EXPLANATORY MEMORANDUM TO

THE FEEDING STUFFS (ENGLAND) REGULATIONS 2005

2005 No. 3281

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

2. Description

This instrument provides for the enforcement of EC Regulation 1831/2003, which introduces new controls on the authorisation and use of feed additives in animal nutrition; and transposes Commission Directive 2004/116 which adds a new yeast-derived bioprotein product to the authorised list of such products. The Regulations also consolidate the various amendments to the Feeding Stuffs Regulations 2000.

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

None.

4. Legislative Background

4.1 The Feeding Stuffs Regulations were last consolidated in October 2000, and have been amended several times since then. It is therefore appropriate to consolidate them again. Consolidation also allows for the removal of superseded provisions relating to feed additives, now controlled by EC Regulation 1831/2003, which has replaced the previous control measure, Directive 70/524/EEC, and applies directly. The Feeding Stuffs (England) Regulations 2005 therefore provide for a range of offences and penalties for breaches of the relevant Articles of the EC Regulation.

4.2 Negotiations on the feed additives proposal commenced in Brussels in 2002, with the objective of consolidating and rationalising the existing rules in order to clarify the procedural aspects of additives authorisation. During the negotiations, the UK gained a number of improvements to the Commission's original proposal, including a seven-year transitional period for the preparation of dossiers for silage agents (the original proposal would have required applicants to conduct trials and submit dossiers before the Regulation came into force) and a lighter regime for some categories (additives for pet food, generic substances already authorised for human food, and additives used in feed for minor animal species). Stakeholder views were sought on several occasions during the negotiations, to help inform the UK line.

4.3 The EU Scrutiny Committee was kept informed of the progress of the feed additives proposal. An initial Explanatory Memorandum was submitted in May 2002, followed by supplementary Memoranda in November 2002 and March and August 2003. European Standing Committee C debated the proposal, as then amended, in July 2003 and passed a motion supporting it.

4.4 Commission Directive 2004/116 adds a new yeast-derived product, *Candida guilliermondii*, to the Annex of Council Directive 82/471/EC, which establishes rules for the authorisation and labelling of certain products (bioproteins) in animal feed. The EU Scrutiny Committee has not considered this measure.

4.5 A transposition note showing how the two measures have been given effect in the Feeding Stuffs (England) Regulations 2005 is attached to this Explanatory Memorandum.

5. Extent

This instrument applies to England. Separate but parallel legislation is expected for Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Feed additive (e.g. vitamin and trace elements) authorisations were subject to the provisions of Directive 70/524/EEC, which was last substantially amended by Directive 96/51/EC. One of the main principles was that only additives on an authorised list could be used in animal feed.

7.2 EC Regulation 1831/2003 strengthens the controls on the authorisation and use of feed additives. It retains the principle that only additives subject to an authorisation based on safety, quality and efficacy may be used in animal feed. Previously, under Directive 70/524/EEC, the competent authority of a Member State presented a dossier for consideration by the Commission and other Member States prior to authorisation. Under the new arrangements, new additives, and applications for changes to the conditions of authorisation for existing additives, will be assessed by the European Food Safety Authority (EFSA). Authorisations will be renewable at ten-year intervals. Existing authorised additives, such as vitamins and trace elements, will be re-evaluated using updated criteria.

7.3 Commission Directive 2004/116/EC amends the Annex to Council Directive 82/471/EC which establishes rules for the authorisation and labelling of certain products (bioproteins) in animal feed. Only authorised bioproteins may be used in feed.

8. Impact

8.1 The Food Standards Agency consulted a range of stakeholder organisations -- trade associations, enforcement bodies, consumer groups -- on the draft Regulations. Ten responses were received in England. The Food Standards Agency in Scotland received four responses to its consultation. The main impact is likely to be on feed

businesses, where feed additive dossiers will be required for the authorisation of silage agents and the re-evaluation of existing feed additive authorisations, but the businesses and trade associations which responded to the consultation did not provide figures to substantiate their concerns, particularly with respect to the potential cost of compiling feed additive dossiers and additional labelling costs. However, the potential additional costs to businesses have to be balanced against the potential effects of additives which have not been properly tested or authorised, which could have adverse consequences for both animal health and the health of human consumers of livestock products.

8.2 EC Regulation 1831/2003 also applies to "medicinal" feed additives (principally coccidiostats and histomonostats -- substances added to feed to kill or inhibit certain parasites, mainly in poultry -- and antibiotic growth promoters). These provisions are the subject of separate Regulations to be made by the Veterinary Medicines Directorate (VMD) of the Department for Environment, Food and Rural Affairs (Defra).

8.3 Directive 2004/116 adds a new yeast-derived product, *Candida guilliermondii*, to the Annex of Council Directive 82/471/EC. This product, which is intended for use in feeds for fattening pigs, extends the existing range of yeast-derived bioproteins authorised for use in animal feed.

8.4 A Regulatory Impact Assessment, which provides more details of the impact of the two measures, is attached to this memorandum.

9. Contact

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

REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

THE FEEDING STUFFS (ENGLAND) REGULATIONS 2005

i) Consolidation of:
The Feeding Stuffs Regulations 2000 and the various amendments made to them; and

ii) Implementation of:
European Parliament and Council Regulation (EC) 1831/2003 of 22 September 2003 on additives for use in animal nutrition (*OJ* No. L268, 18.10.2003, p. 29)
Commission Directive 2004/116/EC of 23 December 2004 amending the Annex to Council Directive 82/471/EEC as regards the inclusion of *Candida guilliermondii* (*OJ* No. L379, 24.12.2004, p.81)

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

2.1 These Regulations consolidate the Feeding Stuffs Regulations 2000 and the various amendments made to them. The continuation in force of these feed measures is not expected to give rise to any new costs, and therefore they have been excluded from the scope of this partial Regulatory Impact Assessment (RIA). The RIA concentrates on the new legislative requirements arising from the EC Regulation on feed additives and the Commission Directive authorising a new bioprotein product for use in animal feed.

i) The Objective

2.2 These Regulations provide for the enforcement of European Parliament and Council Regulation (EC) 1831/2003, which rationalises existing measures for, and introduces new controls on, the authorisation and use of additives in animal nutrition. This Regulation repeals and replaces a number of existing EC measures in this area. One of its main aims is the strengthening of controls on the authorisation and use of feed additives, which in turn should further protect consumers of livestock products and animal health.

2.3 These Regulations also implement Commission Directive 2004/116 adding a new yeast-derived bioprotein product to the existing range of such products. Only bioproteins which have been subjected to a scientific assessment of their safety, quality and efficacy are authorised for use in animal feed.

ii) The Background

EC Regulation 1831/2003

2.4 Feed additives were controlled by Directive 70/524/EEC, which provided that only additives on an authorised list could be used in animal feed, in accordance with prescribed conditions of use. Feed additives include vitamins, trace elements, binders, preservatives and flavourings, which were classed as non-zootechnical additives; and zootechnical additives such as growth promoters and coccidiostats (substances added to feed to kill or inhibit certain parasites, mainly in poultry).

2.5 Additives were added to the list only after an assessment of their safety, quality and efficacy, which had to be demonstrated in the form of an evidence-based dossier of relevant scientific information. The competent authority of a Member State acted as rapporteur for the manufacturers (or other applicants), and presented the dossier for consideration by the Commission and other Member States prior to authorisation. The Commission considered that certain changes to this procedure were necessary in order to rationalise and consolidate the existing rules to clarify the procedural aspects of additives authorisation.

2.6 EC Regulation 1831/2003 retains the principle that only additives subject to an authorisation based on safety, quality and efficacy may be used in animal feed. However, the Regulation introduces a number of changes, which are explained in the following paragraphs.

2.7 Applications and Authorisations Dossiers for new additives, and applications for changes to the conditions of authorisation for existing additives, will be assessed by the European Food Safety Authority (EFSA). The linkage of authorisations for growth promoters and coccidiostats to the person marketing the additive will be retained and extended to enzyme and micro-organism products. Authorisations will be renewable at ten-year intervals.

2.8 Scope Controls on additives, which previously covered only their incorporation in feedingstuffs, are now extended specifically to cover their use in water. Silage agents, used in the ensiling of grass and other feed materials, are brought within the scope of the Regulation. All additives covered by the new measure are divided into functional groups according to their principal function.

2.9 Labelling Directive 1831/2003 includes labelling requirements for additives and premixtures, most of which were a feature of the Directive 70/524/EEC. However, there are certain new requirements, such as labelling for silage agents.

2.10 Antibiotic Growth Promoters From 1 January 2006, these will no longer be authorised as feed additives. The potential impact of the withdrawal of these products is not covered in this Regulatory Impact Assessment because they are subject to separate legislation by the Veterinary Medicines Directorate (VMD) of the Department for Environment, Food and Rural Affairs.

2.11 Re-evaluation of Existing Products Approximately 350 additives which received their current authorisation some years ago, before the existing guidelines

were drawn up, will be re-evaluated using updated criteria. The re-evaluation will cover a number of generic substances such as vitamins and trace elements.

Commission Directive 2004/116/EC

2.12 Rules for the authorisation and labelling of certain products for use in feed are set out in Council Directive 82/471/EEC. Certain products used in animal nutrition - sometimes called bioproteins - are products which can be used as direct and indirect sources of protein, which are usually manufactured via fermentation processes, and which are intended to complement other protein sources in the diet. They are listed in the Annex to the Directive together with the species for which they are intended and the labelling conditions attached to them. The Annex has been amended and extended several times since it was first adopted.

2.13 Commission Directive 2004/116/EC adds a new yeast-derived product, *Candida guilliermondii*, to the Annex to Directive 82/471. *Candida guilliermondii*, which is intended for use in feeds for fattening pigs, extends the existing range of yeast-derived bioproteins authorised for use in animal feed.

iii) Risk Assessment

EC Regulation 1831/2003

2.14 Controls on the use of additives for animal nutrition are necessary to minimise the potential risks to animal health and the ultimate consumers of animal products. One example is the assessment of certain strains of micro-organisms for their toxigenic potential (i.e. their potential to produce toxic substances). Regulation 1831/2003 both strengthens these controls and extends them into new areas.

2.15 Applications and Authorisations The assessment of applications by the European Food Safety Authority (EFSA), rather than by Member States' experts, should provide a more independent approach to the authorisation process, which will be more transparent and thus more robust, increasing consumer protection.

2.16 Additives will now be grouped according to their functional category -- technological, sensory, nutritional and zootechnical. Enzymes and micro-organisms will be classified as zootechnical additives if they conform to the category definition "to affect favourably the performance of animals in good health or used to affect favourably the environment".

2.17 Additive authorisations will be linked to the holders of those authorisations and will be for renewable periods of ten years. This is expected to benefit both manufacturers and feed safety -- manufacturers because they will have exclusive rights to the additives concerned (compared with authorisations for generic additives such as vitamins and trace elements), and feed safety because authorisations will be open to review in the light of new information about an additive's safety and efficacy.

2.18 Scope It is appropriate to bring silage agents and additives used in water and other non-feed media within the scope of these controls, since they involve the use

of substances fed to animals which, if misused, have the potential to compromise animal health and the health of human consumers of animal products.

2.19 The European Commission has indicated that additives used in water and other non-feed media, such as boluses (slow-release capsules) or pastes may be authorised under a general provision in the EC Regulation to permit the circulation of mixtures of additives for end-users.

2.20 The extension of controls to silage agents (chemicals, enzymes and micro-organisms added to grass and other forages to improve the ensiling process and the quality of the resulting silage) will require these products to be specifically authorised for this use. Manufacturers will be required to provide scientific dossiers, including the results of clinical trials, in support of their continued use.

2.21 Re-evaluation of Existing Products Many additives have a long history of use, in both animal feed and food for human consumption, but because they were authorised a number of years ago they will require re-evaluation in the light of current knowledge. There may be resulting consumer health benefits because the full range of authorised additives will be subject to detailed examination.

2.22 The re-evaluation process will cover many generic additives, such as vitamins and trace elements, many of which are relatively innocuous substances already allowed in human food and for which rigorous re-evaluation may be inappropriate or unnecessary. However, it is possible that manufacturers may be unwilling to invest the time and research effort to produce dossiers for these additives because of potentially disproportionate costs. A period of seven years has been allowed for the receipt of valid applications for re-evaluation, but it is not yet clear how long the Commission expects the review as a whole to take.

Commission Directive 2004/116

2.23 When used in feed, the yeast *Candida guilliermondii* will provide particular advantages for farmers raising pigs for fattening because it is an alternative source of dietary protein. The product has already been assessed for safety, quality and efficacy by the relevant scientific committee of the European Food Safety Authority.

iv) Devolution

2.24 EC Regulation 1831/2003 is directly applicable throughout the UK, but needs to be linked to enforcement powers in the Feeding Stuffs Regulations to ensure that appropriate sanctions for non-compliance can be applied. Directive 2004/116 requires transposition into national legislation before it can have effect. The Regulations which give effect to these EC measures will apply only in England. Separate but parallel Regulations will be made in Scotland, Wales and Northern Ireland.

v) Timetable

2.25 EC Regulation 1831/2003 was directly applicable in all Member States from 18 October 2004. Directive 2004/116 should have been transposed by 30 June 2005.

3. OPTIONS

3.1 There are two options:

(i) non-implementation of the measures; or
(ii) full implementation of the measures.

i) Non-Implementation

EC Regulation 1831/2003

3.2 The provisions of EC Regulations are directly applicable in Member States. However, UK practice has been to link these provisions to national enforcement powers via offences and penalties for non-compliance. Failure to link EC Regulation 1831/2003 to the Feeding Stuffs Regulations would mean that its provisions could not be properly enforced in England. This could also give rise to concerns that a measure intended to enhance the safety and integrity of the feed chain and the protection of consumers was being ignored. Non-implementation could also result in legal proceedings against the UK in the European Court of Justice.

3.3 Feed additives need to undergo a safety assessment, aimed at the protection of human and animal health and the environment, before being placed on the market, used or processed within the EU. Non-implementation could potentially have adverse impacts on human health, from harmful residues in products of animal origin or pathogenic strains of micro-organisms, which may lead to costs in terms of treatment. There could also be potential impacts on animal health and welfare.

3.4 One of the benefits of non-implementation might be the saving by manufacturers of the costs of providing dossiers for the authorisation of silage agents and the re-evaluation of existing authorisations. However, this saving would apply only to additives intended for use within the UK; dossiers would be required for additives for use in other Member States.

3.5 The costs of non-implementation would include the costs of infraction proceedings to the UK Government as well as the payment of any penalties imposed, but because of the absence of precedent in this area it is very difficult to estimate what these costs might be. There could also be costs resulting from the use of untested feed and silage agents; poor quality animal feed due to the use of ineffective technological additives (e.g. preservatives, antioxidants); losses in livestock production (e.g. lower milk yields because additives designed to improve feed utilisation were ineffective); impacts on animal welfare such as excess copper in feeds for sheep which causes toxicity (the costs here might relate to deaths of animals or veterinary treatments); effects on consumers from the carry-over of additives to livestock products (e.g. excess vitamin A in human diets can be a

contributing factor to brittle bones); and impacts on the environment through unrestricted use of certain additives. Other costs relate to the loss of benefits identified in paragraph 4.1 below, including those concerning improvements to safeguard animal welfare, human health and in relation to the production and despatch of dossiers.

3.6 Stakeholders were invited to comment on the benefits and costs which might derive from the non-implementation of the Regulation, and if possible to provide a financial estimate of same. Comments were also invited on any potential impacts on the environment. However, no comments on non-implementation were forthcoming; those stakeholders who responded in detail to the consultation appeared to accept that non-implementation was not a practicable option.

Commission Directive 2004/116

3.7 Non-implementation would mean that the newly authorised yeast *Candida guilliermondii* was not available for use in feed for fattening pigs. As with non-implementation of EC Regulation 1831/2003, there could be legal proceedings against the UK in the European Court of Justice.

ii) Full Implementation

3.8 Full implementation of both measures would be consistent with the UK's obligation as a Member State of the EU (the UK voted in favour of both of the measures). EC Regulation 1831/2003 in particular will introduce a number of additional measures on the authorisation and use of feed additives, which will need to be observed by the feed and agricultural industry.

4. BENEFITS

i) Economic

4.1 EC Regulation 1831/2003 contains measures to strengthen feed safety, in particular through the re-evaluation of existing feed additive authorisations and the bringing of silage agents within the scope of the controls. However, these are difficult to quantify. Stakeholders involved in the preparation of dossiers may also experience savings from the need to no longer provide some 30 printed copies of each dossier, at costs of copying and despatching a dossier of around £2000.

4.2 Commission Directive 2004/116 will be of direct benefit to UK manufacturers of *Candida guilliermondii* products, who will be able to sell these into the feed chain in both the UK and other Member States.

ii) Environmental

4.3 The assessment of applications for feed additive authorisations under EC Regulation 1831/2004 includes consideration of the implications of the use of additives on the environment. There is a category of additives which are "substances which favourably affect the environment". Only the holders of the authorisations of those products will have the right to market such products for the

first ten years of authorisation. This might encourage the development of products of this type.

4.4 There are no identifiable environmental benefits arising from the implementation of Commission Directive 2004/116.

iii) Social

4.5 EC Regulation 1831/2003 is one in a range of other measures designed to ensure the protection of human health. Some substances have the potential, if misused, to compromise animal health and the health of the ultimate consumers of animal products, with subsequent costs associated with their treatment and recovery. There may therefore be potential savings from the foregoing of these costs in future because the misuse of these substances will be lessened or avoided, although these savings are difficult to quantify.

4.6 There are no identifiable social or health benefits arising from the implementation of Commission Directive 2004/116.

4.7 Stakeholders were invited to comment on any benefits they anticipated for themselves, for consumers or for others, and if possible to quantify these benefits. They were also asked to provide estimates of the potential costs of dossiers and any savings which might be derived from the new system of dossier assessment by the EFSA. Only one stakeholder responded on this point, expressing concern that the expense of providing animal trial data in support of feed additive dossiers could be beyond the means of small businesses, so threatening their continued viability.

5. COSTS

5.1 Some of the following information was included in the Regulatory Impact Assessment prepared at the time of negotiations in 2002–2003 on the measure subsequently adopted as EC Regulation 1831/2003. Stakeholders were invited to comment and to forward any information which could provide, confirm or update the estimates of costs in this entire section. However, only one comment, on the potential costs for silage agents, was received (see paragraphs 5.8 and 5.9).

i) Economic

5.2 The principal areas identified for EC Regulation 1831/2003 are costs that will be incurred by the feed industry for:

(a) providing dossiers for the re-evaluation of existing feed additive authorisations;
(b) providing dossiers for authorisation of silage agents; and
(c) additional labelling costs.

These cost areas are dealt with in more detail in paragraphs 5.4 onwards.

5.3 The overall usage of some categories of additives would be likely to change if it was not economically viable for some companies to produce dossiers. A similar situation could occur if, for the same reasons, dossiers were not produced and submitted for the re-evaluation of existing additives. It should be noted that UK

companies will not be responsible for the provision of dossiers for all the additives subject to re-assessment. It is likely that the vast majority of dossiers will be provided by companies in other Member States.

5.4 The compliance costs for individual businesses will depend on the type of business and a number of factors.

Manufacturers of Feed Additives and Premixtures

5.5 For the authorisation of new multifunctional feed additives, where efficacy assessments are required for each claim, the Agency estimates additional costs of approximately £100,000. However, for established products subject to re-evaluation, companies may already possess suitable data. In addition, information on generic products such as vitamins and trace elements may be generally available in the published scientific literature. Lower compliance costs might be expected from the lighter assessment regime envisaged for products with a history of safe usage, for additives for use in pet foods which have no implications for the human food chain, and for proof of efficacy for existing authorised products.

5.6 There may be some costs involved in the requirement to include new information on the labels of additives and premixtures. The figures for these costs are likely to be dependent on the technological capabilities of the firms in question and the number(s) of labels printed at any one time.

5.7 The total costs to individual companies will also depend on the number of products owned or marketed. There would be loss of earnings to companies (including to sellers of additives and premixtures) if certain additives or silage agents failed to gain re-authorisation or authorisation.

Manufacturers of Silage Agents

5.8 In the UK there is an existing voluntary industry scheme for the assessment and registration of silage agents which requires the submission of animal trial and other data. Much of this data might be acceptable for the authorisation of silage agents under EC Regulation 1831/2003. In addition, for simple generic substances (e.g. formic and lactic acid used to inhibit fermentation in the ensilage process) information to support authorisation might be available from the existing scientific literature. One trade source indicated that costs for the provision of dossiers for such generic products may be in the order of £5,000--£10,000.

5.9 For non–generic substances such as micro-organisms (which aid fermentation), existing trial data may be acceptable. If new animal trial data had to be commissioned (e.g. for a new silage product), one industry estimate placed the cost at the upper end of scale, at around £200,000. This was broken down as follows:

- additional testing for heavy metals / toxins: £5,000 per annum;
- antibiotic production / resistance: £10,000 per microbial strain;
- transmissibility trials: £20,000;
- new efficacy studies assuming current trials are deemed inadequate because of a duration of less than 100 days: £80,000;

- tolerance testing on target species: £30,000--50,000;
- consumer safety assessment (genotoxicity and oral toxicity): £10,000--20,000;
- irritancy assessment: £10,000--20,000.

5.10 One industry stakeholder expressed concern that the eventual costs could be higher than these estimates, basing this comment on the fact that the requirements for silage dossiers had still to be finalised by the Commission and therefore remained unknown. However, no figures were quoted in support of this assertion.

Feed Compounders and Pet Food Manufacturers

5.11 There could be implications for companies if, as a result of the re-evaluation of existing products, certain additives became unavailable. It is not clear how far feed additive manufacturers would be willing to sponsor dossiers for the re-evaluation of additives. In some cases animal feed and pet food manufacturers (or their trade associations) may take on this task and any attendant expenses.

5.12 There are no identifiable economic costs associated with Commission Directive 2004/116.

Charities and Voluntary Organisations

5.13 No costs are envisaged for charities and voluntary organisations in connection with either of the two measures.

ii) Environmental

5.14 None identified for either of the two measures.

iii) Social

5.15 None identified for either of the two measures.

6. EQUITY AND FAIRNESS

6.1 On the grounds of public safety and animal health, there need to be measures in place to ensure the safe use of additives and other products such as bioproteins in animal nutrition. However, measures to achieve this should be effective and enforceable. EC Regulation 1831/2003 in particular achieves a greater equity in the assessment and subsequent use of additives in animal nutrition, since silage agents, a category of additives hitherto not subject to controls, will be brought within the scope of the legislation.

6.2 In terms of race and equality, the measures will impact equally on businesses and organisations from all sectors.

7. SMALL FIRMS' IMPACT TEST

7.1 A number of the feed additive manufacturers, traders and feed manufacturers

affected by this measure are classified as small businesses. The measure will also apply to some farms. During negotiations on the measure, thirteen stakeholders were approached to carry out a small business impact test. This revealed that some small companies (additive manufacturers) might not have sufficient resources to compile feed additive dossiers if expensive animal trial data is required.

7.2 However, it is not possible at present to quantify these potential costs because the guidelines for the assessment of feed additive dossiers are still under discussion in the Commission and the European Food Safety Authority. Among other things, these guidelines will lay down the nature and scope of the trial data to be provided by applicants for authorisation, and the potential costs to businesses of providing this data can only be assessed once the guidelines have been agreed. The UK is seeking to make the guidelines proportionate, to not overburden industry and to ensure there are less onerous requirements for feed additives intended for non-food producing animals. The Commission consulted European trade associations on a draft of the guidelines during the summer months, and has expressed a hope that a finalised version will be adopted in the autumn. However, this timetable may prove optimistic; negotiations are ongoing, and it is not yet possible to anticipate either their outcome or a date by which they may be concluded.

8. SUSTAINABLE DEVELOPMENT

8.1 Sustainable development can be defined as development that meets the needs of the present without compromising the ability of future generations to meet their own needs. Sustainable development encompasses: environmental protection; prudent use of natural resources; social progress; economic growth and employment considerations. No impact which might result in detriment to future consumers is envisaged from EC Regulation 1831/2003 and Commission Directive 2004/116.

9. COMPETITION ASSESSMENT

9.1 The competition filter was applied to the feed additives proposal at the partial stage, which indicated that a full assessment was not required. However, various sectors are affected by this proposal -- feed additive and premixture manufacturers, product sellers, animal feed manufacturers, and pet food producers. Market concentration in the feed additives market is dependant on the type of additive.

9.2 In the absence of full implementation of EC Regulation 1831/2003 and Commission Directive 2004/116, there is the potential for manufacturers of feed additives and *Candida guilliermondii* products to be disadvantaged in terms of EU trade and unable to operate on a level playing field. For this reason, full implementation is recommended.

10. ENFORCEMENT AND SANCTIONS

10.1 Enforcement of animal feedingstuffs legislation is the responsibility of local authority trading standards departments in Great Britain and the Department of Agriculture and Rural Development in Northern Ireland (DARDNI). Enforcement includes advice on labelling requirements and taking samples of animal feed and

having them analysed for the presence of various ingredients. The penalties for non-compliance with feedingstuffs legislation are set out in the Agriculture Act 1970 and in subordinate legislation made under it. Non-compliance is to be treated as a criminal offence, and would be subject to fines and the option of a prison sentence (section 74A(3) of the Agriculture Act 1970 refers).

10.2 Neither EC Regulation 1831/2003 nor Commission Directive 2004/116 specify any additional levels of sampling and analysis, and the cost to local authority trading standards departments of their implementation is therefore expected to be minimal. There could be some costs to local authorities associated with advice on the labelling requirements of EC Regulation 1831/2003, but these are generally expected to be marginal. The main implications associated with the implementation of the EC Regulation are likely to fall on businesses, and on these grounds it has not been thought necessary to undertake a Public Services Threshold Test.

11. MONITORING AND REVIEW

11.1 The Food Standards Agency will consider proposals from stakeholders for any further changes to the rules that they consider necessary in the light of experience, and the effectiveness, of the new legislation.

12. CONSULTATION

i) Within Government

12.1 Food Standards Agency officials in Scotland, Wales and Northern Ireland were consulted on the enforcement of EC Regulation 1831/2003 and the implementation of Commission Directive 2004/116 and are broadly content with the approach being taken. The views of the Department for Environment, Food and Rural Affairs and the Small Business Service were sought as part of the consultation exercise. The Food Standards Agency in Scotland, Wales and Northern Ireland also sought the views of relevant departments -- respectively, the Scottish Environment and Rural Affairs Department, the National Assembly for Wales, and the Department of Agriculture and Rural Development.

ii) Public Consultation

12.2 The Food Standards Agency in England consulted a range of stakeholder organisations -- trade associations, enforcement bodies, consumer groups -- on the draft Regulations. Ten responses were received in England. The Food Standards Agency in Scotland received four responses to its consultation, but these are not included in the summary in paragraphs 12.3 to 12.6, which relates solely to England.

12.3 Two of the respondents said they had no comments on the draft Regulations and two others expressed a general welcome for the consolidation; no responses to these comments were thought necessary. Two respondents expressed concern about the potential impact on small businesses and others of the cost of applications for additive authorisations under the EC Regulation, in one case noting that the cost of assessing silage agents could be higher than the estimates in paragraphs 5.8 and 5.9 above. Pending the conclusion of discussions on the guidelines for the

assessment of additive dossiers, however, it is not possible to give a substantive response to these concerns.

12.4 A local authority trading standards officer queried the removal of the Schedule of authorised feed additives from the 2000 Regulations, and raised questions over the interpretation of some of the terms in the draft Regulations. The Food Standards Agency has advised in response that the Schedule has been removed because it is covered by EC Regulation 1831/2003 which, because it applies directly, cannot be repeated in national legislation; and that as the terms are derived from EU feed legislation the Agency can only offer an opinion on their meaning: definitive interpretation is a matter for the courts. Similarly, the co-ordinating body for trading standards officers (LACORS) raised a query about one of the definitions given in the draft Regulations; the Agency has pointed out in reply that this is the definition which appears in the relevant Directive and therefore it cannot be amended.

12.5 One trade association queried retention of a reference to animals bred for fur and suggested that since the Commission is shortly to review animal feed labelling requirements these issues should be addressed in subsequent amending legislation. The Agency said in reply that the labelling requirements in the draft Regulations for consultation merely repeated existing provisions, which have to be retained pending the outcome of the Comission's review; and that although the breeding of animals for fur is now prohibited in the UK the manufacture for export of feed for them is not.

12.6 Finally, another trade association submitted a number of minor comments on and corrections to the draft Regulations and suggested a re-ordering of the labelling requirements laid down in Schedule 3 so that they follow a more logical sequence. The Agency has advised that the minor aspects raised repeat provisions in EU legislation, which cannot therefore be varied, but thanked them for the corrections to the Schedules. The Agency sought the views of enforcement officers on the suggested re-ordering of the labelling requirements and has made some changes to the Schedule in consequence. These changes do not affect the labelling requirements themselves.

13. SUMMARY AND RECOMMENDATIONS

13.1 EC Regulation 1831/2003 in particular is intended to sustain and enhance feed and food safety in relation to additives used in animal nutrition. This Regulatory Impact Assessment identifies a number of compliance costs and potential benefits, although in some cases it is difficult to estimate the precise economic or monetary impacts. However, a number of improvements were made to the Commission's original proposal during the course of negotiations, which the Food Standards Agency considers should mitigate its effects on the feed and agricultural industries.

13.2 However, the additional costs to businesses have to be balanced against the protection of human consumers of livestock products. Overall, the provisions of both EC Regulation 1831/2003 and Commission Directive 2004/116 are proportionate to this aim.

Option	Total Costs per annum – Economic, Social, Environmental	Total Benefits per annum – Economic, Social, Environmental
1. Non-implementation	Cost of infraction proceedings (which would be ongoing), plus any financial penalties imposed by the Court (the figure would be at its discretion). Costs attributable to the use of untested additives.	Saving on dossier costs for silage agents and the re-evaluation of existing feed additive authorisations. No permission for the use of *Candida guilliermondii* in animal feed in England.
2. Full implementation	Dossier costs for silage agents and the re-evaluation of existing feed additive authorisations.	Would ensure that the UK is consistent with other Member States. Measures are being introduced to improve feed safety. Future use of *Candida guilliermondii* by English feed manufacturers and farmers permitted.

13.3 In the light of these considerations, it is recommended that Directive 2004/116/EC be implemented in England by the consolidation of the Feeding Stuffs Regulations 2005, and that EC Regulation 1831/2003 be linked to existing enforcement powers by the same Regulations.

Declaration

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

Signed by the responsible Minister: Caroline Flint

Date: 28th November 2005

Parliamentary Under Secretary of State, Department of Health.

Contact Point

Joseph Nicholas
Animal Feed Unit, Food Standards Agency
Rm 415B, Aviation House
125 Kingsway
London WC2B 6NH
Telephone: 020-7276-8462
Fax: 020-7276-8478
E-mail: joseph.nicholas@foodstandards.gsi.gov.uk