

REGULATORY APPRAISAL

1. TITLE OF THE PROPOSAL

THE FEEDING STUFFS (SAMPLING AND ANALYSIS) (AMENDMENT) (WALES) REGULATIONS 2004

1.1 Implementation of Commission Directive 2003/126/EC of 23 December 2003 on the analytical method for the determination of constituents of animal origin for the official control of feedingstuffs (*OJ* No L339, 24.12.2003, p.78)

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

Objectives

2.1 These Regulations will introduce mandatory requirements for the identification by microscopy of ingredients of animal origin in animal feedingstuffs, replacing existing guidelines for microscopic examination under which the means of calculating and evaluating the results are optional. Because there is wide variation in the accuracy of the results obtained under these guidelines, it is necessary to ensure consistent application of microscopic methods throughout the EU. The new EC measure which the Regulations implement therefore specifies the sampling method, the reagents and equipment to be used, and the procedures to be followed in conducting the analysis and calculating and expressing the results. The measure also reflects technical advances in methods of detection, which are aimed at improving the positive identification of very small quantities (less than 0.1%) of animal material.

Background

2.2 The BSE epidemic, in the UK and other EU Member States, has resulted in a progressive tightening of the rules on the use of material of animal origin in feed for farmed livestock. The use of mammalian protein in diets for ruminant animals (sheep and goats as well as cattle) was prohibited throughout the EU in 1988 because it was thought to be the principle cause of the disease. In 1996, the UK extended the prohibition on the use of mammalian protein to feed for all farmed livestock (including fish and horses) to eliminate the possibility of cross-contamination at feed mills manufacturing feed for different species. In December 2000, the EU extended the prohibition on mammalian protein to almost all products of animal origin. Only a small number of such products may still be used for animal feeding, including fishmeal for non-ruminant animals such as pigs and poultry.

2.3 Enforcement of the prohibition on the use of animal material in feed requires both detailed record-keeping by feed compounders, to ensure full traceability throughout the feed chain, and sampling and analysis to confirm adherence to the rules. Commission Directive 98/88/EC established guidelines for the microscopic identification and estimation of ingredients of animal origin in animal feeds but, because these are optional rather than mandatory, there is in practice a wide variation in the accuracy of the results obtained. A harmonised approach, ensuring the relevant procedures are used throughout the EU, is therefore necessary to improve determination rates.

2.4 The measure will principally affect the work of the Veterinary Laboratories Agency (VLA), which is responsible for analysing samples taken by the State Veterinary Service (SVS) as part of its formal programme under the National Feed Audit to verify compliance with transmissible spongiform encephalopathy (TSE) related controls on feed. This includes controls on the use of animal products such as fishmeal, which is currently permitted only in the diets of non-ruminant animals, reflecting concern over the potential for fishmeal to mask the presence of mammalian protein during feed sample analysis. The updated microscopy method introduced by this measure is already being used by the VLA.

2.5 Local Authority Public Protection Departments are responsible for the enforcement of animal feedingstuffs legislation in Wales. This includes *ad hoc* sampling and analysis of feed for a range of purposes and is usually undertaken by agricultural analysts on behalf of Local Authorities who become involved for enforcement purposes in the VLA/SVS work in the event that a breach of TSE-related controls is detected.

Risk Assessment

2.6 It is important that feed producers, livestock farmers and the consumers of animal products have confidence that animal feedingstuffs are free of potential agents of diseases such as BSE. It is therefore also important that there are consistent and universally applied procedures for the sampling and analysis of feedingstuffs to detect products of animal origin.

Devolution

2.7 These Regulations will apply only in Wales; separate but parallel legislation will be made in England, Scotland, and Northern Ireland.

3. OPTIONS

3.1 There are two possible options: non-implementation or full implementation.

Non-Implementation

3.2 Opting out of Directive 2003/126/EC could 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 delayed or ignored. In addition, non-implementation of the Directive would attract undoubtedly successful legal proceedings against the UK in the European Court of Justice, with the UK liable for both the costs of the infraction proceedings and the payment of any penalties imposed.

Full Implementation

3.3 Full implementation of Directive 2003/126/EC would be consistent with the UK's obligations as a member of the EU. Full implementation would also demonstrate commitment to the protection of the safety and integrity of the animal feed chain, and thus the protection of the health of consumers of animal products.

4. BENEFITS

Economic

4.1 **Non-implementation** of Directive 2003/126/EC could have some small cost savings. Because the UK would not be bound by the mandatory procedures for analysis and reporting that it lays down, there could be savings to the agricultural

analysts to whom samples are referred. Those analysts may avoid investment in any new equipment and training which these mandatory procedures might require.

4.2 However, there could be long-term economic benefits to the feed industry, livestock farmers and consumers from **full implementation** of Directive 2003/126/EC. The improved positive identification of very small quantities (less than 0.1%) of animal material due to technical advances in methods of microscopic detection will also help to make clearer distinctions between material of terrestrial (e.g., mammalian and poultry) and fish origin. The chief non-mammalian ingredient used in livestock diets is fishmeal, but this is currently permitted only for non-ruminants such as pigs and poultry and its re-authorisation for use in ruminant feed will depend on the development of validated methods of detection. Even so, the continued use of fishmeal in non-ruminant feed means no increases in the use of more expensive alternative feed materials such as soya bean meal and amino acids. Full implementation of Directive 2003/126/EC could therefore have future cost savings for the feed industry, the livestock farmers who are the customers of its products, and the ultimate human consumers of animal products.

Social

4.3 **Non-implementation** would not appear to have any immediately identifiable social benefits or disadvantages.

4.4 **Full implementation** of Directive 2003/126/EC would ensure that the procedures followed by the UK for the analysis of feedingstuffs containing animal products were consistent with those of other Member States. This could allow meaningful comparisons between the results obtained in different Member States, and thus facilitate the sharing of best practice and perhaps also the identification of common problems. Full implementation would also mean that the latest microscopy methods, which have been developed by experts with practical knowledge and experience of the techniques involved, are being applied in this important area to ensure optimum performance and compliance with feed controls.

Environmental

4.5 There appear to be no immediately identifiable environmental benefits or disadvantages associated with either non-implementation or full implementation of Directive 2003/126/EC. In the longer term, full implementation could help reduce the likelihood of future outbreaks of animal diseases (such as BSE).

5. COSTS

Economic

5.1 **Non-implementation** of Directive 2003/126/EC would not appear to have any additional costs for local authorities and agricultural analysts.

5.2 **Full implementation** of Directive 2003/126/EC would bind the UK to the mandatory procedures laid down for the identification and evaluation of samples of feed containing products of animal origin. Some agricultural analysts, who undertake this type of work on behalf of local authorities, may need to invest in new equipment. The Association of Public Analysts who responded to the public consultation felt this unlikely, as analytical laboratories would already possess the necessary equipment. They did however feel that there could be an issue over the cost of training to familiarise analysts with the new procedures. However, such

potential additional costs were regarded as negligible and would be absorbed by the Association.

Social

5.3 There would appear to be no identifiable social costs associated with either non-implementation or full implementation of Directive 2003/126/EC.

Environmental

5.4 There would appear to be no identifiable environmental costs associated with either non-implementation or full implementation of Directive 2003/126/EC.

6. FINANCIAL IMPLICATIONS FOR WALES

6.1 There are no financial implications for the Welsh Assembly Government or for Local Authorities arising from the making of these Regulations. As discussed in paragraphs 5.2 and 6.2, this type of work is undertaken by agricultural analysts on behalf of Local Authorities. The Association of Public Analysts have advised that any additional costs arising from the work would not be passed on to Local Authorities. Consequently, we have not identified any additional costs for Local Authorities arising from these regulations. The Local Authorities Co-ordinators of Regulatory Services (LACORS) and the Welsh Local Government Association (WLGA) were included in the public consultation and asked to specify any additional costs for Local Authorities arising from these regulations. Local Authority Public Protection Departments are responsible for the enforcement of animal feedingstuff legislation in Wales. Neither LACORS nor WLGA responded to the consultation so, no additional costs have been identified.

6.2 Directive 2003/126/EC does not specify any additional levels of sampling and analysis for the presence of products of animal origin in animal feedingstuffs; it lays down only the procedures to be followed in the taking and analysing of such samples. Consequently there will not be any additional costs to Local Authorities arising directly from the implementation of this measure.

6.3 It is thought there will be little if any impact on feed businesses in Wales arising from the implementation of this measure. There are no "Wales only" feed industry associations but the Agency included a number of GB or UK wide associations in the consultation on these draft Regulations. None identified any likely additional costs to their members as a consequence of the implementation of the measure.

7. EQUITY AND FAIRNESS

7.1. As a consequence of the various prohibitions enacted since 1988, the feed industry is no longer incorporating animal products in feed for farmed livestock other than those few specifically exempted from the existing ban or derogated for use in non-ruminant feed.

7.2. Because the ban on the incorporation of animal material applies throughout the EU, full implementation of Directive 2003/126/EC will not disadvantage the UK feed industry relative to either the feed industries of other Member States or the feed industries of third countries, whose products are required to comply with EC feed legislation if placed on sale in the EU. However, the UK feed industry could be disadvantaged by non-implementation of the measure, as this could give rise to

doubts about the status of its products irrespective of the ban on the incorporation of animal material.

7.3. Full implementation of Directive 2003/126/EC could indirectly benefit consumers of animal products, as it would help confirm the safety of feed for farmed livestock and thus the integrity of both the feed and food chains.

8. CONSULTATION WITH SMALL BUSINESSES (THE SMALL FIRMS IMPACT TEST)

8.1. Approximately one-third of the companies that manufacture animal feed claim small company status. Except in cases where breaches of the rules on the incorporation of animal material in feed are detected, we would not expect them to be affected by this measure.

8.2. Small business stakeholders were included in the consultation on the draft Regulations, but none responded.

9. COMPETITION ASSESSMENT

9.1. Directive 2003/126/EC will chiefly affect enforcement authorities and agricultural analysts. For this reason, it is thought that it will have little if any impact on feed businesses, and is thus unlikely to affect the existing competition status of the UK feed industry. However, there could be some effect on the laboratories which offer analytical services, which are private organisations.

9.2. The Association of Public Analysts, which includes agricultural analysts amongst its membership, indicated that although investment in new equipment might not be necessary there could be an issue over the cost of training in the use of the new procedures, although these potential additional costs were regarded as negligible.

9.3. It should be noted, however, that (as stated in paragraph 6.2 above) Directive 2003/126/EC does not specify any additional level of sampling and analysis for the presence of products of animal origin in animal feedingstuffs. It lays down only the procedures to be followed in the taking and analysing of such samples.

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. This 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 on behalf of Local Authorities.

10.2. 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.

11. MONITORING AND REVIEW

11. 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

Public Consultation

12.1. The Food Standards Agency Wales carried out a consultation from 14 April to 7 July 2004. Stakeholders including consumer and industry representative bodies, and farming unions were invited to comment on the draft Regulations and the draft Regulatory Appraisal. A list of those consulted in Wales is attached at Annex 1. There are no “Wales only” feed industry associations but the Agency included a number of GB or UK wide associations in the consultation on these draft Regulations. Parallel consultations were carried out in England, Scotland and Northern Ireland.

12.2. Nine responses were received UK wide in response to the consultations with three of these in response to the Wales consultation. Two made no comments; one queried the utility of consultation on an EU measure which the UK is required to transpose; and five (including all three of the Wales responses) expressed support for full implementation of Directive 2003/126/EC. The response, from the Association of Public Analysts, indicated that although it was very unlikely that there would be a need for investment in new equipment, because analytical laboratories will already possess the necessary compound microscopes and stereo microscopes, there could be an issue over the cost of training to familiarise analysts with the new procedures for calculating and evaluating the results. However, such potential additional costs were regarded as negligible and would be absorbed by the Association.

12.3. No policy changes to the draft Regulations were identified as a consequence of the public consultation.

13. SUMMARY AND RECOMMENDATIONS

Option	Total Costs per annum – Economic, Social, Environmental	Total Benefits per annum – Economic, Social, Environmental
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).	UK not bound by mandatory procedures for analysis of products of animal origin in feedingstuffs, with possible small cost savings to public / agricultural analysts.
2. Full implementation	Possible costs to agricultural analyst laboratories from investment in new equipment (although this is said to be unlikely) and training of analysts in use of the new procedures. Exact costs are difficult to quantify, but are unlikely to be significant.	Would ensure that analytical procedures followed by the UK are consistent with those of other Member States. This could allow meaningful comparisons between results obtained in different Member States, facilitate sharing of best practice and perhaps also identification of any common problems.

13.1 It is appropriate for sampling and analysis procedures to be updated in the light of technical advances. Directive 2003/126/EC constitutes an advance in methodology of detection, allowing the positive identification of very small quantities (less than 0.1%) of animal material. Consistent application of the new technique throughout the EU will be achieved by repealing previous provisions which established optional methods for calculating and evaluating the results obtained, and introducing in their place mandatory requirements to eliminate the wide variation in the accuracy of the reported results which has prevailed hitherto. It is therefore appropriate to specify the sampling method, the reagents and equipment to be used, and the procedures to be followed in conducting the analysis and calculating and expressing the results.

13.2 It is therefore recommended that Directive 2003/126/EC be implemented in Wales by the Feeding Stuffs (Sampling and Analysis) (Amendment) (Wales) Regulations 2004.

Contact Point

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ANNEX 1

LIST OF STAKEHOLDERS CONSULTED IN WALES

Cate Barrow – Food Business Development Manager	ADAS Wales
Mr Arwyn Davies	Agri-Food Partnership
Judith Nelson, Head of Feed Sector	Agricultural Industries Confederation (AIC)
Mrs Janet Nunn	British Retail Consortium
Mr M Williams	Cardiff Scientific Services
Mr Paul Handby, Development Co-ordinator	Chartered Institute of Environmental Health in Wales
Julie Barratt, Director	Chartered Institute of Environmental Health in Wales
Julian Salmon	Country Land and Business Owners Association
Dr John Taylor	Countryside Council for Wales
Mr R A Ennion	Eurofins Scientific
Moss Jones – Company Secretary	Farm Assured Welsh Livestock
Marilyn James	Farm Assured Welsh Livestock
Mr Arwen Owen, Director of Policy	Farmers' Union of Wales
	Federation of Small Businesses
Alan Horine, Secretary	Guild of Welsh Lamb and Beef Suppliers
Graham Shortland, Chairman	Guild of Welsh Lamb and Beef Suppliers

Gwyn Howells
Susan Perkins
T E Johnson
Mrs Mary James
Dylan Morgan
Mr David Walters, Chief Executive
James Thomas
Mr Lester Lewis
Mr Tony Edwards
Paul Lenartowicz – Vice President
Tim Keohane – Secretary
Mrs Mair Stephens
Lowri Jones
-
Norma Barry
Jo Glenn
Ken Stebbing
Alun Streeter
Christine Carberry
Lindsay Kearton

Elinor Plow, Secretary
Mr Wynfford James
Mr Norman Biggs
Mr M Schuckman
Susan Perkins
Don Thomas – Managing Director

Hybu Cig Cymru
LACORS (Welsh Officer)
Minton, Treharne & Davies Ltd
National Farmers Union (Wales)
National Farmers Union (Wales)
Royal Welsh Agricultural Society
Royal Welsh Agricultural Society
Society of Directors of Public Protection
State Veterinary Service
The Association of Public Analysts
Trading Standards Institute (Wales)
Wales Assembly of Women
Wales Young Farmers' Club
Welsh Agricultural Organisation Society
Welsh Assembly Government
Welsh Assembly Government
Welsh Assembly Government
Welsh Assembly Government
Welsh Black Cattle Society
Welsh Consumer Council
Welsh Council of the Institution of Environmental
Health Officers
Welsh Food Alliance
Welsh Food Directorate
Welsh Food Laboratories
Welsh Food Promotions
Welsh Local Government Association
Welsh Lamb and Beef Promotions

NB: The consultation carried out by the Agency in England included bodies representing GB