIAL FEED AND FOOD CONTROLS (ENGLAND)
REGULATIONS 2007**

2007 No. 3185

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

2. Description

2.1 This instrument provides for the execution and enforcement of the feed and food elements of Regulation (EC) No. 882/2004 on official feed and food, animal health and animal welfare controls. It designates the competent authorities and enforcement authorities and creates relevant offences and penalties. In particular, it provides for the enforcement of rules on official controls of feed and food of non-animal origin imported from outside the Community. Additionally, it provides for the recovery of certain expenses incurred by the competent authorities from feed and food businesses. It revokes and replaces the Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15).

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

3.1 None.

4. Legislative Background

4.1 The instrument is being made to give effect to the feed and food elements of Regulation (EC) No 882/2004 on official controls. The next three paragraphs describe the provisions of this instrument which carry forward the provisions of the Official Feed and Food Controls (England) Regulations 2006.

4.2 Regulation 882/2004 sets out a framework of requirements for the authorities in Member States (the competent authorities) that are responsible for monitoring compliance with feed and food law by feed and food businesses (as well as for checking that animal health and animal welfare rules are adhered to), i.e. for official controls. This framework includes the principles that should be adopted e.g. a risk-based and 'farm to fork' approach, and specifies operational criteria with which the authorities must comply, e.g. they must be audited to assess the effectiveness of their performance. The Regulation also includes rules for official controls of feed and food of non-animal origin imported from outside the Community (third countries), and a framework for financing of official controls.

4.3 The provisions of the EC Regulation apply directly in the Member States. Most of these consolidate previous requirements such that official control arrangements in the UK for feed and food were already generally consistent with these. However, some updating and some new measures are necessary. In particular, national legislation is required to extend the Food Standards Agency's existing function (set out in the Food Standards Act 1999) to monitor and audit enforcement authorities. It is also needed to provide for the enforcement of the requirements for checks of third country imports of feed and food of non-animal origin.

- 4.4 The instrument will be made under the powers given in section 2(2) of the European Communities Act 1972. The enforcement powers and the offences and penalties in the instrument mirror those already provided in the Food Safety Act 1990 and the Food Standards Act 1999.
- 4.5 The instrument revokes and replaces the Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15) which, in turn, revoked and replaced the Official Feed and Food Controls (England) Regulations 2005 (SI 2005/2626). In so doing, it provides the necessary national provision in respect of recovery of expenses arising from:
- official controls which are undertaken following the detection of non-compliance with feed or food law and that exceed the authority's routine control activities, i.e. 'additional official controls' (these are required in order to check the extent of a problem, ensure that corrective action has been taken, or to substantiate the non-compliance); and
 - administrative actions in cases of non-compliance with feed or food law where assistance and co-operation with the other Member States and the Commission has been necessary.
- 4.6 The replacement instrument will also amend the definitions of Community legislation in Schedule 1. These amendments will reflect corrections made to EC Regulation 882/2004 and to the EC Regulations on food hygiene, and the adoption of new Commission Regulations on transitional and implementing measures made under the EC legislation. Other amendments are being made to reflect changes in domestic legislation that is referred to in the Official Feed and Food Controls (England) Regulations 2006. Additionally, the areas of responsibilities designated to the competent authorities in Schedules 4 and 5 are being updated.
- 4.7 The replacement instrument also updates the legal powers of the authorities responsible for controls of feed and food of non-animal origin from outside the Community to help ensure more effective application of the rules in this area.

5. Extent

- 5.1 This instrument applies in England. Parallel legislation is being developed in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

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

7. Policy Background

- 7.1 The objective of the EC Regulation is to create a more comprehensive and integrated, risk-based, 'farm to fork' approach to official controls. The underpinning aim is to improve the consistency and effectiveness of controls within Member States and across the EU and to provide safeguards to consumers. The EU Regulation also aims to provide a greater degree of transparency for consumers about enforcement arrangements. In addition, it aims to harmonise the funding of official controls in order to create a more level playing field for businesses. The national legislation will provide the enforcement powers required in relation to provisions in the EU

Regulation and will contribute to the anticipated benefits of a more consistent and effective control system.

- 7.2 Around 800 interested parties, including all local authorities in England (these authorities are responsible for enforcement of the main body of feed and food law), were consulted on the revisions to the Official Feed and Food Controls (England) Regulations 2006, the associated Regulatory Impact Assessment (RIA) and on Guidance Notes on the provision on charges for expenses for 'additional official controls' (these aim to ensure consistency of application). A total of 15 responses were received. The majority of comments related to the Guidance Notes.
- 7.3 In general, stakeholders accepted in principle that charges should be imposed for 'additional official controls' but concerns were expressed as to how these charges may be applied in a fair and consistent manner. There was also concern that there was no formal right of appeal. These concerns have been given careful consideration by the Agency and the Guidance Notes have been revised where appropriate. The Guidance also now highlights that the civil courts will provide the most appropriate forum for dealing with grievances in respect of these charges.
- 7.4 An analysis of the consultation responses is included in the RIA attached at Annex 1.

8. Impact

- 8.1 The RIA relates to the revisions made to SI 2006/15 only, and in particular to the new provisions on recovery of expenses incurred by the competent authorities. The costs to businesses for 'additional official controls' and for administrative expenses in cases where assistance and co-operation with the other Member States and the Commission is necessary will be off-set by savings to the competent authorities (and indirectly to the taxpayer). The provisions will apply only where there is non-compliance with feed or food law such that the charges may provide an incentive to businesses to comply with legal requirements. This may contribute to a reduction in food-borne disease and in contamination incidents and to increased consumer protection but such an effect is unlikely to be significant.

9. Contact

- 9.1 Catriona Stewart at the Food Standards Agency (Tel: 020 7276 8498 or email: catriona.stewart@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT - THE OFFICIAL FEED AND FOOD CONTROLS (ENGLAND) REGULATIONS 2007

Important note - The Statutory Instrument (SI) which is the subject of this Regulatory Impact Assessment (RIA) replaces the Official Feed and Food Controls (England) Regulations 2006 which in turn replaced the Official Feed and Food Controls (England) Regulations 2005. This RIA, therefore, focuses only on those measures that are being introduced for the first time in the 2007 Regulations. It should be read together with the RIA that was prepared for the 2005 Regulations as this, in effect, covers all the other provisions in the 2007 Regulations (a separate RIA was not prepared for the 2006 Regulations as only minor amendments to references to legislation were made). That RIA concluded that the measures provided do not introduce any new or significant costs for the competent authorities or for feed and food businesses. It is available on the website of the Food Standards Agency at <http://www.food.gov.uk/multimedia/pdfs/foodfeedsiria2005.pdf>.

1. **Title of proposal**

1.1 The proposal is for an SI with the title: the Official Feed and Food Controls (England) Regulations 2007.

2. **Purpose and intended effect**

Objectives

2.1 The SI revokes and replaces the Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15) which, in turn, revoked and replaced the Official Feed and Food Controls (England) Regulations 2005 (SI 2005/2626). These previous SIs gave effect, in England, to aspects of the feed and food elements of Regulation (EC) No 882/2004 on official controls¹ that applied from 1 January 2006. The principal purpose of replacing the current SI is to give effect to a provision in Regulation 882/2004 that applied from 1 January 2007. It will also give effect to a provision that applied from 1 January 2006 that was not covered by the preceding SIs. Some other minor amendments are also being made. The overall objective of the replacement SI remains the same, i.e. to contribute to delivering the anticipated benefits of a more effective and consistent enforcement system and, consequently, raise standards of food safety and consumer protection.

Devolution

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

Background

Regulation (EC) No 882/2004 on official controls

2.3 Regulation 882/2004 on official feed and food, animal health and animal welfare controls (which is the subject of a separate RIA²) was adopted in April 2004. Most of its provisions applied from 1 January 2006 and others from 1 January 2007. Detailed information on the feed and food elements of the Regulation is provided in the RIA for SI

¹ 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.

² The RIA for Regulation 882/2004 on official controls is available on the FSA website at: <http://www.food.gov.uk/multimedia/pdfs/offcriapr04.pdf>

2005/2626 and in Q&A Notes published by the Food Standards Agency (FSA).³ As regards this RIA, the detailed information set out in paras 2.4 to 2.8 is relevant.

Expenses arising from additional official controls

2.4 Regulation 882/2004 includes provisions on financing of official controls. These place a general obligation on Member States (MSs) to ensure that controls are properly funded but, in broad terms, it is left to the MS to decide how. In doing so, however, the MS must operate within a defined framework and must take account of certain principles in calculating fees where these are imposed. The framework requires mandatory fees for certain control activities. This includes a requirement for the competent authorities to charge feed/food businesses for the expenses arising from control activities which are undertaken following the detection of non-compliance (with feed or food law) and that exceed the competent authority's normal control activities - i.e. 'additional official controls' (this requirement is at Article 28 of the Regulation). Further information about this requirement is provided at Annex A of this RIA.

2.5 'Additional official controls' are those that exceed an authority's 'normal control activities' which are those required by Community and national legislation and, in particular, those described in the 'multi-annual national control plan' (NCP) for the MS. Regulation 882/2004 requires that such a plan be in place from 1 January 2007 and Commission Guidance⁴ suggests that it should cover a period of three to five years. It should detail the roles and responsibilities of the competent authorities involved in official controls and set out their planned control activities for the period of the plan. The NCP for the UK was published in December 2006 and the latest version of it is available on the FSA website at the link below.

<http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk>

2.6 As regards policy in applying this provision, the Commission indicated during the negotiations that liability to pay a charge under the provision was likely to arise only in serious or significant cases as these would not be foreseen in the NCP (e.g. major dioxin incidents). Given this, although all cases will need to be considered on a case-by-case basis, in practice, it is expected that the provision will apply only infrequently (a small number of cases annually). The Agency is developing, in parallel to the SI, guidance for applying the provision based on this policy approach.

2.7 Clearly, the NCP is key to applying this provision. Preparation of the first UK NCP was a major exercise and, although it was in place on time, it delayed the work on applying the Article 28 charging provision. The Agency also delayed initiating work on applying Article 28 in the expectation that the Commission would establish more detailed implementing rules with the aim of ensuring a harmonised approach across all MSs (the Commission is empowered to do this under Regulation 882/2004). In the event, the Commission has not yet started work on developing these rules.

Co-ordinated assistance and follow-up by the Commission

2.8 The Regulation includes provisions concerning arrangements for the competent authorities of the different MSs to work together and with the Commission where the results of official controls indicate repeated non-compliance with feed/food law and action is needed in more than one MS. From the discussions that took place during the negotiations on

³ Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules - Q&A Notes for enforcement authorities on the feed and food elements (Revision 1, January 2006) - available on the FSA website at: <http://www.food.gov.uk/multimedia/pdfs/offcqaquidancenotes.pdf>

⁴ Commission Decision 2007/363/EC setting out guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council. Official Journal L138, 30.5.2007, 24-49.

Regulation 882/2004, it is understood that this does not relate to those issues which must be reported using the Rapid Alert System for Feed and Food (RASFF)⁵ but rather only to intra-Community trade and where the issues that have arisen do not impose a serious risk to human or animal health or to consumer interests. It would include more minor issues such as mislabelling of food, and food composition issues. In such cases and where official controls indicate repeated non-compliance or other risks, MSs are required to charge feed/food businesses for expenses arising from: (a) the administrative actions required to inform the Commission and the competent authorities of the other MSs and (b) the costs incurred by the Commission if it sends an inspection team to investigate (the provision is not concerned with the costs of the controls themselves). Again, further detail is provided at Annex A of this RIA.

Application of EU Regulation 882/2004 in the UK

2.9 Regulation 882/2004 is directly applicable in the MSs (i.e. its provisions are in themselves the law in MSs) but some measures are required at national level to give effect to its provisions. For the most part, responsibility for applying the feed and food elements of Regulation 882/2004 in the UK lies with the FSA. The Department for Environment, Food and Rural Affairs (Defra) and the Agriculture/Rural Affairs Departments in the Devolved Administrations⁶ have responsibility between them for those feed and food elements that fall outside the FSA's remit (e.g. beef labelling, standards for organic products, protected food names; residues of pesticides and veterinary drugs, medicated feed etc.). Arrangements are in place for joint working across the Departments with a view to ensuring consistency of approach.

2.10 As regards FSA areas of responsibility, most of the provisions of Regulation 882/2004 which applied from 1 January 2006 are given effect by the Official Feed and Food Controls (England) Regulations 2006 (2006/15). This SI is now being updated and amended.

The Official Feed and Food Controls (England) Regulations 2007

2.11 An explanation of the provisions of the 2007 Regulations is given at Annex B.

2.12 The principal purpose of introducing this SI and replacing SI 2006/15 is to give effect to the provision at Article 28 of Regulation 882/2004 on expenses arising from additional official controls (see paras 2.4 to 2.7 above). This applied from 1 January 2007.

2.13 The SI will also introduce a new measure to allow the competent authorities to recover certain expenses where assistance and co-operation between the Member States and the Commission (see para 2.8 above) has been necessary. This measure applied from 1 January 2006 but was missed when the original 2005 SI was introduced.

2.14 In addition, some of the definitions required for interpretation of the SI are being amended to reflect recent changes to Community and other national legislation. Also, the schedules which set out the responsibilities of the designated competent authorities are being updated to include reference to those provisions in Regulation 882/2004 that applied from 1 January 2007. ***These particular amendments have no cost implications and are not, therefore, considered further in this RIA.***

2.15 Finally, some of the measures relating to controls of feed and food of non-animal origin from outside the EU are also being amended to: (a) help ensure more effective application and enforcement by the competent authorities and by officials of Her Majesty's Revenue and Customs; and (b) to reformulate the provision on liability for charges such that

⁵ More information on RASFF is available at: http://ec.europa.eu/food/food/rapidalert/index_en.htm

⁶ Scottish Executive Directorate General Environment, the Welsh Assembly Government Department for Rural Affairs, and the Department of Agriculture and Rural Development for Northern Ireland.

it is consistent with the new provisions on expenses (see Annex B of this RIA). ***These particular amendments to the imports provisions are cost neutral to enforcement and industry stakeholders and are not, therefore, considered further in this RIA.***

Rationale for Government intervention

2.16 A risk assessment for Regulation 882/2004 as a whole was included in the associated RIA (see footnote 2). 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 also lead, in turn, to increased consumer confidence in food produced within the Community and in imported food.

2.17 As regards expenses arising from additional official controls, the RIA for Regulation 882/2004 concluded that there will be some transfer of costs from the competent authorities to businesses as MSs will be required to charge in these cases. It was considered that incidents where charges would apply (serious or significant cases only) will occur only infrequently or uniquely and concluded that it was not possible to quantify what the costs may be.

2.18 The new measures included in the Official Feed and Food Controls (England) Regulations 2007 will also contribute to delivering the anticipated benefits of a more effective and consistent enforcement system. If there is no Government intervention, Regulation 882/2004 will not be applied fully in the UK. There would then be a risk of challenge from the European Commission following inspection by its Food and Veterinary Office of UK official control arrangements and their compliance with the requirements of Regulation 882/2004.

3 Consultation

Within Government

3.1 Consultation at official level has been ongoing throughout the drafting of the SI and RIA and, in particular, with Defra and the Agriculture/Rural Affairs Departments in the Devolved Administrations. These Departments are responsible for applying the relevant provisions in respect of feed and food law for which they are responsible (see para 2.9 above).

Public Consultation

3.2 A full 12 week public consultation on the draft SI, this RIA and on Guidance Notes on the provision in the SI on expenses arising from additional official controls was undertaken between 27 April and 20 July 2007. During this time, the Agency also engaged with stakeholders on a less formal basis. This included discussion with the Agency's Enforcement Liaison Group,⁷ as well as participation in relevant seminars and training courses etc.

3.3 In addition, the FSA worked with the Enterprise Directorate of the Department for Business, Enterprise and Regulatory Reform (BERR)⁸ to bring the consultation to the attention of small businesses and to specifically seek their views on the charging provisions. A letter was sent on the FSA's behalf by the Enterprise Directorate to feed and food business registered on its 'Small Firms Database'.

⁷ The Enforcement Liaison Group is a stakeholder group which was established to strengthen and develop links between the FSA and local authority food law enforcement services. As well as representatives from enforcement authorities, membership comprises representatives from consumer, professional and industry bodies. The Group provides a forum for discussion of strategic food law enforcement issues.

⁸ Formally the Small Business Service - it was renamed following the formation of the Department for Business, Enterprise and Regulatory Reform.

3.4 The FSA also wrote to all interested parties included in the original public consultation on 30 August 2007 to bring some additional proposed technical amendments to the draft SI to their attention and to provide them with the opportunity to comment.⁹

3.5 A summary of the responses on the specific issues on which views were sought, together with details of other significant points raised by stakeholders, is given at Annex D (a summary will also be published on the Agency's website in due course). In essence, the majority of comments made related to the proposals on applying the provision on expenses arising from additional official controls (as outlined in the Guidance Notes). In general, stakeholders accepted in principle that charges should be imposed but there were a number of concerns as regards how the provision may be applied in a fair and consistent manner by the competent authorities, and that there was no formal right of appeal in the domestic legislation. There were no objections to any of the other proposed measures: (a) recovering certain administrative costs associated with assistance and co-operation between Member States and the Commission; (b) updating the legal powers of the authorities responsible for controls of feed and food of non-animal origin from outside the EU; and, (c) the changes to the definitions in the SI to reflect changes to Community and national legislation.

3.6. All responses received as part of the consultation exercise and interested parties letter were given careful consideration. This RIA, the SI, and the Guidance Notes have been revised, where appropriate, in the light of stakeholders' views.

4 Options

4.1 A legal basis in domestic legislation is required to give effect in England to the particular elements of Regulation 882/2004 that this RIA covers. The policy options are, therefore, limited to the following:

- **Option 1** - Do nothing. This would mean that it would not be possible to apply these particular elements of Regulation 882/2004 in England as the competent authorities would not have the necessary legal powers.
- **Option 2** - Adopt the SI to ensure that the competent authorities for England may fulfil their obligations under Regulation 882/2004 and that provision is made for them to charge for: expenses arising from additional official controls; and, expenses associated with cases where co-ordinated assistance with the other MSs and follow-up by the Commission has been necessary. As regards expenses arising from additional official controls, application of this must be linked to the UK's NCP which aims to describe the 'normal control activities' of the relevant authorities. Guidance on what constitutes these 'additional control activities' and on when Article 28 charges may apply has been developed by the FSA.

5. Costs and Benefits

Sectors and groups affected

Competent authorities

5.1 The provisions that this RIA covers relate to charging by the competent authorities. These are the authorities that are responsible for organising and undertaking official feed and food controls. In the UK, this responsibility is held centrally but, in practice, day to day responsibility for official control functions is divided between central and local Government.

⁹ These amendments: (a) provide a legal basis for HMRC officers to exchange information with the enforcement authorities; and (b) update the definitions of certain Community legislation to reflect corrigenda that were issued by the European Commission during the consultation period. A copy of the letter is available at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/infoupdate/offcupdate11>

This is illustrated in the figures at Annex C of this RIA. The scope of the SI which is the subject of this RIA is restricted to those areas of feed and food law for which the FSA is responsible at central Government level and to England only. The relevant competent authorities are: the FSA (including the Meat Hygiene Service, and other Government Agencies that undertake official control functions on behalf of the FSA), and feed and food law enforcement services of local and port health authorities.

Feed and food businesses

5.2 The charges will be levied against feed and food businesses. There are approximately 91,000 feed business establishments in the UK (breakdown figures for each country of the UK are not available). This includes producers of feed materials, manufacturers of additives and premixtures, manufacturers of compound feedingstuffs, importers, distributors, retailers and farms. With regard to food, there are approximately 477,000 establishments in England which include slaughterhouses, cutting plants, manufacturers, processors, packers, importers, distributors and wholesalers, retailers, and restaurants and caterers. There are also approximately 119,000 holdings making up the primary food production sector in England.

Consumers

5.3 The proposed measures will contribute towards the overall expected benefits of application of Regulation 882/2004, i.e. a reduction in food-borne disease, a reduction in contamination incidents, and to increased consumer protection. In addition, relevant costs that, indirectly, currently fall to the taxpayer will fall in future to the feed and food industry.

Social and environmental impacts

5.4 The Agency believes that the SI will have no impact on racial equality or on social or environmental sustainability issues.

Administrative burdens

5.5 This SI does not include any new information obligations on businesses and the Agency considers that there are no new administrative costs arising from it which are over and above those that a business would incur commercially.

Analysis of costs and benefits

Benefits

Option 1

5.6 This option will maintain the *status quo* and so will not generate any incremental benefit.

Option 2

Expenses arising from 'additional official control activities'

5.7 Costs arising from additional controls currently fall to the tax payer but will, in future, fall to businesses. There will, therefore, be an indirect saving to taxpayers (this is estimated at £10.1 million - an explanation is provided at paragraphs 5.10 - 5.17 below). This follows the 'polluter pays' principle thereby creating an additional incentive for complying with legal requirements. Although it is not possible to quantify the effect, and albeit that this is not likely to be significant, this in turn may contribute towards a reduction in contamination incidents and food-borne disease and the costs associated in dealing with these.

Co-ordinated assistance and follow-up by the Commission

5.8 This relates to administrative costs of informing the other MSs and of travel and subsistence costs associated with the Commission sending an inspection team to investigate cases where repeated non-compliance has been found. Businesses will only be subject to charges where they have not complied with feed/food law such that this too follows the 'polluter pays' principle.

Costs

Option 1

5.9 As there would be no change to current arrangements for financing of official controls, there would be no compliance costs for the competent authorities or for businesses. However, to do nothing would leave the UK in breach of an EU obligation to apply Regulation 882/2004. There is also a risk of challenge from the European Commission following inspection by its Food and Veterinary Office of UK enforcement arrangements and their compliance with the requirements of Regulation 882/2004. In view of this, the FSA considers that Option 1 is not viable.

Option 2

Costs for the competent authorities

5.10 In relation to both expenses arising from additional official control activities and co-ordinated assistance and follow-up by the Commission, there may be new administrative costs for the competent authorities in terms of collection of monies, including: (a) invoicing and general administrative costs; and (b) costs for pursuing unpaid monies through the courts. As regards (a), such costs should not be significant as competent authorities will already have procedures in place and the number of cases per year is expected to be small. Similarly, in relation to (b), overall costs are not anticipated to be significant given the number of cases per year is expected to be small.

Costs for other Government bodies

5.11 In cases where charges are made for additional official controls, it is possible that some additional public expenditure may arise as a consequence of an increase in business requests for referee chemical analysis or microbiological examination of samples. Such referee analysis or examination is undertaken in cases where there is a dispute between a business and the enforcement authorities as regards laboratory findings. The Government Chemist¹⁰ acts as the referee laboratory and the cost of the service, with the exception of a nominal administration fee, is borne by the Department for Innovation, Universities and Skills (DIUS).¹¹ In the case of samples submitted to the referee laboratory, typical costs range from £5,000 for a simple case to £30,000 for a complex investigation. It is, however, not possible to estimate of the number of additional referee samples that may be submitted annually or the complexity of any associated investigations (see para 5.13 below). However, given the small number of anticipated incidents to which expenses arising from additional official controls will apply, it is not likely that any costs associated with additional referee sample analysis or examination will be significant.

Costs for businesses - expenses arising from additional official controls

5.12 Where there is compliance with feed/food law, the proposed measures have no implications.

¹⁰ More information on the Government Chemist is available at: <http://www.lgc.co.uk/>

¹¹ More information on DIUS is available at: <http://www.dius.gov.uk/>

5.13 In terms of total potential costs where non-compliance is detected and 'additional controls' are necessary, annual costs may be estimated on the basis of the typical amount that businesses would be charged per incident and the expected annual number of incidents to occur. However, as highlighted previously, this is extremely difficult to do as it is not possible to predict the number, nature or extent of serious or significant incidents that may occur and where charges will be appropriate. It is also important to recognise that the cost of an incident may vary widely from case to case depending on the type of additional control activities undertaken and the volume of such controls that are required. The variations include costs for:

- Enforcement or inspection visits: costs vary depending on the degree and nature of activity that the enforcement officer must undertake.
- Sampling activities - the average cost lies between £25 and £100 per sample depending on the type of product being sampled.¹²
- Chemical analysis or microbiological examination – costs range between £50 and £400 per sample.¹³ Exceptionally the costs of particularly complex analysis, as in the case of dioxin, may start at £700 per sample.¹⁴

5.14 Notwithstanding these points, an indication of annual costs to all competent authorities in England has been estimated as described below.

5.15 With regard to labour costs (officer time) associated with feed/food incidents, it can be estimated that in the order of 20 officer days per year may be allocated to dealing with incidents by each of the 388 local authorities in England.¹⁵ This suggests a total annual cost of £1.4 million to local authorities handling incidents in England.

5.16 In 2006, the total number of incidents reported to the Agency by local authorities (under the provisions of the *Food Law Code of Practice*) was 1352, of which 10 were classified as 'high' in accordance with the Agency's Incident Response Protocol,¹⁶ giving an average labour cost of around £1,000 per incident. Taking into account that a serious or significant incident may require a much greater allocation of officer time it may be concluded that such incidents represent a labour cost of £10,000.

5.17 In addition to labour costs, however, there will be costs for sampling and analysis, and depending on the nature of the incident, these may represent a significant proportion of the total charges made. It may be suggested that in dealing with a serious or significant incident, the competent authority may need to take an additional 2,000 samples at a cost of £100 each and have these analysed at a typical cost of £400 per sample. Based on the frequency of 10 serious incidents occurring annually (this was the number that occurred in 2006), this would represent an upper bound estimate of the annual cost in England of £10.1 million.

5.18 The incidents that were classified as 'high' are described in the FSA Annual Report of Incidents 2006¹⁷ and duplicated at Annex E of this RIA. It should be noted that the application of expenses arising from additional official controls was not considered in these cases as Article 28 has only applied since 1 January 2007. These incidents are provided only as examples of the type of incident where charges for additional official controls **may** be applied and in identifying them no judgement has been made as to whether such charges

¹² Source: Data provided to the FSA in relation to its imported food sampling programme.

¹³ Source: Data provided to the FSA in relation to its imported food sampling programme.

¹⁴ Source: Data provided to the FSA by the Government Chemist in its consultation response.

¹⁵ Source: Estimate of resource allocated in a cross-section of local authority service plans.

¹⁶ Classification 'high' describes severe incidents that are complex and widespread. More information on the Incident Response Protocol is at: <http://www.food.gov.uk/consultations/ukwideconsults/2006/prevrespfood>.

¹⁷ Report is available at: <http://www.food.gov.uk/multimedia/pdfs/incidentsar.pdf>

would have been appropriate. They are being used for indicative purposes only in the absence of real situations where Article 28 has been used. The post-implementation review of the measures will be important in re-considering the costs to businesses.

Costs for businesses - expenses associated with co-coordinated assistance with the other MSs and follow-up by the Commission

5.19 The costs incurred here are likely to be insignificant. As regards informing the other MSs and the Commission of a problem where there is repeated non-compliance, this would be achieved via a single email. As regards follow-up by the Commission, costs relate to travel and subsistence expenses associated with a visit to a MS to investigate issues where repeated non-compliance is found. Such visits are expected to take place only very infrequently.

5.20 Annual total costs for this are estimated at approximately £10,000. This is based on the assumption that there would be two visits of four days duration, and with a Team of three inspectors. Costs are based on travel and subsistence costs for officials of the Commission's Inspection Services (the Food and Veterinary Office).¹⁸

6. Small Firms' Impact Test

6.1 The provisions on charging will apply to all feed/food businesses including small businesses. As with all feed and food business, the charging provisions are expected to affect only a few small businesses annually. Where charges are being levied for expenses arising from additional official controls, Regulation 882/2004 requires that consideration be given, amongst other things, to the interests of feed/food businesses with a low throughput. It does not, however, specify the degree to which a reduction in charges should be made. As the potential effect of charging will vary widely from sector to sector, depending on the nature of the incident, the control activities that are needed, and on local factors etc. case by case consideration is the most appropriate option.

6.2 The BERR's Enterprise Directorate was involved in the development of the RIA for Regulation 882/2004 where the impact of the transfer of costs was first considered. It has also been involved in the development of this RIA.

6.3 As regards consulting with small businesses, the Association of Convenience Stores was invited to comment on the relevant issue in advance of consultation. The consultation itself was targeted at trade associations representing small businesses and the Agency provided details of the consultation to individual small businesses through the 'Small Firms Database' administered by the BERR's Enterprise Directorate.

7. Competition Assessment

7.1 On the basis of a Competition Filter Test, the provisions in the SI that affect businesses are unlikely to have a negative impact on competition. These provisions apply to all new and existing feed/food businesses but are expected to affect only a very small number of businesses annually. In view of this, any effect on competition will be negligible.

8. Enforcement, sanctions and monitoring

8.1 The new provisions in the SI relate to charges made to businesses by the competent authorities for official controls and related activities. These represent fees for official control activities (specifically for 'additional official controls') and recovery of costs for certain administrative expenses. They do not represent penalties and there are no criminal law

¹⁸ Staff Regulations of Officials of the European Communities (Annex VII: Remuneration and reimbursement of expenses (European Community website at: http://ec.europa.eu/civil_service/docs/toc100_en.pdf).

sanctions for non-payment. Bad debts will be pursued via normal channels and businesses that fail to pay will be sued via the courts.

8.2 The effectiveness of the new provisions in the SI will be monitored via feedback from stakeholders as part of the ongoing policy process. The arrangements for engaging with stakeholders are described in para 9.3 below.

8.3 It is also a requirement under Regulation 882/2004 for each MS to report annually to the Commission on its NCP. These reports will also provide a more formal means of monitoring the effectiveness of the proposed measures.

9. Implementation and delivery plan

Implementation of the SI

9.1 The SI will be laid before Parliament by 16 November 2007 with a coming into force date of 14 December 2007.

Delivery plan

Guidance for businesses and for enforcers

9.2 Guidance Notes on applying the provision in the SI on expenses arising from additional official controls have been developed by the Agency and stakeholders were consulted on these at the same time as on the SI and the partial RIA. The responses received have been taken into consideration in finalising the Guidance Notes and these will be published on the FSA website.

Engagement with stakeholders

9.3 The Agency has developed a strategy for engaging with stakeholders regarding Regulation 882/2004 and its application in England (and elsewhere in the UK). This includes on-going FSA website updates on all aspects of application of the Regulation and a website log of frequently asked questions. In addition, the Agency's Enforcement Liaison Group and its Animal Feed Law Enforcement Liaison Group¹⁹ is regularly updated and provided with information. The Agency will also participate in key external events and conferences etc.

10. Post implementation review

10.1 The SI and associated Guidance Notes on the provision on expenses arising from additional official controls will be kept under review and any feedback received from stakeholders will be considered. The Guidance Notes will be also kept under review and revised in the light of the experience of the competent authorities in applying Article 28 charges and the establishment of relevant case law.

10.2 Regulation 882/2004 empowers the Commission to develop detailed implementing rules regarding the provision on charges for expenses arising from additional official controls with a view to ensuring uniform application. Such rules are unlikely to impact on the legal measure included in the SI for England but they may impact on the Guidance Notes. The SI and Guidance will, therefore, be reviewed if and when the Commission introduces such implementing rules and revised if appropriate.

¹⁹ This Group provides a forum to discuss animal feed law and related matters and identify common problems and agree a co-ordinated approach to feed law enforcement. Membership of the Group comprises representatives from all of the competent authorities with responsibility for feed law enforcement in the UK, as well as LACORS.

10.3 In addition, the European Commission is required under the provisions of Regulation 882/2004 to undertake a review of its application. The focus of the review will be the provisions on financing of official controls. The review should have been undertaken in 2007 but was delayed as the new framework on financing had only just come into operation. The Commission is now expected to initiate a review of the impact of the framework in 2008. The UK will feed into this and will review the SI and any other application measures as part of that.

10.4 The annual reports on implementation of the UK National Control Plan - see above - will also provide the basis to review the effectiveness of the application measures put in place in England (and throughout the UK).

11. Summary and Recommendation

11.1 The proposed SI will ensure that the provisions on charges for expenses arising from additional official controls and expenses associated with cases where co-ordinated assistance with the other MSs and follow-up by the Commission has been necessary are applied in England. The cost to feed/food businesses will be off-set by savings for the competent authorities (and indirectly to the taxpayer). The provisions will apply only where there is non-compliance with feed/food law. The charges may, therefore, provide an incentive to businesses to comply with legal requirements. This may contribute to a reduction in food-borne disease and in contamination incidents and to increased consumer protection but such an effect is unlikely to be significant.

Summary costs and benefits table

<i>Option</i>	<i>Total cost per year</i>	<i>Total benefit per year</i>
1. Do nothing	None. This option will leave the UK in breach of an EU obligation to apply Regulation 882/2004 and open to challenge from the European Commission.	None.
2. Adopt the SI to ensure that competent authorities in England may fulfil their obligations under Regulation 882/2004	Feed/food businesses not in compliance with feed/food law, an upper bound estimate of the annual cost in England of £10.1 million. Total annual expenses of £10,000 associated with co-ordinated assistance with other MSs and follow-up by the Commission. Additional public expenditure that may arise as a consequence of an increased recourse to the use of referee samples. It is not possible to quantify these costs.	Reduced cost to taxpayers of an estimated £10.1 million The additional incentive for businesses to comply with feed and food law may contribute to a reduction in contamination incidents and food-borne disease and the costs associated with these.

11.2 In view of the above, it is recommended that option 2 to introduce the SI into English law is adopted.

12. **Declaration**

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs.

Signed...Dawn...Primarolo...

Date...06/11/2007.....

Contact point

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List of Annexes

- Annex A: Recovery of expenses
- Annex B: The Official Feed and Food Controls (England) Regulations 2007 – summary of provisions
- Annex C: Division of responsibility for feed and food controls in the UK
- Annex D: Summary of consultation responses
- Annex E: FSA Annual Report of Incidents 2006

ANNEX A

RECOVERY OF EXPENSES

Expenses arising from additional official controls

Legal requirement

1. Rules on the financing of official controls are set out in Regulation 882/2004 at Articles 26 to 29. These place a general obligation on MSs to ensure that official controls are properly financed but, in broad terms, it is left to the MS to decide how. In doing so, however, the MS must operate within a defined framework and should take account of certain principles in calculating fees or charges where these are imposed. The framework requires mandatory fees for official controls in certain sectors and this includes a requirement to charge for the expenses arising from control activities which are undertaken following the detection of non-compliance and that exceed the competent authority's normal control activities - i.e. 'additional official controls'. This requirement is at Article 28.

2. Article 28 must be read with Article 29 which requires that in setting the level of expenses, account is taken of the principles laid down in Article 27. Those that are relevant are set out at Article 27(4)(a) and 27(5). In practice, this means that the level of expenses charged for 'additional official controls' should not exceed the actual costs of the competent authority for the controls undertaken. In addition, MSs should consider the interests of businesses with a low throughput, and the needs of businesses located in regions subject to particular geographical constraints.

Relevant definitions

3. In interpreting the legal requirement, the following definitions are relevant:

- **'Official controls'** are defined for the purposes of Regulation 882/2004 at Article 2(1). In effect, these are any form of check carried out by the competent authorities in the Member States to verify whether or not feed/food business operators are complying with the requirements set out in 'feed law'/'food law' (and animal health and welfare rules). Such checks include, for example, inspections, audits, monitoring, surveillance, sampling and analysis etc. Enforcement measures (formal enforcement actions taken in order to address or correct any non-compliances found, e.g. issuing of improvement notices, detention or destruction of feed/food, or taking prosecutions etc.) instituted by the competent authorities following these checks do not constitute 'official controls'.
- **'Competent authorities'** are defined for the purposes of Regulation 882/2004 at Article 2(4). In effect, these are the central authority or authorities of a MS that are responsible for national official control arrangements as well as other authorities that have responsibility for monitoring compliance with, and enforcement of the law.
- **'Operators'** means 'feed business operators' and 'food business operators' as defined in Regulation (EC) No 178/2002 on General Food Law.²⁰
- **'Non-compliance'** is defined for the purposes of Regulation 882/2004 at Article 2(10) as 'non-compliance with feed or food law' (and with the rules for the protection of animal health and welfare).
- **'Normal control activities'** are the routine control activities required under Community or national law (this includes emergency safeguard measures adopted, for example, under Regulation 178/2002) and, in particular, are those described in the single integrated national control plan of the Member State. The requirement to have such a plan in place is also set out in Regulation 882/2004. The UK National Control Plan for

²⁰ 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. Official Journal L31, 1.2.2002, 1-24.

the period from January 2007 to March 2011 is published on the FSA website at the link below. As well as describing the roles and responsibilities of the different authorities and associated bodies that are involved with official feed and food controls and how these authorities and other bodies work together, it sets out the planned routine official control activities during the period of the plan. For local authority feed and food law regulatory services, these planned control activities are set out in more detail in each authority's Service Delivery Plan which must be in place under the terms of the *Framework Agreement on Local Authority Food Law Enforcement*.²¹

<http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk>

- **'Additional official controls'** are those undertaken following the detection of non-compliance and which exceed the routine activities of the competent authority. The additional controls are required to check the extent of a problem, to verify whether corrective action has been taken, and to detect and/or substantiate non-compliance. The *type (nature) and range* of control activities that may be undertaken is the same as for routine controls, e.g. sampling and analysis. It is the *level* of such activities, i.e. a level over and above that which applies routinely, that characterises 'additional official controls'.
- **'Actual costs'** should be calculated by reference to Annex VI of Regulation 882/2004. This lists the criteria that should be taken into account. These are the salaries and costs (facilities, tools, equipment, training, travel and associated costs) of staff involved in carrying out official controls, and costs of sampling and laboratory analysis.

Co-ordinated assistance and follow-up by the Commission

Legal requirement

4. Detailed requirements for the provision of administrative assistance and co-operation are set out at Articles 34 to 40 of Regulation 882/2004. These provisions aim to continue and improve previous arrangements whereby the competent authorities of the different Member States may work together and with the Commission where the results of official controls indicate that action is needed in more than one country. To facilitate assistance, each Member State is required to designate a 'liaison body' but this does not preclude direct contacts by individual authorities. The provisions relate to intra-Community trade issues and require the competent authorities of a MS on request to provide information and documentation to the competent authority in another MS where this will assist with investigations within its jurisdiction. In addition, where a competent authority in one MS becomes aware of a problem that may have implications in another MS(s), it should pass on relevant information to the other MS(s) without request.

5. Where an issue may have a particular relevance at Community level, the Commission will become involved and will co-ordinate any action needed (Article 40). In particular, where repeated non-compliance is found, the relevant competent authority must inform the other MSs and the Commission. The Commission may then send an Inspection Team (in collaboration with the MS reporting the non-compliance) to investigate (carry out an on-the-spot check) in the MS in which the feed or food originates and may request the competent authority of that MS to intensify official controls and report on the action and measures taken.

6. Article 40(4) requires the competent authority to charge feed/food business operators for: (a) administrative expenses incurred in informing the Commission and the competent authorities of the other MSs where repeated non-compliance has been found; and (b) the costs incurred by the Commission if it sends an inspection team to carry out an 'on-the-spot' check.

²¹ More information is available at: <http://www.food.gov.uk/multimedia/pdfs/frameworkjuly04.pdf>.

ANNEX B

THE OFFICIAL FEED AND FOOD CONTROLS (ENGLAND) REGULATIONS 2007 – SUMMARY OF PROVISIONS

Important note - the following summary has been prepared solely for the purposes of this RIA and aims to explain only the principal elements of the SI. The SI revokes and replaces the Official Feed and Food Controls (England) Regulations 2006 (SI2006/15). *Where provisions have been amended or new provisions have been included, this is highlighted using red italicised text.*

Preliminary (Part 1)

These measures provide for the following:

- **Title, commencement and application (regulation 1)** - This specifies the date on which the SI comes into force and that it applies in England only.
- **Interpretation (regulation 2, and schedules 1 to 3)** - This provides definitions that are relevant to interpretation of the SI. This includes definitions of Community legislation, 'relevant feed law', and 'relevant food law'. *These are being updated to reflect recent changes to Community and national legislation.*

Main provisions (Part 2)

These measures provide for the following:

- **Competent authorities (regulation 3 and schedules 4 and 5)** - The Food Standards Agency, local authorities and port health authorities are designated as having responsibility with regard to official controls relating to feed and food. This covers areas of feed/food law for which the Agency has responsibility at central level only. Those areas of feed/food law for which Defra has responsibility at central level do not fall within the scope of this SI. *Schedules 4 and 5 are being updated to make reference to the provisions in Regulation 882/2004 on financing of official controls - these applied from 1 January 2007.*
- **Exchanging and providing information (regulation 4)** - This provides a mechanism for the competent authorities to share information on enforcement activity - an 'information gateway'. This includes, for example, information or data that may be required for the national control plans that the UK must prepare and for the annual reports on implementation of these plans which the UK must submit to the European Commission.
- **Obtaining information (regulation 5)** - This gives powers to the competent authorities to require 'control bodies' (i.e. private bodies or companies undertaking official control tasks on behalf of a competent authority) to make available to them any information and records associated with the carrying out of official controls. Again, for example, this includes information that may be needed to ensure that obligations in the EU Regulation for monitoring and reporting enforcement activity may be met.
- **Powers to issue codes of recommended practice (regulation 6)** - This provides a power to the Secretary of State to issue codes of practice for local and port health authorities providing direction with regard to the manner in which their duties to enforce feed and food law should be carried out.
- **Extension of the Agency's function to monitor the performance of enforcement authorities (regulations 7 to 10)** - The existing function is set out in the Food Standards Act 1999. The provisions in the 1999 Act give the Agency the function of monitoring,

setting standards for, and auditing the performance of enforcement authorities. The provisions restrict this function to the enforcement of: the Food Safety Act 1990 and regulations made under it; Part IV of the Agriculture Act 1970 and regulations made under that part of the Act that are concerned with animal feed; and some, but not all, feed and food legislation made under the European Communities Act 1972. The SI includes parallel provisions to those in the 1999 Act to cover other areas of 'feed law'²² and 'food law'²³ for which the Agency has responsibility and which fall within the scope of EU Regulation 882/2004.

- **Right of appeal for food businesses dissatisfied with decisions relating to the approval of food establishments (regulations 12 and 13)** - The requirements for establishments to be approved is set out in EU legislation on food hygiene.²⁴ However, the procedures to be followed by the authorities responsible for granting approvals are set out in Regulation 882/2004.
- **Staff of the competent authorities of other MSs to accompany staff of the competent authorities in England when they undertake official controls (regulation 14)** - This applies when the authorities in England are carrying out investigations as a follow-up to the results of enforcement checks in the other MS. This ensures that an obligation in Regulation 882/2004 to provide administrative assistance and co-operation to other MSs is fulfilled in England.
- **Enforcement officers entering premises for the purposes of executing and enforcing official controls to take European Commission Experts with them (regulation 15)** - This means that Commission experts may enter those premises for the purposes of Article 45 of EU Regulation 882/2004 (this is concerned with Commission audits of the enforcement arrangements in MSs). This includes premises of competent authorities and of businesses etc.

This part of the SI also includes associated offences and penalties and, where appropriate, identifies the authorities that will enforce the various requirements and provides them with the necessary enforcement powers.

Provisions on official controls on feed and food of non-animal origin from third countries (Part 3)

These measures provide for the following:

- **Interpretation of this part of the Regulations (regulation 22)** - This provides definitions that are relevant to interpretation of this part of the SI. *The definition of 'product' is being amended to reflect a change in Community legislation.*
- **Designation of the 'enforcement authorities' for this part of the SI (regulations 23 and 24)** - These authorities are responsible for enforcing the requirements for businesses relating to non-POAO feed and food imported from outside the Community. These are local authorities and port health authorities.
- **Functions of the Commissioners (regulation 25)** - This specifies that Her Majesty's Revenue and Customs (HMRC) will carry out the functions of the customs services in relation to import controls for feed and food of non-animal origin.

²² 'Feed law' means the laws, regulations and administrative provisions governing feed in general, and feed safety in particular, whether at Community or national level; it covers all stages of production, processing and distribution of feed and the use of feed.

²³ 'Food law' means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers all stages of production, processing and distribution of food.

²⁴ 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 L226, 25.6.2004, 22-82.

- **Local and port health authorities at English borders may defer enforcement to inland local authorities in the UK (regulation 26)** - This flexibility may be needed for practical reasons, for example where special facilities are needed in order to undertake any checks and which may not be available at ports.
- **Prohibition on introduction of certain feed and food (regulation 27)** - *This regulation has also been revised such that there is a prohibition on feed and food being imported into the Community if it does not comply with the feed and food safety requirements (as set out at Articles 14 and 15 of the General Food Law Regulation 178/2002).²⁵ This change is being made such that officers of Her Majesty's Revenue and Customs may withhold clearance of consignments pending official control by the competent authorities. A consequential amendment has also been made to regulation 39 such that it is still an offence if any person introduces prohibited feed or food into England.*
- **Importers to provide facilities for the enforcement authorities to carry out checks on their products (regulation 28)** - This requires businesses to ensure that there are appropriate facilities for the enforcement authorities to carry out official controls on their products.
- Powers for the enforcement authorities to take action in case of non-compliance or suspicion of non-compliance (regulations 29 and 30) - These include powers to put consignments under official detention, to order destruction of the feed or food, to order recall or withdrawal of products, to order re-dispatch of consignments etc. *Regulation 30 is being amended such that an authorised officer of an enforcement authority will be required to serve a notice where he proposes to place a consignment under official detention because of suspicion of non-compliance and until the results of official controls are known. Some other minor technical revisions to regulation 30 are also being made.*
- **Right of appeal for feed and food businesses (regulations 31 and 32)** - This provides for businesses that are dissatisfied with decisions taken by the enforcement authority with regard to action in case of non-compliance to appeal against these.
- **Emergency declarations (regulation 33)** - This provides a mechanism for the Agency and Defra (the Secretary of State) to make declarations suspending or imposing conditions on the import of any product where there is a serious risk to animal or public health. The suspension or conditions will apply with immediate effect. In particular, it may be used to ensure that Emergency Decisions made at EU level under Article 53 of the General Food Law Regulation (178/2002) may be implemented in England without delay.
- **Costs (regulation 34)** - This provision allows local and port health authorities to recover costs associated with enforcement measures that have been taken in cases of non-compliance and suspected non-compliance. This includes, for example, costs associated with detention or destruction etc. It does not include costs for official control activities. *The formulation of this regulation has been updated to ensure consistency with the new provisions at regulations 41 and 42.*
- **Enforcement powers for food authorities (regulations 35 to 37)** - These provide powers to officers of food enforcement authorities to take samples and specify conditions for analysis of these. They also provide relevant powers of entry. Equivalent provisions for feed enforcement authorities are set out in the Feed (Hygiene and Enforcement) (England) Regulations 2005 which came into force on 1 January 2006.
- **Obstruction etc. of officers (regulation 38)** - This makes it an offence to obstruct an officer of the competent authorities in undertaking their duties
- **Offences and penalties (regulation 39)** - This sets out offences and penalties for businesses that fail to comply with the requirements set out on imports in the SI.

²⁵ 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. Official Journal L31, 1.2.2002, 1-24.

Regulation 39(1)(c) makes it an offence if the person responsible for introducing any product into England fails to provide adequate facilities for the enforcement officer to carry out checks on products (as required by regulation 28).

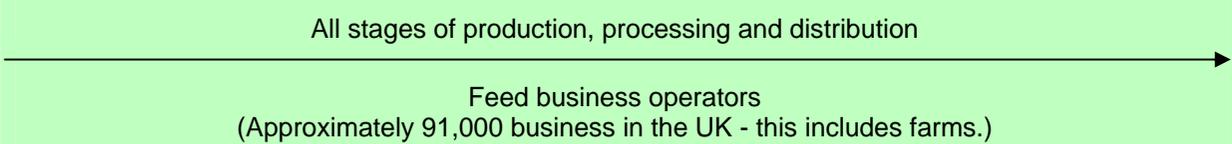
Recovery of expenses (Part 4)

- ***Expenses arising from additional official controls (regulation 41)*** – This new measure provides a power to the competent authorities to recover the costs arising from 'additional official controls' carried out following the detection of non-compliance and that exceed the competent authority's 'normal control activities'.
- ***Expenses arising in respect of co-ordinated assistance and follow-up by the Commission (regulation 42)*** - This new measure provides a power for the competent authorities to recover costs associated with the administrative actions required to inform the Commission and the competent authorities of the other MSs where repeated non-compliance is found and where the issue may have implications in other MSs, and for the costs incurred by the Commission if it sends an inspection team to investigate such cases.

ANNEX C

DIVISION OF RESPONSIBILITY FOR OFFICIAL FEED AND FOOD CONTROLS IN THE UK²⁶

Division of responsibility for official feed controls - at a glance

Developing and Implementing feed law	FSA		Defra (and agencies), SE DG Environment, WAG-RA and DARD			
	<ul style="list-style-type: none"> • General - traceability, rapid alert system (RASFF), official controls • Import controls • Labelling • Composition and standards • Biological safety - e.g. feed hygiene • Chemical safety - prohibited and undesirable substances • Biotechnology - Genetically modified feed 		<ul style="list-style-type: none"> • Animal by-products - feed ban, <i>Salmonellas</i> etc. • Medicated feed • Chemical safety - specified feed additives 			
Ensuring that feed satisfies the requirements of feed law	Farm	All stages of production, processing and distribution 				Fork
Official controls in respect of feed law	Central level			Local level		
	VMD	PSD	Animal Health	DARD	Local authorities in England and Wales	Local authorities in Scotland
	<ul style="list-style-type: none"> • Medicated feed • Specified feed additives • Veterinary medicine drug residue surveillance 	<ul style="list-style-type: none"> • Pesticide residue monitoring & enforcement 	<ul style="list-style-type: none"> • Animal protein in feed ban 	<ul style="list-style-type: none"> • All feed law controls in Northern Ireland 	<ul style="list-style-type: none"> • Official controls and enforcement of the main body of feed law, including imported feed (all feed law not enforced by Defra and its Agencies) 	<ul style="list-style-type: none"> • Official controls and enforcement of the main body of feed law, including imported feed (all feed law not enforced by Defra and its Agencies)

²⁶ Key to abbreviations: FSA - Food Standards Agency; Defra - Department for the Environment, Food and Rural Affairs; SE DG - Scottish Executive, Directorate General Environment; WAG-RA - Welsh Assembly Government, Department for Rural Affairs; DARD - Department of Agriculture and Rural Development for Northern Ireland; VMD - Veterinary Medicines Directorate; PSD - Pesticide Safety Directorate; SERPID – Scottish Executive Rural Payments and Inspections Directorate; TSEs - transmissible spongiform encephalopathies; MHS - Meat Hygiene Service; SRM - specified risk material; AH(DH) – Animal Health Dairy Hygiene; EMI - Egg Marketing Inspectorate; RPA - Rural Payments Agency.

Division of responsibility for official food controls - at a glance

Developing and Implementing food law	FSA <ul style="list-style-type: none"> • General - traceability, rapid alert system (RASFF), official controls • Import controls - public health aspects, fish/fishery products and products of non-animal origin • Labelling - general, nutritional, health claims • Composition and standards - e.g. bottled waters, fat spreads, chocolate, foods for particular nutritional use • Biological safety - e.g. food hygiene, TSEs • Chemical safety - e.g. additives, contaminants, food contact materials, irradiation • Biotechnology - genetically modified food 		Defra (and its agencies), SE DG Environment, WAG-RA and DARD <ul style="list-style-type: none"> • Imports controls - animal health aspects for products of animal origin • Labelling - beef labelling and protected food names • Composition and standards - organic produce • Biological safety - certain rules relating to TSEs • Residues of pesticides (PSD) • Residues of veterinary products (VMD) 								
Ensuring that food satisfies the requirements of food law	<p style="text-align: center;">Farm</p>	<p style="text-align: center;">All stages of production, processing and distribution</p> <hr style="border: 1px solid black;"/> <p style="text-align: center;">Food business operators (Approximately 600,000 establishments, plus approximately 195,000 holdings at primary production level.)</p>			<p style="text-align: center;">Fork</p>						
Official controls in respect of food law	<p style="text-align: center;">Central level</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> FSA <ul style="list-style-type: none"> • Inspection and approval of food irradiation facilities • Approval of fresh meat premises • Classification of shellfish harvesting areas • Natural mineral water recognition MHS <ul style="list-style-type: none"> • Hygiene controls - fresh meat • SRM controls AH(DH) (on behalf of the FSA) <ul style="list-style-type: none"> • Hygiene controls - milk production holdings EMI/SERPID (on behalf of the FSA) <ul style="list-style-type: none"> • Hygiene controls - egg production units </td> <td style="width: 50%; vertical-align: top;"> Defra (on UK-wide basis) <ul style="list-style-type: none"> • Organisation of protected food names scheme • Overseeing system for certification of organic produce • Organisation of beef labelling scheme VMD <ul style="list-style-type: none"> • Veterinary medicine drug residue surveillance PSD <ul style="list-style-type: none"> • Pesticide residue monitoring & enforcement RPA <ul style="list-style-type: none"> • Beef labelling </td> </tr> </table>		FSA <ul style="list-style-type: none"> • Inspection and approval of food irradiation facilities • Approval of fresh meat premises • Classification of shellfish harvesting areas • Natural mineral water recognition MHS <ul style="list-style-type: none"> • Hygiene controls - fresh meat • SRM controls AH(DH) (on behalf of the FSA) <ul style="list-style-type: none"> • Hygiene controls - milk production holdings EMI/SERPID (on behalf of the FSA) <ul style="list-style-type: none"> • Hygiene controls - egg production units 	Defra (on UK-wide basis) <ul style="list-style-type: none"> • Organisation of protected food names scheme • Overseeing system for certification of organic produce • Organisation of beef labelling scheme VMD <ul style="list-style-type: none"> • Veterinary medicine drug residue surveillance PSD <ul style="list-style-type: none"> • Pesticide residue monitoring & enforcement RPA <ul style="list-style-type: none"> • Beef labelling 	<p style="text-align: center;">Local level</p> <table border="0" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> DARD <ul style="list-style-type: none"> • Hygiene controls - fresh meat, milk production holdings/liquid milk premises, egg production units/packing stations • SRM controls • Organisation of protected food names scheme • Overseeing system for certification of organic produce • Beef labelling </td> <td style="width: 50%; vertical-align: top;"> SE DG Environment <ul style="list-style-type: none"> • Beef labelling </td> </tr> </table>		DARD <ul style="list-style-type: none"> • Hygiene controls - fresh meat, milk production holdings/liquid milk premises, egg production units/packing stations • SRM controls • Organisation of protected food names scheme • Overseeing system for certification of organic produce • Beef labelling 	SE DG Environment <ul style="list-style-type: none"> • Beef labelling 	Local authorities in England and Wales <ul style="list-style-type: none"> • Official controls and enforcement of the main body of food law, including imported food controls (all food law except that enforced by the central Departments and Agencies) 	Local authorities in Scotland <ul style="list-style-type: none"> • Official controls and enforcement of the main body of food law, including imported food controls (all food law except that enforced by the central Departments and their Agencies) • AH(DH) role - hygiene controls at milk production holdings 	District Councils in Northern Ireland <ul style="list-style-type: none"> • Official controls and enforcement of the main body of food law (all food law except that enforced by DARD)
FSA <ul style="list-style-type: none"> • Inspection and approval of food irradiation facilities • Approval of fresh meat premises • Classification of shellfish harvesting areas • Natural mineral water recognition MHS <ul style="list-style-type: none"> • Hygiene controls - fresh meat • SRM controls AH(DH) (on behalf of the FSA) <ul style="list-style-type: none"> • Hygiene controls - milk production holdings EMI/SERPID (on behalf of the FSA) <ul style="list-style-type: none"> • Hygiene controls - egg production units 	Defra (on UK-wide basis) <ul style="list-style-type: none"> • Organisation of protected food names scheme • Overseeing system for certification of organic produce • Organisation of beef labelling scheme VMD <ul style="list-style-type: none"> • Veterinary medicine drug residue surveillance PSD <ul style="list-style-type: none"> • Pesticide residue monitoring & enforcement RPA <ul style="list-style-type: none"> • Beef labelling 										
DARD <ul style="list-style-type: none"> • Hygiene controls - fresh meat, milk production holdings/liquid milk premises, egg production units/packing stations • SRM controls • Organisation of protected food names scheme • Overseeing system for certification of organic produce • Beef labelling 	SE DG Environment <ul style="list-style-type: none"> • Beef labelling 										

ANNEX D

SUMMARY/EVALUATION OF THE RESPONSES TO THE PUBLIC CONSULTATION ON THE DRAFT OFFICIAL FEED AND FOOD CONTROLS (ENGLAND) REGULATIONS 2007, ASSOCIATED GUIDANCE NOTES ON EXPENSES ARISING FROM ADDITIONAL OFFICIAL CONTROLS AND REGULATORY IMPACT ASSESSMENT

Executive summary

1. The consultation took place from 27 April to 20 July 2007 (separate consultations were undertaken in Scotland, Wales and Northern Ireland on the parallel legislation for these countries). The full consultation package is available on the FSA website at:

<http://www.food.gov.uk/consultations/consulteng/2007/offceng07>

2. As a supplementary exercise, the Agency sent a letter to all consultees concerning some additional proposed amendments to the SI. This included a proposed amendment which would permit HMRC officials to pass information to local/port health authorities on consignments of feed/food that had been presented for customs purposes but which have not undergone the necessary statutory health controls. It also included amendments to update further some of the definitions that are required for interpretation of the SI to reflect some recent corrections that have been made to Community legislation. The letter is available on the FSA website at the following link:

<http://www.food.gov.uk/multimedia/pdfs/offcupdate11eng.pdf>

3. The consultation package was sent directly to 797 interested parties in England. This included the Heads of Service in all English local authorities who were sent the website link. The Enterprise Directorate (formally the Small Business Service) of the Department for Business, Enterprise and Regulatory Reform, on behalf of the Agency, also made details of the consultation available to individual small feed and food businesses through the Small Firms Database. In addition, the package was posted on the FSA and LACORS websites to reach a wider stakeholder base. Given the broad scope of the provision such a wide consultation was considered appropriate.

4. Substantive responses were received to the main consultation from 10 stakeholders in England and 5 responses to the supplementary letter. Although the response rate was low, comments were received from key enforcement stakeholders and also from a number of industry stakeholders potentially affected by the proposals on charging. These responses are summarised in brief in the table overleaf in terms of the specific questions or issues on which comments were requested. The range of views expressed are described and, where respondents raised significant concerns or expressed a view contrary to the approach suggested, these are attributed to the stakeholder concerned.

5. A summary of the consultation responses will be made available on the FSA website in due course and copies of individual replies will be available in the FSA library.

Summary of consultation responses

Question/issue raised in consultation	Summary of responses	FSA evaluation
<u>Comments on the proposed legislation</u>		
<p>1. Controls of feed and food of non-animal origin from outside the EU</p> <p>Amendments were proposed to: (a) help ensure more effective application and enforcement by the competent authorities; (b) provide the necessary legal basis for officials of Her Majesty's Revenue and Customs to co-operate with, and pass information to, local/port health authorities; and (c) to reformulate the provision on liability for charges such that it is consistent with the new provisions on expenses.</p>	<p>Respondents that commented agreed with the proposals. Enforcement stakeholders highlighted that guidance may be needed in respect of enforcement powers.</p>	<p>The proposed amendments will be made to the SI with the exception of the provision to permit HMRC officials to pass information to local/port health authorities. A number of legal issues still need to be resolved in respect of this but the Agency will seek to conclude this work and give effect to this provision by means of an amendment to the SI early in 2008.</p> <p>The Agency will review its Practice Guidance for local/port health on import controls and revise it, where appropriate, to reflect the practical application of the amended measures.</p>
<p>2. Recovery of expenses arising from additional official controls</p> <p>This new measure requires feed/food business operators to pay the competent authority on demand for expenses arising from 'additional official controls' (i.e. controls or checks carried out following the detection of non-compliance <u>and</u> which exceed the competent authority's normal control activities).</p>	<p>The majority of respondents accepted the principle that businesses should be liable for costs of additional official controls.</p> <p>Notwithstanding this, concern was expressed by a number of respondents as to how such charges will be applied in a fair and consistent manner, and also that there was no formal right of appeal included in the SI.</p> <p>The Association of Independent Meat Suppliers, opposed the new provision on the basis that it was not necessary as the UK already complies with the requirement in EU legislation to charge via the power of courts to award costs where a prosecution has been taken for non-compliance.</p>	<p>It is not correct to say that the UK is already compliant with the EU requirement. The new provision is not a fine or a penalty but rather a charge or fee for undertaking official controls and it is a fundamental principle of UK law that before a compulsory charge can be levied on the citizen, Parliament must sanction it by appropriate legislation. In view of this, the legal provision will be retained otherwise the UK will be in breach of its EU obligations to give effect to the Article 28 charging provision.</p> <p>The concerns regarding fairness and consistency are noted, and the Agency has developed Guidance Notes to try to address these issues.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation
<p>3. Recovery of expenses relating to co-ordinated assistance with other Member States and follow-up by the Commission on intra-Community trade issues</p> <p>This new measure requires feed/food business operators to pay the competent authority on demand costs associated with administrative actions required to inform the Commission and the competent authorities of the other Member States where repeated non-compliance with feed/food law is found and where the issue may have implications in other Member States, and for the costs incurred by the Commission if it sends an inspection team to investigate such cases.</p>	<p>Respondents that commented accepted this proposal.</p>	<p>This provision will be retained.</p>
<p>4. Definitions and designation of competent authorities</p> <p>It was proposed that some of the definitions required for interpretation of the SI be amended to reflect recent changes to Community and other national legislation. Also, it was proposed that the Schedules which set out the responsibilities of the designated competent authorities be updated to include reference to those provisions in Regulation 882/2004 that applied from 1 January 2007.</p>	<p>No objections were raised.</p>	<p>The necessary amendments will be made.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation
Comments on the partial Regulatory Impact Assessment		
<p>5. Options</p> <p>Two options were proposed: do nothing - this would mean it was not possible to apply the Article 28 provision of Regulation 882/2004 in England as the competent authorities would not have the legal powers; or, adopt the SI to ensure that the competent authorities can fulfil their obligations under Regulation 882/2004.</p>	<p>Only one respondent commented on the options, supporting the second of these.</p>	<p>The Agency proposes to proceed with the second option. Not to do so, would leave the UK in breach of its EU obligations.</p>
<p>6. Social and environmental impacts</p> <p>Stakeholders were invited to comment on the Agency's assessment that the proposed measures will not have any impact on racial equality or on social or environmental sustainability issues.</p>	<p>The only stakeholder that commented agreed that the SI was unlikely to have an impact on these issues.</p>	<p>These issues will be re-assessed as part of post-implementation review of the measures in the SI.</p>
<p>7. Administrative burdens</p> <p>Stakeholders were asked to consider if there were any new administrative costs arising from the SI, and for evidence of costs that would be incurred and which are over and above those that a business would incur commercially.</p>	<p>No comments were received nor evidence provided of any additional burdens in relation to this question.</p>	<p>The Agency's view that there are no new administrative costs arising from the SI is maintained.</p> <p>As with social and environmental impacts, administrative burdens will be reassessed as part of post-implementation review of the measures in the SI.</p>
<p>8. Costs</p> <p>Stakeholders were asked for their views and comments on the Agency's assessment of costs to the competent authorities and businesses and to provide any cost information that may help to estimate the level of annual costs for 'additional official controls'.</p>	<p>Additional information on costs was provided by the Government Chemist (GC) in relation to dioxin analysis. The GC also suggested that the new provision may increase the incentive for businesses to challenge the results of controls such that the referee service it provides (costs mainly fall to Government) to resolve disputes between business and enforcement authorities may be used more heavily,</p> <p>A request was made to provide further information on the type of incidents that were used as the basis of the estimates of costs given in the RIA.</p>	<p>The comments on analytical costs have been reflected in the full RIA.</p> <p>As regards the incidents cited, further information is provided with the proviso that Article 28 charges did not apply at the time these incidents occurred and that the incidents have been used only to provide an indication of the types of incidents where charges should be considered and where they may apply.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation
Comments on the draft Guidance Notes on expenses arising from additional official controls		
<p>9. General issues</p>	<p>A number of respondents expressed concerns about how Article 28 charges:</p> <p>(a) in the meat sector, differ from 'additional charges' imposed by the MHS;</p> <p>(b) affect the wider framework of penalties and sanctions; and,</p> <p>(c) potential inconsistency in Agency Guidance with any that may be produced at EU level.</p> <p>The importance of consistency in approach by the Agency and Defra in applying Article 28 charges was highlighted.</p>	<p>The Guidance Notes have been amended to:</p> <p>(a) clarify that 'additional charges' apply where there is inefficiency on the part of the food business operator and enable the MHS to recoup its costs for 'routine' rather than 'additional' official controls;</p> <p>(b) highlight that Article 28 charges do not constitute a penalty or a sanction but rather represent a fee for control activities; and</p> <p>(c) emphasise that that the guidance will be kept under review and revised in the light of developments at EU level.</p> <p>As regards consistency, the Agency is continuing to work closely with Defra (and the other Agriculture/Rural Affairs Departments) with a view to ensuring consistency of approach where this is appropriate.</p>
<p>10. Legal requirements and definitions</p> <p>This section aims to explain the background to the requirement for competent authorities to charge for expenses arising from additional official controls, and to put the remaining sections of the Guidance into context.</p>	<p>Three main issues of concern were raised in respect of this section:</p> <p>(a) whether all revisits to a feed/food business establishment should warrant Article 28 charges or whether 'routine revisits' would be exempt;</p> <p>(b) whether the costs of taking formal enforcement actions, e.g. legal fees incurred in taking prosecutions, constitute expenses arising from additional official controls; and,</p> <p>(c) whether the costs of providing advice to non-compliant business would be charged such that businesses may be reluctant to seek advice where needed.</p>	<p>The Guidance Notes have been amended to clarify that:</p> <p>(a) competent authorities are expected to plan to undertake a degree of revisits to check on correction of non-compliance and in such cases, consideration will need to be given to the various indicative factors listed in the guidance in determining if the revisit is 'routine' or 'additional';</p> <p>(b) formal enforcement actions do not constitute 'official controls' so that costs for such actions may not be recovered using Article 28; and,</p> <p>(c) advisory or educational activities and information/intelligence gathering by competent authorities do not constitute 'official controls' so that costs of these activities may not be recovered using Article 28.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation
<p>11. Circumstances in which charges will be made</p> <p>This section aims to clarify when the competent authority can charge for expenses arising from additional official controls.</p>	<p>Respondents were concerned that the guidance provided may be interpreted differently by different competent authorities.</p> <p>There were some suggestions that providing more concrete examples of when charges apply would be helpful.</p>	<p>As Article 28 charges have yet to be applied, it is not possible to give concrete examples. The examples that are provided and the guidance that is given, however, will be kept under review and amended to reflect any developments at EU level, and in the light of the experience of the competent authorities across the UK and the establishment of relevant case law.</p>
<p>12. Competent authorities that can levy charges</p> <p>This section aims to clarify which competent authorities can levy charges for expenses arising from additional official controls.</p>	<p>One respondent questioned whether local/port health authorities may make the decision to levy charges without any requirement to consult with the Agency.</p>	<p>The Guidance Notes have been amended to highlight that where local authorities are the competent authority, any decision to use Article 28 is for them but they are recommended strongly to seek advice from their representative bodies or the Agency before any such charges are levied.</p>
<p>13. Feed and food business operators subject to charges</p> <p>This section aims to clarify who the charges can be levied against for expenses arising from additional official controls.</p>	<p>One industry respondent disagreed with the Agency's proposal that in cases where the cost and time involved in ascertaining who has been at fault as regards the non-compliance is disproportionate to the charges being made, the competent authority should consider charging the operator owning or keeping the goods at the time the non-compliance is detected and the additional controls are carried out.</p>	<p>As it is the EU legislation that provides for this option, the Agency proposes to retain it.</p>
<p>14. Activities subject to charges</p> <p>This section aims to clarify what the competent authorities can charge for as regards expenses arising from additional official controls.</p>	<p>Enforcement stakeholders requested clarification as regards the costs of formal enforcement actions.</p>	<p>As highlighted above, the Guidance has been amended to clarify that formal enforcement actions do not constitute 'official controls' so that costs for such actions may not be recovered using Article 28.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation
<p>15. Level of Charges</p> <p>This section aims to clarify how much the competent authority can charge as regards expenses arising from additional official controls, and what specific factors should be taken into account in calculating the charge for particular businesses.</p> <p>Stakeholders were specifically asked to comment on the proposed route for challenging whether charges are reasonable or not i.e. through the civil courts.</p>	<p>A number of respondents were concerned about the potentially costly process of challenging an Article 28 charge through a civil court.</p>	<p>It is considered that civil court proceedings embarked on by the competent authority for recovery of an Article 28 charge that an operator declines to pay is the best means for airing a grievance concerning an Article 28 charge. County Court judges are best placed to determine whether or not a defence against payment has been made by the defendant. An appeal to a (Magistrates') court or to an appointed person would be a lengthier and more cumbersome process.</p>

ANNEX E

FSA ANNUAL REPORT OF INCIDENTS 2006

Incidents by classification level

In 2006 the Food Standards Agency handled 10 incidents that were classified as high (1% of the total number). Those incidents were:

- Dioxins in imported cod liver oil;
- Undeclared milk protein in infant formula;
- Aflatoxins in imported broken rice;
- Processing of rejected milk consignments into curd cheese;
- Cheese recovery operations;
- National outbreak of *salmonella* Montevideo;
- National outbreak of *salmonella* Ajiobo;
- Contamination of imported rice with GM strains;
- Paralytic shellfish poisoning (PSP) toxin in mussels;
- Over Thirty Month (OTM) cow entering the food chain without being BSE tested.