

EU REGULATION ON OFFICIAL FEED AND FOOD CONTROLS – APPLICATION IN THE UK

Executive Summary

1. This paper updates the Board on stakeholder consultation on the application in the UK of the EU Regulation on official feed and food controls.
2. The Board is asked to:
 - **note** on-going developments at EU level regarding detailed implementing rules on official feed and food controls;
 - **note** the outcome of the public consultation on the draft national legislation, associated guidance for importers of products of non-animal origin and Regulatory Impact Assessment, and on general guidance on the EU Regulation;
 - **agree** the way forward as outlined in the table at Annex C;
 - **agree** the proposed approach as the basis for seeking Ministerial agreement to the national legislation;
 - **note** the progress regarding co-ordinated stakeholder consultations on other application measures which apply from 1 January 2006.

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EU REGULATION ON OFFICIAL FEED AND FOOD CONTROLS - APPLICATION IN THE UK

Issue

1. To update the Board on stakeholder consultations on the application in the UK of the new EU Regulation on official feed and food enforcement controls and to seek its agreement to the proposed way forward.

Strategic aims

2. The aim is to apply the new Regulation by means of a flexible and proportionate approach that protects consumers without imposing unnecessary burdens on the enforcement authorities carrying out controls or on the businesses that are subject to them. This may be achieved by working in partnership with our enforcement stakeholders, particularly with local authorities, including port health authorities, and their representative and professional bodies to ensure a committed and co-ordinated approach to enforcement.

Background

3. An information paper (INFO 05/03/01) was provided to the Board in March 2005. This provided a summary of the provisions of EU Regulation 882/2004 on official controls. The Board was asked to note the proposed approach to application in the UK and the arrangements for stakeholder consultation. The paper also highlighted the intention to come back to the Board for discussion on the way forward following this consultation.
4. EU Regulation 882/2004 on official controls for **feed** and **food** law, and **animal health** and **animal welfare** rules was adopted in April 2004. It sets out the approach that competent authorities of Member States must adopt for official controls, i.e. for monitoring and enforcing compliance of businesses with feed and food law and for ensuring that animal health and animal welfare rules are adhered to. This includes a framework for financing of inspections and other enforcement controls. It also sets out how the European Commission, through its Food and Veterinary Office, will check that the national control systems in Member States comply with the requirements of the Regulation. The provisions apply from 1 January 2006, except those on financing which apply from 1 January 2007.

Risk

5. The adoption of EU Regulation 882/2004 changes the legal basis for arrangements for the enforcement of feed and food legislation. The associated risks relate to the potential for misunderstanding and confusion for the enforcement authorities that are familiar with long-standing arrangements. This is being addressed through the provision of appropriate guidance and updated enforcement instructions etc. If no action is taken, however, there is a risk of challenge from the European Commission following inspection by its Food and Veterinary Office of UK arrangements and their compliance with the requirements of the new Regulation. There is also a risk of challenge from third parties such as businesses that believe that they have been disadvantaged by UK failure to apply the EU requirements.

Application of the new Regulation in the UK

6. The FSA has overall responsibility for application in respect of the feed (with its implications for food safety) and food elements of the EU Regulation and has been liaising closely with Defra and the devolved Agriculture Departments, which are dealing with the animal health and animal welfare aspects. Application of the feed and food elements is being taken forward in two phases to correspond to the 1 January 2006 and 1 January 2007 application dates.
7. A series of legal and administrative measures are needed for the first phase of application. Those on which the Agency lead have been subject to a series of co-ordinated public consultations, some of which are now complete and others of which are still underway. Details are provided at Annex A. As highlighted in INFO 05/03/01 the Board will be kept informed with regard to the second phase of application and issues that require decisions will be brought back to the Board in due course.

On-going developments at EU level

8. A number of developments at EU level are having an impact on the application of Regulation 882/2004 in the UK. These relate to the provisions on audit of competent authorities, the preparation of the national control plan and annual reports, and the harmonised rules on import controls of 'high risk' feed and food of non-animal origin (non-POAO) from third countries. All of these represent new requirements at EU level and details of the developments are given at Annex B.

Outcome of consultation on national legislation, guidance material and Regulatory Impact Assessment (RIA)

9. The draft national legislation provides powers to the competent authorities to allow them to fulfil their obligations under the EU Regulation and implements the new rules for controls of third country imports of non-POAO feed and food. Consultations were launched on 31 March and ended on 30 June. The consultation package included associated guidance for importers and a partial RIA. It also included draft guidance for enforcers on the EU Regulation itself. Full details are available on the FSA website.
10. A summary of the responses received on the specific issues on which views were sought, together with details of other significant points raised by stakeholders, is given at Annex C. The majority of comments received related to the provisions for third country import controls for non-POAO and, in particular, to those measures which were included in anticipation of the EU implementing rules for 'high risk' products. The main objection from stakeholders to the Agency's proposals was with regard to the role envisaged for Her Majesty's Revenue and Customs (HMRC) in import controls. The Agency has amended its proposed approach in line with the views expressed on this issue and details are given in paras 11 and 12. Other points for the Board's attention that were raised in the consultation responses, are also considered below.
11. Subject to agreement by the Board, it is proposed that the Agency seeks Ministerial agreement to the national regulations on the basis of the approach set out in the table at Annex C.

Particular issues for Board attention

Import controls for non-POAO

Role of Her Majesty's Revenue and Customs (HMRC)

12. Following initial discussions with interested parties, the FSA envisaged that HMRC would be involved in import controls for non-POAO feed and food and specifically in: undertaking documentary checks; detaining 'high-risk' non-POAO that is not pre-notified or presented at a designated point of entry; and exchange of information on these matters with the relevant control authority. This position was reflected in the draft national legislation on which the Agency consulted.

13. On further consideration, however, HMRC has now concluded that customs officers do not have the necessary technical expertise to undertake documentary checks and that HMRC should not, therefore, be a designated enforcement authority for this purpose. This view was very strongly supported by enforcement stakeholders responding to the consultation. FSA Officials believe that we should accept these views and that such checks should be undertaken by local and port health authorities. This approach also acknowledges concerns expressed by industry stakeholders regarding potential for duplication of effort and confusion between the role of Customs and that of local/port health authorities in checking documentation. HMRC will still be required under Regulation 882/2004 to cooperate closely with the enforcement authorities, particularly with regard to release of consignments and with regard to arrangements for controls of 'high-risk' products once these are in place. FSA officials will continue to work in partnership with local and port health authorities and with HMRC to facilitate this.

Provisions for imports of 'high risk' non-POAO

14. The proposed national implementing legislation anticipated that the EU list of 'high risk' products would have been available by now. It, therefore, included provisions requiring importers to give prior notification to the enforcement authorities of the arrival of consignments and requiring that these must be routed via designated UK ports.

15. Enforcement stakeholders supported these provisions and recognised that these are important in terms of safeguarding public health. Indeed, they believed that the provisions do not go far enough and should be extended to all non-POAO imports and not just to those considered to be 'high risk'. Whilst recognising the need to protect public health, industry stakeholders expressed concern that the arrangements may cause disruption to trade and sought reassurance that products would be identified as 'high risk' on the basis of appropriate risk assessment.

16. As there has been no progress at EU level in establishing the list of 'high risk' non-POAO, it will not be possible at this stage to include the proposed measures in the national legislation as had been anticipated. Nonetheless, in the light of the comments offered during the consultation, it is proposed that once the list of products has been agreed in Brussels, the national legislation will be amended to include them. It is not intended, however, to extend the provisions to all non-POAO as this would be going beyond the requirement of the EU Regulation and would be disproportionate on the basis of risk. Guidance on the practical

application of the measures will be provided to enforcers to ensure that the concerns of all stakeholders are dealt with.

Fees for 'high risk' non-POAO import controls

17. The national legislation anticipated that mandatory fees *may* be introduced under the EU implementing rules. Both industry and enforcement stakeholders supported the introduction of fees but it was highlighted that these must be mandatory across the EU to ensure that trade is not distorted by variations in charging practices. This is in line with the position taken by the UK during the original negotiations and it is intended to pursue this line once the Commission issues its proposals for implementing rules.

Emergency declarations

18. The proposed national legislation also provides a mechanism for ensuring that where there is a serious and imminent risk to animal or public health, control measures may be put in place rapidly. In particular, it may be used to ensure that Emergency Decisions made at EU level may be implemented in the UK without delay. It does so by giving the Agency and Agriculture Ministers powers to make declarations regarding import conditions for particular products. These conditions would apply with immediate effect, and avoid any delay that would have resulted if legislation were to have been made, pending any necessary further legislation.

19. The need for such a mechanism was recognised by enforcement and industry stakeholders. The policy intention, therefore, is to retain this.

Other issues

Co-operation and co-ordination issues

20. A common theme in the consultation responses is the need for co-operation between enforcement authorities and co-ordination to avoid duplication and to ensure consistency in approach, particularly with respect to import controls. Further, the need for transparency with regard to the division of enforcement responsibilities was highlighted.

21. The Agency acknowledges the importance of co-ordination and co-operation and its strategic plan for 2005 to 2010 recognises the need for partnership working to achieve this. The plan emphasises that the FSA will continue to work with local

authorities and their representative and professional bodies to improve consistency and effectiveness of enforcement. In particular, the Agency will continue to work closely with HMRC, the four UK Agriculture Departments and with local and port health authorities to ensure that imported food controls are in place at borders and inland. This will build on and aim to strengthen existing avenues of communication and co-operation which are already well developed (e.g. the 'Step change' project on improving the co-ordination and delivery of imported food controls).

22. Consultation responses on co-ordination and co-operation issues will be taken into account in revising the draft guidance on import controls for importers and that for enforcers. The Agency's *Local Authority Resource Pack on Import Controls* will be reviewed. In the wider context, further consideration will be given to the provisions on co-operation in the review of the *Food Law Code of Practice* for local authorities to reflect the requirements of the new food hygiene legislation and those of the official control regulation, and also in the Code of Practice for feed law which is currently being drafted and will be subject to consultation beginning in September 2005.

23. With regard to transparency about responsibilities, a detailed description of the system for feed and food controls in the UK will be required as part of the national control plan (see para 8) and the intention is that relevant information from this will be published.

Audit of competent authorities

24. The FSA's current audit schemes covering the MHS, DARD's Veterinary Service and local authorities generally comply with the Commission's proposed guidelines (see para 7). However, the requirement to audit all authorities across all their activities within a five year period is not met in respect of local authority feed and food law enforcement services in England. To introduce such a programme would have a significant financial impact on the FSA. In view of this, and subject to stakeholder views, it is proposed that the UK continues to press for a risk-based and proportionate approach allowing flexibility on the focus of the audit programme. It will be important to ensure that the guidelines take account of the various enforcement arrangements in the different Member States.

Impact

25. Delivery of the necessary national legislation, guidance material for industry and enforcers will contribute towards the FSA fulfilling its obligations to apply the EU Regulation properly and effectively. At this stage, it is still not clear whether the Commission guidelines will have an impact on current audit arrangements that the FSA has in place but officials will work with local authority partners to ensure that any impact is minimised. The preparation of the national control plan and annual reports is the other main issue that may have an impact on the FSA but until the Commission issues its guidelines, it is difficult to assess what the extent of that impact may be.

Conclusion

26. The approach being proposed to application of the new EU official control Regulation seeks to ensure a flexible and proportionate approach to official controls that is compatible with ensuring consumer protection and effective food safety.

Board action required

27. The Board is asked to:

- **note** on-going developments at EU level regarding detailed implementing rules on official feed and food controls;
- **note** the outcome of the public consultation on the draft national legislation, associated guidance for importers of products of non-animal origin and Regulatory Impact Assessment, and on general guidance on the EU Regulation;
- **agree** the way forward as outlined in the table at Annex C;
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- **note** the progress regarding co-ordinated stakeholder consultations on other application measures which apply from 1 January 2006.

PROGRESS ON PACKAGE OF MEASURES TO APPLY EU REGULATION 882/2004 AS REGARDS FEED AND FOOD CONTROLS

The proposed package of measures for applying the EU Regulation is outlined below. Progress on taking these forward is also noted. For those measures that do not apply UK or GB wide, individual measures are being developed in England, Scotland, Wales and Northern Ireland as indicated.

Measure	Progress
Legal measures	
<p>Official feed and food controls SI (FSA lead) <i>Separate legal instruments are being developed in England, Scotland, Wales and Northern Ireland.</i></p> <p>These instruments include general provisions to ensure that the FSA's powers relating to audit and monitoring of enforcement activity are extended to cover responsibilities of enforcement authorities under Regulation 882/2004. They also apply the provisions in Regulation 882/2004 on official controls of third country imports of non-POAO.</p> <p>An associated Regulatory Impact Assessment has been developed.</p>	<p>Consultations in each country took place from 31 March to 30 June 2005.</p> <p>Regulations scheduled to come into force on 1 January 2006.</p>
<p>Feed (hygiene and enforcement) SI (FSA Lead) <i>Separate legal instruments are being developed in England, Scotland, Wales and Northern Ireland.</i></p> <p>The instruments include provisions to meet certain requirements of Regulation 882/2004 relating to the enforcement of animal feed legislation.</p>	<p>Consultations in each country took place from 1 June to 24 August 2005.</p> <p>Regulations scheduled to come into force on 1 January 2006.</p>
<p>'Bridging SI' (FSA lead) <i>This is a Westminster SI which is needed to provide certain transitional measures in Scotland.</i></p> <p>A transitional measure is needed to apply Regulation 882/2004 in respect of certain 'non-medicinal' zootechnical additives until a transfer of competence to Scottish Ministers is effected by means of a Scotland Act Order.</p>	<p>This policy issue was covered by the consultations on the Scottish SI on official feed and food controls - 31 March to 30 June 2005.</p> <p>SI scheduled to come into force on 1 January 2006.</p>

Measure	Progress
<p>Amendment of legislation on specified feed (zootechnical) additives and medicated feed (VMD lead)</p> <p><i>UK wide measure</i></p> <p>Legal measures needed to apply Regulation 882/2004 in this area have been incorporated into the <i>Veterinary Medicinal Products Regulations 2005</i> and, specifically into Schedule 5 on medicated feedingstuffs and specified feed additives.</p>	<p>Consultations took place from 4 January to 5 May 2005 and from 17 May to 8 August 2005.</p> <p>FSA provided a response that highlighted issues for VMD to consider with a view to ensuring consistency of approach.</p> <p>The new Regulations will replace all existing UK legislation on veterinary medicines. Although most provisions will come into force on 30 October 2005, those on zootechnical additives and medicated feed will come into force on 1 January 2006 in line with Regulation 882/2004.</p>
<p>Amendment of the Products of Animal Origin (Third Country Import) Regulations (Defra/devolved Agriculture Departments lead)</p> <p>Some minor technical amendments are needed to implement Regulation 882/2004.</p>	<p>Amended Regulations scheduled to come into force on 1 January 2006.</p>
<p>Amendments to pesticides legislation (PSD lead)</p> <p><i>UK wide measure</i></p> <p>Some minor amendments may be needed to implement Regulation 882/2004.</p>	<p>The most appropriate way of applying Regulation 882/2004 is currently being given consideration.</p>
<p>Administrative measures</p>	
<p>Code of Practice/Practice Guidance for English local authorities (FSA lead)</p> <p><i>Codes/practice guidance applying in Scotland, Wales and Northern Ireland are also being updated.</i></p> <p>Some updating of the Food Safety Act 1990, Section 40 Code of Practice (and associated Practice Guidance) for local authority food law enforcement is proposed. The Code is also to be made under the new official feed and food control (OFFC) SI (and new hygiene regulations) so that it extends to the responsibilities of local authorities under Regulation 882/2004 (and that it reflects the new food hygiene regulations).</p>	<p>Consultations took place in England from 16 May to 8 August and in Wales from 2 June to 25 August, and responses are currently being analysed.</p> <p>The Codes for Scotland, Wales and Northern Ireland are currently being updated and consultations will begin in due course.</p>

Measure	Progress
<p>Code of Practice for Local authority/DARD feed law enforcement (FSA lead) <i>Consideration will be given to developing separate Codes for England, Scotland, Wales and Northern Ireland as drafting progresses.</i></p> <p>A new Code of Practice for feed law enforcement is being prepared following a recommendation to the UK by the Commission's Food and Veterinary Office. It is proposed that this is drafted to reflect the general requirements for local authorities under Regulation 882/2004.</p>	<p>Consultation has been postponed to enable the draft Code to be updated to take account of with new and forthcoming legislation. External consultation will now commence in September 2005.</p>
<p>Framework Agreement of Local Authority Food Law Enforcement (FSA Lead) <i>UK wide measure</i></p> <p>Some updating of the Framework Agreement is proposed so that it reflects the revised Food Safety Act Code of Practice and the new Code on feed (see above).</p>	<p>Review to be undertaken by December 2005, consulting with stakeholders as necessary.</p>
<p>Border Inspection Post Manual (Defra/DARD in NI lead) <i>UK wide measure</i></p> <p>This includes enforcement instructions for the authorities responsible for controls on third country imports of POAO. Some updating of the Manual is proposed to ensure that it reflects the general requirements of Regulation 882/2004.</p>	<p>The manual is updated on a six monthly basis, with the next update due in January 2006. It is anticipated that this will incorporate guidance in respect of the application of 882/2004 and the consequent changes to Products of Animal Origin (Third Country Import) Regulations.</p>
<p>Meat Hygiene Service (MHS) Manual for Official Controls (MHS lead) <i>As far as possible this will be the basis for a UK document with changes in NI to reflect services provided by DARD Veterinary Service.</i></p> <p>This is being revised in the light of the new food hygiene legislation. The revision will also take account of the general provisions for enforcement authorities in Regulation 882/2004.</p>	<p>Consultation took place on the MHS Manual from 9 May to 5 August 2005 and on the instructions for the DARD Veterinary Service from 23 May to 12 August. Responses are currently being analysed.</p>
<p>MHS Service Level Agreements (MHS lead) <i>GB measure. Similar revisions will be required to the Service Level Agreement between FSA-NI and DARD's Veterinary Service.</i></p> <p>MHS Service Level Agreements with the FSA/Defra and devolved Agriculture Departments are being revised to ensure that they take account of the general requirements for enforcement authorities in Regulation 882/2004 and also the new food hygiene legislation</p>	<p>To be finalised following consultation on MHS Manual for official controls/DARD instructions, and in place by 1 January 2006.</p>

Measure	Progress
<p>Dairy Hygiene Inspectorate (DHI) enforcement instructions (FSA lead) <i>England and Wales measure. In Scotland - Dairy Hygiene Inspection instructions to Local Authorities are contained in Enforcement Codes of Practice and this will similarly need to be revised. In Northern Ireland, similar instructions will be issued to DARD's Quality Assurance Branch.</i></p> <p>These instructions are being revised in the light of the new food hygiene legislation. The revision will also take account of the general provisions for enforcement authorities in Regulation 882/2004.</p>	<p>Consultation took place from 23 May to 23 August 2005 and responses are currently being analysed.</p>
<p>DHI Service Level Agreement with FSA (FSA lead) <i>England and Wales measure. Similar revisions will be needed to the Service Level Agreement between FSA-NI and DARD's Quality Assurance Branch.</i></p> <p>This Service Level Agreement is to be revised to ensure that it takes account of the general requirements for enforcement authorities in regulation 882/2004 and also the new food hygiene legislation.</p>	<p>The new SLA has been prepared and is ready for signing. It will take effect on 1 January 2006.</p>
<p>FSA agreement with the UK Accreditation Service (FSA lead) <i>UK-wide measure.</i></p> <p>It is proposed to revise this and extend the role of UKAS to audit official food laboratories and, in due course, to accredit/audit official feed laboratories.</p>	<p>Consultation on the proposal to extend the role of UKAS for food laboratories formed part of the packages issued on 31 March 2005.</p>
<p>General guidance on Regulation 882/2004 (FSA lead) <i>UK wide measure.</i></p> <p>It is proposed that general guidance on the Regulation will be developed. This will, principally be aimed at the enforcement authorities but will also available to all stakeholders.</p>	<p>Consultation on the proposed guidance formed part of the packaged issued on 31 March 2005.</p>

Measure	Progress
<p>Guidance on imported food controls for enforcers and for industry (FSA lead) <i>Existing guidance for enforcers is UK –wide.</i> <i>Guidance for importers on the provisions in the new OFFC SIs will be prepared separately for England, Scotland, Wales and Northern Ireland.</i></p> <p>The existing guidance for enforcers on imported food controls will be revised to reflect the new requirements for import controls in Regulation 882/2004. This will form part of the Practice Guidance (see above).</p> <p>Guidance is being produced for industry on the effects of the imports provisions in the OFFC national SIs.</p>	<p>Guidance for enforcers –consultation took place from 16 May to 8 August 2005.</p> <p>Guidance for industry - consultation took place from 31 March to 30 June 2005.</p>

**ON-GOING DEVELOPMENTS IN EUROPE IN RELATION TO REGULATION
882/2004**

Commission guidelines for audit of the competent authorities

1. In July 2005 the Commission issued draft guidelines for the conduct of audits of the competent authorities involved in undertaking official controls. The guidelines are non-binding but, nonetheless, Member States are required to take account of them. In general, the guidelines accord with accepted good audit practice. The audit programme should be risk-based and a systemic approach to the audit process should be adopted. Reporting should be balanced to include positive findings as well as areas for improvement. The process should be subject to independent scrutiny and transparency for all relevant stakeholders is considered important. The Commission is also advocating that all competent authorities should be audited across all their activities within a five year period. This last point seems inconsistent with a risk-based approach.
2. Stakeholder views on this have been sought (the consultation package is available on the FSA website at:
<http://www.food.gov.uk/foodindustry/Consultations/ukwideconsults/euregs8822004uk> and these will help inform the UK position. The Commission plans to adopt its guidelines at the 20/21 September 2005 meeting of the Standing Committee on the Food Chain and Animal Health.

Commission guidelines on national control plans and annual reports

3. The Commission has not yet issued a draft of its guidelines but this is expected imminently. Like the audit guidelines, these will be non-binding but Member States will be required to take account of them in preparing their plans and reports. The Commission has indicated that the emphasis will be on providing a detailed description of the control system and a clear breakdown of responsibilities between the different competent authorities. Key issues for the Commission will be the arrangements for audit of competent authorities and the mechanisms in place for ensuring co-ordination and co-operation within and between the different authorities.

4. The Agency will consult with stakeholders as soon as a draft is available. The views expressed will help inform the UK position when the document is discussed by the Member States which is expected to be at a meeting in September.

Third country imports of 'high risk' feed and food of non-animal origin

5. Paper INFO 05/03/01 highlighted that Regulation 882/2004 introduces harmonised rules for third country imports of feed and food of non-animal origin (non-POAO). For those considered 'high risk', the requirements are to be similar to those that currently apply to animal products (importers will be required to pre-notify the relevant enforcement authority of the arrival of consignments and will be required to import these via specific designated ports). EU implementing rules are to be established to identify these 'high risk' products and to specify the level of controls that these should be subject to. Mandatory fees for these controls are to be considered at the same time. Although the Commission indicated last year that this was a priority area, no proposals have yet been issued and are not now expected until October at the earliest. Consequently, these measures are very unlikely to be in place, as had been expected, by 1 January 2006. We cannot legislate at the national level until the EU rules are in place. However, current safeguard measures will continue to apply and further measures may be introduced under the provisions of the EU General Food Law Regulation (178/2002) such that public and animal health protection will not be compromised by the delay.

EVALUATION OF THE RESPONSES TO THE CONSULTATION ON THE OFFICIAL FEED AND FOOD CONTROLS REGULATIONS 2005, ASSOCIATED GUIDANCE FOR INDUSTRY ON IMPORTS PROVISIONS AND RIA, AND ON THE GENERAL GUIDANCE FOR ENFORCERS ON EU REGULATION 882/2004

Executive summary

1. Separate consultations were undertaken in England, Scotland, Wales and Northern Ireland. The full consultation packages are available on the FSA website at:

<http://www.food.gov.uk/foodindustry/Consultations/consulteng/feedfoodcontrols>

<http://www.food.gov.uk/foodindustry/Consultations/consultscot/feedfoodscot>

<http://www.food.gov.uk/foodindustry/Consultations/consultwales/feedfoodcontrols/wales>

<http://www.food.gov.uk/foodindustry/Consultations/consultni/feedfoodni>

2. The consultation packages were sent direct to 944 interested parties in England, 230 in Scotland, 102 in Wales, and 450 in Northern Ireland. In addition, the packages were posted on the FSA website to reach a wider stakeholder base and heads of Service in local authorities were sent the website link. Given the broad scope of the EU Regulation such a wide consultation was considered appropriate.
3. Responses were received from 21 stakeholders in England, 11 in Scotland, one in Wales and five in Northern Ireland. Although the response rate was low, comments were received from key enforcement and industry stakeholders potentially affected by the main provisions in the legal instruments, i.e. those relating to third country imports of feed and food of non-animal origin. Taking all the responses together, 45% were from enforcement bodies, 37% from industry and 18% from other interested parties.
4. Responses are summarised in the table overleaf in terms of the specific questions or issues on which comments were requested. The range of views expressed are described and, where respondents raised significant concerns or

expressed a view contrary to the approach suggested, these are attributed to the stakeholder concerned.

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

Summary of consultation responses

Question/issue raised in consultation	Summary of responses	FSA evaluation/proposed way forward
<u>Comments on the proposed legislation</u>		
<p>1. Designation of competent authorities</p> <p>As both the FSA and Defra/the devolved Agriculture Departments have responsibility at central level for official controls relating to feed and food law, it was proposed that a single legal instrument be introduced in each country of the UK to apply EU Regulation 882/2004 in respect of all the feed and food law elements. 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.</p> <p>Given the role envisaged for Customs in official controls of third country imports of feed and food of non-animal origin (non-POAO), it was also proposed that Her Majesty's Revenue and Customs (HMRC) would also be designated as a competent authority.</p>	<p>Those stakeholders that commented all agreed that a single legal instrument would be sensible given that the aim of the new EU Regulation is to develop more integrated control systems.</p> <p>It was highlighted, however, that the roles and responsibilities of the various authorities involved and the relationships between them is complex and can be confusing. It was suggested that clarification for stakeholders was needed.</p> <p>With regard to designation of HMRC as a competent authority in respect non-POAO import controls, neither enforcement stakeholders nor HMRC itself favoured this. In addition, industry stakeholders expressed concern that such arrangements would lead to duplication of effort and potential confusion over responsibilities - see also point 5 below.</p>	<p>Following further discussions with Defra and the devolved Agriculture Departments, in the interests of transparency, it is now proposed that the FSA legal instruments should have a narrower scope and apply Regulation 882/2004 as it relates to 'feed' and 'food' only (rather than more widely to 'feed law' and 'food law'). Defra and the other Agriculture Departments do have some responsibilities for 'feed' and 'food' (e.g. organic products, and beef labelling). However, these Departments now plan to undertake further and more detailed consultation with stakeholders with respect to these areas. Once that consultation is complete, the FSA instruments may be amended so that all the feed and food elements of Regulation 882/2004 are covered in a single instrument in each country of the UK. Alternatively, Defra and the devolved Agriculture Departments may make separate legislation as they will also be legislating for the other aspects of feed and food law (i.e. those measures that relate to animal health and welfare issues) as well as other animal health and welfare rules.</p> <p>A full description of the division of responsibilities for all official feed and food controls will be required for the multi-annual national control plan that the UK must prepare under EU Regulation 882/2004. It is</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation/proposed way forward
		<p>proposed that relevant information from this is made available to stakeholders.</p> <p>The FSA accepts the views expressed by stakeholders and will not designate HMRC as a competent authority (see point 5 below).</p>
<p>2. Exchanging and obtaining information</p> <p>It was proposed that a legal basis was provided to permit competent authorities to share information and allow them to obtain information and data from private bodies involved in enforcement activities so that they may fulfil their obligations under EU Regulation 882/2004 such as on monitoring and reporting on enforcement activity and production of the UK multi-annual control plan and annual reports to the Commission.</p>	<p>Those stakeholders that commented, supported these provisions. Concerns about potential problems with data protection issues were highlighted by one respondent.</p>	<p>The provisions in the SI are secondary legislation and so do not override the provisions of primary legislation such as the Data Protection Act.</p>
<p>3. Powers in relation to audit of competent authorities</p> <p>It was proposed that the provisions in the Food Standards Act 1999 which give the Agency the function of monitoring and auditing the enforcement activity of the enforcement authorities be extended to reflect the scope of EU Regulation 882/2004 - i.e. all feed law and food law. Defra responsibilities for 'feed law' and 'food law' would be identified as exceptions to the Agency's function and agreement on responsibly and arrangements for audit reached between the two Departments.</p>	<p>Those stakeholders that commented agreed with the proposals.</p>	<p>It has been recognised that the need to define those areas of feed and food law for which Defra and the devolved Agriculture Departments are responsible, for the purposes of excluding them from the Agency's function, is extremely complex. In addition, the possibility of changes in responsibility between Departments may not be discounted. In view of this, it has been concluded that amendment of primary legislation is not the best way forward. Instead, a more practical solution would be to retain the current powers in the 1999 Act and create parallel provisions in the secondary legislation (that may be more easily amended) to cover other aspects of feed and food law for which the Agency is responsible.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation/proposed way forward
<p>4. Rights of appeal in relation to approval of feed and food business establishments</p> <p>The requirements for businesses to be approved are included in the new EU feed hygiene and food hygiene legislation but the procedures that the competent authority should follow for approving establishments are set out in Regulation 882/2004. In view of this, it was proposed that the right of appeal in relation to approvals is included in the national OFFC legislation rather than that applying the hygiene legislation.</p>	<p>Industry stakeholders welcomed the inclusion of the right of appeal but did not express a preference for the legal instrument in which this should be included. Enforcement stakeholders, however, suggested that the rights of appeal should be included in the national legislation implementing the EU legislation on feed and food hygiene.</p>	<p>It is proposed that the right of appeal as regards decisions relating to approval of <i>feed establishments</i> is moved to the national legislation implementing the EU feed hygiene Regulation as this already includes appeals in relation to registration of feed establishments.</p> <p>It is, however, proposed that the right of appeal in relation to <i>food establishments</i> is retained in the OFFC regulations as there is no similar need for a right of appeal in respect of registration.</p>
<p>5. Responsibilities for enforcement</p> <p>It was proposed that HMRC would be designated as an enforcement authority with the role undertaking documentary checks of non-POAO imported from third countries.</p>	<p>HMRC do not believe that customs officers have the necessary technical expertise to check feed and food documentation, and so do not believe that HMRC should be designated as an enforcement authority for documentary checks.</p> <p>Respondents representing the interests of port health authorities and environmental health officers (APHA, Corporation of London and CIEH¹) strongly supported the HMRC view.</p> <p>Industry stakeholders expressed concern about customs involvement and about the potential for duplication of effort and confusion.</p>	<p>In the light of the comments received, it is intended to accept that Customs Services should not take on this role. The situation with respect to feed is more complicated than for food in that Customs are required under existing legislation (Directive 95/53) to carry out such checks (although there are issues around the consistency with which this role is fulfilled). Directive 95/53 is, however, being revoked so it would be difficult to continue to legislate but it is considered that it is worth pursuing discussions with LACORS and HMRC with a view to addressing the issue through an Memorandum of Understanding.</p>

¹ APHA = Association of Port Health Authorities, CIEH = Chartered Institute of Environmental Health officers.

Question/issue raised in consultation	Summary of responses	FSA evaluation/proposed way forward
<p>6. Deferred enforcement and execution</p> <p>These powers allow the enforcement authority at the point of entry to defer enforcement to an inland authority. This might sometimes be necessary if specific facilities are required for examination of consignments. The powers may be used for any third country imports of feed and food of non-animal origin including those that are identified as 'high risk' feed and food of non-animal origin. The provisions essentially continue existing provisions for deferred enforcement in the current national rules on imported food ² which will be revoked by the new legislation.</p>	<p>The CIEH and APHA opposed this provision in respect of 'high risk' non-POAO on the basis that controls would be outside a customs controlled area and enforcement authority staff would not have the manpower or resource or specific expertise to control these consignments in most cases.</p>	<p>This provision is regarded as a flexibility that may work to the advantage of the enforcement authorities.</p> <p>For now, it will apply only for 'low risk' non-POAO as 'high risk' products will not be covered by the legislation at this stage. - see point 7 below. The FSA will revisit the issue with regard to 'high risk' products when the EU proposals are issued and will liaise further with stakeholders at that time.</p>
<p>7. Provisions on 'high risk' non-POAO from third countries</p> <p>Various measures were proposed to 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.</p>	<p>The majority of comments on these provisions were about the practical application of the measures and technical points about interpretation.</p> <p>The principles, of requiring prior notification and importation at designated ports were recognised as important measures for public and animal health protection.</p> <p>Enforcement stakeholders believed that such provisions should be extended to all non-POAO feed and food.</p> <p>Industry stakeholders were concerned about the potential for disruption of trade and also urged quick progress on identifying the 'high risk' products.</p>	<p>As there has been no progress at EU level with regard to 'high risk' non-POAO, it will not be possible at this stage to include the proposed measures in the domestic legislation.</p> <p>Nonetheless, in the light of the comments offered during the consultation, it is proposed that once the list of products has been agreed in Brussels, the national legislation will be amended to include the provisions envisaged.</p> <p>It is not intended, however, to extend the provisions to all non-POAO as this would be going beyond the requirement of the EU Regulation and is contrary to the UK negotiating line which recognised that such a regime presents practical difficulties, particularly at road borders, and has</p>

² Imported Food Regulations 1997, SI 1997 No 2537.

Question/issue raised in consultation	Summary of responses	FSA evaluation/proposed way forward
		<p>significant cost implications for the enforcement bodies and industry.</p> <p>Guidance on import controls will be amended to reflect the practical application of the measures once these are in place in order to address the concerns about disruption of trade etc.</p>
<p>8. Powers to make declaration in cases of serious risk to animal and public health</p> <p>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 without delay.</p>	<p>Comments on these provisions were principally about the practical application of this measure. The need for the measure was recognised by both enforcement and industry stakeholders.</p>	<p>The policy intention is to retain this measure. Although this mechanism may be used for EU decisions relating to 'high risk' non-POAO in the future under Regulation 882/2004, it may also be used in respect of safeguard measures adopted at EU level under Regulation 178/2002.</p>
<p>9. Liability for charges</p> <p>This is included to provide a mechanism for charging where: a) fees for imports controls for 'high risk' non-POAO 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.</p>	<p>A range of views on charging for 'high risk' products were expressed. There is concern that unless fees are mandatory across the Community, different arrangements in different Member States will distort trade patterns.</p>	<p>As 'high risk' products will not be covered in the national legislation at this stage, the enabling power to charge for controls will be taken out for now. It is proposed that the FSA continues to press at EU-level for mandatory charges for these products as this is in line with arrangements for POAO that are similarly considered to represent a 'high risk'. It is also consistent with the negotiating line agreed across Whitehall at Ministerial Level for the negotiations on Regulation 882/2004.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation/proposed way forward
<p>10. Implementation of Article 12 of the EU General Food Law Regulation (178/2002)</p> <p>It was proposed that the national OFFC legislation 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) 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.</p>	<p>Those respondents that commented, agreed with this proposal.</p>	<p>This provision will be retained.</p>
<p><u>Comments on the Partial Regulatory Impact Assessment</u></p>		
<p>11. Costs</p> <p>Stakeholders were requested to provide information to help us to assess the financial impact on both the enforcement authorities and businesses in performing official controls or complying with the requirements for 'high risk' non-POAO feed and food.</p>	<p>Both industry and enforcement stakeholders commented that the estimated costs of implementing the provisions on 'high risk' non-POAO import controls were too low. However, respondents did not feel able, at this stage, to provide any additional costings as it is not yet clear how extensive the list of such products will be.</p>	<p>Officials will continue to liaise with stakeholders as this matter progresses in Brussels so that further and accurate estimations may be made.</p>
<p><u>Comments on the Guidance Notes for enforcers on the feed and food elements of Regulation 882/2004</u></p>		
<p>12. Role of UKAS</p> <p>Stakeholder views were sought on a proposal to amend the FSA/UKAS agreement to extend the role of UKAS to undertake the audit or inspection of those official control laboratories that are privately run.</p>	<p>The Association of Public Analysts highlighted that privately owned Public Analyst Laboratories and Local Authority Laboratories undertaking commercial work should be treated in the same manner.</p> <p>The Association also questioned the proposed extended role of UKAS given that the accreditation process already includes auditing.</p>	<p>Although audit is part of the accreditation process, this does not cover performance against the requirements of specific Regulations etc. It is proposed that officials will work closely with both the Association of Public Analysts and with UKAS to establish how best to incorporate this aspect.</p>

Question/issue raised in consultation	Summary of responses	FSA evaluation/proposed way forward
<p>13. Liaison body arrangements</p> <p>Stakeholder views were sought on a proposal that the liaison body function should be undertaken by the Agency under the new arrangements.</p>	<p>Stakeholders supported this proposal. LACORS currently undertakes this function with regard to food and highlighted that feedback from stakeholders suggested that there is a high level of satisfaction and that local authorities will and should expect the same level of service from the FSA.</p>	<p>In view of the extended role, it is proposed that the FSA provides the liaison body function.</p>
<p><u>Comments on Guidance for importers</u></p>		
<p>14. Format and content</p> <p>Stakeholder views were sought on the format and content of the guidance.</p>	<p>Both industry and enforcement stakeholders suggested that this guidance also needed to cover the requirements in Regulation 882/2004 and that some points were not clear.</p>	<p>Officials are reflecting on the points made and will revise the document in the light of these.</p>