

**EXPLANATORY MEMORANDUM TO
THE OFFICIAL CONTROLS (ANIMALS, FEED AND FOOD) (ENGLAND)
REGULATIONS 2006**

2006 No. 3472

1. This explanatory memorandum has been prepared by the Department for Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 This instrument provides, in relation to animal health & welfare legislation and some feed and food law (described in the Explanatory Note to the S.I.), for the application and enforcement of Regulation No. (EC) 882/2004 on official controls performed to ensure verification of compliance with feed and food law, animal health and animal welfare rules. The Statutory Instrument:

- designates the competent authorities who carry out official controls (principally, the Secretary of State and local authorities);
- provides for the sharing of information between competent authorities for purposes of Regulation 882/2004;
- provides for inspectors exercising their powers under animal health & welfare legislation and relevant feed & food law to bring officials of other member States and the EU Commission for purposes of Regulation 882/2004;
- provides independent powers of entry for auditors carrying out audits required under Regulation 882/2004;
- provides powers for the Secretary of State to ascertain compliance by local authorities with the audit obligation under Regulation 882/2004, and to appoint auditors to carry out audits of local authority competent authorities;
- makes provision for payment of charges which may be made to recover expenses incurred by competent authorities in certain circumstances;
- creates offences and provides for penalties in relation to obstructing auditors and inspectors or those officers enforcing these Regulations, or providing false or misleading information to an auditor or inspector or an officer enforcing the Regulations;
- makes necessary consequential amendment to the Official Feed and Food Controls (England) Regulations 2006 (S.I. 2006/15) as amended by S.I. 2006/1179, which partially apply Regulation 882/2004 in relation to policy areas for which the Food Standards Agency have responsibility.

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 animal health and welfare elements, as well as certain feed and food elements, of an EU Regulation on official controls. Regulation (EC) 882/2004, which is directly applicable, sets out a framework of requirements for the authorities in Member States (the competent authorities) for arrangements for enforcing the requirements of feed and food, and animal health and animal welfare legislation. These competent authorities are responsible for organising and undertaking official controls which are activities carried out to verify compliance with feed and food law and animal health and welfare rules. Regulation 882/2004 imposes a number of standards and requirements upon competent authorities in their execution and enforcement of animal health and welfare rules, and feed and food law. Competent authorities must be designated as such for the purposes of Regulation 882/2004, and must undergo audits of their enforcement and other work checking compliance with EU legislation. Member States must ensure effective co-ordination between competent authorities at regional and local level. Regulation 882/2004 also provides for co-operation between Member States and the Commission in dealing with particular cases of non-compliance in feed and food law, and for the Commission to carry out general and specific audits in member States. Regulation 882/2004 also provides a framework for the financing of official controls.

4.2 Most of the provisions of Regulation 882/2004 consolidate existing requirements so that existing enforcement arrangements in the UK are generally already consistent with them. However, some statutory application of Regulation 882/2004 is required, in particular to ensure compliance with the auditing obligations upon competent authorities, and to ensure that inspectors have powers to bring Commission and other Member State officials with them when carrying out official controls.

4.3 The instrument is being 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 are in keeping with those provided for in the Animal Health Act 1981 as amended, although the maximum period of imprisonment is three months, rather than six (offences are summary only).

4.3 The instrument complements the Official Feed and Food Controls (England) Regulations 2006 referred to in paragraph 2.1 above. Those Regulations revoked and re-enacted with changes the Official Feed and Food Controls (England) Regulations 2005 which were the subject of an Explanatory Memorandum laid before Parliament in September 2005.

5. Territorial Extent and Application

5.1 This instrument applies to England.

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

Policy

- 7.1 The objective of the EU Regulation is to create a more comprehensive and integrated, risk-based, 'farm-to-fork' approach to official controls. It does so by consolidating and extending existing legislative requirements. The aim is to improve the consistency and effectiveness of controls across the EU and, as a consequence, raise standards of food safety and consumer protection. The EU Regulation also aims to provide a greater degree of transparency for consumers about enforcement arrangements. The national legislation will provide the enforcement powers required in relation to provisions in the EU Regulation that applied from 1 January 2006 as well as making provision for payment of charges which may be imposed by competent authorities after 1 January 2007. The Department expects that the S.I. will contribute to the anticipated benefits of a more consistent and effective control system.

Consultation

- 7.2 Around 300 interested parties, plus local authorities in England and the Food Standards Agency, were consulted on the draft instrument, as well as the partial Regulatory Impact Assessment and associated guidance material. A total of eight responses, of varying degrees of substance, were received.
- 7.3 The main substantive area of concern related to the process for recovering expenses where there has been non-compliance causing additional (non-routine) official controls by competent authorities. Respondents were concerned this could place extra burdens on food business operators. It was suggested that there should be an appeals process by which decisions to charge in situations of non-compliance could be challenged.
- 7.4 This issue was considered carefully by the Department. Regulation 882/2004 requires Member States to charge for expenses incurred in the event that non-compliance by an operator leads to additional official controls (Article 28 of Regulation 882/2004) or leads to involvement of the Commission or intensified controls where the non-compliance has effects in other Member States. (Article 40.4). The charging obligations themselves are directly applicable. The S.I. provides for the payment of these charges.
- 7.5 The Department considers that express statutory provision for challenging these charges is unnecessary. These can be disproportionately costly to operate; the charges are not penalties, and an operator who objects to the appropriateness of a charge made under Articles 28 or 40.4 can dispute the use of the charging powers, including the reasonableness of the charge, in the course of debt recovery proceedings which the competent authority may take. The Department's view is therefore that this should adequately protect the rights of operators from excessive or inappropriate charges being made, and that the S.I. takes the most appropriate approach in balancing the interests of all parties.
- 7.6 The other main area of concern for consultees was in relation to the need for co-operation and co-ordination between enforcement authorities in order to

avoid duplication. This is a matter of policy, not for the S.I. as such, and the point made by consultees has been accepted. Defra is considering how better to improve internal co-ordination, in particular in respect of audits of control activity. Also, Defra will continue to work closely with local authorities and their representative bodies as well as with the Devolved Administrations to strengthen existing structures.

8. Impact

- 8.1 A Regulatory Impact Assessment is attached to this explanatory memorandum.
- 8.2 The impact on the public sector is minimal. The instrument provides certain powers to competent authorities, i.e. public sector enforcement bodies carrying out compliance verification checks, to ensure that they can comply fully with the requirements of Regulation 882/2004. Compliance with Regulation 882/2004 will lead to improved compliance verification and improved enforcement.
- 8.3 There are small impacts on farmers and other business operators at whose premises animal health and welfare legislation, and the relevant feed and food law, is enforced. They will be required to allow entry to auditors monitoring competent authorities' performance of official controls, a power which may be exercised without the inspector. In practice, policy will be to carry out such on-site audits on a risk basis and to co-ordinate these visits so that any disruption to the farmer, etc, will be minimal. Farmers and business operators will also be required to allow inspectors to bring other officials with them, but it is thought this will have no more than a minimal impact if at all.

9. Contact

- 9.1 Stefan Pietrzyk at the Department for Environment, Food and Rural Affairs on (tel: 020 7904 6923 or email at Stefan.pietrzyk@defra.gsi.gov.uk) can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

1.1 The Official Controls (Animals, Feed and Food) (England) Regulations 2006.

2. Purpose and intended effect of measure

Objectives

2.1 The Official Controls (Animals, Feed and Food) (England) Regulations 2006 will help ensure compliance in England with the requirements of Regulation (EC) 882/2004 which applies from 1 January 2006. Although the provisions of Regulation 882/2004 are directly applicable, certain measures are required in domestic legislation to apply and enforce the animal health and welfare elements as well as the feed and food elements for which Defra is responsible of Regulation 882/2004 in England.

2.2 The Regulations will contribute to more consistent and effective enforcement of feed and food, and animal health and welfare law. In doing so there will be increased standards of food safety, consumer protection and of animal health and of animal welfare.

2.3 The Official Controls (Animals, Feed and Food) (England) Regulations 2006 apply in England only. Separate and parallel legislation will apply in Scotland, Wales and Northern Ireland.

Background

General : EU Regulation 882/2004

2.4 Regulation (EC) 882/2004 (Regulation 882/2004) on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules, was adopted in April 2004. It deals with arrangements for the monitoring of compliance with, and the enforcement of animal health and animal welfare rules, and feed and food law. It sets out the general approach to be taken and the principles that need to be adopted by the competent authorities of Member States that have responsibility for undertaking official controls, i.e. verifying compliance with animal health and welfare rules and feed and food law. Amongst other things, it requires Member States to draw up a single integrated national control plan on the structure and organisation of animal health and welfare, feed and food controls and plant health controls; as well as requiring annual reports on the results of controls and audits carried out in the previous year. It includes a framework for financing of controls and includes new harmonised rules for official controls on feed and food on non-animal origin (non-POAO) imported from third countries. Regulation 882/2004 also provides the legal basis for the

European Commission to carry out assessments of the effectiveness of national enforcement arrangements.

2.5 Regulation 882/2004 introduced, with effect from 1 January 2006, general principles for Member States to follow in monitoring and verifying that the relevant animal health and welfare, and feed and food legislative requirements already placed on businesses are being fulfilled. In doing so it addresses the wide variation in the way Member States have been enforcing Community legislation in respect of animal health and welfare rules, and feed and food law. The actual legal requirements that businesses and farmers must comply with remain unchanged.

2.6 The main provisions of Regulation 882/2004 applied from 1 January 2006. The provisions relating to the financing framework apply from 1 January 2007.

2.7 The overall objective of Regulation 882/2004 is to ensure the safety of the food and feed chains through a more consistent approach to monitoring and enforcement of legal requirements. Enforcement of high levels of animal health and welfare contribute to :

- the quality and safety of food,
- the prevention of spread of animal diseases, and
- the humane treatment of animals.

The aim is to create a more comprehensive and consistent, integrated, risk-based, EU-wide approach to official controls.

2.8 Defra has responsibility in England for application of Regulation 882/2004 in relation to animal health and animal welfare rules, as well as certain limited elements of feed and food law, most of which are listed at paragraph 2.10 below. The Devolved Administrations have this responsibility in Scotland, Wales and Northern Ireland. The Food Standards Agency (FSA) has overall UK responsibility for application of Regulation 882/2004 in respect of official controls for monitoring and enforcing feed and food law. Arrangements are in place for joint working across the Departments with a view to ensuring consistency of approach.

2.9 In a number of respects the obligations placed on Member States in general, and on enforcing bodies more specifically, represent current best practice. They also pre-empt some of the recommendations of the Hampton Report on “Reducing administrative burdens : effective inspection and enforcement”¹. For example the use of risk assessments as the basis for regulatory intervention; Regulation 882/2004 requires official controls to be carried out regularly on the basis of risk assessment. This approach, which is one of Philip Hampton’s main recommendations, has already been adopted by numerous regulators, and has resulted in more effective targeted interventions.

The Official Controls (Animals, Feed and Food) (England) Regulations 2006

¹ A copy of the report is available on the H M Treasury website at <http://www.hm-treasury.gov.uk/media/A63/EF/bud05hamptonv1.pdf>

2.10 The S.I. relates to England only. It deals with the animal health and animal welfare elements of Regulation 882/2004, as well as some feed and food law responsibilities that fall to Defra; these are:

- TSEs in relation to BSE testing, including sampling controls on bovine, ovine and caprine animals slaughtered for human consumption,
- animal by-products,
- beef labelling,
- organic products including imported organic food products,
- pesticide residues,
- the import from third countries and intra-Community trade in products of animal origin,
- veterinary medicines residues,
- protected name food products and specific character food products.

2.11 Separate legislation has been put in place by the Food Standards Agency for the generality of feed and food not covered above. Details of the FSA's legislation, the Official Feed and Food Controls (England) Regulations 2006 (SI 2006/15), can be found at the Office of Public Sector Information website at the following address :
http://www.opsi.gov.uk/si/si2006/uksi_20060015_en.pdf

2.12 The main provisions of the Defra legislation relate to :

- Designation of the Secretary of State and local authorities as competent authorities in England responsible for undertaking official controls;
- Provisions for the exchange of information among competent authorities;
- Independent powers for auditors to enter premises, examine and copy records as appropriate for the purposes of carrying out an audit under the provisions of Regulation 882/2004, and to be accompanied by others if reasonably necessary;
- Obligations on designated competent authorities to provide information about their audits when requested by the Secretary of State;
- Powers for the Secretary of State to require auditors to carry out audits of local authorities², and if necessary to require the local authority to assist the auditor;
- Inspectors may bring with them European Commission experts for the purposes of general or specific audits to monitor the performance of the authorities in undertaking official controls;
- Inspectors may bring with them staff of the competent authorities of other Member States during investigations required in England following the results of enforcement checks in another Member State;
- Payment arrangements when competent authorities charge the costs of official controls dealing with repeated non-compliance where this charging is required in Article 40(4) of Regulation 882/2004;

² The term "local authority" in this RIA includes "food authorities".

- Payment arrangements when competent authorities charge costs of additional controls that have to be applied as a result of non-compliance where this charging is required in Article 28 of Regulation 882/2004;
- Powers of entry for officers authorised by a competent authority to enforce the provisions of the England regulations;
- Offences and penalties in respect of obstruction of auditors or others authorised to enter premises under the Regulations, and supplying false or misleading information;
- Amendment of the FSA's Official Feed and Food Controls (England) Regulations 2006 in relation to TSEs in the definition of "relevant food law" in Schedule 3.

Rationale for Government intervention

2.13 The Food Standards Agency issued a risk assessment on the generality of Regulation 882/2004 as part of the associated RIA² that was prepared during negotiations of Regulation 882/2004. In summary, the principal risk was considered to be the threat to consumers of unsafe and poor quality food not being identified by enforcement authorities in the Member States because of ineffective and inconsistent monitoring and enforcement arrangements. It was concluded that the new arrangements would :

- contribute towards a reduction in food-borne disease,
- a reduction in contamination incidents, and
- to increased consumer protection & confidence, with a concomitant reduction in the costs associated with these.

2.14 A more consistent approach to the enforcement of animal health and animal welfare rules would contribute to improvements in food quality and safety. The major risk identified was that by not introducing appropriate legislation in England, and other countries of the UK, Regulation 882/2004 would not be fully and effectively applied in the UK.

2.15 The Official Controls (Animals, Feed and Food) Regulations (England) Regulations 2006 will contribute to delivering the anticipated benefits identified above. If there was no Government intervention, that is to say the Official Controls (Animal, Feed and Food) (England) Regulations 2006 were not to be adopted, the provisions of Regulation 882/2004 might not be fully and effectively applied in England. In addition, there would be risk of challenge by the European Commission and possible infraction proceedings for not fulfilling our legal obligations to implement EU legislation.

3. Consultation

Within Government

² The RIA for Regulation 882/2004 on official controls is available on the FSA website at : <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodfeedregupdate1104>

3.1 Defra has consulted with the Food Standards Agency, LACORS and the Devolved Administrations during the drafting of the S. I. and the RIA. Consultation will continue as the RIA is developed further. The Home Office was consulted in relation to the offences and penalties at regulation 17 of the S.I.

Public Consultation

3.2 The Department carried out a formal consultation with stakeholders and other interested parties from 1 September 2006 to 26 November 2006. Of the eight responses received only two were substantive. A summary of the responses is attached at Annex A. One of the responses bore directly on the charging provisions at regulation 13(2) in the S.I. It was suggested that a full and transparent appeals mechanism should be introduced which would “prove beyond all reasonable doubt” that a non-compliance had occurred, and would adjudicate on the level of the costs to be recovered.

3.3 The Department takes the view that an appeals mechanism of the sort envisaged by the resposdee would not be appropriate in the circumstances. Firstly, no penalty as such is involved. The charging provision in the S.I. relates to recovery of expenses the competent authority has had been put to in applying additional controls to deal with a non-compliance – the point being to ensure that it is the non-compliant party who is required to bear the costs rather than the sector concerned generally. Secondly, where a business operator objects to the charge imposed on him, he may put his objections to the Court as and when the competent authority sues to recover the debt. The party charged will be protected by the Court’s adjudication in such proceedings as to whether the use of the charging powers was appropriate, including whether a non-compliance had occurred.

4. Options

4.1 Regulation 882/2004 is directly applicable in Member States. The UK is therefore obliged to ensure that the necessary framework, both legal and administrative, is provided to ensure full compliance with it. Therefore, realistically there is only one option, i.e. provide the legal basis to ensure full compliance with Regulation 882/2004. However, for the sake of balance this RIA also considers the possibility of a “do nothing” option.

- **Option 1** - Do nothing, i.e. not introduce the proposed Official Controls (Animals, Feed and Food) (England) Regulations 2006. This would mean that certain elements of the EU Regulation could not be applied in England because the necessary legal powers would not be available.
- **Option 2** – Ensure that the legal framework for full compliance is in place, i.e. adopt the proposed S. I. which will ensure that competent authorities in England can fulfil their obligations under Regulation 882/2004.

5. Costs and benefits

Sectors and groups affected

Competent authorities

5.1 The Official Controls (Animals, Feed and Food) (England) Regulations 2006 designates those competent authorities responsible for the purposes of Regulation 882/2004 in relation to animal health and welfare law and those elements of feed and food law that Defra is responsible for. The competent authorities designated under the S.I. are the Secretary of State, Local Authorities, and Food Authorities.

Feed and food businesses

5.2 Feed and food businesses are defined for the purposes of Regulation 882/2004 under Regulation (EC) 178/2002³. This establishes that food and feed businesses include any undertaking “carrying out activities related to any stage of production, processing and distribution” of food or animal feed. This includes primary production in respect of the production, rearing or growing of primary products, and therefore covers farming enterprises.

Social and environmental impacts

5.3 The Official Controls (Animals, Feed and Food) (England) Regulations 2006 will enable Defra to fulfil its legal commitments in relation to the implementation of European law. There are no implications in respect of equity or fairness.

5.4 The S.I. will not have any impact on economic, social or environmental sustainability issues.

5.5 The S.I. has been assessed for any impact on race equality in the light of guidance provided by the Commission for Racial Equality. The assessment has revealed that there are no racial equality impacts to the legislation. This is because the draft Regulations merely designate the Secretary of State and local authorities as competent authorities in England, introduce certain powers, including independent powers of entry to food business premises for the purposes of carrying out audits under the EC Regulation, and other powers of entry for certain European Commission and other officials, as well as offences and penalties relating to obstruction of authorised persons and furnishing false or misleading information. These powers will ensure that competent authorities can comply fully with the various requirements of Regulation 882/2004.

5.6 A legal aid impact test has been applied to the independent powers of entry and the obstruction, and provision of false or misleading information offences associated with the powers of entry. No implications for the Courts

³

http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32002R0178&model=guichett

or in relation to legal aid have been identified. This is because the levels of obstruction or furnishing of false or misleading information are not expected to increase as a result of these powers.

Benefits

Option 1

5.7 This is not a feasible option because Regulation 882/2004 is directly applicable in Member States and non-compliance or under-implementation would be in breach of Community obligations. Therefore, there are no benefits. In fact, failure to apply the Regulation could lead to infraction proceedings or other challenges by the Commission against the UK.

Option 2

5.8 This is the only realistic option. Most of the requirements of the Regulation are in some form or other already being complied with. However, there are some elements which need new powers or provisions in law to permit enforcement authorities to fully implement all the provisions of Regulation 882/2004.

5.9 In particular, the S. I. will ensure that Defra is able to provide information to the European Commission on enforcement arrangements and activity (including information on the performance of the enforcement authorities) in England as required by Regulation 882/2004, as well as providing for information to be shared between competent authorities. Such information assists not only the Commission but the UK's own competent authorities in identifying where improvements in the effectiveness and consistency of enforcement are needed. Additionally, these provisions support the Government's Better Regulation approach.

5.10 It is expected that where a Member State can show robust control systems, the frequency of Commission inspections might be reduced. Since Commission investigations can involve a considerable amount of time and resource, any potential reduction in their frequency and intensity could be viewed as a benefit.

Costs

Costs for competent authorities

Option 1

5.11 As there would be no change to current enforcement arrangements there would be no compliance costs for the competent authorities or others. However, were infraction proceedings to be brought by the Commission for failure to apply fully all the requirements in Regulation 882/2004, this could lead to costs for the UK.

Option 2

5.12 The main provisions of the S. I. in relation to carrying out official controls are considered to be cost neutral. The principal provisions simply designate the Secretary of State and local authorities, as appropriate, as competent authorities for the purposes of the Regulation. They also provide certain powers to auditors to allow auditing of enforcement activity, and they facilitate assistance and co-operation between competent authorities.

5.13 The provisions also enable the exchange of information about enforcement activity between competent authorities. This supports the Government's Better Regulation approach by informing the risk-based approach to compliance checks and on-site audits, by ensuring that competent authorities can co-ordinate their inspection and enforcement regimes.

5.14 Regulation 882/2004 requires designated competent authorities to carry out or to have carried out audits of their control systems to ensure they are achieving the objectives of the Regulation. The Official Controls (Animal, Feed and Food) (England) Regulations 2006 will introduce a provision whereby the Secretary of State could require an auditor to carry out audits of a local authority competent authority and to require the competent authority to provide assistance in the audit. These powers are included because as the central competent authority for animal health and welfare and certain feed and food activities Defra needs to be assured that designated competent authorities are fulfilling all their requirements under the EU legislation, including those relating to the carrying out of audits. The auditor appointed by the Secretary of State to carry out the audit of the local authority could be either an internal local authority auditor or, more likely, an external auditor. In the latter case, this would help ensure independence of the audit process.

5.15 In addition, the S.I. makes provision for the FSA to audit local authorities on behalf of the Secretary of State in relation to the areas covered by the S.I. If this option is exercised, the FSA auditors would rely on powers under the Official Feed and Food Controls (England) Regulations 2006. There would be a cost to Defra in charges by the FSA for carrying out this work. A lot of detailed work still needs to be carried out in order to establish a workable system and it is therefore too early to identify the level of costs likely to be involved.

5.16 The Commission has developed guidelines on the criteria for the conduct of official control audits. These guidelines have been published and are available on the Commission website at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_278/l_27820061010en00150023.pdf

5.17 A joint FSA/ Defra/ Devolved Administrations consultation was carried out on these guidelines last Summer. Copies of the consultation documentation and a summary of the responses can be found on the FSA website at : <http://www.food.gov.uk/multimedia/pdfs/consultationresponse/offcconsultationresponses.pdf>

5.18 Stakeholders' views were that some of the Commission's audit criteria might have resource implications, e.g. the need for all competent authorities to carry out risk-based audits across all their activities over a 5-year cycle, and the requirement for on-site visits. It is not possible at present to assess whether, and to what degree any additional burdens would be placed on enforcement authorities by these rules. Wherever possible the intention is to minimise any potential additional resource burdens by using existing regimes or adapting existing ones as appropriate. By providing the facility for animal health and welfare controls audits to be carried out with audits for other purposes, there is scope for reducing any resource burdens on competent authorities.

Costs for business

5.19 There are no discernable significant direct or indirect costs to businesses because the level of compliance verification checks that are already carried out by the competent authorities is not expected to increase, and no new compliance checks are introduced. In fact, as compliance checks are to be carried out increasingly on a risk basis, there is, potentially, scope for reducing the frequency of them in some cases, thereby reducing any costs associated with such visits.

5.20 The Official Controls (Animals, Feed and Food) (England) Regulations 2006 provides certain powers for auditors for the purposes of Regulation 882/2004, i.e. independent powers of access to premises and to examine and copy records. The intention is that these on-site audits will be carried out on a risk basis. Consequently, no significant increase in the level of on-farm or other business premises' visits and therefore no additional associated costs are envisaged. It is not realistic at this stage to identify the likely number of such on-site audits. However, it is believed that it is highly unlikely that any one premises would receive such a visit more than once a year in the absence of any significant or repeated non-compliance. Although, if the Commission or another Member State raised concerns about a particular producer, or problems emerged during a general or specific audit visit of a particular premises by the Commission, there might be a need for follow-up visits.

5.21 In order to quantify any likely impact on producers of the auditors' powers calculations have been made of a hypothetical audit visit based on average farmers' hourly earnings. Based on data from the 2005 Annual Survey of Hours and Earnings (ASHE) published by the Office of National Statistics (see http://www.statistics.gov.uk/downloads/theme_labour/ASHE_2005/2005_occ4.pdf) average hourly farmer income is estimated at £7.91. The on-site audits would not be expected to last more than 2 hours. This represents an estimated cost, in farmers' time, of under £16 per visit where such a visit is carried out. Defra will endeavour to ensure that any such visits are co-ordinated with visits for other purposes so as to reduce any cumulative burden and stress on farmers. Such visits would be made at a time convenient for the business operator concerned and notified in advance.

5.22 Regulation 882/2004 requires, under Article 28, competent authorities to recover the costs of expenses where additional controls have had to be applied as a result of non-compliance and which exceed the competent authority's normal control activities. For the purposes of Regulation 882/2004 "normal control activities controls" are defined as "*the routine control activities required under Community or national law, and in particular, those described in the [national control plan]*". Charging non-compliant business operators for the costs of controls which exceed the normal or routine control activities is in line with Defra's charging principle of "polluter pays". The specific conditions under which this charging requirement would be applied and the levels of charge involved have yet to be agreed, and much work and consultation with stakeholders still needs to be carried out.

5.23 The S.I. also provides for the recovery of reasonable expenses by the competent authority where a Member State of destination reports repeated non-compliance and the report results in a visit by a European Commission inspection team or the introduction of intensified official controls by the competent authority concerned. This provision is expected to be used only unusually and only in circumstances of repeated non-compliance by a feed or food business operator. This approach is consistent with the Principles set out in the Defra Charging Handbook.

6. Small Firms Impact Test

6.1 There are no discernable direct or indirect costs to businesses because the level of compliance verification checks that are already carried out is not expected to increase, and no new checks are introduced. In fact, as checks are to be carried out increasingly on a risk basis, there may be scope for reducing the frequency of them in some cases.

6.2 The Small Business Service, the Office of Fair Trading and the Cabinet Office Better Regulation Executive have been consulted in the development of this partial RIA.

7. Competition Assessment

7.1 A competition assessment is not required for this RIA because the proposal impacts primarily on public sector enforcement bodies carrying out compliance verification checks. As such there would be no direct impact on private sector companies or charities. The provisions relating to exchange of information between competent authorities might potentially affect competition if such exchange was uncontrolled and not secure and if the database was violated.

8. Enforcement, sanctions and monitoring

8.1 The main provisions of the S. I. are enabling powers to allow the competent authorities in England to fulfil certain requirements in Regulation 882/2004.

8.2 In regard to the monitoring of enforcement action and to the provision of information to other competent authorities, steps will be taken and systems

put in place to moderate the data exchange only to that information actually required to ensure consistent application of Regulation 882/2004, to limit access to the information and to ensure that transmission is secure. It is envisaged that the shared information would be used to ensure efficient and effective co-ordination between competent authorities, and to inform risk analyses for the purpose of targeting compliance verification checks and on-site audits.

9. Implementation and delivery plan

9.1 The S.I. will come into force early in 2007.

9.2 The S.I. provides powers to ensure full implementation of Regulation (EC) 882/2004. As such it does not involve a change in policy because the provisions of the EU Regulation are directly applicable in Member States. Defra and the other competent authorities designated under the S.I. are responsible for ensuring that the provisions of the EU Regulation are applied. The roles and responsibilities of the various competent authorities in delivering the requirements of the control systems to which Regulation 882/2004 relates are set out in the national control plan mentioned in section 10(2) below. The national control plan has been published on the FSA website at <http://www.food.gov.uk/foodindustry/regulation/europeleg/feedandfood/ncpuk>

Compensatory Simplification Measures

9.3 The purpose of the S.I. is to designate competent authorities and to provide certain powers to ensure that the requirements of Regulation 882/2004 are fully complied with. Many of the legal requirements are already complied with through available legislation and administrative procedure. However, some statutory provision is needed to cover identified gaps which cannot otherwise be filled. The overall effect of full compliance with Regulation 882/2004 will be enhanced compliance verification of animal health and welfare rules and certain feed and food laws. This will lead to more effective enforcement. Since compliance verification will be more risk-based there may be scope for reducing administrative burdens where compliance can be shown to be robust. There is, however, no scope for removing or simplifying existing regulations as a result of introducing this legislation.

10. Post implementation review

10.1 The European Commission is required to review the application of Regulation 882/2004 by May 2007. As part of this review, the UK will review the application of the measures in the S.I. and any other measures that may have been taken to apply the provisions of the EU Regulation.

10.2 Member States are required under Regulation 882/2004 to prepare a single integrated multi-annual national control plan which describes the structure and organisation of the control systems for feed and food and animal health and welfare, as well as for plant health. The plan is to be reported on annually and is to be updated regularly in the light of certain factors. The review and reporting on the implementation of the plan will provide an

opportunity to review the measures in place as well as those under the Official Controls (Animals, Feed and Food) (England) Regulations 2006.

11. Summary and Recommendation

11.1 The S. I. will ensure that those elements of Regulation 882/2004 which need to be given effect by domestic legislation will be applied in England. These provisions will ensure improved and more consistent enforcement of animal health and welfare rules and, as appropriate, feed and food law. The measures provided for in the S.I. do not introduce any new or significant costs to the competent authorities or to feed or food businesses.

11.2 In view of the above, it is recommended that the S.I. is introduced into English law.

12. Declaration and publication

12.1 I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed Barry Gardiner

Date 28th December 2006

[.....]

Parliamentary Under Secretary of State
Department for Environment, Food and Rural Affairs

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CONSULTATION ON THE OFFICIAL CONTROLS (ANIMALS, FEED AND FOOD) (ENGLAND) REGULATIONS 2006, PARTIAL REGULATORY IMPACT ASSESSMENT AND ON THE GENERAL GUIDANCE FOR ENFORCERS – SUMMARY OF RESPONSES

1. Introduction

1.1 On 1st September 2006 we published a consultation paper seeking views on the provisions we had proposed in the draft Statutory Instrument (S.I.), The Official Controls (Animals, Feed and Food) (England) Regulations 2006. On 20th October the S.I. was re-issued to include a new provision giving effect to the Article 28 requirements of Regulation (EC) 882/2004, which requires competent authorities to charge for the cost of additional controls in the event of non-compliance.

1.2 The proposed S.I. would implement in England the provisions of 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 legislation.

The main issues on which we were seeking stakeholders' views were:

- designation of the Secretary of State and local authorities as competent authorities in England responsible for undertaking official controls
- sharing information between competent authorities
- independent powers of entry for auditors
- inspectors to be accompanied by others e.g. European Commission experts
- powers for the Secretary of State in relation to audits of competent authorities
- recovery of expenses under certain circumstances
- charging provision under Article 28.

1.3 The consultation document, partial Regulatory Impact Assessment (RIA) and draft notes for enforcement authorities were sent to over 300 stakeholders and interested organisations. The consultation was also made available on the Defra website.

1.4 A small number of responses were received, with the National Farmers' Union (NFU) and Local Authority Co-ordinators of Regulatory Services (LACORS) providing substantive comments. Their responses to specific questions are in Annex A. All respondents were asked if they were content for their views to be made public; a full set of these responses is available from the contact point provided below. We are grateful for all responses received.

1.5 This paper tries to reflect the views offered. We have taken these into account in finalising the national legislation and supporting RIA and in revising the guidance material.

This report will be published on the Defra website in due course.

2. General Summary

2.1 The majority of respondents welcomed and supported implementation of Regulation (EC) 882/2004. The NFU and LACORS agreed with the majority of proposals within the consultation.

2.2 However, the NFU expressed their concern in relation to:

- The on-site audits and the need to co-ordinate visits in order to reduce burden on farmers' time.
- Article 28 provisions and in particular the lack of any formal appeals mechanism. Whilst the NFU agrees in principle with the requirement for the recovery of cost in the event of repeated non-compliance, they believe it is imperative that, in practice, the approach follows the better regulation principles and is consistent, proportionate, transparent and accountable. Their main concern is about the lack of a formal mechanism for appealing against charges imposed for non-routine official controls. There should be a process of appeal whereby decisions can be challenged if businesses feel they are unfounded (please see NFU comments in Annex A, Regulation 13, question 10, point 14).

We support the first point, but it is more a matter to be reflected in policy, than in the S.I. itself. On the second point about an appeals mechanism, the view we take is that such a mechanism is not required. Firstly, the charging provision does not relate to a penalty, but to the recovery of expenses in dealing with non-compliance, obliging the non-compliant party to bear the costs rather than the sector concerned generally, say. This approach is in line with Defra's charging strategy i.e. "the polluter pays" principle.

In addition, there is already an inherent challenge mechanism through the courts where charges can be disputed. The opportunity to challenge the charge could arise in the course of any legal action taken by the competent authority to recover the charge. Business operators can ask the Court to consider whether the powers in the EU Regulation have been applied properly, including whether the charge is reasonable. We believe that this mechanism is sufficient to protect business operators from excessive or inappropriate charges being made under Article 28 and is the most appropriate approach for balancing the interests of all parties.

2.3 LACORS expressed their concern about the audit requirements for the competent authorities, which might impose additional burden on local authorities. They believe that the audit regime of local authorities should reflect the wider commitment of the UK government to reduce auditing of local authorities and to concentrate on those authorities whose performance is weak. LACORS felt that there is a need for co-operation and co-ordination between enforcement authorities in order to avoid duplication of official controls.

Defra is considering how better to improve Department's internal co-ordination and will continue to work closely with local authorities and colleagues from Devolved Administrations to improve existing structure of official controls.

2.4 In addition, at the 4th meeting of consumer representatives and membership organisations with the Defra Chief Veterinary Officer on 7th September Consumer Group organisations agreed that the proposed regulations reflect their requests for assurance that food law was being enforced consistently across the EU. They welcomed the emphasis on enforcement system, but they felt that we need to be realistic about the workload of enforcement agencies. Opportunities to combine inspections of farms to reduce the number of visits without undermining effectiveness of controls would be valuable.

2.5 With regard to the partial RIA, the NFU suggested that although the cost element states that the main provisions of the S.I. will be cost neutral, two costs might arise: the first might result from the exchange of information between government departments as enabled by the main provisions, and the second might result from external auditors ensuring the independence of the audit process. The points have been noted.

3. List of Respondents

- British and Irish Association of Zoos and Aquariums (BIAZA)
- British Meat Processors Association (BMPA)
- Consumer Group organisations: Which?, National Council of Woman, Foodaware, Townswomen's Guilds, National Consumers' Federation
- FACE-UK
- Local Authority Co-ordinators of Regulatory Services (LACORS)
- Meat and Livestock Commission (MLC)
- National Farmers' Union (NFU)
- Shechita UK

Annex A

Responses to the draft Statutory Instrument the Official Controls (Animals, Feed and Food) (England) Regulations 2006

No	Organisation	Summary of Comments
REGULATION 5 - the designation of local authorities as competent authorities, including where they act as food authorities		
Q1. Defra wishes to make sure that the obligations of Regulation 882/2004 imposed on Local Authorities by the proposed SI extend only so far as their current area of responsibility.		
1	National Farmers' Union	Whilst they agree that local authorities should not be expected to inspect legislative areas for which they are not responsible, it is not clear to the NFU how this proposal fits in with an extension of their roles. For example, the role of Trading Standards Officers has extended to include the inspection of food hygiene on farm premises; this is work they had not undertaken previously. Would the obligation imposed on Local Authorities by the regulation prevent their role being extended?
2	LACORS	LACORS agrees that the designation should be limited to their current legislative obligations.
REGULATION 6 - on exchanging information		
Q2. Do you see any problems with this facility for sharing information on official controls between competent authorities?		
3	National Farmers' Union	The NFU agreed with this approach. They believe that consideration should be given to competent authorities sharing information in order to achieve a risk based approach to inspection and targeted compliance verification checks. They encourage an approach that included coordination and data sharing between competent authorities and farm assurance schemes that meant those belonging to an assurance scheme would be considered as a lower risk. They are supportive of a reduction of administrative burdens of enforcement and inspection.
4	LACORS	LACORS agrees that there should be a statutory basis for the sharing of information between competent authorities.
REGULATION 7 - on powers for auditors		
Q3. Defra wishes to ensure that independent powers of entry etc for auditors which can be exercised independently of inspectors' visits are proportionate, bearing in mind that audits of official controls need to be independent of the activity being audited if the audit is to be robust and to ensure consistency across all sectors. Your views on this would be appreciated.		
Q4. Do you agree that auditors should be able to bring others with them, e.g. technical experts, when carrying out an on-site audit ?		

No	Organisation	Summary of Comments
5	National Farmers' Union	<p>The NFU sees a consistent and robust approach to inspections as vital and it is welcomed therefore. They agree that auditors should have independent powers of entry as long as they are proportionate and do not impose unnecessary burdens on farmers by entering farms at inconvenient times. The intrusion into a farmer's management time should be minimised.</p> <p>They believe that farmers should be given as much advance warning of an audit visit as possible. Farmers should be told what will be inspected and why. They are concerned that the consultation provides no information about what action will be taken if on an audit visit farm standards are found to be below the required level. They believe the competent authority should issue information about this. They recommend a pragmatic, 'light touch', approach on a verification visit, with advice provided on measures required to achieve compliance.</p> <p>They agree that auditors should be able to bring technical experts to sites where this would be beneficial. It is essential that any threats to biosecurity are considered when the visit is planned.</p> <p>They welcome audits being based on risk assessments in line with the Hampton Review. However they would like further explanation of how these will be identified, and like examples of who would carry out these risk assessments. The consultation is unclear whether these audits will be performed on high risk businesses or local authorities that have a poor performance record, for example.</p>
6	LACORS	<p>LACORS agrees that the powers of auditors should be independent of those who are audited. They believe, however, that the inclusion of on site visits as part of an auditing regime is onerous. For that reason they are pleased that it is intended that on site visits will be used only where a risk assessment of the enforcement activities dictates that it is necessary. They hope that this will mean that on site visits are exceptional.</p> <p>If DEFRA chooses to use FSA auditors to carry out OFFC compliance checks it is likely that technical experts will be needed at on site visits because auditors are not experienced in the animal health and welfare field.</p>
<p>REGULATION 8 - on Secretary of State's powers in relation to local authority audits</p> <p>Q5. Do you have any views on this approach, specifically do you agree that the Secretary of State should be able to organise audits of local authorities?</p>		
7	LACORS	<p>LACORS agrees that in the unlikely event of an authority not carrying out internal or external audits there should be a contingency for requiring that those audits take place. In this case procedures should be agreed including an opportunity for central local government (LACORS etc) to support authorities in this situation before the Secretary of State's powers must be invoked.</p>

No	Organisation	Summary of Comments
REGULATION 9 - on auditing powers for audits undertaken by the Food Standards Agency		
Q6. If such arrangements between the Secretary of State and the FSA are entered into in the future do you agree that FSA auditors, when acting on behalf of the Secretary of State, should operate under the audit provisions of the Official Feed and Food (England) Regulations 2006 ?		
8	LACORS	LACORS agrees.
REGULATION 1 - on Community controls		
Q7. Do you agree that Commission experts' visits and examination of records should be restricted in this way, or should they have independent powers ?		
9	National Farmers' Union	The NFU agrees that the Commission expert's visits and examination of records should be restricted in order to remain consistent with the approach taken with existing legislation. Providing the experts with independent powers may pose threats to biosecurity and will not achieve the transparency that is required. They agree that competent authorities should help those of other Member States where the results of an official control in one Member State requires action in a number of Member States to prevent ramifications. Also, information should be passed between Member States if it might be useful.
10	LACORS	LACORS agrees that Commission experts should inspect only when accompanied by UK auditors.
Regulation 11 - on local authorities' duties in respect of Title IV duties		
Q8. Do you support this approach?		
11	LACORS	LACORS support this approach but again say that procedures should be agreed including an opportunity for central local government (LACORS etc) to support authorities in this situation before the Secretary of State's powers must be invoked.
REGULATION 12 - on facilitating assistance and co-operation		
Q9. (a) Officials from another Member State may attend by agreement with Defra or another competent authority. We have accordingly provided in this power for other Member State officials to attend with Defra or local authority inspectors. Do you agree with this approach? (b) Commission experts are required to be accompanied by an inspector. Do you have any views on this restriction ?		

No	Organisation	Summary of Comments
12	National Farmers' Union	<p>The NFU agrees with this approach but it should be applied consistently throughout all Member States. They think this should take place where activities may have ramifications in another Member State or similar activities have happened in another Member State that warrant officials attending with Defra. Sharing data and best practices may be of useful when deciding on action or enforcement proportionate to a specific control. Consideration should also be given to using this approach for benchmarking other Member States on enforcement and risk based inspections to achieve better regulatory principles.</p> <p>They agree that Commission experts should be accompanied by an inspector.</p>
13	LACORS	LACORS agrees that UK inspectors should be present at investigations by inspectors of other Member States and their accompanying experts.
REGULATION 13 - on recovery of expenses		
Q10. Do you agree with the approach we have taken in respect of the obligation to recover expenses in the event of repeated non-compliance ?		
14	National Farmers' Union	<p>Whilst the NFU agrees in principle with the requirement for the recovery of cost, they believe it is imperative that, in practice, the approach follows the better regulation principles and is consistent, proportionate, transparent and accountable.</p> <p>Their main concern is about appeals. There should be a process of appeal whereby decisions can be challenged if businesses feel they are unfounded. They question why businesses must go to court to contest charges, which places an additional burden on farmers as well as incurring further costs. It may be that the cost of appeal compared to the amount of the penalty sometimes dissuades businesses from mounting a justifiable challenge.</p> <p>As part of an approach in which responsibility and cost is shared, government and industry should agree how such an appeal process would work in order to maximise efficiency of enforcement and compliance.</p> <p>In their response to the Macrory Review, they commented on the need for a full and transparent mechanism of appeal in which the criminal court is reached only at the end of the process. They suggested that the process should be transparent to businesses at all stages and require proof beyond reasonable doubt that non-compliance has occurred. Businesses should have a right of appeal to a specialist tribunal if they thought that the costs being recovered were not proportionate. This would not only relieve pressure on the courts but also ensure that the costs recovered are proportionate and consistent as reviewed by a specialist expert tribunal.</p>
REGULATIONS 14 and 15 - on interpretation and enforcement		

No	Organisation	Summary of Comments
REGULATION 16 - on powers of enforcement officers		
Q11. Do you have any views on the provisions under regulations 14, 15 & 16 ?		
15	LACORS	LACORS has no adverse comment.
REGULATION 17 - on obstruction offences and penalties		
Q12. Should the obstruction of an auditor, an inspector or anyone accompanying them, or an enforcement officer be an offence ? Are the proposed penalties appropriate for summary offences of this nature?		
Q13. Should providing false or misleading information be an offence ? Are the proposed penalties appropriate ?		
16	National Farmers' Union	<p>While NFU accepts that obstruction of an inspector may merit a criminal sanction, they disagree that obstruction of any or all of the accompany person(s) should be considered in the same way. There is a risk of a large number of individuals requiring entry, for example, to a small farm office where records are kept. They emphasise that this situation is an inspection rather than a Commission-authorized 'raid', and a sense of proportion should apply. The offence of obstruction should be limited to that of the enforcement officer, who has the power to enter premises and inspect records. The accompanying officials do not have that power themselves.</p> <p>The approach should be proportionate considering that false or misleading information may be given as a result of problems with the Regulation or enforcement either through poorly written guidance or a lack of advice.</p>
17	LACORS	<p>LACORS say that the terminology in these provisions is confusing. It is unclear whether Regulation 17 creates an offence of obstruction of local authority inspectors in their duties. This should be clarified in any accompanying guidance to the legislation.</p> <p>LACORS accepts the offence and proposed penalties.</p>
REGULATION 19 - on time limits for prosecution		
Q14. Should the time limits for prosecution be extended ? If so are the proposed time limits appropriate ?		
18	National Farmers' Union	The NFU sees no justification for extending the time limits. In the interests of legal certainty for farm businesses and good administration generally, a six month time limit is appropriate.
19	LACORS	LACORS accepts the time limits proposed.

