

# PARTIAL REGULATORY APPRAISAL

## 1. TITLE OF PROPOSAL

### THE FEEDING STUFFS (WALES) 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)

## 2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

These Regulations consolidate the Feeding Stuffs Regulations 2000 and the various amendments made to them. However, the continuation in force of these existing 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 Appraisal (RA). The RA concentrates on the new legislative requirements arising out of the EC Regulation 1831/2003.

### 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.
- 2.3 One of the main aims of the Regulation is to strengthen controls on the authorisation and use of feed additives. This in turn should further protect consumers of livestock products and animal health.
- 2.4 Devolution - Regulation (EC) 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. The Regulations which give effect to this EC measure will apply only in Wales. Separate but parallel Regulations will be made in England, Scotland, and Northern Ireland and these are being consulted upon separately.
- 2.5 Timetable - EC Regulation 1831/2003 was directly applicable in all Member States from 18 October 2004.

## ii) The Background

- 2.6 Feed additive 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, 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 the growth of certain parasites, mainly in poultry).
- 2.7 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.
- 2.8 Additives were added to the list only after an assessment of their safety, quality and efficacy, which was 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.
- 2.9 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.
- 2.10 Re-evaluation of Existing Products. Around 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, but these authorisations will not be linked to the persons marketing the products.
- 2.11 Scope. The existing controls on additives cover their incorporation in feedingstuffs, and 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.
- 2.12 Antibiotic Growth Promoters. From 1 January 2006, these will no longer be authorised as feed additives. Growth promoters are subject to regulation by

the Veterinary Medicines Directorate (VMD) of the Department for Environment, Food and Rural Affairs, and are not subject to the Feeding Stuffs Regulations (Wales) 2005. This Regulatory Appraisal does not therefore cover the potential impact of the withdrawal of antibiotic growth promoters, or other implications of VMD's legislation.

- 2.13 Labelling. Directive 1831/2003 includes labelling requirements for additives and premixtures. Most of these were a feature of the previous Feed Additives Directive (70/524/EEC). However, there are certain new requirements, e.g. labelling requirements for silage agents.

**iii) Risk Assessment**

- 2.14 It is important that the use of additives for animal nutrition is subject to controls in order 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 contains provisions which both strengthen these controls and extend them into new areas.
- 2.15 Applications and Authorisations. The assessment of applications by the European Food Safety Authority (EFSA), compared with the current situation, in which assessment is undertaken by Member States' experts, should provide a more independent approach to the authorisation process. The UK agrees with this change, considering that the process will be more transparent and thus more robust, to the benefit of consumer protection. However, it is important that EFSA is properly resourced for the task, including the assessment of silage agents and the re-evaluation of existing products.
- 2.16 As additives will now be grouped according to their functional category, 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". The authorisations for these products will be linked to the holders of the authorisations and will be for renewable periods of ten years. This approach will have advantages for both manufacturers, who will then have exclusive rights to the additives concerned (compared with authorisations for generic additives such as vitamins and trace elements, which can be used by anyone), and for feed safety, as authorisations will then be open to review in the light of new information about an additive's safety and efficacy.
- 2.17 Re-evaluation of Existing Products. Many additives have a long history of use, in both animal feed and food for human consumption. However, as they were authorised a number of years ago, they will require re-evaluation in the light of current knowledge. There may be resulting benefits to consumer health because the full range of authorised additives will be subject to detailed examination.

- 2.18 The re-evaluation process will cover many generic additives, such as vitamins and trace elements, for which manufacturers may be unwilling to invest the time and research effort to produce dossiers because of potentially disproportionate costs. However, a period of seven years has been allowed for re-evaluation.
- 2.19 A number of these generic additives are relatively innocuous substances already allowed in human food and for which rigorous re-evaluation may be inappropriate or unnecessary. The re-evaluation of additives for use in feed for non-food-producing animals should not need to be as rigorous as that for additives for feed for farmed livestock, as these products have few (if any) implications for the human food chain.
- 2.20 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 consumers of animal products.
- 2.21 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. Further clarification is being sought on how the assessment and authorisation of such products may be carried out. For example, it might be necessary for guidelines to be introduced for the assessment of dossiers for these products. However, when the Regulation was adopted, the Council of Ministers called on the Commission to propose separate legislation to cover these uses.
- 2.22 The extension of the controls regime 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, otherwise they would have to be removed from the market. This will require manufacturers to provide scientific dossiers in support of their continued use, to include the results of clinical trials.
- 2.23 During negotiations on the Regulation, the UK gained a number of improvements to the Commission's original proposal including:
- a 7 year transitional period for applicants to prepare dossiers for silage agents. The Commission's original proposal would have meant that silage agents would have had to be assessed and authorised by the time the Regulation came into force (November 2004). This would not have been sufficiently long for manufacturers to carry out trials and complete dossiers for authorisation;
  - a lighter regime for the authorisation/ re-evaluation of some categories of additives such as additives for pet foods, generic substances already

authorised for human food and additives used in feed for minor animal species.

### **3. OPTIONS**

3.1 There are two options:

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

#### **i) Non-Implementation**

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 Wales. 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 through a Community procedure before being placed on the market, used or processed within the Community. The safety assessment aims to protect human health, animal health and the environment. In the absence of these Regulations we consider there could be potential 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. Also there could be potential impacts on animal health and welfare.

3.4 The benefits of non-implementation might include the avoidance by manufacturers of the costs of providing dossiers for the evaluation of silage agents and the re-evaluation of existing feed additive 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, no costs associated with these have been included in the formal calculations. There might be costs resulting from the use of untested feed and silage agents. It is considered such costs may be attributable to poor quality animal feed because technological additives (e.g. preservatives, antioxidants) used were ineffective; 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 below in section 4 below, including those concerning improvements to safeguard on animal welfare, human health and in relation to the production and despatch of dossiers.

**Stakeholders are invited to comment on the benefits and costs that might arise if the Regulation was not implemented and if possible provide a financial estimate of these. Also on any impacts on the environment.**

**ii) Full Implementation**

3.6 Full implementation would be consistent with the UK's obligation as a Member State of the EU (the UK voted in favour of the measure). It will introduce a number of additional measures on the authorisation and use of feed additives. These will need to be observed by the feed and agricultural industry.

**4. BENEFITS**

**i) Economic**

4.1 The EC Regulation 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 300 printed copies of each dossier, at costs of copying and despatching a dossier of around £2000.

**ii) Environmental**

4.2 The assessment of applications for feed additive authorisations 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.

**iii) Social – Health Benefits**

4.3 This measure 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.

**Stakeholders are invited to comment on any benefits they anticipate for themselves, consumers, or others, and if possible quantify these. In particular it would be helpful to receive an estimate of the costs of printing dossiers and the savings in this area likely to be achieved under the new system of dossier assessment by EFSA.**

## **5. COSTS**

The following information was included in the Regulatory Appraisal prepared at the time of negotiations in 2002–2003. **Stakeholders are invited to comment and provide any up to date information which will confirm or update the estimates of costs in this entire section.**

### **i) Economic**

5.1 The principal areas identified 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 the section on Compliance Costs for Typical Business below.

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, e.g. silage agents. A similar situation could occur if, for the same reasons, dossiers were not produced and submitted for the re-evaluation of existing additives.

5.2 *Compliance Costs for a Typical Business.* The compliance cost for individual businesses depends on the type of business and a number of factors.

#### (a) Manufacturers of Feed Additives and Premixtures

5.3. 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, e.g. vitamins and trace elements, may be generally available in the published scientific literature. It is likely that the Commission or EFSA will require a lighter assessment regime for such products with a history of safe usage, which could lower compliance costs. The same should apply to additives for use in pet foods, as these products have no implications for the human food chain. There should also be lighter requirements for proof of efficacy for existing authorised products.

5.4. 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.

- 5.5. The total cost to individual companies also depends on the number of products owned or marketed. There would be loss of earnings to companies (including to sellers of additives/premixtures) if certain additives or silage agents failed to gain re-authorisation or authorisation.

(b) Manufacturers of Silage Agents

- 5.6 In the UK there is an existing voluntary industry scheme for the assessment of silage agents. For registration under this scheme animal trial and other data must be submitted. It is expected that much of this data might be acceptable for the assessment of silage agents under 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 existing scientific literature. One trade source indicated for the provision of dossiers for such generic products costs may be in the order of £5,000 - £10,000.

- 5.7 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 upper end of scale at £200,000. This cost was broken down as follows:

- Additional testing for heavy metals / toxins: £5k per annum
- Antibiotic production / resistance: £10K per microbial strain
- Transmissibility trials: £20K
- New efficacy studies assuming current trials are deemed inadequate because of a duration of less than 100 days: £80K
- Tolerance testing on target species: £30–50K
- Consumer safety assessment (genotoxicity and oral toxicity): £10–20K
- Irritancy assessment: £10–20K

(c) Feed Compounders and Pet Food Manufacturers

- 5.8 There could be implications to 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.

**Charities and Voluntary Organisations**

- 5.9 No costs are envisaged for charities and voluntary organisations.

**ii) Environmental**

5.10 None identified.

**iii) Social**

5.11 None identified.

**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 in animal nutrition. However, measures to achieve this should be effective and enforceable. The Regulation 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 policy will impact equally on businesses and organisations from all sectors.

**7. CONSULTATION WITH SMALL BUSINESS: THE SMALL FIRMS' IMPACT TEST**

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.

**8. SUSTAINABLE DEVELOPMENT**

We have considered the issue of sustainable development which 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.

**9. COMPETITION ASSESSMENT**

9.1 The competition filter was applied to this proposal at the partial stage and 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 dependent on the type of additive.

- 9.2 In the absence of full implementation there is the potential for manufacturers of feed additives to be disadvantaged in terms of EU trade and unable to operate on a level playing field.

## **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.
- 10.2 Enforcement includes taking samples of animal feed and having them analysed for the presence of various ingredients. In general, analyses are undertaken by accredited agricultural analysts.
- 10.3 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 (e.g. section 74A(3) of the Agriculture Act refers).

## **11. MONITORING AND REVIEW**

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 The Food Standards Agency in Scotland, Wales and Northern Ireland are already being consulted on the enforcement of Regulation 1831/2003 and are content with the approach being taken. The views of Agriculture Departments (the Scottish Environment and Rural Affairs Department and the Department for Environment, Food and Rural Affairs), and the Small Business Service, will be sought as part of the consultation exercise. The Food Standards Agency in Wales will involve the National Assembly for Wales in its consultation exercise. Similarly, the Food Standards Agency in Northern Ireland will involve the Department of Agriculture and Rural Development in Northern Ireland in its consultation exercise.

### **ii) Public Consultation**

- 12.2 *Note to stakeholders: this section will be completed after the public consultation has been completed.* A summary and discussion of the responses to the consultation will be prepared by the Food Standards Agency and incorporated in the full version of the Regulatory Impact Assessment submitted for ministerial signature. A summary of the responses, omitting

those where confidentiality has been requested, will also be published on the Agency's website.

### 13. SUMMARY AND RECOMMENDATIONS

The measure is designed to sustain and enhance feed and food safety in relation to additives used in animal nutrition. This Regulatory Appraisal 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. Overall, the protection of consumers of livestock products is of paramount importance and the measure's provisions will achieve this end.

<b>Option</b>	<b>Total Costs per annum – Economic, Social, Environmental</b>	<b>Total Benefits per annum – Economic, Social, Environmental</b>
1. Non-implementation	Costs 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.	Avoidance of dossier costs for silage agents and the re-evaluation of existing feed additive authorisations.
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 introduced to improve feed safety.

A detailed recommendation to Ministers will be drawn up at the conclusion of the consultation process.

#### **Contact Point**

Jayne Griffiths  
 Food Standards Agency Wales  
 11<sup>th</sup> Floor, Southgate House  
 Wood Street  
 Cardiff CF10 1EW  
 Telephone: 029 2067 8908  
 Fax: 029 2067 8918  
 E-mail: [jayne.griffiths@foodstandards.gsi.gov.uk](mailto:jayne.griffiths@foodstandards.gsi.gov.uk)