EXPLANATORY MEMORANDUM TO

THE ANIMAL FEED (ENGLAND) REGULATIONS 2010

2010 No. 2503

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the Instrument

2.1 The Regulations will provide for the enforcement in England of European Parliament and Council Regulation (EC) No. 767/2009 of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation(EC) No (1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directive 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC. ("Regulation 767/2009").

2.2 The Regulations will also provide for the continuing enforcement of Regulation (EC) No. 1831/2003 on additives for use in animal nutrition, and for the continuing implementation of Directive 2002/32/EC on undesirable substances in animal feed and 2008/38/EC establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes.

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

3.1 None.

4. Legislative Context

4.1 Regulation 767/2009 is part of the Commission's modernisation and simplification programme, which replaces five separate Directives in this area and brings their provisions together in one comprehensive document. It is intended to ensure the harmonised application of feed labelling provisions throughout the EU and facilitate the functioning of the internal market by simplifying certain technical requirements. The Regulation also removes a number of burdens on the feed industry, in particular an existing requirement for a dossier assessment of new bioprotein products before they are brought to market and the compulsory percentage declaration of the ingredients of compound feed. The Regulation also introduces two voluntary measures, a Catalogue of feed materials and Codes of Practice for good labelling, which are expected to achieve the same harmonised results as at present but without the need for prescriptive legislation.

5. Territorial Extent and Application

5.1 This instrument applies to England. Separate but parallel legislation is being made in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

The Parliamentary Under-Secretary of State for Public Health has made the following statement regarding Human Rights:

In my view the provisions of the Animal Feed (England) Regulations 2010 are compatible with the Convention rights.

7. Policy Background

- ***What is being done and why***

7.1 EU Regulations apply directly in Member States and their provisions cannot be repeated in national legislation. However, it is necessary to repeal existing secondary legislation which implements the now-replaced Directives and to introduce a new measure to provide for the enforcement of Regulation 767/2009 by linking its provisions to the powers already available to local authority enforcement officers under Part 4 of the Feed (Hygiene and Enforcement) (England) Regulations 2005.

7.2 The Animal Feed (England) Regulations 2010 (the new measure) will (a) repeal the existing secondary legislation -- the Feeding Stuffs (England) Regulations 2005 -- which transposes the Directives the Regulation has replaced; (b) re-enact those EU feed measures which remain outside the Regulation's scope and make the references to the Annexes to them ambulatory so that amendments to those Annexes will take effect without having to be transposed into national law; (c) designate competent authorities for the enforcement of the Regulation's provisions; (d) increase the penalties for breaches of feed labelling and composition; and (e) amend primary legislation (the Agriculture Act 1970) where it repeats, conflicts or overlaps with the Regulation.

- ***Consolidation***

7.3 Regulation 767/2009 is itself a consolidatory measure. The changes to national feed legislation introduced as a consequence of the Regulation -- the repeal of one Instrument and the various amendments to it, and its replacement by another Instrument -- are considered by the Food Standards Agency to amount to a consolidation of the legislation. The consolidation extends to a number of amendments to the Feeding Stuffs (England) Regulations 2005, which chiefly concerned undesirable substances in animal feed.

8. Consultation outcome

8.1 The Food Standards Agency undertook a public consultation on the draft text of the Regulation in April-May 2008, to gather views in advance of the negotiations commencing in Brussels. There were further discussions and meetings with key stakeholder groups both throughout the negotiations and subsequent to the measure's formal adoption. Apart from queries over points of detail, the UK feed industry -- the stakeholder group most affected -- has consistently indicated its broad support for the principles of Regulation 767/2009.

8.2 A formal public consultation on the draft Animal Feed (England) Regulations 2010 ran from 31 March 2010 to 18 June 2010, and attracted ten substantive

responses raising points on which clarification or further information was sought. There were also a number of other responses which made broad general comments on various issues related to Regulation 767/2009 without raising specific questions. The comments received were not considered to warrant any changes to the draft Animal Feed (England) Regulations 2010. Further details about the consultation responses are provided in the attached Impact Assessment.

9. Guidance

9.1 The Food Standards Agency is drawing up guidance to the interpretation and enforcement of Regulation 767/2009, to assist both the feed industry and enforcement authorities, and has requested input from these and other stakeholder groups on issues they would like to see covered. It is currently expected that the guidance will be available (on the Agency's website) this autumn.

10. Impact

10.1 The EU Regulation will have mainly positive impacts on industry. The major positive impacts include the removal of the mandatory percentage declaration of compound feed ingredients, which the UK feed industry considers has revealed commercially sensitive information, compromised future investment in new feed formulations, and costs it over £43 million per year. Other positive impacts include the introduction of a procedure for the authorisation of new nutritional purposes, which will help the development and marketing of new dietetic feed products, and the removal of the current requirement for the prior authorisation of new bioproteins (a type of high protein feed material). A negative impact for industry includes a requirement for the more detailed labelling of additives (e.g., vitamins, trace elements) incorporated in compound feeds. The positive impacts are considered to outweigh the negative ones.

10.2 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on the OPSI website.

11. Regulating Small Business

11.1 The legislation will apply equally to small businesses -- although it introduces some new burdens, these are outweighed by the burdens which are being removed. Further, while the general approach to enforcement is to treat small businesses in a proportionate fashion, to exempt them would be a breach of Regulation 767/2009 and could potentially compromise the safety of the feed chain.

11.2 No steps have therefore been taken to minimise the potential impact of the legislation on firms employing up to 20 people.

12. Monitoring and Review

12.1 There is no requirement in the EU Regulation for a review to be undertaken within a fixed period. However, the Food Standards Agency will seek feedback from the UK feed industry and enforcement bodies on the application of the Regulation to help inform future discussions in the Standing Committee on the Food Chain and Animal Health on the appropriateness and proportionality of the Regulation and any proposed amendments to it. Continuing stakeholder engagement (from formal and

informal feedback and meetings with key stakeholder groups, including annual feed stakeholder meetings) will be the main means of obtaining this feedback.

13. Contact

Tim Franck or Joseph Nicholas in the Animal Feed Branch at the Food Standards Agency can answer queries regarding the instrument -- telephone 020 7276 8471 or e-mail <tim.franck@foodstandards.gsi.gov.uk> (Tim Franck) or telephone 020 7276 8462 or e-mail <joseph.nicholas@foodstandards.gsi.gov.uk> (Joseph Nicholas).

Title:

The Animal Feed (England) Regulations 2010

Lead department or agency:

Food Standards Agency

Other departments or agencies:

Impact Assessment (IA)

IA No: FoodSA 0019

Date: 01/09/2010

Stage: Final

Source of intervention: EU

Type of measure: Secondary legislation

Contact for enquiries:
Joseph Nicholas, 020 7276 8462

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Without regulation, manufacturers of feed might fall below the required standards of quality and safety and/or the market may not be able to provide purchasers of feed with the information necessary to make informed choices. Government intervention is therefore necessary to ensure that producers and suppliers of feed adhere to standards and make information available to their customers. European Regulation 767/2009 replaces and brings together in a single comprehensive document the provisions of five existing Directives. These Directives are currently transposed into national legislation via the Feeding Stuffs (England) Regulations 2005, which will now need to be revoked and replaced by a new measure to provide for the enforcement of the European Regulation.

What are the policy objectives and the intended effects?

European Parliament and Council Regulation 767/2009 is part of the Commission's modernisation and simplification agenda. It is intended to ensure the harmonised application of labelling and other feed-related provisions throughout the EU and facilitate the functioning of the internal market by simplifying technical requirements and reducing administrative burdens.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

The UK played a full part in the negotiations on the draft Regulation in Brussels, seeking changes to the text originally tabled by the Commission to improve it for UK stakeholders. The options now are (1) do nothing to provide for its enforcement or (2) amend current legislation to provide for its enforcement. Option 1 would mean leaving existing legislation in place, including a provision on the mandatory percentage declaration of compound feed ingredients which is estimated to cost the UK feed industry over £43 million a year and has potentially compromised the commercial confidentiality of its feed formulations. Option 2 would remove this burden and be commensurate with the UK's obligations under the Treaty on the Functioning of the European Union. It is therefore the preferred option.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 01/2016
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

Ministerial Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: ***Anne Milton*** ..... Date: 13th October 2010 .....

Summary: Analysis and Evidence

Policy Option 2

Description:

Provide for the enforcement of Regulation 767/2009

Price Base Year 2009	PV Base Year 2009	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: £294

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	£0.414		£0.55	**£5.113**

Description and scale of key monetised costs by 'main affected groups'

European Regulation 767/2009/EC introduces fuller additive labelling for compound feed. This will have one-off transition costs from investment in new equipment £411,000) and continuing annual costs from sampling (£546,000).

Other key non-monetised costs by 'main affected groups'

Cost of the extension of additives labelling requirements to the manufacturers of feed for non-food-producing animals (e.g, horses and pets).

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	N/A		£34.744	**£299.069**

Description and scale of key monetised benefits by 'main affected groups'

The repeal of the mandatory percentage declaration of compound feed ingredients will remove an administrative burden for the feed industry £34.744 million). It is also expected to restore industry support for feed research and technical assistance to farmers, with increased profitability for both.

Other key non-monetised benefits by 'main affected groups'

There are likely to be benefits from (a) the removal of the current requirement for prior authorisation of bioprotein products, which will remove an administrative burden for the feed industry, and (b) the introduction of a procedure for approving new nutritional purposes, which will allow new products to be brought to market.

Key assumptions/sensitivities/risks **Discount rate (%)** 3

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB: 0	AB savings:	Net:	Policy cost savings:	**Yes/No**

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			01/09/2010		
Which organisation(s) will enforce the policy?			Local authorities		
What is the annual change in enforcement cost (£m)?					
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**		**Non-traded:**
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**		**Benefits:**
Annual cost (£) per organisation (excl. Transition) (Constant Price)	**Micro** 1	**< 20** 1,681	**Small** 1,681	**Medium** 1,681	**Large** 1,681
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	17
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	18
Small firms Small Firms Impact Test guidance	Yes	18
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	18
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	19
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	19
Human rights Human Rights Impact Test guidance	No	19
Justice system Justice Impact Test guidance	No	19
Rural proofing Rural Proofing Impact Test guidance	No	19
Sustainable development Sustainable Development Impact Test guidance	No	19

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

No.	Legislation or publication
1	Consultation on the draft text of the European Parliament and Council Regulation: http://www.food.gov.uk/consultations/consulteng/2008/feedmarketeng08
2	Consultation version of the Impact Assessment for the draft Animal Feed (England) Regulations 2010: http://www.food.gov.uk/consultations/consulteng/2010/animalfeedregs2010eng
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs			N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring cost		£0.53	£0.51	£0.49	£0.48	£0.46	£0.44	£0.43	£0.42	£0.40
Total annual costs	£0.96	£0.53	£0.51	£0.49	£0.48	£0.46	£0.44	£0.43	£0.42	£0.40
Transition benefits	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Annual recurring benefits	£34.74	£33.57	£32.43	£31.34	£30.28	£29.25	£28.26	£27.31	£26.39	£25.49
Total annual benefits	£34.74	£33.57	£32.43	£31.34	£30.28	£29.25	£28.26	£27.31	£26.39	£25.49

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office Excel Worksheet

Evidence Base (for summary sheets)

1. Problem under Consideration

1.1 The production process for animal feed involves different processes and practices depending on the price and availability of the feed materials (ingredients) used, the species and categories of animals for which the feed is intended, and in some cases the preferences and requirements of feed purchasers. Because purchasers cannot observe feed production processes for themselves, there is an information asymmetry; in consequence, purchasers of feed will not have access to all the information they need to make an informed choice about the products they buy. Regulation is therefore necessary to ensure (a) that feed producers and suppliers provide certain information to purchasers, without which the market may not function efficiently, and (b) that feed is fit for its intended purposes and meets general safety requirements, including adherence to any restrictions which may be imposed on the use of certain ingredients on the grounds of their potential risk to animal health and the human consumers of animal products (milk, eggs and meat, including fish meat).

1.2 Animal feed legislation is a harmonised area in the EU. Its requirements are currently set out in twelve separate European measures, some of which have been amended and extended on numerous occasions. Many of these measures, and their amendments, are Directives which have had to be individually transposed into national legislation, resulting in frequent amendments having to be made to the principal Statutory Instrument which governs aspects of the labelling, marketing and composition of animal feed. Five of the twelve measures, covering the main aspects of the marketing and use of animal feed, have now been replaced by a directly applicable European Regulation which brings their provisions together into a single comprehensive document which is expected to be of benefit to all stakeholders.

2. Rationale for Intervention

2.1 EU animal feed legislation covers labelling declarations of the ingredients used (including the additives and the GM varieties which have been authorised for use in feed), analytical declarations for protein, fibre, ash, etc., the name and address of the business, the batch number and shelf-life of the feed product, and certain allowable claims. EU feed legislation also specifies the maximum permitted levels of certain undesirable substances (contaminants), lays down a list of prohibited ingredients which must never be used in feed, and provides a list of permitted dietetic purposes for which certain feeds may be promoted.

2.2 These provisions are laid down in the following twelve separate measures:

- Council Directive 79/373/EEC of 2 April 1979 on the circulation of compound feedingstuffs;
- Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition;
- Commission Directive 82/475/EEC of 23 June 1982 laying down the categories of ingredients which may be used for the purposes of labelling compound feedingstuffs for pet animals;
- Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes;
- Council Directive 96/25/EC of 29 April 1996 on the circulation and use of feed materials;
- European Parliament and Council Directive 2002/32/EC of 7 May 2002 on undesirable substances;
- European Parliament and Council Regulation 178/2002 of 28 January 2002 laying down the general principles and requirements of food law. In EU law, food law includes feed law;
- European Parliament and Council Regulation 1829/2003 of 22 September 2003 on genetically modified food and feed;
- European Parliament and Council Regulation 1831/2003 of 22 September 2003 on additives for use in animal nutrition;
- Commission Decision 2004/217/EC of 1 March 2004 on materials whose circulation or use for animal nutrition is prohibited;
- European Parliament and Council Regulation 183/2005 of 12 January 2005 laying down requirements for feed hygiene; and
- Commission Directive 2008/38/EC of 5 March 2008 establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes.

It should be noted that none of this legislation applies to the labelling of medicines incorporated in animal feed (medicated feedingstuffs), which are covered by other measures for which Defra's Veterinary Medicines Directorate is responsible.

2.3 Compound feeds are manufactured mixtures of two or more ingredients, often in pelleted form, which may contain additives. "Certain products" used in animal nutrition are chiefly amino acid substitutes (known as bioproteins). Feedingstuffs intended for particular nutritional purposes are dietetic products formulated to meet the needs of animals whose digestive capability is temporarily or chronically impaired. Feed materials are single ingredients either fed singly to animals or used in the manufacture of compound feeds. Undesirable substances are (a) naturally occurring environmental contaminants (e.g. arsenic, fluorine and heavy metals such as cadmium and mercury) which cannot be wholly avoided and (b) contaminants which arise during process and transport (e.g. aflatoxin and dioxins) and for which maximum upper limits are set to minimise the risk to animal and human health. Additives are substances added to feed to perform various technical or nutritional functions (vitamins, flavourings, colourants, binders, etc.). Genetically modified feeds are derived in whole or in part from crops the genome of which has been altered either directly or by the insertion of genes from another organism.

2.4 This legislation applies to feed for food-producing animals (i.e., farmed livestock) and also covers feed for pet animals, farmed and ornamental fish, zoo and circus animals and, in certain circumstances, creatures living freely in the wild. This is for two reasons: firstly, because the separation of feed for farmed livestock from feed for other categories of animals would in practice result in the duplication of many legislative provisions; and, secondly, because the inclusion of feed for both food-producing and non-food-producing animals acts as a safeguard against the potential for cross-contamination of the feed manufacturing and supply chain.

2.5 Nine of the twelve measures listed in paragraph 2.2 above are currently implemented in England by the Feeding Stuffs (England) Regulations 2005 (which have been amended a number of times). The exceptions are European Regulation 1829/2003 on genetically modified feed and food, the feed-related provisions of which are enforced by the Genetically Modified Animal Feed (England) Regulations 2004; and European Regulation 183/2005 on feed hygiene, which is enforced by the Feed (Hygiene and Enforcement) (England) Regulations 2005. This latter measure also enforces the feed-related provisions of European Regulation 178/2002 on the general principles of food law, the third of the exceptions. (Separate but parallel legislation applies in Scotland, Wales and Northern Ireland.)

2.6 Five of the nine measures implemented by the Feeding Stuffs (England) Regulations 2005 have been revoked and replaced by European Parliament and Council Regulation 767/2009/EC of 13 July 2009 on the placing on the market and the use of feed, which applies in Member States from 1 September 2010. The five measures concerned, which cover the majority of the provisions on the marketing and use of feed, are:

- Directive 79/373 on compound feedingstuffs;
- Directive 82/471 on certain products used in animal nutrition;
- Directive 93/74 on feedingstuffs intended for particular nutritional purposes;
- Directive 96/25 on feed materials; and
- Decision 2004/217 on prohibited ingredients.

Most of these Directives' provisions are carried forward unchanged into the new Regulation.

2.7 However, the Regulation also introduces a number of amendments to this legislation, some of which represent a tightening up of existing requirements and others a relaxation of them. Those amendments which might be regarded as tightening existing requirements are as follows:

- extension of the feed safety principles of feed law to feed for non-food-producing animals, so ensuring consistency in the application of feed hygiene and traceability measures;
- introduction of a demarcation between complementary feeds and premixtures, to tighten controls on products with high levels of additives;
- a requirement that claims for a feed's composition or function be subject, on the request of a purchaser or a competent authority, to scientific substantiation;
- fuller additive labelling; and
- a requirement that contaminated feed being sent for cleaning or detoxification be labelled as such to prevent its diversion back into the feed chain.

Those amendments which can be regarded as relaxing existing requirements are as follows:

- abolition of the existing requirement for the ingredients of compound feeds to be declared by their percentage weight of inclusion;
- abolition of the existing requirement for a dossier assessment of new bioproteins, which will instead be subject to post-surveillance for their safety in use; and
- the introduction of a Catalogue of feed materials and Codes of Practice for good labelling, voluntary measures which are to be drawn up by the European feed industry and are expected to achieve the same harmonised results as at present but without the need for prescriptive legislation.

A further amendment, the introduction of a procedure for submissions to the Commission for the approval of new nutritional purposes, might be regarded as neutral because although it imposes a new requirement on industry it will also create the scope for industry to develop and promote specially formulated dietetic feeds for the management of various chronic conditions;

2.8 The four measures implemented by the Feeding Stuffs (England) Regulations 2005 which remain outside the scope of the Regulation are:

- Directive 82/475 setting out a list of categories which may be used for labelling compound feed for pets;
- Directive 2002/32 specifying the maximum permitted levels of certain undesirable substances;
- Commission Regulation 1831/2003 on additives for use in animal nutrition, which covers the authorisation and labelling of additives used or sold as they are (i.e., without incorporation in a feedingstuff); and
- Directive 2008/38 consolidating and setting down the list of particular nutritional purposes for which dietetic feedingstuffs may be promoted. This is a separate measure from Directive 93/74, which concerns the rationale for and labelling of dietetic feed products;

2.9 Because European Regulations apply directly in Member States, it will be necessary to revoke those provisions in national legislation which either repeat, conflict or overlap with the provisions of the Regulation.

3. Policy Objective

3.1 Regulation 767/2009 is to some extent a consolidatory and simplificatory measure, and applies directly in Member States -- i.e., it does not need transposition into national legislation. However, there would need to be extensive amendments made to the Feeding Stuffs (England) Regulations 2005 (which have already been amended several times) to remove those of its provisions which conflict with those of the Regulation, as well as to put in place new provisions to allow for its enforcement. It has therefore been decided that it would be easier and simpler to repeal the existing legislation in its entirety and to make a new set of Regulations -- the Animal Feed (England) Regulations 2010. These will:

- provide for the enforcement of certain provisions of Regulation 767/2009;
- designate competent authorities for the enforcement of the selected provisions;
- re-enact those provisions of the Feeding Stuffs (England) Regulations 2005 (as amended) which do not repeat, conflict or overlap with the provisions of Regulation 767/2009;
- make the references to the lists of categories of feed materials for non-food-producing animals, undesirable substances, products for particular nutritional purposes and the Annexes to Regulation 767/2009 ambulatory;
- increase the penalties for breaches of animal feed legislation relating to labelling and composition; and
- modify or amend primary legislation (the Agriculture Act 1970) to disapply its provisions where they repeat, conflict or overlap with the provisions of Regulation 767/2009.

Further details of these proposed changes are given in the remainder of this section.

Provide for the Enforcement of Certain Provisions of Regulation 767/2009

3.2 Although European Regulations apply directly in all Member States and their provisions cannot be repeated in national legislation, it is necessary for them to be linked to domestic powers and penalties in order to provide for their enforcement. For feed legislation, this is achieved by linking the Articles to the powers already held by local authority enforcement officers. These powers, which are set out in Part 4 of the Feed (Hygiene and Enforcement) (England) Regulations 2005, include the right to enter premises, inspect records, take samples for the purpose of analysis to confirm that products comply with

the requirements of the legislation, detain and dispose of non-compliant products, and -- in cases of serious breaches of the legislation -- initiate prosecutions.

3.3 However, it is not necessary for all of the provisions of Regulation 767/2009 to be linked to enforcement powers, because in some cases the provisions are not aimed at persons within a Member State and in other cases failure to adhere to certain of these provisions will not constitute a breach of a statutory duty. For example, it will not be an offence to fail to follow the Community Codes of good labelling practice envisaged under Article 25, because the use of these codes by the feed industry is voluntary.

3.4 A list of the provisions of Regulation 767/2009 to be linked to enforcement powers is set out in Schedule 1 to the Animal Feed (England) Regulations 2010.

3.5 This list includes Commission Regulation 242/2010 of 19 March 2010 establishing the Catalogue of feed materials provided for under Article 24 of Regulation 767/2009. A revised and extended version of this Catalogue is currently under discussion in Brussels, but its adoption is not envisaged before 1 September 2010 -- i.e., until after the Regulation applies in Member States. In that case, it may be necessary to make an amending Statutory Instrument to replace the reference in Schedule 1 to Regulation 242/2010, which will have been repealed, with a reference to the Regulation establishing the revised Catalogue.

Designate Competent Authorities

3.6 Regulation 767/2009 refers in several of its provisions to the role of competent authorities in their enforcement or interpretation. It is therefore necessary to designate the competent authorities in question. For the most part, this is local authorities, the trading standards departments of which are mainly responsible for the day-to-day enforcement of animal feed legislation in England. However, in a limited number of instances it is necessary to designate the Food Standards Agency as a competent authority, either because there are circumstances in which it may be necessary for the Agency to work in tandem with or in place of a local authority or because it is the body which will be required to engage with the Commission for the fulfilment of certain duties laid down in Regulation 767/2009.

3.7 A list of those provisions of the Regulation which require the designation of competent authorities is set out in regulation 5 of the Animal Feed (England) Regulations 2010.

Re-enact Certain Provisions of the Feeding Stuffs (England) Regulations 2005 (as amended)

3.8 As explained in paragraph 2.8 above, four of the nine measures covered by the Feeding Stuffs (England) Regulations 2005 (as amended) remain outside the scope of Regulation 767/2009. It is therefore necessary for the provisions relating to the implementation and enforcement of these measures to be re-enacted in the Animal Feed (England) Regulations 2010 in order that they continue to have effect in England.

3.9 Re-enactment of the provisions of Directives 82/475, 2002/32 and 2008/38 will include making the references to their Annexes ambulatory -- see paragraphs 3.10 to 3.13 below. Re-enactment of European Regulation 1831/2003 will be by linking its provisions to powers of enforcement, as before.

Make Ambulatory References to the Lists of Categories of Feed Materials for Non-Food-Producing Animals, Undesirable Substances and Products for Particular Nutritional Purposes

3.10 As explained at paragraphs 2.8 and 3.8, Directive 2002/32 on undesirable substances and Directive 2008/38 setting down the list of particular nutritional purposes are outside the scope of Regulation 767/2009. The Animal Feed (England) Regulations 2010 implement the lists in the Annexes to these Directives by reference to them. These references are ambulatory, meaning that future amendments to the lists in the Annexes -- which are usually made by comitology in the Standing Committee on the Feed Chain and Animal Health -- will take effect when they are expressed to do so in the relevant amending EU legislative act rather than, as now, having to be individually transposed into national law by amending Statutory Instruments.

3.11 It should be noted that the Commission has indicated that it is considering replacing the Annex to Directive 2003/32 with a Regulation, although there is as yet no timetable for this. If and when this takes place, it will be necessary to make an amending Statutory Instrument to change the relevant reference.

3.12 Article 17.4 of Regulation 767/2009 empowers the Commission to establish a list of categories of ingredients which may be used for the labelling of feed for non-food-producing animals (such as pets) instead of the individual feed materials. This list would in due course replace that laid down by Directive 82/475 which, as explained in paragraph 2.8, is outside the scope of the Regulation. However, there is as yet no timetable for this, nor is it clear what form the new list may take (whether an amendment to the existing Directive, or a new Directive, or an amendment to the Regulation). For consistency with the treatment of Directives 2002/32 and 2008/38, therefore, it has been decided to make the reference to Directive 82/475 ambulatory as well.

3.13 Ambulatory references will also be made to the Annexes of Regulation 767/2009. These cover technical provisions relating to labelling declarations and will be subject to amendment by comitology procedures following discussions and a vote in the Standing Committee on the Feed Chain and Animal Health.

Increase the Penalties for Breaches of Animal Feed Legislation

3.14 The current penalties for failure to comply with the requirements of the Feeding Stuffs (England) Regulations 2005 (as amended) are set out in section 74A of the Agriculture Act 1970. The maximum penalty available to the courts for offences under this is a three month term of imprisonment and/or a fine at level 5 on the standard scale. The standard scale of fines for summary-only offences is set out in section 52 of the Criminal Justice Act 1982, as amended, and ranges from £200 at level 1 to £5,000 at level 5.

3.15 Although the Agriculture Act 1970 has been modified several times in line with the requirements of contemporary legislation, the scale of penalties has not kept pace with the increased recognition of the role that animal feed plays in the safety of the food chain. It is now felt that these penalties, in particular the maximum of the fines available, are no longer "effective, proportionate and dissuasive", as required by Article 31 of Regulation 767/2009, and that the opportunity should therefore be taken to revise them.

3.16 The need for the modernisation of penalties for breaches of animal feed legislation was recognised when the Feed (Hygiene and Enforcement) (England) Regulations 2005 were made. These provide for the option of unlimited fines and prison terms of a maximum of two years for serious breaches of feed hygiene legislation. There is therefore a strong case for treating breaches of feed composition and labelling requirements, and of the maximum permitted levels for undesirable substances, in a comparable fashion, so that such breaches, if sufficiently serious, are prosecuted as indictable offences, with the potential penalty of a level of fine imposed at the discretion of the Crown Court and not limited by statute.

3.17 The rationale for this is that when the level of penalties was first established in the Act, it was largely focused on protecting the purchaser of feed from malpractice by the seller. However, it is now widely acknowledged that marketing feed which does not comply with legal standards and requirements can have serious consequences for public health -- for example, the Belgian dioxin crisis of 1999 and the Irish dioxin incident of 2008. The potential for wider and more serious consequences resulting from non-compliance indicates a need for the courts to have adequate powers to match the level of the fine to the seriousness of the offence and the size of the feed business concerned. Stakeholders, including those responsible for feed law enforcement, have previously expressed their support for the proposed increases in the range of available penalties. The increased penalties have also been agreed with the Ministry of Justice.

3.18 It should be noted that the three-month term of imprisonment which is the maximum that may currently be imposed for breaches of the Feeding Stuffs (England) Regulations 2005 is not being increased.

Amendments to Primary Legislation

3.19 As well as containing powers to make secondary legislation, Part IV of the Agriculture Act 1970 includes a number provisions which deal directly with feed law. Many sections of the Act now overlap

with the provisions of Regulation 767/2009. Sections 73 and 73A of the Act have already been disapplied, except in respect of feed for non-food-producing animals, in order to avoid duplication of the feed-related provisions of European Regulation 178/2002; these sections are now to be disapplied altogether as a consequence of the extension of these feed-related provisions to non-food-producing animals by Regulation 767/2009. Other sections of Part IV of the Agriculture Act 1970 are also to be disapplied. By agreement with the Office of Parliamentary Counsel, this is to be achieved either by inserting a provision into the relevant sections stating that all or parts of them which concern animal feed no longer apply in those cases where feed is instead governed by the provisions of Regulation 767/2009; or by directly amending relevant sections to remove from them any reference to animal feed.

3.20 Those sections of the Agriculture Act 1970 to be disapplied or amended are dealt with in regulation 14 of the Animal Feed (England) Regulations 2010.

4. Description of Options

4.1 There would appear to be two options available:

- Option 1: do nothing. Existing national legislation which implements the repealed EU measures would therefore remain in place, at continuing costs to the feed industry; or
- Option 2: make legislation to provide for the enforcement of EC Regulation 767/2009 in national law.

Option 1: do nothing

4.2 Doing nothing would mean leaving all the existing legislation in place, which would mean that UK feed labelling would be out of step with that in other Member States and could have an adverse effect on potential sales of UK feed products. Retaining all the existing legislation would also mean retaining the current requirement for the mandatory percentage declaration of the ingredients of compound feed, which the UK feed industry considers to be commercially sensitive and to have compromised its intellectual investment is its feed formulation. The UK feed industry has estimated that this requirement has cost it over £43 million per year[2].

4.3 Doing nothing could also deny the UK feed industry the opportunity to make submissions for new nutritional purposes and thus to develop and market new dietetic feeds for the management of various chronic conditions. Doing nothing could in addition deny the UK feed industry continued participation in the development of the Catalogue of feed materials and the Codes of Practice for good labelling, and thus to ensure that they reflect the concerns and interests of UK businesses.

4.4 Lastly, doing nothing would be a breach of the UK's obligations as an EU Member State, and could give rise to infraction proceedings against the UK by the Commission in the European Court of Justice under Article 258 of the Treaty on the Functioning of the EU. If infracted, the UK could be faced with potentially unlimited daily fines until the Regulation is enforced in national law and other associated measures, such as the repeal of incompatible national provisions, are also taken.

Option 2: provide for the enforcement of EC Regulation 767/2009 in national law

4.5 Making legislation to provide for the enforcement of Regulation 767/2009 would remove a number of current administrative burdens from the feed industry. These include -- in particular -- an existing requirement to submit a scientific dossier in support of an application for authorisation of a new bioprotein; and the existing requirement for the mandatory percentage declaration of the ingredients of compound feed. The requirement to submit a dossier in support of an authorisation for a new bioprotein is considered by the Commission to have been a deterrent to bringing new products to market, and thus potentially a restriction on business. As explained at paragraph 4.2 above, removal of the requirement for percentage ingredient declaration will remove an existing burden and lead to reduced costs for the UK feed industry of almost £44 million per year.

4.6 Providing for the enforcement of the Regulation will also allow for the introduction of the Community Catalogue of feed materials and the Codes of Practice for good labelling described at paragraph 4.3 above. These are expected to deliver the same harmonised controls as at present, but

[2] As per the consultation version of the Impact Assessment at http://www.food.gov.uk/consultations/consulteng/2010/animalfeedregs2010eng

without the need for prescriptive legislation, and thus represent the removal of another administrative burden for both regulators and the feed industry.

4.7 Making legislation to provide for the enforcement of Regulation 767/2009 will also be commensurate with the UK's obligations as an EU Member State under the Treaty on the Functioning of the EU.

5. Costs and Benefits of Each Option

Option 1 -- do nothing

5.1 There are no incremental costs and benefits associated with doing nothing, because it is the baseline against which the other option is compared.

Option 2 -- provide for the enforcement of Regulation 767/2009 in national law

5.2 There will be significant savings to both the feed industry and enforcement authorities from the repeal of the existing requirement for the mandatory percentage declaration of the ingredients of compound feed. The Agricultural Industries Confederation (AIC), the trade association for feed compounders and feed merchants, estimated in 2008 that the savings to be realised from the removal of this burden would be £42.74 million per year for the UK as a whole. This has since been uprated to represent 2009 prices[3]. The annual benefit for England is now calculated as £34.744 million per year. Table 1 illustrates the costs of compliance with the current requirement, broken down by devolved administration, which will be translated into savings under Option 2.

Table 1: Benefits of Regulation 767/2009 broken down by devolved administration

% of feed businesses by devolved administration *	100%	80.25%	3.7%	4.84%	11.11%
	UK	**England**	**Wales**	**Scotland**	**N.Ireland**
Current administrative costs:					
Updating labels and responding to customer enquiries	£1,013,030	£812,925	£37,520	£50,026	£112,559
Current loss of formulation expertise allied to R&D:					
Loss to livestock industry from absence of research into optimisation of feed materials usage (at £2 per tonne for 13 million tonnes annual production)	£26,338,780	£21,136,058	£975,510	£1,300,680	£2,926,531
Loss to livestock industry from absence of nutritional, formulation and analytical support (at 44p per tonne for 13 million tonnes annual production)	£5,814,792	£4,666,191	£215,363	£287,150	£646,088
	UK	**England**	**Wales**	**Scotland**	**N.Ireland**
Current loss of profitability to customers:					
Incremental benefits in animal performance, animal health and product quality foregone	£10,130,300	£8,129,253	£375,196	£500,262	£1,125,589
Total current costs of compliance with percentage ingredient declaration:	**£43,296,902**	**£34,744,428**	**£1,603,589**	**£2,138,119**	**£4,810,767**
Rounded:	**£43,297,000**	**£34,744,000**	**£1,604,000**	**£2,138,000**	**£4,811,000**

* Devolved administration figures have been estimated by applying Standard Industrial Classification codes 10.91 (Manufacture of prepared feeds for farm animals) and 10.92 (Manufacture of prepared pet foods) as outlined in the Competition Assessment (see the Annex). Source: ONS Inter-Departmental Business Register (2009).

Figures provided by the Agricultural Industries Confederation (AIC), the trade association for feed compounders and feed merchants. Figures have been uprated to represent 2009 prices.

[3] Figures uprated by 1.3% using calendar year 2009 from Treasury GDP deflator, http://www.hm-treasury.gov.uk/data_gdp_fig.htm The % uprating has been updated from the consultation document due to the deflator series being updated. The deflator used in the consultation was 2.52%.

Repeal of the existing requirement for mandatory percentage declaration will therefore remove the considerable existing cost burden and so represent a significant saving to the UK feed industry.

5.3 The repeal of Directive 82/471concerning certain products used in animal nutrition, which will remove the requirement to submit a dossier of scientific evidence in support of a new bioprotein product, will clearly have savings for the feed industry. However, it is difficult to quantify this because no new bioprotein products in the categories covered by the Directive have been submitted for authorisation for several years, with the consequence that there is no recent record of actual costs from which potential savings can be extrapolated. In addition, several of the categories formerly covered by the Directive were transferred to EC Regulation 1831/2003 on feed additives at the time that measure came into force. Although this latter legislation still requires a dossier assessment, the costs of this are a separate issue to those which may be associated with Regulation 767/2009.

5.4 Regulation 767/2009 also introduces a number of new provisions which are expected to have benefits for stakeholders, as follows:

- A requirement to label contaminated feed which is being sent for cleaning or detoxification, to prevent its diversion back into the feed chain before cleaning has taken place. This is likely to have health benefits for animals and the human consumers of animal products, although these benefits cannot be quantified because data on the volumes of feed sent for cleaning and on the extent to which any diversion actually occurs has never been collected and therefore is not available;
- Adoption of a formal procedure for the consideration and authorisation of new nutritional purposes. This will permit the development and marketing of new dietetic feeds, but it is difficult to quantify the potential benefits of this because information on the nature of the market for such new products is lacking and may not become available until after the authorisation of the new nutritional purposes for which they may be promoted;
- Extension of the principles of food law to feed for non-food-producing animals. This will ensure that the manufacturers and merchants of such feed comply with provisions on safety and traceability, thus reducing the potential for breaches of them in the event of cross-contamination. This extension could also have benefits for non-feed producing animals and their owners, although it is difficult to quantify these potential benefits in the absence of information on the extent of either breaches of or compliance with feed safety requirements. However, it is thought likely that, through compliance their trade association's codes of practice, pet food manufacturers will already be adhering to analogous provisions.

5.5 There may also be some costs associated with Regulation 767/2009, in particular the requirement to label all additives subject to a maximum permitted level, which will chiefly affect feed manufacturers. The Agricultural Industries Confederation (AIC) calculated in 2008 that for livestock feed this provision would incur a one-off cost of £505,000 and have a continuing annual cost of £672,000 in the UK at 2008 prices. These figures have been uprated for 2009 prices[4] and are shown in Table 2, which outlines the costs by devolved administration. These provisions will impose a one off cost for feed businesses England of £411,000 and annual costs of £546,000.

[4] Figures uprated by 1.3% using calendar year 2009 from Treasury GDP deflator http://www.hm-treasury.gov.uk/data_gdp_fig.htm The % uprating has been updated from the consultation document due to the deflator series being updated. The deflator used in the consultation was 2.52%.

Table 2: Costs of Regulation 767/2009 broken down by devolved administration

% of feed businesses by devolved administration *	100%	80.25%	3.7%	4.84%	11.11%
	UK	**England**	**Wales**	**Scotland**	**N.Ireland**
One-off costs:					
Modification(s) to labelling software	£5,065	£4,065	£188	£250	£563
New labelling applicators (assumed cost per applicator of £5,000 affecting 100 manufacturing sites)	£506,515	£406,463	£18,760	£25,013	£56,279
Total one-off costs attributable to labelling of all additives:	**£511,580**	**£410,527**	**£18,947**	**£25,263**	**£56,842**
Rounded:	**£512,000**	**£411,000**	**£19,000**	**£25,000**	**£57,000**
Continuing annual costs:					
Additional analyses for trace elements to ensure the accuracy of declarations (£48 per sample at 1 sample per 1,000 tonnes of feed for 13 million tonnes annual production)	£632,131	£507,265	£23,412	£31,216	£70,237
Analysis for antioxidants to ensure the accuracy of declarations (£50 per sample at 1 sample per 5,000 tonnes of feed, assuming 20% of production contains antioxidants)	£26,339	£21,136	£976	£1,301	£2,927
Analysis of colourants to ensure the accuracy of declarations (£100 per sample at 1 sample per 5,000 tonnes of feed, for feed for laying hens only)	£22,287	£17,884	£825	£1,101	£2,476
Total continuing annual costs attributable to labelling of all additives:	**£680,756**	**£546,286**	**£25,213**	**£33,618**	**£75,640**
Rounded:	**£681,000**	**£546,000**	**£25,000**	**£34,000**	**£76,000**

* Devolved administration figures have been estimated by applying Standard Industrial Classification codes 10.91 (Manufacture of prepared feeds for farm animals) and 10.92 (Manufacture of prepared pet foods) as outlined in the Competition Assessment (see the Annex). Source: ONS Inter-Departmental Business Register (2009).

Figures provided by the Agricultural Industries Confederation (AIC), the trade association for feed compounders and feed merchants. Figures have been uprated to represent 2009 prices.

5.6 The pet food industry may also face additional costs from the requirement to label all additives. However, responses to the earlier consultation while the EU Regulation was still under negotiation did not reflect the potential costs to the whole industry, so they are not included in the above table.

5.7 There may also be costs associated with the removal of the existing derogation for the labelling of the analytical constituents (protein, fibre, ash, etc.) of agri-industrial products with a moisture content of more than 50% ("moist feeds"). These are typically spent grains from the brewing and distilling industries, which have had a traditional end-use in the animal feed chain for a long period of time but for which analytical declarations have not hitherto been provided because the products' high moisture content (which itself may be liable to evaporation or settling) hinders accurate analysis. Moist feed producers are therefore likely to incur some costs in the sampling and analysis of their products -- capital costs for the investment in new equipment and operating costs for its continued use -- to provide such declarations. It is not possible to estimate these costs because it is not known what volumes of product may be affected, in particular whether the same volumes will continue to be sent for feed use rather than sent for another, for example as biomass for incineration for the production of energy.

5.8 It should be noted, however, that the derogation for moist feeds may be restored by way of a revision to the Catalogue of feed materials. In addition to the agreed names and descriptions of the materials listed, the Catalogue specifies the analytical constituents to be provided, and it is thought that it may be possible to exempt some types of moist feed the moisture content of which falls within a certain range. If this is agreed, then the likely costs to moist feed producers of sampling and analysis will be reduced.

5.9 Regulation 767/2009 also introduces a requirement that complementary feeds should not contain levels of additives of more than 100 times the maxima of additives in complete feeds may have cost implications for manufacturers of complementary feeds with levels greater than this new upper limit due to the need to reformulate these products. However, these costs cannot be quantified because data on the number of complementary feed products potentially affected or the possible costs of their reformulation is not available. In addition, there is scope for their manufacturers to submit them for consideration as products for new nutritional purposes (see paragraph 5.4 above), which if successful would permit them to remain on the market without reformulation.

5.10 Regulation 767/2009 also amends the limits of variation (the upper and lower tolerances within which a product's actual analytical content may differ from that declared on the label). This could have potential cost implications for feed manufacturers, who suggested while the Regulation was still under negotiation that in certain cases they might be unable to meet the new limits. Following the formal adoption of the Regulation, however, these limits were reviewed and amended by the Standing Committee on the Food Chain and Animal Health, in some cases being relaxed (for example, the tolerances for declarations in respect of moist feeds have been widened). However, stakeholders have not commented further on the revised tolerances, and in consequence it has not been possible to quantify their potential impact.

5.11 There is a new requirement for claims made in support of products to be understandable by purchasers and verifiable by enforcement officials, and for scientific substantiation of them to be available on request. This may have some cost implications for manufacturers who need to revise the claims they make. However, the number of claims to which this might potentially apply and the costs of revising them is expected to be relatively small, and to impact mostly on niche products marketed for particular conditions or species.

5.12 Pet food manufacturers will be required to provide contact details on labels for purchasers to obtain further information about their products, which might have some cost implications. However, these costs are expected to be minimal because labels already supply contact details, and where any changes have to be made it is expected that these would be incorporated into the relabelling of products during the transition period granted by the Regulation for the pet food industry to use up existing stocks of labels.

5.13 The requirement mentioned at paragraph 5.4 above to label contaminated feed which is being sent for cleaning or detoxification, to prevent its diversion back into the feed chain, may have some costs. However, these costs cannot be quantified because data on the volumes of feed sent for cleaning or detoxification, and on the extent to which any diversion actually occurs, has never been collected and therefore is not available.

5.14 The Codes of Practice for good labelling may have some costs associated with their development and introduction, even though the provisions they set out will concern voluntary rather than mandatory labelling statements. However, it is not possible to quantify these costs because discussions on the scope and content of the Codes are continuing, and in consequence their final form is not yet known.

5.15 It will be necessary for all feed business operators to spend some time becoming familiar with the Regulation. There may be a one-off cost associated with this, although it is likely to be small because the Regulation primarily consolidates existing measures with which businesses are already familiar.

6. Administrative Burden and Policy Saving Calculations

6.1 This section applies only to England, and may be subject to change due to the revised methodology for the 2010-2015 simplification targets. It refers to changes in the stock of legislation measured as part of the previous government's Administrative Burdens Measurement Exercise (ABME) in 2005, which concerned England alone.

6.2 The administrative burden which arose from the requirement in the Feeding Stuffs (England) Regulations 2005 (as amended) to provide information on the labelling of compound feedingstuffs to indicate the percentage by weight of each ingredient was estimated at £2,004,443. This requirement

has been removed by Regulation 767/2009, leading to a reduction in the administrative burden of £2.22 million in 2009 prices[5].

6.3 In addition, there could be policy savings from the use of ambulatory references to the Annexes to Regulation 767/2009 and the lists of categories of feed materials for non-food-producing animals, maximum permitted levels for undesirable substances and particular nutritional purposes. Firstly, it will no longer be necessary for regulators to make amending Statutory Instruments to transpose any future amendments to these measures into national law, which will reduce the administrative burdens on central government. Secondly, the feed industry is generally consulted on proposed changes to feed legislation while they are under discussion in the Standing Committee, and will therefore be able to take advantage of such changes as soon as they are expressed to take effect in the relevant EU Directive or Regulation.

7. Consultation

Previous Consultation

7.1 The Food Standards Agency undertook a public consultation from 9 April 2008 to 21 May 2008 on the original text of the Regulation as published by the Commission, before formal negotiations commenced in Brussels. (The documents for this consultation can be found at: http://www.food.gov.uk/consultations/consulteng/2008/feedmarketeng08) This attracted 23 responses. There was a broad general welcome for the Regulation from all respondents, although most had queries or concerns about some points of detail.

7.2 There was a particular welcome for the repeal of mandatory percentage declaration of the ingredients of compound feed. Other measures which also received support included the introduction of a formal procedure for the authorisation of new nutritional purposes; the requirement for claims to be scientifically substantiated; the labelling of contaminated feed intended for detoxification; and the introduction of a demarcation between complementary feeds and premixtures based on a maximum level of additives. General concerns were expressed, however, about the impact of this demarcation on products with high levels of additives such as boluses, pastes and drenches; the removal of the derogation for labelling the analytical constituents of moist feeds; the requirement for the fuller labelling of additives in compound feed; and the tightened limits of variation.

7.3 Some of these concerns, in particular those related to products with high levels of additives and the simplified limits of variation, were partially allayed as a consequence of the negotiations in Council Working Group and, subsequent to the measure's formal adoption, in the Standing Committee on the Food Chain and Animal Health, where amendments to certain of the measure's technical provisions were agreed.

7.4 Throughout 2008 and 2009 -- i.e. during the negotiations on the measure and subsequent to its adoption -- the Food Standards Agency held a number of meetings with key stakeholder groups -- industry trade associations and enforcement bodies -- to both hear their views of the measure and keep them apprised of developments in Brussels. The issue was also discussed at the general stakeholder meetings which the Agency's Animal Feed Branch hosts each year.

Formal Consultation on the Animal Feed (England) Regulations 2010

7.5 The Food Standards Agency undertook a formal public consultation from 31 March 2010 to 18 June 2010 on the draft Animal Feed (England) Regulations 2010 to provide for the enforcement of European Regulation 767/2009 on the placing on the market and the use of feed. The documents for this consultation can be found at http://www.food.gov.uk/consultations/consulteng/2010/animalfeedregs2010eng) Comments were particularly invited on the following points:

- whether all of the Articles of the Regulation 767/2009 which require to be enforced were correctly identified. If stakeholders considered otherwise, they were asked to identify any

[5] Figures uprated by 10.71% from Treasury GDP deflator http://www.hm-treasury.gov.uk/data_gdp_fig.htm The % uprating has been updated from the consultation document due to the deflator series being updated. The deflator used in the consultation was 2.52%.

Articles which they considered did not require to be enforced and/or those Articles which they considered had been omitted;

- whether the competent authorities for the enforcement of the Regulation were correctly designated. As explained in paragraph 3.6 above, this is for the most part local authorities, although in a limited number of instances it is necessary to designate the Food Standards Agency. If it was considered that any of the designations were incorrect, stakeholders were asked to state the designations considered to be incorrect and suggest potential alternatives;
- whether all of the provisions of the Feeding Stuffs (England) Regulations 2005 (as amended) which require to be re-enacted were correctly identified. Again, if stakeholders considered that any provisions had been omitted, or that any provisions which are listed did not require re-enactment, they were asked to provide appropriate supporting arguments;
- whether it is appropriate to insert ambulatory references to (a) the Annexes to Regulation 767/2009 and to (b) the lists of categories of feed materials for non-food-producing animals, maximum permitted levels for undesirable substances and particular nutritional purposes in the Annexes to Directives 82/475, 2002/32 and 2008/38 respectively, so that future amendments to these Annexes can enter into force without requiring to first be transposed into law in England. If stakeholders considered that such ambulatory references were inappropriate, they were asked state why they considered that the Annexes and future amendments to them should continue to be given effect in domestic law by the method they are at present, i.e. by Statutory Instruments which amend existing Statutory Instruments;
- whether it is appropriate to increase the penalties for breaches of feed labelling and feed composition provisions, as explained at paragraphs 3.14 to 3.18 above. If it was considered that the penalties should remain as set out in the Agriculture Act 1970, or should be increased to a lesser level than that proposed, stakeholders were asked to provide appropriate statements in support of any argument that such breaches should be treated less seriously than breaches of the requirements of the Feed (Hygiene and Enforcement) (England) Regulations 2005. If they considered that the increase in the penalties should be greater than that provided for by the draft Animal Feed (England) Regulations 2010, they were asked to provide similar supporting arguments;
- whether those provisions of Part IV of the Agriculture Act 1970 which concern matters now covered by Regulation 767/2009 were appropriately disapplied. If it was considered that any or all of these provisions should continue to have effect rather than be discontinued in this fashion, stakeholders were asked to both name the sections in question and to state why in their opinion they should be retained, and to outline how any potential repetition of or contradiction with the Regulation might be resolved.

7.6 Comments were also invited on the potential benefits and costs identified and discussed in section 5 above. Stakeholders who wished to dispute these calculations and to put forward alternative figures for the benefits and costs were requested to provide detailed arguments in support of their case. Similarly, stakeholders who considered that there were potential benefits or costs associated with Regulation 767/2009 which are not addressed in section 5 above were also requested to provide detailed arguments in support of their case.

7.7 Comments were also invited on an additional issue. This concerned an apparent inconsistency in EU legislation with respect to certain of the definitions to be applied. Regulation 178/2002 on the general principles of food law defines “feed” as “any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals”. This definition is also used in Regulations 767/2009 and 1831/2003 on feed additives. However, Directive 2002/32 on undesirable substances uses a slightly different definition for the term “products intended for animal feed”. Similarly, Regulations 178/2002, 1831/2003 and 767/2009 use the term “placing on the market” to mean holding feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves”, whereas Directive 2002/32 uses a very similar form of words to define the term “putting into circulation”.

7.8 The Food Standards Agency's view was that there is no meaningful difference between the wording of each pair of definitions and the terms concerned, and this view has been forwarded to the Commission with a request that it consider the matter with a view to arriving at a consistent terminology. The Commission advised in response that it was considering standardising the definitions on those used

in Regulation 178/2002, which would be the Agency's preference. However, comments on the definitions to help inform the forthcoming discussions were invited.

Results of the Consultation

7.9 There were ten substantive responses to the consultation, raising points on which clarification or further information was sought, and a number of other responses which made broad general comments on various issues related to Regulation 767/2009 without raising specific questions. All those responding indicated their agreement with the approach to the enforcement of the Regulation outlined in the list of bullet points in paragraph 7.5 above, and none dissented from the potential benefits and costs discussed in section 5.

7.10 Three responses raised queries over the application of the transitional period allowed for in the Regulation, under which pet food labelled in accordance with existing requirements may be placed on the market until 31 August 2011 and, after that date, remain on the market until stocks are exhausted. (This transitional period had been agreed because of the long lead times for the re-origination of pet food labelling, which typically occurs over a three-year period, as opposed to livestock feed labelling which is usually generated at the point of production.) Two of these responses requested that the transitional period be revised to cover supplies of labels held in stock after 31 August 2011 as well as product on the market; the third requested that the transitional period be extended to cover feed for horses as well as pets. However, it is thought unlikely that the Commission would wish to consider amending the scope of the transitional period unless further evidence is provided.

7.11 Four responses queried the use of the term "complementary feedingstuff", which has been present in feed legislation for many years but was suggested to be less meaningful to purchasers than the more user-friendly "dietary supplement", although this term has no legal basis. However, the Agency suggested in response that the latter term might be interpreted in a different way to the former, as meaning something which could be fed freely, whereas complementary feeds are required to be labelled with instructions for their use to prevent animals from receiving excess doses of the high levels of additives these products typically contain.

7.12 Two local authorities asked whether there would be training available on the enforcement of the Regulation's provisions. The Agency has advised in response that this is not one of the envisaged priorities for the current financial year, but that general stakeholder guidance to the interpretation and enforcement of the Regulation would be drawn up which should go some way to assisting local authority enforcement officers.

7.13 One response queried the application of the Regulation to feed for creatures living freely in the wild (typically wild birds visiting garden bird feeders). The Agency responded by pointing out that the provisions on undesirable substances have applied to such feed since they were first introduced, in part because it is not always possible to separate the production of feed for wild animals from that for other animals (for example, dried mealworms may be fed to both farmed poultry and wild birds), nor in some cases its storage and marketing prior to use. It was also pointed out that feed for game intended to be shot and processed for human consumption is already subject to other legislative requirements such as traceability and hygiene, and the bringing of feed for all wild animals within the ambit of Regulation 767/2009 is therefore not as unusual as it may appear.

7.14 Two responses focused on technical matters concerning the declaration of additives and the limits of variation, requesting that these issues be covered in the Agency's guidance to the interpretation and enforcement of the Regulation. One response also covered the definition of feed discussed in paragraphs 7.7 and 7.8 above, suggesting that the definition given in Regulation 178/2002 was too broad by comparison with that used in the other two measures.

Post-Consultation

7.15 The Agency's Animal Feed Branch has had further meetings with trade associations and enforcement bodies to discuss aspects of the Regulation. The Agency is also drawing up guidance to the interpretation and enforcement of the Regulation, which is expected to be published (on the Agency's website) later this year.

8. Wider Impacts

Race Equality Issues

8.1 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any implications for or impact on race equality issues.

Disability Equality Issues

8.12 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any implications for or impact on disability equality issues.

Gender Equality Issues

8.3 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any implications for or impact on gender equality issues.

Competition Assessment

8.4 An accurate picture of the feed sector's economic position is not available, as detailed information on the capital formation, market share, turnover and geographical location of animal feed businesses has not been collected for some years. However, it is known from data compiled by the Office for National Statistics for the Inter-Departmental Business Register that in 2009 there were 405 premises manufacturing prepared feeds for farm animals in the UK. These figures will include firms producing pet food and feed for horses as well as feed for farmed livestock, although they exclude firms producing fish meal and oil seed cake. Using regional data on the number of employees, the premises can be categorised by size as follows:

Region	**Micro**	**< 20**	**Small**	**Medium**	**Large**	**Total**
UK	250	40	60	50	5	405
England	201	32	48	40	4	325
Wales	9	1	3	2	0	15
Scotland	12	2	3	2	0	20
Northern Ireland	28	4	7	6	1	45

Notes: Sizes are defined by number of employees per premises as follows: Micro -- less than 10 employees; <20 -- 10-19 employees; Small -- 21-49 employees; Medium -- 50-249 employees; Large -- more than 250 employees.

Distribution of premises by employee size is available only at UK level. For individual regions, the UK distribution of premises by size is applied to the total number of animal feed manufacturing premises in each region; some rounding errors may therefore occur in the rows reporting regional figures.

Source: ONS Inter-Departmental Business Register (2009) SIC codes -- 10.91 Manufacture of prepared feeds for farm animals and 10.92 Manufacture of prepared pet foods.

8.5 The Food Standards Agency's assessment is that the Animal Feed (England) Regulations 2010 will have little direct impact on competition in the UK feed industry. It will not limit the number or range of businesses operating in the sector by imposing exclusive rights to supply products or by creating a licensing scheme for them; it will not raise the costs of feed ingredients to some suppliers relative to others or alter the costs of entering or leaving the feed market; it will not limit the ability of businesses to compete by attempting to control the prices charged, to limit the scope for innovation or to restrict the ability to advertise feed products; and it will not limit incentives to compete by exempting any businesses from general competition law or by amending existing intellectual property rights.

8.6 However, it is possible that the repeal of mandatory percentage ingredient declaration could have some indirect impact on competition in the feed sector because it will mean that businesses are no longer required to declare their feed formulations on product labels, which at present allows other firms to appropriate the details of those formulations and offer identical products at lower prices because they have no research budget to recoup. Against this, however, should be set the disincentive to innovation

and research attributable to mandatory percentage ingredient declaration because of the requirement to declare commercially sensitive product formulations.

Small Firms Impact Test

8.7 Regulation 767/2009 contains a number of benefits for feed businesses. It is expected that small and medium-sized enterprises will benefit in particular from the repeal of the requirement to declare the ingredients of compound feed by their percentage weight of inclusion, the current costs of which are likely to bear more heavily on them than on larger companies.

Greenhouse Gas Assessment

8.8 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any implications for or impact on greenhouse gas emissions.

Wider Environmental Issues

8.9 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any implications for or impact on wider environmental issues other than those discussed under the sustainable development heading at paragraph 8.14 below.

Health and Well-Being

8.10 The Agency considers that the Animal Feed (England) Regulations 2010 may have some long-term implications for or impact on issues concerning health and well-being -- see the third bullet point at paragraph 8.14 for further information.

Human Rights

8.11 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any implications for or impact on human rights issues.

Justice System

8.12 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any implications for or impact on the justice system.

Rural Proofing

8.13 The Agency considers that the Animal Feed (England) Regulations 2010 are unlikely to have any particular implications for rural areas.

Sustainable Development

8.14 Potential impacts under the three pillars of sustainable development (environment, economy and society) have been considered in the preparation of this Impact Assessment.

- *Environment* -- Regulation 767/2009 is primarily a consolidation and updating of existing labelling and marketing requirements, and will not require that feed be subjected to any more processing, transportation, storage or other treatment than it is at present. In consequence, the potential environmental impacts of the Regulation are likely to be broadly neutral, because it will have no more effect on the physical environment than previous feed legislation. However, it is possible that the requirement to label material being sent for detoxification or decontamination could have some beneficial effects because it will ensure that such material is capable of being reprocessed for use in the feed chain rather than having to be disposed by landfill, incineration or re-despatch to its country of origin, all of which have some associated environmental costs.
- *Economy* -- Regulation 767/2009 will impose some additional costs on feed business operators through the requirement for the fuller labelling of the additive content of compound feed, which it has been calculated could impose a continuing annual cost of £689,000 for the UK as a whole. Against this, however, should be set the expected reduction in administrative burdens for the feed industry of almost £44 million per year from the repeal of the requirement

for the mandatory percentage declaration of the ingredients of compound feeds. There will also be some savings to industry from the abolition of the requirement for a dossier assessment of new bioprotein products and thus the need to fund clinical trials of these products before they can be brought to market. There may also be some additional savings to central government and local enforcement authorities from the introduction of the voluntary Community Catalogue of feed materials and the Code of Practice for good labelling, which may reduce the marginal costs associated with the controls set down in the previous legislative regime. There will also be some reduction in administrative burdens for central government from the introduction of ambulatory references to the lists of categories of feed materials for non-food-producing animals, maximum permitted levels for undesirable substances and particular nutritional purposes, which in future will not require to be updated by amending Statutory Instruments whenever changes to these provisions are voted on by the Standing Committee on the Feed Chain and Animal Health.

- *Society* -- Regulation 767/2009 does not seem likely to have any impact on social questions relating to (for example) safety at work, the rate of crime, the population's level of skills and education, or community cohesion and the provision of community services. However, it may have some impact on the health of both animals and the human consumers of animal products (milk, meat and eggs) through the abolition of the requirement for a dossier assessment of new bioprotein products before they are brought to market, as this could allow potentially hazardous products to enter the feed and food chains. However, it is intended that post-marketing surveillance should identify and remove such products, and the likely risks should therefore be short-term. Any other health impacts will be broadly neutral, because the Regulation will not alter any of the existing provisions relating to the protection of animal and human health (e.g. through the setting of maximum permitted levels for undesirable substances).

It is therefore considered that, on balance, option 2 -- providing for the enforcement of European Regulation 767/2009 on the placing on the market and the use of feed -- is the relatively more sustainable of the two options identified in section 4 because the positive impacts (most of which are economic) are assessed as outweighing the negative ones. It is also considered that it is more proportionate to the requirements of feed business operators and local authority trading standards departments.

Enforcement

8.15 Local authority trading standards departments in England are mainly responsible for the day-to-day enforcement of the Animal Feed (England) Regulations 2010. This is unchanged from the previous arrangements for the enforcement of animal feed legislation.

9. Summary, Preferred Option and Implementation Plan

9.1 European Parliament and Council Regulation (EC) 767/2009 of 13 July 2009 on the placing on the market and the use of feed is part of the Commission's modernisation and simplification programme. It replaces five separate Directives on various aspects of animal feed labelling, marketing and composition, bringing their provisions together into a single Regulation which applies directly in all member States from 1 September 2010. The Regulation abolishes the existing requirement for the percentage declaration of the ingredients of compound feed, which the UK feed industry estimates has cost it over £43 million a year, and introduces a Catalogue of feed materials and Codes of Practice for good labelling, which are to be drawn up by the European feed industry and are expected to achieve the same harmonised results as at present but without the need for prescriptive legislation.

9.2 The Regulation also introduces a number of other amendments to existing feed legislation. These include the extension of the feed safety principles of feed law to feed for non-food-producing animals, a demarcation between complementary feeds and premixtures to ensure greater control of products with high levels of additives, a procedure for the approval of new nutritional purposes for which dietetic feeds may be promoted, a requirement that scientific substantiation of claims for a feed's composition or function be available on request, fuller additive labelling, the abolition of the existing requirement for the dossier assessment of new bioproteins, and a requirement that contaminated feed being sent for cleaning be labelled as such to safeguard against its diversion back into the feed chain. The Regulation applies directly in all Member States without requiring transposition into national legislation.

9.3 The preferred option is therefore to make legislation -- the Animal Feed (England) Regulations 2010 -- to provide for the enforcement of the Regulation by providing penalties for the infringement of specific provisions and by creating links between those provisions and the powers already granted to enforcement officers under Part 4 of the Feed (Hygiene and Enforcement) (England) Regulations 2005. The Animal Feed (England) Regulations 2010 will also:

- repeal the existing secondary legislation -- the Feeding Stuffs (England) Regulations 2005 (as amended) -- which transposes the Directives the Regulation has replaced;
- re-enact those EU feed measures which remain outside the Regulation's scope and make the references to their Annexes ambulatory so that amendments to them will take effect without having to be transposed into national law;
- designate competent authorities for the enforcement of the Regulation's provisions;
- increase the penalties for breaches of feed labelling and composition; and
- amend primary legislation (the Agriculture Act 1970) where it repeats, conflicts or overlaps with the Regulation.

9.4 The Regulation is broadly supported by the UK feed industry, whose views were taken into account by the Food Standards Agency prior to and during the negotiations on it. The Agency has continued to liaise with key stakeholder groups and enforcement bodies following the adoption of the Regulation, and is preparing guidance to its interpretation and enforcement to assist with its application in England.

9.5 It is anticipated that the Animal Feed (England) Regulations 2010 will be reviewed not less than five years after 1 September 2010 (i.e., the date from which Regulation 767/2009 applies in Member States).

Annexes

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: To evaluate the practical application in England of the various amendments to existing legislation on the labelling, marketing and composition of animal feed introduced by Regulation 767/2009 and to ensure that the ambulatory references to other feed legislation are applied correctly.
Review objective: To formulate UK views for input to future discussions in the Standing Committee on the Food Chain and Animal Health on the appropriateness and proportionality of the Regulation and any proposed amendments to it.
Review approach and rationale: A proportionate approach, which will be limited to a desk review. Feedback from the UK feed industry and enforcement bodies on the application of the Regulation will be sought and acted upon as part of the review and policy development cycles.
Baseline: Existing legislation on the labelling, marketing and composition of animal feed.
Success criteria: Discussions in the Standing Committee on the Food Chain and Animal Health are influenced by the UK's views. There are no unintended consequences for feed legislation and the UK feed industry from the application of the Regulation and the use of ambulatory references to other feed legislation.
Monitoring information arrangements: Continuing stakeholder engagement (from formal and informal feedback and meetings with key stakeholder groups, including the annual feed stakeholder meetings) will be the main tool.
Reasons for not planning a PIR: