

Background

EU Regulation 882/2004 on official controls¹

4. The proposed SI (Appendix 1) is required to apply certain elements of EU Regulation 882/2004 on official controls. The EU Regulation is about arrangements for enforcement of feed and food law requirements and animal health and animal welfare rules. It sets out the general approach that must be taken, and the principles that must be adopted, by the authorities in EU Member States that have responsibility for monitoring and enforcing this legislation (i.e. the 'competent authorities' responsible for organising and undertaking 'official controls'). It also establishes a framework for financing of official controls. In addition, it provides the legal basis for the European Commission to assess the effectiveness of national enforcement arrangements. Details of the requirements of the EU Regulation are set out in Annex A to the RIA which is enclosed at Appendix 2 of this letter. The text of the EU Regulation may be downloaded from the European Commission's website at:

http://europa.eu.int/servlet/portail/RenderServlet?search=DocNumber&lg=en&nb_docs=25&domain=Legislation&coll=&in_force=NO&an_doc=2004&nu_doc=882&type_doc=Regulation

Application of EU Regulation 882/2004 in the UK

5. The provisions of the EU Regulation apply from 1 January 2006, except those on financing which apply from 1 January 2007. Although the Regulation is directly applicable, action is needed to give it effect in the UK. Given the wide scope of the EU Regulation, responsibility for applying it is divided; the Food Standards Agency (FSA) has overall responsibility for the feed and food elements; and, the Department for Environment, Food and Rural Affairs (Defra) and the devolved Agriculture Departments, for the animal health and animal welfare aspects.

6. With regard to the feed and food elements, application is being taken forward in two phases to correspond to the 1 January 2006 and 1 January 2007 application dates. This consultation forms a part of the first phase of application. Additional co-ordinated consultation on other aspects of phase 1 application will take place during 2005. Details of this are included at Annex C to the RIA which is enclosed at Appendix 2 to this letter. The second phase of application will be concerned with the financing of enforcement inspections and other controls, and public consultation on the options for application (including options for financing of import controls) will take place in due course.

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.

Details of this consultation

The Official Feed and Food Controls (England) Regulations 2005

7. The draft SI gives effect in England to those feed and food elements of EU Regulation 882/2004 applying from 1 January 2006 for which a domestic legal basis is needed. The provisions of the SI will enable the competent authorities to meet their obligations under the EU Regulation, principally with respect to monitoring and reporting of enforcement activity. Specific provisions are also included for the organisation and enforcement of new rules on checks (official controls) of feed and food of non-animal origin (non-POAO) imported from outside the Community. A summary explaining the principal provisions of the SI is enclosed at Appendix 3 to this letter.

8. Separate SIs are being made in Scotland, Wales and Northern Ireland. These are subject to separate consultation exercises in those countries.

9. ***Your comments on any aspect of the SI are welcome.*** In particular, however, we should be grateful for your views on the following points:

- ***Regulation 3 on competent authorities*** – Both the FSA and Defra have responsibility at central level for official controls. It is, therefore, proposed that a single SI be introduced to apply all the feed and food elements of EU Regulation 882/2004 rather than having an Agency SI and a separate Defra SI. The only exception to this is in the areas of medicated feed and zootechnical additives. In these cases, Defra has been designated as the competent authority for EU Regulation 882/2004 in the Draft Veterinary Medicines Regulations 2005. These draft Regulations are the subject of a separate consultation. Details are available on the website of the Veterinary Medicines Directorate at: <http://www.vmd.gov.uk/>
- ***Regulations 4 and 5 on exchanging and obtaining information*** – These provide a legal basis for the competent authorities to share information and to obtain information and data from private bodies involved in enforcement activities. This is required in order to fulfil obligations in EU Regulation 882/2004 such as on monitoring and reporting on enforcement activity.
- ***Regulation 7 on amending the Food Standards Act 1999*** – This extends to all areas of feed and food law (as defined for the purposes of EU Regulation 882/2004), the FSA's existing function to monitor and audit the performance of the relevant enforcement authorities. As drafted, this presently includes areas of feed and food law for which Defra is the competent authority and/or is responsible for enforcing the legislation. The intention is that these Defra areas will be identified in the revised SI as exceptions to the Agency's function and agreement on responsibility for audit will be reached between the two Departments. The proposed amendment is in the individual territorial SIs but because the Act itself applies UK-wide, consideration is being given to a UK-wide amendment.
- ***Regulation 8 on rights of appeal in relation to approval of feed and food business establishments*** – The requirements for businesses to be approved

are included in the new EU Feed Hygiene and EU Food Hygiene legislation^{2, 3}. The right of appeal is included in this draft SI rather than the SIs applying the feed and food hygiene legislation⁴ because the procedures that the competent authority should follow for approving establishments are set out in EU Regulation 882/2004. The alternative which is being considered is to include them in the SIs implementing the feed and food hygiene legislation.

- **Regulation 23 on suspension of designated points of entry** – This provides powers to the Agency and Defra to suspend the designation of a point of entry that deals with ‘specified products’ (‘high risk’ feed and food of non-animal origin). This is believed necessary to ensure that public and animal health is safeguarded.
- **Regulations 24 to 27 relating to ‘specified products’** – These measures will give effect to the provisions on ‘high risk’ non-POAO feed and food set out in Regulation 882/2004. Such ‘high risk’ products are to be identified at EU level by means of implementing rules.
- **Regulation 33 on serious risk to animal and public health** – This provision is proposed as a mechanism of ensuring that where there is a serious risk to animal or public health, control measures may be put in place rapidly. In particular, it can be used to ensure that Emergency Decisions made at EU level may be implemented in England without delay.
- **Regulation 34 on liability for charges** – This is included to provide a mechanism for charging where: a) fees for imports controls for ‘specified products’ are set in Community legislation (there is not yet any agreement on this but the provision anticipates fees being set); and, b) the enforcement authority incurs costs in respect of actions taken in the case of non-compliance (or suspicion of non-compliance), e.g. costs of detention or destruction of feed or food.
- **Regulation 41 on amending the General Food Regulations 2004** – It is proposed that the draft SI is used as a means of amending the General Food Regulations 2004 such that they implement Article 12 of the EU General Food Law Regulation (178/2002)⁵ which sets out the conditions of export of food to third countries. The amendment provides an associated defence for businesses for products that were sold domestically but were intended for export.

Partial Regulatory Impact Assessment (RIA)

² Regulation (EC) No 1831/2003 of the European Parliament and of the Council laying down requirements for feed hygiene. Official Journal L35, 8.2.2005, 1-22.

³ 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.

⁴ The Food Hygiene (England) Regulations 2005 and The Feed Hygiene (England) Regulations 2005 (both these SIs are currently in draft form).

⁵ 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.

10. A partial RIA for the proposed SI is enclosed at Appendix 2. The purpose of the RIA is to assess and record the likely costs and benefits for enforcement authorities, businesses and consumers of the measures provided in the draft SI.

11. We would welcome your comments on any aspect of the partial RIA. In particular, we would be grateful for any information which will help us to assess the financial impact on both the enforcement authorities and businesses in organising or complying with the requirements for 'high risk' non-POAO feed and food.

Draft FSA Guidance for industry on the import provisions of the SI

12. The Agency has produced draft guidance on the requirements of the SI for importers of non-POAO feed and food from outside the Community – see Appendix 4. The aim is to help businesses to understand what provisions apply to them and to guide them through what is required.

13. We would welcome your comments on whether this guidance is clear and helpful and presented in a way that helps you to understand what the legal requirements are. If there are areas which you think need further explanation or clarification, please let us know.

Draft FSA Guidance Notes for enforcement authorities on the feed and food elements of EU Regulation 882/2004

14. Draft Guidance Notes on the feed and food elements of the EU Regulation have been prepared in Question and Answer format – see Appendix 5. The scope of the Notes is restricted to those aspects of the EU Regulation relating to official controls in respect of feed law and food law. They do not relate to the animal health and animal welfare elements for which Defra and the Agriculture Departments in the devolved countries have responsibility. As the EU Regulation places obligations on those authorities responsible for monitoring and enforcing feed and food law, the Guidance Notes are aimed primarily at these authorities. However, the Notes may also provide useful information for the feed and food industries, and for consumers.

15. Your comments on any aspect of the Guidance Notes are welcome but we would be particularly grateful for views from enforcement stakeholders on the points dealt with at:

- ***Question 21 on the audit/inspection of 'control bodies' by the UK Accreditation Service; and***
- ***Question 48 on the FSA taking on the role as a single liaison body to deal with enquiries for administrative assistance and co-operation with other Member States and with the Commission.***

Enquiries

16. Enquiries relating to the contents of this letter may be addressed to me. My contact details are given in paragraph 3.

Comments on the consultation process itself

17. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to assist us to improve the quality of future consultations, please feel free to share your thoughts with us by using the **Consultation Feedback Questionnaire** which is enclosed at Appendix 6.

18. If any of the mailing information used to send you this letter has changed, please advise us direct using the Feedback Questionnaire.

19. If you would like to be included on future FSA consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Feedback Questionnaire.

Publication of personal data and confidentiality of responses

20. As the publication of responses may include personal data, such as your full name and contact address details, please advise us of any objections to this by fully completing and returning the **Publication of Personal Data Form** at Appendix 7, together with your response to the consultation. Return of this form does not mean that we will treat your response to the consultation as confidential.

21. In accordance with the provisions of freedom of information legislation, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure.

22. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

23. A list of interested parties to whom this letter is being sent appears in Appendix 8. Please feel free to pass this document to any other parties with an interest in the subject matter, or send us their full contact details and we will arrange for a copy to be sent to them direct.

24. A copy of this consultation package is available on our website at www.food.gov.uk, where a summary of the responses received will be published in due course.

25. This consultation has been prepared in accordance with the Cabinet Office's Code of Practice on Consultation, available at: <http://www.cabinet-office.gov.uk/regulation/consultation/code.asp>. The Consultation Criteria have been reproduced within Appendix 9. For details, please contact, Khaleda Ahmed, Room 315B Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8630, e-mail: khaleda.ahmed@foodstandards.gsi.gov.uk

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

Yours faithfully,

Troy Sinclair
Official Control Regulation Implementation Team

Consultation letter enclosures

- Appendix 1: Draft Official Feed and Food Controls (England) Regulations 2005
- Appendix 2: Partial Regulatory Impact Assessment (RIA)
- Appendix 3: Summary of principal provisions of draft SI
- Appendix 4: Guidance for importers of feed and food on the draft SI
- Appendix 5: Guidance notes on the feed and food law elements of Regulation 882/2004
- Appendix 6: Consultation Feedback Questionnaire
- Appendix 7: Publication of Personal Data Form
- Appendix 8: List of interested parties
- Appendix 9: Cabinet Office Consultation Criteria

Partial Regulatory Impact Assessment - Annexes

- Annex A: Requirements of EU Regulation 882/2004 on official controls
- Annex B: New and optional provisions in Regulation 882/2004
- Annex C: Outline of package of measures to apply EU Regulation 882/2004 as regards feed and food controls
- Annex D: Draft Official Feed and Food Controls (England) Regulations 2005 – summary of provisions
- Annex E: Responsibility for enforcement of feed and food law in England