EXECUTIVE NOTE
The Feeding Stuffs (Scotland) and the Feed (Hygiene and Enforcement) (Scotland) Amendment Regulations 2006 S.S.I. 2006/578

The above instrument is made under powers conferred by section 2(2) of the European Communities Act 1972(a) and of all other powers enabling them in that behalf. The instrument is subject to negative resolution procedure.

Policy Objectives

1. The Feeding Stuffs (Scotland) and the Feed (Hygiene and Enforcement) Amendment Regulations 2006, further to this known as the Regulations, will apply to Scotland only. There will be separate but parallel legislation for England, Wales and Northern Ireland.

2. These Regulations are intended to provide for the implementation in Scotland of the provisions of Directives 2005/86/EC, 2005/86/87/EC and 2006/13/EC, which amend or extend the maximum permitted levels of certain undesirable substances (contaminants) in animal feedingstuffs.

3. These substances are camphechlor, a pesticide banned in the EU, lead, fluorine, cadmium and dioxins and dioxin-like PCBs (polychlorinated biphenyls).

4. The opportunity is also being taken to correct an omission, relating to the limits of variation for moisture in compound pet food, from Schedule 4 of the Feeding Stuffs (Scotland) Regulations 2005.

Consultation

5. The Food Standards Agency carried out a public consultation in Scotland between 19 June 2006 and 11 September 2006, to seek views on the draft Regulations from a wide range of stakeholders including consumer organisations, non-Governmental organisations, the food industry, and enforcement authorities. Two Scottish responses were received to the consultation. These responses did not raise any significant issues.

Manpower and Financial Effects

6. The measure does not have implications for central government or Local Authorities.

Food Standards Agency Scotland
November 2006

LIST OF INTERESTED PARTIES

ABP Scotland
Agriculture Industries Confederation (AIC)
AHDA
AIC Scottish Council
Allied Distillers
Alsop Transport Services
Association of Meat Inspectors
Association of Public Analysts of Scotland
Assured Chicken Production (ACP)
Barbour Index
Biotechnology and Biological Sciences Research Council
British Egg Industry Council
British Egg Products Association
British Goat Society
British Marine Finfish Association
British Poultry Council
British Trout Association
British Veterinary Association
Business Gateway
Caledonian Cheese Company
Campden & Chorleywood Food Research
Association Group
Charis Innovative Food Services Ltd
Chilled Food Association Ltd
Commercial Microbiology Ltd
Co-operative Group (CWS) Ltd
CoSLA
Dairy Herd Health & Productivity Service
Dairy UK – Scotland
Davidson Bros (Shotts) Ltd
Diageo
Dundee College
Edinburgh Smoked Salmon
Express Dairies Direct Service
Falkirk Council Development Services
Federation of Small Businesses Scotland
First Milk
Fisheries Research Services
Food Certification (Scotland) Ltd
Food Training and Consulting Company
FRS Marine Laboratory
Fusion Linking
Glasgow Caledonian University
Glasgow Metropolitan College
Glasgow Scientific Services
Glasgow University Veterinary School
Glengorm Estate
Glenside Organics
Grampian Country Food Group
Green City Wholefoods
Greenpeace
Greggs, Scotland
Guinness UDV
Halal Food Authority
Harbro, Scotland
Highland Cattle Society
Highlands & Islands Enterprise
Independent Farming Group Scotland
Institute of Auctioneers and Appraisers in
Scotland
James Finlay Ltd
LACORS
Landcatch Ltd
Macaulay Land Research Institute
Malt Distillers Association of Scotland
Marks & Spencer
McAusland Cranford
Meat & Livestock Commission
Moray Seafood Ltd
Moredun Research Institute
Napier University
National Beef Association
Natural Environmental Research Council
NBA Scotland
Neogen Europe Ltd
NFU Scotland
North Atlantic Fisheries College
Organic Food Federation
Orkney Meat Ltd
Puremalt Products Ltd
Quality Meat Scotland

Quality Trout UK Ltd
Road Haulage Association Ltd
Robert Gordon University
Robert Wiseman Dairies
Roslin Institute
Rowett Research Institute
Royal College of Nursing
Royal Environmental Health Institute for
Scotland
Royal Society of Edinburgh
Ruma
Sanquhar Academy
Scotch Whisky Association
SCOTSS
Scottish Agriculture College
Scottish Association of Master Bakers
Scottish Chambers of Commerce
Scottish Civic Forum
Scottish Consumer Council
Scottish Council for Development and Industry
Scottish Crofting Foundation
Scottish Crop Research Institute
Scottish Egg Producer Retailers Association
Scottish Enterprise
Scottish Environment Protection Agency
Scottish Environmental Research Centre
Annex 5
Scottish Federation of Meat Traders Association
Scottish Flour Millers Association
Scottish Food & Drink Federation
Scottish Food Quality Certification Ltd
Scottish Food Safety Officers Association
Scottish Gamekeepers Association
Scottish Local Authorities
Scottish Quality Salmon
Scottish Retail Consortium
Scottish Rural Property and Business Association
Scottish Salmon Smokers Association
Scottish Sea Farms Ltd
Scottish Seed & Nursery Trade Association
Scottish Water
Sea Fish Industry Authority
SEERAD
Shetland Acquaculture
Shetland Seafood Quality Control
SIMBOIS
Society of CO's Environmental Health in
Scotland
Spitfire Resources
Strathaird Salmon Ltd
SWRI
Tesco Stores Ltd
Trading Standards Institute
UK Association of Frozen Food Producers
UNIQ Prepared Foods
United Fish Products
University of Aberdeen
University of Glasgow
University of Paisley
USDAW
Verner Wheelock Associates
W Forrest & Sons Ltd
2 Members of the Public

FULL REGULATORY IMPACT ASSESSMENT

1. TITLE OF THE PROPOSAL

THE FEEDING STUFFS (SCOTLAND) AND THE FEED (HYGIENE AND ENFORCEMENT) (SCOTLAND) AMENDMENT REGULATIONS 2006
S.S.I. 2006/578

Implementation of Directives 2005/86/EC, 2005/87/EC and 2006/13/EC of the European Parliament.

2. PURPOSE AND INTENDED EFFECT OF THE MEASURE

i) Objectives

2.1 These Regulations are intended to provide for the implementation in Scotland of Directives 2005/86/EC, 2005/87/EC and 2006/13/EC. These Directives are intended to sustain and enhance feed safety, and thus to protect the health of human consumers of animal products as well as animal health. The measures revise or introduce maximum permitted levels (MPLs) for the following undesirable substances (contaminants) in animal feed (the new and amended MPLs are set out in Schedule 2 to the Regulations):

(a) Camphechlor -- a pesticide banned in the EU. The MPL is being reduced for fish, other aquatic animals, their products and by-products and for feedingstuffs for fish. The MPL for fish oil is being revised upwards in recognition of the fact that some consignments would have difficulty complying with the new limit, even though they are considered not to be a significant hazard to consumer safety. Once effective decontamination technologies have been developed, it is likely that the MPL for fish oil will be reduced to its former level, or even lower;

(b) Lead -- the MPL is being reduced for phosphates, green fodder and mineral feeds. MPLs are being introduced for certain feed materials and for certain feed additives and premixtures which are thought to have the highest lead levels;

(c) Fluorine -- MPLs are being introduced or amended for certain feed materials, including marine crustaceans such as krill and the minerals calcium carbonate and magnesium oxide. There will be a new MPL for the feed additive vermiculite (a binding agent); and the MPL for complementary feedingstuffs will be recast into two bands depending on the phosphorus content of the feed;

(d) Cadmium -- MPLs are being introduced for certain groups of feed additives and premixtures (i.e., mixtures of additives intended for use in a compound feed rather than direct feeding to animals) which are thought to have higher levels of cadmium; and the MPL for mineral feedingstuffs is being recast into two bands depending on their phosphorus content. The MPL for complete feedingstuffs is being extended to cover feeds for fish and pets. The extension to cover fish takes account of changes to

formulations of fish feed, which include higher ratios of fish oil and fishmeal, while the extension to cover pets is considered appropriate on animal welfare grounds; and

(e) Dioxins and dioxin-like PCBs -- an MPL is being introduced for dioxins in premixtures. MPLs are also being introduced for the sum of dioxins and dioxin-like PCBs, covering the same range of feed materials and feeding stuffs. It is intended that the MPLs for the sum of dioxins and dioxin-like PCBs will be reviewed in future when a clearer picture of the relative toxic load provided by each has emerged.

ii) The Background

2.2 An important safeguard in the protection of animal and human health is the setting of MPLs for undesirable substances. Undesirable substances are generally naturally occurring environmental contaminants which are present at low levels in feed and food products, primarily vegetable crops drawing nutrients directly from the soil (e.g. arsenic, lead and mercury); and process contaminants which may be introduced into the feedingstuff either during or as a consequence of its treatment, manufacture and storage (e.g. dioxins).

2.3 The Commission had agreed that MPLs for undesirable substances, many of which were established some years previously and have never been subject to a proper risk assessment, should be reviewed by the former Scientific Committee on Animal Nutrition (SCAN). The risk assessments are currently being conducted by a scientific panel of the European Food Safety Authority (EFSA) which took over SCAN's responsibilities. EFSA has produced Opinions on camphechlor, a non-systemic insecticide, the use of which has been phased out throughout most of the world; lead, where contamination of food is a public health concern; fluorine, where excessive exposure is associated with dental and skeletal abnormalities; cadmium, which is toxic to all categories of animals; and dioxins and dioxin-like PCBs, which are persistent in the environment. The three Directives to be transposed into national law by these Regulations represent legal recognition of these Opinions in Community feed law.

2.4 One of the three measures to be transposed, concerning dioxins and dioxin-like PCBs, introduces the concept of "action thresholds" below the statutory MPLs. The intention is that, where sampling determines that an action threshold has been exceeded, there should be an investigation of the possible source(s) of the contamination by local authority trading standards departments, in co-operation with the feed businesses concerned.

iii) Rationale for Government Intervention

2.5 Camphechlor, due to its persistence and chemical properties, is still found at low levels in the environment, particularly marine environments. It is thought appropriate to replace the existing MPL for feed in general with limits on its presence in fish oil, fish meal and fish feed in order to ensure that these products do not present any unacceptable risks to human health and animal health.

2.6 Lead is prevalent in the environment. Animals can be exposed to it through feed, with cattle and sheep being the most sensitive to toxicity. Lead accumulates to some extent in kidney and liver tissue, which can potentially cause adverse health effects in animals and problems for the food chain.

2.7 Fluorine is an essential element in animal diets. However, excessive exposure can occur in proximity to industrial sites, which had or have high fluorine emissions. Although consumers and farmed livestock are not generally exposed to unacceptably high levels of fluorine, maximum limits are necessary to help prevent adverse effects on teeth and bones. These adverse effects can include staining and weakening of dental enamel, leading to tooth decay, and the stimulation of new bone formation, including bone spurs and brittle material prone to fracture.

2.8 Exposure to cadmium cannot be completely avoided due to the metal's prevalence in the environment, and it tends to accumulate in the kidneys of longer-lived animals (e.g. cattle and horses). Consumption may in turn contribute to human exposure, which might progress to conditions such as osteoporosis. Exposure can also affect the absorption of trace elements, particularly copper, possibly resulting in copper deficiency in ruminants.

2.9 Dioxin and dioxin-like PCBs are persistent environmental pollutants of historic origin which do not degrade easily. As a result dioxins and dioxin-like PCBs tend to bio-accumulate and are present at very low levels in most animal feeds and food products for human consumption, especially fat-containing foods (i.e. milk, meat, fish and eggs). Adverse effects on humans include developmental effects on young children, disruption to endocrine systems, and even cancer.

iv) Devolution

2.10 Separate but parallel legislation will be made in England, Wales and Northern Ireland.

3. CONSULTATION

i) Within Government

3.1 Food Standards Agency officials in England, Wales and Northern Ireland have been consulted on the implementation on the proposed measures. The views of Agriculture Departments (the Scottish Environment and Rural Affairs Department and the Department for Environment, Food and Rural Affairs) and the Federation of Small Businesses Scotland were sought as part of the consultation exercise. Food Standards Agency officials in Wales and Northern Ireland involved the National Assembly for Wales and the Department of Agriculture and Rural Development for Northern Ireland in their respective consultation exercises. There were no objections to the implementation of these measures.

ii) With the Public

3.2 Stakeholders were kept informed of developments during negotiations in Brussels on the revised MPLs but made no comments. The feed industry was also invited to comment on the draft Regulations to transpose these MPLs into national legislation, and to provide any supporting financial or other data.

3.3 There were two responses to the public consultation in Scotland, only one response provided substantive comments, who supported the measures introduced to sustain and enhance the safety of animal feedstuffs.

4. OPTIONS

4.1 There would appear to be two possible options: non-implementation or full implementation of the measures.

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i) Non-Implementation

4.2 Non-implementation could give rise to concerns that measures intended to enhance the safety and integrity of the feed chain and to protect consumers and of animal health were being ignored. Non-implementation could also lead to legal proceedings against the UK in the European Court of Justice, as the terms of all three measures require the implementation of all their provisions. The costs of non-implementation would include those in respect of infraction proceedings against the UK Government, as well as any financial penalties imposed.

4.3 In addition, non-implementation could disadvantage UK feed manufacturers as their products might be perceived as not complying with EC feed law, even if they had in fact complied with the revised MPLs set out in the Directives. Consequently, this could lead to manufacturers losing market share in other Member States.

ii) Implementation

4.4 Full implementation of the proposed measures would provide additional safeguards on feed safety. It would be consistent with the UK's obligations as a member of the EU. Full implementation could also benefit UK feed producers, as they would be able to continue selling the full range of their products on other markets within the EU.

5. COSTS AND BENEFITS

i) Sectors and Groups Affected

5.1 The provisions of all three Directives will have a direct effect on the feed industry, which will be required to take action to ensure that its products comply with the new or revised MPLs.

5.2 The provisions of all three Directives, which will enhance feed safety, will also have a consequential beneficial impact on human consumers of animal products.

5.3 Voluntary organisations and charities are unlikely to be affected by the provisions of these three Directives.

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

ii) Analysis of Costs and Benefits

5.5 It is difficult to quantify the potential costs and benefits associated with the introduction or revision of MPLs for undesirable substances in animal feed. In addition, some of the potential costs and benefits may be non-monetary in their nature and thus difficult to translate into purely financial terms. In some cases, feed manufacturers may not need to take any action, as existing feeds may comply with the new MPLs.

5.6 Costs and benefits could include the following:

Costs

- monetary costs associated with the removal of camphechlor from fish oil;
- any costs associated with vigilance to ensure that potential contamination by lead, fluorine and dioxins and dioxin-like PCBs is kept low and sources of supply are kept under consistent review;
- possible costs associated with undertaking additional sampling and analysis work, at least in the short term, resulting in increases in the prices of feed which could disadvantage livestock producers unable to pass on the higher costs to their customers;
- the possibility that UK feed producers could lose market share elsewhere in the EU as a result of non-implementation, which may prompt doubts over whether UK feed products conform to the requirements of the legislation; and
- the likelihood that local authorities and feed businesses will incur additional costs in the event that "action thresholds" have been exceeded – this would involve relevant parties investigating the possible source(s) of the contamination.

Benefits

- increased sales for UK feed manufacturers, who will be able to continue selling their products into the feed chain in both the UK and other Member States;
- health benefits for farmed livestock and human consumers of animal products, providing purchasers with more confidence in the feed products they buy, helping to promote sales by UK manufacturers;
- reductions in the quantities of lead and cadmium ingested by farmed livestock and other animals, ensuring reductions in the quantities subsequently excreted on pasture land also used by wildlife;
- social benefits associated with the reduction of toxic substances present in the feed and food chains; and
- advantages for pet owners and their pets, potentially resulting in improvements to the health of these animals and pet owners paying less in veterinary fees.

iii) Summary of Costs and Benefits

5.7 Full implementation of the measures may help UK manufacturers maintain their market share and access to the feed chain in the EU. In the short term, there might be increased financial costs associated with additional sampling to ensure that the new MPLs are met. The measures may also have indirect environmental benefits, because of the reduction in heavy metals excreted to pasture, and might benefit pet owners who will have access to safer pet foods. Other economical, environmental, and social costs and benefits appear to be either unquantifiable or unidentifiable at this stage.

6. SMALL FIRMS IMPACT TEST

6.1 Approximately one-third of the companies that manufacture animal feed claim small company status. Feed industry trade associations have advised the Agency in response to previous consultations that they would prefer to be the point of contact for all their members, including small businesses, so that they can provide information on the potential impact on them of new legislative measures. However, no small firms specifically commented on the potential impact on them.

7. TEST RUN OF BUSINESS FORMS

7.1 No new or additional forms will be introduced.

8. COMPETITION ASSESSMENT

7.1 The UK feed industry is highly fragmented, with two large national compounders accounting for nearly 50% of market share. The remainder is divided between smaller compounders that have significant capacity in particular regions or areas of the UK, and co-operative or farmer-controlled compounders that typically have a single mill. The trend over the past ten years has been towards consolidation, with mergers reducing the number of individual firms and many of the co-operatives

converting to limited companies. Reliable statistics on business numbers are difficult to obtain, but the Inter-Departmental Business Register (a database of the Office of National Statistics) for 2004 showed 260 firms with less than ten employees, 105 with less than fifty, 45 with under two hundred and fifty, and 5 with over two hundred and fifty employees. A return from the then HM Customs & Excise for the same year showed that 70 companies had a turnover of over £5million each, while 40 companies had turnovers of less than £50,000.

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9. ENFORCEMENT, SANCTIONS AND MONITORING

9.1 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 the sampling and analysis of feed products to determine the accuracy of labelling declarations for protein, fibre, etc. and to ensure that the levels of any undesirable substances are within the permitted maxima.

9.2 The penalties for non-compliance with feedingstuffs legislation are set out in the Agriculture Act 1970 and in subordinate legislation made under section 2(2) of the European Communities Act 1972, namely the Feed (Hygiene and Enforcement) (Scotland) Regulations 2005. Non-compliance is to be treated as a criminal offence, and would be subject on conviction to fines and/or imprisonment.

10. IMPLEMENTATION AND DELIVERY PLAN

10.1 The measure will be implemented in Scotland by the Feeding Stuffs (Scotland) and the Feed (Hygiene and Enforcement) (Scotland) Amendment Regulations 2006. Separate but parallel legislation will be made in England, Wales and Northern Ireland.

11. POST-IMPLEMENTATION REVIEW

11.1 Within six months of the making of the legislation, the Food Standards Agency will carry out an informal survey of feed industry stakeholders to ascertain the ease or difficulty of compliance with the new and revised MPLs.

12. SUMMARY AND RECOMMENDATION

12.1 The two stakeholder responses received in Scotland either signalled agreement to the revised MPLs or did not comment on whether they were likely to have an impact on the feed industry.

12.2 This Regulatory Impact Assessment identifies some potential compliance benefits and costs, although in many cases it is difficult to estimate the precise economic or monetary impacts.

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 (the figure would be at the Court's discretion). Possible loss of market share by UK feed producers due to doubts over compliance with MPLs.	No identifiable benefits from non-implementation.
2. Full implementation	Possible additional costs for UK feed producers attributable to a need to ensure that products conform to the new requirements.	Possible benefits for UK feed manufacturers, who will retain the ability to sell calcium carbonate and complementary feeds into other EU markets. Possible health benefits for consumers of animal products through enhancements to feed safety. Reduction of inputs of toxic substances into the feed and food chain.

12.3 For the reasons discussed in this Regulatory Impact Assessment, the Minister is invited to sign the Feeding Stuffs (Scotland) and the Feed (Hygiene and Enforcement) (Scotland) Amendment Regulations 2006 and the associated RIA at Annex 1.

Declaration

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

Signed by the responsible Minister _____

Date _____

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