

EXECUTIVE NOTE

The Official Controls (Animals, Feed and Food) (Scotland) Regulations 2007 SSI/2007/ 91

1. The above instrument was made in exercise of the powers conferred by section 2(2) of the European Communities Act 1972. The instrument is subject to negative resolution procedure.

Policy Objectives

2. This instrument provides, in relation to animal health & welfare legislation and some areas of feed and food law (described in the Explanatory Note to the SSI.), for the application and enforcement 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 rules.

3. Regulation (EC) No. 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. The Statutory Instrument therefore:

- designates the competent authorities who carry out official controls (principally, Scottish Ministers 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 Scottish Ministers 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;

4. Most of the provisions of Regulation 882/2004 consolidate existing requirements so that existing enforcement arrangements 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.

5. The instrument complements the Official Feed and Food Controls (Scotland) Regulations 2005.

Consultation

6. Around 65 interested parties, including local authorities in Scotland 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 8 responses were received.

Financial Effects

7. A Regulatory Impact Assessment is attached to this executive note.

8. The impact of the instrument is primarily on the public sector. It 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.

9. 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 when monitoring competent authorities' performance of official controls, a power which may be exercised without the inspector. In practice, the 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. It is expected however, this will have no more than a minimal impact if at all.

Scottish Executive Environment and Rural Affairs Department
9 February 2007

FINAL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

1.

1.1 The Official Controls (Animals, Feed and Food) (Scotland) Regulations 2007.

2. Purpose and intended effect of measure

2.1 Objective

2.1.1 The Official Controls (Animals, Feed and Food) (Scotland) Regulations 2007 will help ensure compliance in Scotland with the requirements of Regulation (EC) No. 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 of Regulation 882/2004 in Scotland, as well as the feed and food elements for which SEERAD is responsible.

2.1.2 The regulations will contribute towards more consistent and effective enforcement of feed and food, and animal health and welfare law. By doing so there is the potential to deliver increased standards of food safety, consumer protection and of animal health and welfare.

2.2 Devolution

2.2.1 The regulations apply in Scotland. Parallel legislation will apply in England, Wales and Northern Ireland.

3. Background

3.1 General : Regulation 882/2004

3.1.1 Regulation 882/2004 deals with arrangements for the monitoring of compliance with, and the enforcement of animal health and animal welfare rules, as well as 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. Regulation 882/2004 also provides the legal basis for the European Commission to carry out assessments of the effectiveness of national enforcement arrangements.

3.1.2 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 legal requirements that businesses and farmers must comply with remain unchanged.

3.1.3 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.

3.1.4 SEERAD has responsibility in Scotland 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. The other UK Administrations have this responsibility in England, Wales and Northern Ireland. The 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.

3.2 Draft Scottish Statutory Instrument (SSI) : The Official Controls (Animals, Feed and Food) (Scotland) Regulations 2007

3.2.1 The SSI relates to Scotland 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 SEERAD (identified at paragraph 2.1 above).

3.2.2 Separate legislation has been put in place by the Food Standards Agency for the generality of feed and food aspects. Details of the FSA's legislation, the Official Feed and Food Controls (Scotland) Regulations 2005 (SSI 2005/616), can be found at the Office of Public Sector Information website at the following address: http://www.opsi.gov.uk/legislation/scotland/ssi2005/ssi_20050616_en.pdf

3.2.3 The main provisions of the SEERAD legislation relate to:

- Designation of the Scottish Ministers and local authorities as competent authorities in Scotland 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 Scottish Ministers;](#)
- Powers for Scottish Ministers to require auditors to carry out audits of local authorities¹, and if necessary to require the local authority to assist the auditor;

¹ The term "local authority" in this RIA includes "food authorities".

- Inspectors to 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 Scotland following the results of enforcement checks in another Member State;
- [A mechanism for the competent authorities to charge the costs of official controls dealing with repeated non-compliance where this charging is required in Article 40\(4\) of Regulation 882/2004. Also a mechanism to comply with the requirement set out in Article 28 of Regulation 882/2004 to charge operators responsible for non-compliance for expenses incurred in additional controls to deal with the non-compliance;](#)
- [Powers of entry for officers authorised by a competent authority to enforce the provisions of the Scottish 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;](#)

4. Risk assessment

4.1 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.

4.2 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 Scotland, and other countries of the UK, Regulation 882/2004 would not be fully and effectively applied in the UK.

5. Consultation

5.1 Within Government

5.1.1 SEERAD has consulted with the Food Standards Agency, COSLA and the other UK Administrations during the drafting of the S.S. I. and the RIA.

² The RIA for Regulation 882/2004 on official controls is available on the FSA website at : <http://food.gov.uk/multimedia/pdfs/euhygiene2004riafull.pdf>
<http://www.food.gov.uk/multimedia/pdfs/hyg2005riaeng.pdf>

5.2 Public Consultation

5.2.1 The Department carried out a formal consultation on the implications of the SSI with stakeholders and other interested parties. Eight responses were received. A summary of the responses will be posted on the Scottish Executive website.

6. Options

6.1 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. The options are as follows:

- **Option 1** - Do nothing, i.e. not introduce the proposed Official Controls (Animals, Feed and Food) (Scotland) Regulations 2007. This would mean that certain elements of the EU Regulation could not be applied in Scotland 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 SSI which will ensure that competent authorities in Scotland can fulfil their obligations under Regulation 882/2004.

7. Cost and Benefits

7.1 Sectors and groups affected by the proposed SSI

7.1.1 Most of the provisions of the draft SSI will affect the competent authorities which have responsibility for the execution and enforcement (excluding functions of prosecution) of animal health and animal welfare rules and the small number of feed and food law elements that are the responsibility of SEERAD. Responsibility for monitoring and enforcement in Scotland is held centrally by SEERAD. Day-to-day responsibility for execution and enforcement is often divided between central and local authorities. At the local level, much of the enforcement is carried out by local authorities.

7.1.2 The provisions of Regulation 882/2004 relate to ensuring that monitoring and enforcement of the rules is carried out by the relevant competent authority consistently and on a risk basis. As such Regulation 882/2004 and thereby the implementing legislation which is the subject of this RIA, as well as this RIA, do not, in the main, relate to the enforcement or monitoring of business activities; they merely address how the enforcement or monitoring is carried out and verified by competent authorities. Farmers and other food businesses will be required to give access to auditors to premises and powers are given for this. There are, however, no significant direct requirements on farmers or other food business operators from either Regulation 882/2004 or the Scottish implementing regulations.

8. Benefits

Option 1

8.1 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

8.2 The Regulation will provide the legal basis to ensure full compliance with Regulation 882/2004. 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.

8.3 In particular, the SSI will ensure that SEERAD is able to provide information to the European Commission on enforcement arrangements and activity (including information on the performance of the enforcement authorities) in Scotland 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.

8.4 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.

9. Costs

9.1 Costs for competent authorities

Option 1

9.1.1 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

9.1.2 The main provisions of the SSI in relation to carrying out official controls are considered to be cost neutral. The principal provisions simply designate Scottish Ministers 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.

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

9.1.4 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 Scottish regulations would introduce a provision whereby Scottish Ministers could require an auditor to carry out audits of a local authority as 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 SEERAD 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 Scottish Ministers 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.

9.1.5 In addition, the SSI makes provision for Scottish Ministers to arrange for the FSA to carry out audits in relation to the areas covered by the SSI. Under these circumstances the FSA auditors would rely on powers under the Official Feed and Food Controls (Scotland) Regulations 2005. There would be a cost to SEERAD in charges by the FSA for carrying out this work. 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.

9.1.6 The Commission has developed guidelines on the criteria for the conduct of official control audits. These guidelines were published as a Commission decision on 29 September 2006: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_278/l_27820061010en00150023.pdf

9.2 Costs for business

9.2.1 There are no discernable 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.

9.2.2 The SSI 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. We do not therefore envisage any significant increase in the level of on-farm or other business premises' visits and therefore no additional associated costs. However, it is impossible at this stage to assess the likely number of such on-site audits. It is believed though 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. However, 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.

9.2.3 In order to try 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.

9.2.4 The SSI 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 food business operator.

10. Issues of equity and fairness

10.1 The SSI will enable SEERAD to fulfil its legal commitments in relation to the implementation of European law. There are no implications in respect of equity or fairness.

10.2 The SSI will not have any impact on economic, social or environmental sustainability issues.

11. Small Firms' Impact Test

11.1 There are no discernible 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.

11.2 No new business forms will be introduced by the legislation.

12. Competition Assessment

12.1 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.

13. Enforcement and sanctions

13.1 The main provisions of the SSI are enabling powers to allow the competent authorities in Scotland to fulfil certain requirements in Regulation 882/2004.

13.2 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 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.

13.3 In addition, the Commission's inspection services will undertake controls to ensure that enforcement arrangements in Scotland, and the other countries of the UK, are complying fully with the requirements in Regulation 882/2004.

13.4 Responsibility for monitoring and enforcement in Scotland is held centrally by SEERAD. Day-to-day responsibility for execution and enforcement is often divided between central and local authorities. At the local level, much of the enforcement is carried out by Local Authorities. The draft SSI makes it an offence to obstruct auditors, inspectors and those accompanying them, and enforcement officers. There is also an offence of providing false or misleading information to an auditor, an inspector or an enforcement officer. The penalty on summary conviction for offences is a fine at level 5 on the standard scale (currently £5000) or 3 months imprisonment or both.

14. Monitoring and review

14.1 The effectiveness of the SSI will be monitored via feedback from enforcement authorities and other stakeholders as part of the on-going policy process.

14.2 The preparation of the annual enforcement control reports for the Commission will provide a more formal means of monitoring and reviewing the effectiveness of the SSI.

14.3 In addition, the Commission is to undertake a review of the application of Regulation 882/2004 by 20 May 2007. The review will in particular consider a re-evaluation of the scope of Regulation 882/2004 in respect of the animal health and welfare requirements.

14.4 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 the place as well as those under the Official Controls (Animals, Feed and Food) (Scotland) Regulations 2007.

15. Legal Aid Impact Test

15.1 A legal aid impact test has been applied to the independent powers of entry etc. for auditors and others for the purposes of the Regulation, as well as the obstruction and provision of false or misleading information offences associated with those powers. No implications for the courts 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.

16. Summary and recommendation

16.1 The SSI will ensure that those elements of Regulation (EC) No. 882/2004 which need to be given effect by domestic legislation will be applied in Scotland. 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 in the SSI do not introduce any new or significant costs to the competent authorities or to feed or food businesses.

17. Declaration

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

Signed:..... Date:.....

Ross Finnie, Minister for Environment and Rural Development

Contact Point:

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